Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tisagenlecleucel (Kymriah®)

Novartis Pharma GmbH

Modul 4 A - Separater Anhang 4-H.1 (Teil 1)

Refraktäre oder rezidivierte pädiatrische akute lymphatische B-Zell-Leukämie

Studie CCTL019B2202 (ELIANA)

Stand: 31.08.2023

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Table 219g => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement (Safety Set) 9425
Table 219h => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy (Safety Set) 9441
Table 219i => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like (Safety Set) 9463
Table 219j => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes (Safety Set) 9484

Table 219k => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region (Safety Set) 9517
Table 219l => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy (Safety Set) 9561
Table 219m => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT (Safety Set) 9596
Table 219n => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden (Safety Set) 9627
Table 219o => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence (Safety Set) 9660
Table 219p => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome (Safety Set) 9690
Table 219q => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion (Safety Set) 9722
Table 219r => Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses (Safety Set) 9763
Table 220a => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age (Enrolled set) 9836
Table 220b => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender (Enrolled set) 9850
Table 220c => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race (Enrolled set) 9857
Table 220d => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity (Enrolled set) 9871
Table 220e => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry (Enrolled set) 9882
Table 220f => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL (Enrolled set) 9891
Table 220g => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement (Enrolled set) 9896
Table 220h => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy (Enrolled set) 9898
Table 220i => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like (Enrolled set) 9906

Table 220j => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes (Enrolled set) 9911
Table 220k => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region (Enrolled set) 9918
Table 220l => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy (Enrolled set) 9927
Table 220m => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT (Enrolled set) 9935
Table 220n => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden (Enrolled set) 9943
Table 220o => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence (Enrolled set) 9949
Table 220p => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome (Enrolled set) 9956
Table 220q => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion (Enrolled set) 9963
Table 220r => Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses (Enrolled set) 9978

Table 31a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years

	All patients N=33				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	26 (78.8)	(61.1, 91.0)	26 (78.8)	(61.1, 91.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	26 (78.8)	(61.1, 91.0)	26 (78.8)	(61.1, 91.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	All patients N=33				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	29 (87.9)	(71.8, 96.6)	29 (87.9)	(71.8, 96.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	28 (84.8)	(68.1, 94.9)	28 (84.8)	(68.1, 94.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (3.0)		1 (3.0)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18

	All patients N=14				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	11 (78.6)	(49.2, 95.3)	11 (78.6)	(49.2, 95.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	11 (78.6)	(49.2, 95.3)	11 (78.6)	(49.2, 95.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male

	All patients N=46				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	37 (80.4)	(66.1, 90.6)	37 (80.4)	(66.1, 90.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	36 (78.3)	(63.6, 89.1)	36 (78.3)	(63.6, 89.1)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.2)		1 (2.2)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female

	All patients N=34				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	29 (85.3)	(68.9, 95.0)	29 (85.3)	(68.9, 95.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	29 (85.3)	(68.9, 95.0)	29 (85.3)	(68.9, 95.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White

	All patients N=59				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	50 (84.7)	(73.0, 92.8)	50 (84.7)	(73.0, 92.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	49 (83.1)	(71.0, 91.6)	49 (83.1)	(71.0, 91.6)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.7)		1 (1.7)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian

	All patients N=10				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	6 (60.0)	(26.2, 87.8)	6 (60.0)	(26.2, 87.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	6 (60.0)	(26.2, 87.8)	6 (60.0)	(26.2, 87.8)	0.0014*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	10 (90.9)	(58.7, 99.8)	10 (90.9)	(58.7, 99.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	10 (90.9)	(58.7, 99.8)	10 (90.9)	(58.7, 99.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	All patients N=15				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	13 (86.7)	(59.5, 98.3)	13 (86.7)	(59.5, 98.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	13 (86.7)	(59.5, 98.3)	13 (86.7)	(59.5, 98.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other

	All patients N=65				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	53 (81.5)	(70.0, 90.1)	53 (81.5)	(70.0, 90.1)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	52 (80.0)	(68.2, 88.9)	52 (80.0)	(68.2, 88.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.5)		1 (1.5)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (83.3)	(35.9, 99.6)	5 (83.3)	(35.9, 99.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (83.3)	(35.9, 99.6)	5 (83.3)	(35.9, 99.6)	0.0004*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease

	All patients N=74				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	61 (82.4)	(71.8, 90.3)	61 (82.4)	(71.8, 90.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	60 (81.1)	(70.3, 89.3)	60 (81.1)	(70.3, 89.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.4)		1 (1.4)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	2 (100.0)	(15.8, 100.0)	2 (100.0)	(15.8, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (50.0)	(1.3, 98.7)	1 (50.0)	(1.3, 98.7)	0.2775*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (50.0)		1 (50.0)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	64 (82.1)	(71.7, 89.8)	64 (82.1)	(71.7, 89.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (82.1)	(71.7, 89.8)	64 (82.1)	(71.7, 89.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	0.1500*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	All patients N=79				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	65 (82.3)	(72.1, 90.0)	65 (82.3)	(72.1, 90.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (81.0)	(70.6, 89.0)	64 (81.0)	(70.6, 89.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.3)		1 (1.3)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31h
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	0.1500*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31h
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No

	All patients N=79				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	65 (82.3)	(72.1, 90.0)	65 (82.3)	(72.1, 90.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (81.0)	(70.6, 89.0)	64 (81.0)	(70.6, 89.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.3)		1 (1.3)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	0.1500*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	All patients N=79				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	65 (82.3)	(72.1, 90.0)	65 (82.3)	(72.1, 90.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (81.0)	(70.6, 89.0)	64 (81.0)	(70.6, 89.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.3)		1 (1.3)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	21 (77.8)	(57.7, 91.4)	21 (77.8)	(57.7, 91.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	21 (77.8)	(57.7, 91.4)	21 (77.8)	(57.7, 91.4)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	45 (84.9)	(72.4, 93.3)	45 (84.9)	(72.4, 93.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	44 (83.0)	(70.2, 91.9)	44 (83.0)	(70.2, 91.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.9)		1 (1.9)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Europe

	All patients N=28				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	25 (89.3)	(71.8, 97.7)	25 (89.3)	(71.8, 97.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	24 (85.7)	(67.3, 96.0)	24 (85.7)	(67.3, 96.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (3.6)		1 (3.6)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US

	All patients N=45				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	36 (80.0)	(65.4, 90.4)	36 (80.0)	(65.4, 90.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	36 (80.0)	(65.4, 90.4)	36 (80.0)	(65.4, 90.4)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Rest of World

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (71.4)	(29.0, 96.3)	5 (71.4)	(29.0, 96.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (71.4)	(29.0, 96.3)	5 (71.4)	(29.0, 96.3)	0.0012*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes

	All patients N=48				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	41 (85.4)	(72.2, 93.9)	41 (85.4)	(72.2, 93.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	40 (83.3)	(69.8, 92.5)	40 (83.3)	(69.8, 92.5)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.1)		1 (2.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	25 (78.1)	(60.0, 90.7)	25 (78.1)	(60.0, 90.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	25 (78.1)	(60.0, 90.7)	25 (78.1)	(60.0, 90.7)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes

	All patients N=13				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	12 (92.3)	(64.0, 99.8)	12 (92.3)	(64.0, 99.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	12 (92.3)	(64.0, 99.8)	12 (92.3)	(64.0, 99.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	All patients N=67				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	54 (80.6)	(69.1, 89.2)	54 (80.6)	(69.1, 89.2)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	53 (79.1)	(67.4, 88.1)	53 (79.1)	(67.4, 88.1)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.5)		1 (1.5)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low

	All patients N=26				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	25 (96.2)	(80.4, 99.9)	25 (96.2)	(80.4, 99.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	24 (92.3)	(74.9, 99.1)	24 (92.3)	(74.9, 99.1)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (3.8)		1 (3.8)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High

	All patients N=54				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	41 (75.9)	(62.4, 86.5)	41 (75.9)	(62.4, 86.5)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	41 (75.9)	(62.4, 86.5)	41 (75.9)	(62.4, 86.5)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	11 (100.0)	(71.5, 100.0)	11 (100.0)	(71.5, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	10 (90.9)	(58.7, 99.8)	10 (90.9)	(58.7, 99.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (9.1)		1 (9.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	All patients N=69				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	55 (79.7)	(68.3, 88.4)	55 (79.7)	(68.3, 88.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	55 (79.7)	(68.3, 88.4)	55 (79.7)	(68.3, 88.4)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (83.3)	(35.9, 99.6)	5 (83.3)	(35.9, 99.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (83.3)	(35.9, 99.6)	5 (83.3)	(35.9, 99.6)	0.0004*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No

	All patients N=74				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	61 (82.4)	(71.8, 90.3)	61 (82.4)	(71.8, 90.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	60 (81.1)	(70.3, 89.3)	60 (81.1)	(70.3, 89.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.4)		1 (1.4)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	34 (85.0)	(70.2, 94.3)	34 (85.0)	(70.2, 94.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	33 (82.5)	(67.2, 92.7)	33 (82.5)	(67.2, 92.7)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.5)		1 (2.5)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	32 (80.0)	(64.4, 90.9)	32 (80.0)	(64.4, 90.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	32 (80.0)	(64.4, 90.9)	32 (80.0)	(64.4, 90.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (83.3)	(35.9, 99.6)	5 (83.3)	(35.9, 99.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (83.3)	(35.9, 99.6)	5 (83.3)	(35.9, 99.6)	0.0004*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	All patients N=22				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	18 (81.8)	(59.7, 94.8)	18 (81.8)	(59.7, 94.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	18 (81.8)	(59.7, 94.8)	18 (81.8)	(59.7, 94.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	All patients N=17				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	14 (82.4)	(56.6, 96.2)	14 (82.4)	(56.6, 96.2)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	14 (82.4)	(56.6, 96.2)	14 (82.4)	(56.6, 96.2)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	All patients N=35				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	29 (82.9)	(66.4, 93.4)	29 (82.9)	(66.4, 93.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	28 (80.0)	(63.1, 91.6)	28 (80.0)	(63.1, 91.6)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.9)		1 (2.9)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: <10 years

	All patients N=41				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	26 (63.4)	(46.9, 77.9)	26 (63.4)	(46.9, 77.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	26 (63.4)	(46.9, 77.9)	26 (63.4)	(46.9, 77.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	29 (72.5)	(56.1, 85.4)	29 (72.5)	(56.1, 85.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	28 (70.0)	(53.5, 83.4)	28 (70.0)	(53.5, 83.4)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.5)		1 (2.5)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=18

	All patients N=17				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	11 (64.7)	(38.3, 85.8)	11 (64.7)	(38.3, 85.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	11 (64.7)	(38.3, 85.8)	11 (64.7)	(38.3, 85.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Male

	All patients N=55				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	37 (67.3)	(53.3, 79.3)	37 (67.3)	(53.3, 79.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	36 (65.5)	(51.4, 77.8)	36 (65.5)	(51.4, 77.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.8)		1 (1.8)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Female

	All patients N=43				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	29 (67.4)	(51.5, 80.9)	29 (67.4)	(51.5, 80.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	29 (67.4)	(51.5, 80.9)	29 (67.4)	(51.5, 80.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: White

	All patients N=70				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	50 (71.4)	(59.4, 81.6)	50 (71.4)	(59.4, 81.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	49 (70.0)	(57.9, 80.4)	49 (70.0)	(57.9, 80.4)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.4)		1 (1.4)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Asian

	All patients N=15				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	6 (40.0)	(16.3, 67.7)	6 (40.0)	(16.3, 67.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	6 (40.0)	(16.3, 67.7)	6 (40.0)	(16.3, 67.7)	0.0168*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Other

	All patients N=13				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	10 (76.9)	(46.2, 95.0)	10 (76.9)	(46.2, 95.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	10 (76.9)	(46.2, 95.0)	10 (76.9)	(46.2, 95.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	13 (72.2)	(46.5, 90.3)	13 (72.2)	(46.5, 90.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	13 (72.2)	(46.5, 90.3)	13 (72.2)	(46.5, 90.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	53 (66.3)	(54.8, 76.4)	53 (66.3)	(54.8, 76.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	52 (65.0)	(53.5, 75.3)	52 (65.0)	(53.5, 75.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.3)		1 (1.3)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (62.5)	(24.5, 91.5)	5 (62.5)	(24.5, 91.5)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (62.5)	(24.5, 91.5)	5 (62.5)	(24.5, 91.5)	0.0029*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	61 (67.8)	(57.1, 77.2)	61 (67.8)	(57.1, 77.2)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	60 (66.7)	(55.9, 76.3)	60 (66.7)	(55.9, 76.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.1)		1 (1.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	2 (100.0)	(15.8, 100.0)	2 (100.0)	(15.8, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (50.0)	(1.3, 98.7)	1 (50.0)	(1.3, 98.7)	0.2775*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (50.0)		1 (50.0)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	64 (66.7)	(56.3, 76.0)	64 (66.7)	(56.3, 76.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (66.7)	(56.3, 76.0)	64 (66.7)	(56.3, 76.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (100.0)	(2.5, 100.0)	1 (100.0)	(2.5, 100.0)	0.1500*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	65 (67.0)	(56.7, 76.2)	65 (67.0)	(56.7, 76.2)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (66.0)	(55.7, 75.3)	64 (66.0)	(55.7, 75.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.0)		1 (1.0)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32h
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	1 (33.3)	(0.8, 90.6)	1 (33.3)	(0.8, 90.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (33.3)	(0.8, 90.6)	1 (33.3)	(0.8, 90.6)	0.3859*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32h
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	65 (68.4)	(58.1, 77.6)	65 (68.4)	(58.1, 77.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (67.4)	(57.0, 76.6)	64 (67.4)	(57.0, 76.6)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.1)		1 (1.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	1 (50.0)	(1.3, 98.7)	1 (50.0)	(1.3, 98.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (50.0)	(1.3, 98.7)	1 (50.0)	(1.3, 98.7)	0.2775*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	65 (67.7)	(57.4, 76.9)	65 (67.7)	(57.4, 76.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	64 (66.7)	(56.3, 76.0)	64 (66.7)	(56.3, 76.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.0)		1 (1.0)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	21 (70.0)	(50.6, 85.3)	21 (70.0)	(50.6, 85.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	21 (70.0)	(50.6, 85.3)	21 (70.0)	(50.6, 85.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	45 (66.2)	(53.7, 77.2)	45 (66.2)	(53.7, 77.2)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	44 (64.7)	(52.2, 75.9)	44 (64.7)	(52.2, 75.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.5)		1 (1.5)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: Europe

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	25 (78.1)	(60.0, 90.7)	25 (78.1)	(60.0, 90.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	24 (75.0)	(56.6, 88.5)	24 (75.0)	(56.6, 88.5)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (3.1)		1 (3.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: US

	All patients N=57				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	36 (63.2)	(49.3, 75.6)	36 (63.2)	(49.3, 75.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	36 (63.2)	(49.3, 75.6)	36 (63.2)	(49.3, 75.6)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: Rest of World

	All patients N=9				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (55.6)	(21.2, 86.3)	5 (55.6)	(21.2, 86.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (55.6)	(21.2, 86.3)	5 (55.6)	(21.2, 86.3)	0.0056*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	41 (70.7)	(57.3, 81.9)	41 (70.7)	(57.3, 81.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	40 (69.0)	(55.5, 80.5)	40 (69.0)	(55.5, 80.5)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.7)		1 (1.7)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	25 (62.5)	(45.8, 77.3)	25 (62.5)	(45.8, 77.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	25 (62.5)	(45.8, 77.3)	25 (62.5)	(45.8, 77.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	12 (70.6)	(44.0, 89.7)	12 (70.6)	(44.0, 89.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	12 (70.6)	(44.0, 89.7)	12 (70.6)	(44.0, 89.7)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	54 (66.7)	(55.3, 76.8)	54 (66.7)	(55.3, 76.8)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	53 (65.4)	(54.0, 75.7)	53 (65.4)	(54.0, 75.7)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.2)		1 (1.2)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	25 (89.3)	(71.8, 97.7)	25 (89.3)	(71.8, 97.7)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	24 (85.7)	(67.3, 96.0)	24 (85.7)	(67.3, 96.0)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (3.6)		1 (3.6)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	41 (58.6)	(46.2, 70.2)	41 (58.6)	(46.2, 70.2)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	41 (58.6)	(46.2, 70.2)	41 (58.6)	(46.2, 70.2)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	11 (100.0)	(71.5, 100.0)	11 (100.0)	(71.5, 100.0)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	10 (90.9)	(58.7, 99.8)	10 (90.9)	(58.7, 99.8)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (9.1)		1 (9.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	55 (63.2)	(52.2, 73.3)	55 (63.2)	(52.2, 73.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	55 (63.2)	(52.2, 73.3)	55 (63.2)	(52.2, 73.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (71.4)	(29.0, 96.3)	5 (71.4)	(29.0, 96.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (71.4)	(29.0, 96.3)	5 (71.4)	(29.0, 96.3)	0.0012*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	61 (67.0)	(56.4, 76.5)	61 (67.0)	(56.4, 76.5)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	60 (65.9)	(55.3, 75.5)	60 (65.9)	(55.3, 75.5)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (1.1)		1 (1.1)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	34 (85.0)	(70.2, 94.3)	34 (85.0)	(70.2, 94.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	33 (82.5)	(67.2, 92.7)	33 (82.5)	(67.2, 92.7)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.5)		1 (2.5)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	32 (80.0)	(64.4, 90.9)	32 (80.0)	(64.4, 90.9)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	32 (80.0)	(64.4, 90.9)	32 (80.0)	(64.4, 90.9)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	5 (62.5)	(24.5, 91.5)	5 (62.5)	(24.5, 91.5)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (62.5)	(24.5, 91.5)	5 (62.5)	(24.5, 91.5)	0.0029*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	18 (60.0)	(40.6, 77.3)	18 (60.0)	(40.6, 77.3)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	18 (60.0)	(40.6, 77.3)	18 (60.0)	(40.6, 77.3)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	14 (77.8)	(52.4, 93.6)	14 (77.8)	(52.4, 93.6)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	14 (77.8)	(52.4, 93.6)	14 (77.8)	(52.4, 93.6)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	0		0		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Achieved BOR of CR or CRi within 3 months	29 (69.0)	(52.9, 82.4)	29 (69.0)	(52.9, 82.4)	
With bone marrow MRD negative (i.e. MRD% < 0.01%)	28 (66.7)	(50.5, 80.4)	28 (66.7)	(50.5, 80.4)	<.0001*
With bone marrow 0.01% <= MRD% < 5%	0		0		
With bone marrow MRD% >= 5%	0		0		
Bone marrow MRD not available	1 (2.4)		1 (2.4)		

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 194a
Overall survival (OS) by Age
Full analysis set

Age: <10 years	**All patients N=33**
Events/Total (%)	16/33 (48.5)
Maximum follow-up (months)	86.5
Median follow-up (months)	23.13
Percentiles (95% CI) [1]	
25th	13.3 (5.3, 19.1)
50th	53.6 (16.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.9 (77.9, 98.4)
Month 6	87.9 (70.9, 95.3)
Month 9	81.8 (63.9, 91.4)
Month 12	75.8 (57.3, 87.1)
Month 15	69.6 (50.8, 82.3)
Month 18	63.1 (44.2, 77.1)
Month 21	59.6 (40.6, 74.3)

Age: <10 years	
	All patients N=33
Month 24	59.6 (40.6, 74.3)
Month 27	59.6 (40.6, 74.3)
Month 30	59.6 (40.6, 74.3)
Month 33	59.6 (40.6, 74.3)
Month 36	59.6 (40.6, 74.3)
Month 39	59.6 (40.6, 74.3)
Month 42	59.6 (40.6, 74.3)
Month 45	55.9 (36.9, 71.2)
Month 48	52.1 (33.3, 68.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194a
Overall survival (OS) by Age
Full analysis set

Age: >=10 years to <18 years

	All patients N=33
Events/Total (%)	10/33 (30.3)
Maximum follow-up (months)	67.1
Median follow-up (months)	54.70
Percentiles (95% CI) [1]	
25th	32.2 (4.0, NE)
50th	NE (46.8, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.9 (77.9, 98.4)
Month 6	90.9 (74.4, 97.0)
Month 9	87.9 (70.9, 95.3)
Month 12	84.7 (67.1, 93.4)
Month 15	84.7 (67.1, 93.4)
Month 18	84.7 (67.1, 93.4)
Month 21	84.7 (67.1, 93.4)

Age: >=10 years to <18 years	
	All patients N=33
Month 24	81.6 (63.5, 91.3)
Month 27	81.6 (63.5, 91.3)
Month 30	75.1 (56.2, 86.7)
Month 33	71.5 (52.2, 84.1)
Month 36	71.5 (52.2, 84.1)
Month 39	71.5 (52.2, 84.1)
Month 42	71.5 (52.2, 84.1)
Month 45	71.5 (52.2, 84.1)
Month 48	67.7 (48.1, 81.3)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194a
Overall survival (OS) by Age
Full analysis set

Age: >=18

	All patients N=14
Events/Total (%)	7/14 (50.0)
Maximum follow-up (months)	65.1
Median follow-up (months)	34.32
Percentiles (95% CI) [1]	
25th	11.6 (2.0, 57.4)
50th	57.4 (10.2, NE)
75th	NE (57.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	85.7 (53.9, 96.2)
Month 6	85.7 (53.9, 96.2)
Month 9	85.7 (53.9, 96.2)
Month 12	64.3 (34.3, 83.3)
Month 15	64.3 (34.3, 83.3)
Month 18	57.1 (28.4, 78.0)
Month 21	57.1 (28.4, 78.0)

Age: >=18	
	All patients N=14
Month 24	57.1 (28.4, 78.0)
Month 27	57.1 (28.4, 78.0)
Month 30	57.1 (28.4, 78.0)
Month 33	57.1 (28.4, 78.0)
Month 36	57.1 (28.4, 78.0)
Month 39	57.1 (28.4, 78.0)
Month 42	57.1 (28.4, 78.0)
Month 45	57.1 (28.4, 78.0)
Month 48	57.1 (28.4, 78.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194b
Overall survival (OS) by Gender
Full analysis set

Gender: Male

	All patients N=46
Events/Total (%)	20/46 (43.5)
Maximum follow-up (months)	86.5
Median follow-up (months)	44.94
Percentiles (95% CI) [1]	
25th	14.0 (8.6, 44.3)
50th	NE (32.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	95.7 (83.7, 98.9)
Month 6	91.3 (78.5, 96.6)
Month 9	84.7 (70.5, 92.4)
Month 12	78.0 (62.9, 87.5)
Month 15	73.5 (58.0, 84.0)
Month 18	68.8 (53.0, 80.2)
Month 21	68.8 (53.0, 80.2)

Gender: Male	
	All patients N=46
Month 24	66.3 (50.4, 78.2)
Month 27	66.3 (50.4, 78.2)
Month 30	66.3 (50.4, 78.2)
Month 33	63.7 (47.6, 76.0)
Month 36	63.7 (47.6, 76.0)
Month 39	63.7 (47.6, 76.0)
Month 42	63.7 (47.6, 76.0)
Month 45	61.0 (44.8, 73.8)
Month 48	55.7 (39.5, 69.2)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194b
Overall survival (OS) by Gender
Full analysis set

Gender: Female

	All patients N=34
Events/Total (%)	13/34 (38.2)
Maximum follow-up (months)	66.0
Median follow-up (months)	50.46
Percentiles (95% CI) [1]	
25th	15.2 (2.3, 57.4)
50th	NE (28.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	88.2 (71.6, 95.4)
Month 6	85.3 (68.2, 93.6)
Month 9	85.3 (68.2, 93.6)
Month 12	76.5 (58.4, 87.5)
Month 15	76.5 (58.4, 87.5)
Month 18	73.5 (55.3, 85.3)
Month 21	70.5 (52.0, 82.9)

Gender: Female	
	All patients N=34
Month 24	70.5 (52.0, 82.9)
Month 27	70.5 (52.0, 82.9)
Month 30	64.3 (45.8, 78.0)
Month 33	64.3 (45.8, 78.0)
Month 36	64.3 (45.8, 78.0)
Month 39	64.3 (45.8, 78.0)
Month 42	64.3 (45.8, 78.0)
Month 45	64.3 (45.8, 78.0)
Month 48	64.3 (45.8, 78.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194c
Overall survival (OS) by Race
Full analysis set

Race: White

	All patients N=59
Events/Total (%)	21/59 (35.6)
Maximum follow-up (months)	86.5
Median follow-up (months)	53.55
Percentiles (95% CI) [1]	
25th	21.2 (8.6, 57.4)
50th	NE (53.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.2 (82.9, 97.4)
Month 6	89.8 (78.8, 95.3)
Month 9	84.7 (72.6, 91.7)
Month 12	81.2 (68.7, 89.1)
Month 15	79.5 (66.7, 87.8)
Month 18	75.8 (62.6, 84.9)
Month 21	75.8 (62.6, 84.9)

Race: White	
	All patients N=59
Month 24	73.9 (60.5, 83.4)
Month 27	73.9 (60.5, 83.4)
Month 30	70.2 (56.4, 80.3)
Month 33	70.2 (56.4, 80.3)
Month 36	70.2 (56.4, 80.3)
Month 39	70.2 (56.4, 80.3)
Month 42	70.2 (56.4, 80.3)
Month 45	68.1 (54.1, 78.6)
Month 48	66.0 (51.9, 76.9)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194c
Overall survival (OS) by Race
Full analysis set

Race: Asian

	All patients N=10
Events/Total (%)	5/10 (50.0)
Maximum follow-up (months)	61.1
Median follow-up (months)	24.21
Percentiles (95% CI) [1]	
25th	11.6 (0.4, 32.2)
50th	32.2 (0.4, NE)
75th	NE (32.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	80.0 (40.9, 94.6)
Month 6	80.0 (40.9, 94.6)
Month 9	80.0 (40.9, 94.6)
Month 12	70.0 (32.9, 89.2)
Month 15	60.0 (25.3, 82.7)
Month 18	60.0 (25.3, 82.7)
Month 21	60.0 (25.3, 82.7)

Race: Asian	
	All patients N=10
Month 24	60.0 (25.3, 82.7)
Month 27	60.0 (25.3, 82.7)
Month 30	60.0 (25.3, 82.7)
Month 33	45.0 (12.7, 73.4)
Month 36	45.0 (12.7, 73.4)
Month 39	45.0 (12.7, 73.4)
Month 42	45.0 (12.7, 73.4)
Month 45	45.0 (12.7, 73.4)
Month 48	45.0 (12.7, 73.4)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194c
Overall survival (OS) by Race
Full analysis set

Race: Other

	All patients N=11
Events/Total (%)	7/11 (63.6)
Maximum follow-up (months)	60.3
Median follow-up (months)	19.12
Percentiles (95% CI) [1]	
25th	10.9 (5.3, 19.1)
50th	19.1 (10.2, NE)
75th	NE (15.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	90.9 (50.8, 98.7)
Month 9	90.9 (50.8, 98.7)
Month 12	63.6 (29.7, 84.5)
Month 15	63.6 (29.7, 84.5)
Month 18	54.5 (22.9, 78.0)
Month 21	45.5 (16.7, 70.7)

Race: Other	
	All patients N=11
Month 24	45.5 (16.7, 70.7)
Month 27	45.5 (16.7, 70.7)
Month 30	45.5 (16.7, 70.7)
Month 33	45.5 (16.7, 70.7)
Month 36	45.5 (16.7, 70.7)
Month 39	45.5 (16.7, 70.7)
Month 42	45.5 (16.7, 70.7)
Month 45	45.5 (16.7, 70.7)
Month 48	36.4 (11.2, 62.7)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194d
Overall survival (OS) by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	All patients N=15
Events/Total (%)	8/15 (53.3)
Maximum follow-up (months)	66.0
Median follow-up (months)	28.32
Percentiles (95% CI) [1]	
25th	8.6 (0.5, 28.2)
50th	28.3 (6.8, NE)
75th	NE (28.3, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	86.7 (56.4, 96.5)
Month 6	86.7 (56.4, 96.5)
Month 9	73.3 (43.6, 89.1)
Month 12	66.7 (37.5, 84.6)
Month 15	66.7 (37.5, 84.6)
Month 18	60.0 (31.8, 79.7)
Month 21	60.0 (31.8, 79.7)

Ethnicity: Hispanic or Latino	
	All patients N=15
Month 24	60.0 (31.8, 79.7)
Month 27	60.0 (31.8, 79.7)
Month 30	46.7 (21.2, 68.7)
Month 33	46.7 (21.2, 68.7)
Month 36	46.7 (21.2, 68.7)
Month 39	46.7 (21.2, 68.7)
Month 42	46.7 (21.2, 68.7)
Month 45	46.7 (21.2, 68.7)
Month 48	46.7 (21.2, 68.7)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194d
Overall survival (OS) by Ethnicity
Full analysis set

Ethnicity: Other

	All patients N=65
Events/Total (%)	25/65 (38.5)
Maximum follow-up (months)	86.5
Median follow-up (months)	46.75
Percentiles (95% CI) [1]	
25th	17.9 (9.1, 45.6)
50th	NE (46.8, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.8 (84.4, 97.6)
Month 6	89.2 (78.7, 94.7)
Month 9	87.7 (76.8, 93.6)
Month 12	79.8 (67.8, 87.8)
Month 15	76.7 (64.3, 85.2)
Month 18	73.4 (60.7, 82.5)
Month 21	71.7 (58.8, 81.1)

Ethnicity: Other	
	All patients N=65
Month 24	70.0 (57.0, 79.7)
Month 27	70.0 (57.0, 79.7)
Month 30	70.0 (57.0, 79.7)
Month 33	68.1 (54.9, 78.1)
Month 36	68.1 (54.9, 78.1)
Month 39	68.1 (54.9, 78.1)
Month 42	68.1 (54.9, 78.1)
Month 45	66.1 (52.8, 76.5)
Month 48	62.2 (48.6, 73.2)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194e
Overall survival (OS) by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory	**All patients N=6**
Events/Total (%)	2/6 (33.3)
Maximum follow-up (months)	66.0
Median follow-up (months)	29.50
Percentiles (95% CI) [1]	
25th	28.3 (1.7, NE)
50th	NE (1.7, NE)
75th	NE (28.3, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	83.3 (27.3, 97.5)
Month 6	83.3 (27.3, 97.5)
Month 9	83.3 (27.3, 97.5)
Month 12	83.3 (27.3, 97.5)
Month 15	83.3 (27.3, 97.5)
Month 18	83.3 (27.3, 97.5)
Month 21	83.3 (27.3, 97.5)

Response status at study entry: Primary refractory	
	All patients N=6
Month 24	83.3 (27.3, 97.5)
Month 27	83.3 (27.3, 97.5)
Month 30	62.5 (14.2, 89.3)
Month 33	62.5 (14.2, 89.3)
Month 36	62.5 (14.2, 89.3)
Month 39	62.5 (14.2, 89.3)
Month 42	62.5 (14.2, 89.3)
Month 45	62.5 (14.2, 89.3)
Month 48	62.5 (14.2, 89.3)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194e
Overall survival (OS) by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease	**All patients N=74**
Events/Total (%)	31/74 (41.9)
Maximum follow-up (months)	86.5
Median follow-up (months)	47.52
Percentiles (95% CI) [1]	
25th	14.0 (8.6, 32.2)
50th	NE (44.3, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.2 (84.5, 97.1)
Month 6	89.2 (79.5, 94.4)
Month 9	85.1 (74.7, 91.5)
Month 12	76.9 (65.4, 84.9)
Month 15	74.1 (62.4, 82.6)
Month 18	69.8 (57.8, 79.0)
Month 21	68.3 (56.3, 77.7)

Response status at study entry: Relapsed disease	
	All patients N=74
Month 24	66.8 (54.7, 76.4)
Month 27	66.8 (54.7, 76.4)
Month 30	65.3 (53.1, 75.1)
Month 33	63.8 (51.5, 73.7)
Month 36	63.8 (51.5, 73.7)
Month 39	63.8 (51.5, 73.7)
Month 42	63.8 (51.5, 73.7)
Month 45	62.2 (49.8, 72.3)
Month 48	59.0 (46.5, 69.5)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive	**All patients N=2**
Events/Total (%)	0/2 (0.0)
Maximum follow-up (months)	61.4
Median follow-up (months)	60.73
Percentiles (95% CI) [1]	
25th	NE
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive	
	All patients N=2
Month 24	100 (100, 100)
Month 27	100 (100, 100)
Month 30	100 (100, 100)
Month 33	100 (100, 100)
Month 36	100 (100, 100)
Month 39	100 (100, 100)
Month 42	100 (100, 100)
Month 45	100 (100, 100)
Month 48	100 (100, 100)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Non-Positive	**All patients N=78**
Events/Total (%)	33/78 (42.3)
Maximum follow-up (months)	86.5
Median follow-up (months)	44.94
Percentiles (95% CI) [1]	
25th	14.0 (8.6, 28.3)
50th	NE (44.3, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.3 (83.7, 96.5)
Month 6	88.5 (79.0, 93.8)
Month 9	84.6 (74.4, 90.9)
Month 12	76.8 (65.7, 84.7)
Month 15	74.1 (62.8, 82.5)
Month 18	70.1 (58.5, 79.0)
Month 21	68.7 (57.0, 77.8)

Philadelphia chromosome/BCR-ABL: Non-Positive	
	All patients N=78
Month 24	67.3 (55.5, 76.6)
Month 27	67.3 (55.5, 76.6)
Month 30	64.4 (52.4, 74.0)
Month 33	62.8 (50.8, 72.7)
Month 36	62.8 (50.8, 72.7)
Month 39	62.8 (50.8, 72.7)
Month 42	62.8 (50.8, 72.7)
Month 45	61.3 (49.2, 71.3)
Month 48	58.1 (45.9, 68.5)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194g
Overall survival (OS) by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1
Events/Total (%)	1/1 (100.0)
Maximum follow-up (months)	10.5
Median follow-up (months)	10.48
Percentiles (95% CI) [1]	
25th	10.5 (NE, NE)
50th	10.5 (NE, NE)
75th	10.5 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	0.0 (NE, NE)
Month 15	0.0 (NE, NE)
Month 18	0.0 (NE, NE)
Month 21	0.0 (NE, NE)

Mixed-lineage leukemia rearrangement: Yes	
	All patients N=1
Month 24	0.0 (NE, NE)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194g
Overall survival (OS) by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	All patients N=79
Events/Total (%)	32/79 (40.5)
Maximum follow-up (months)	86.5
Median follow-up (months)	46.75
Percentiles (95% CI) [1]	
25th	15.2 (8.6, 32.2)
50th	NE (45.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.4 (83.9, 96.5)
Month 6	88.6 (79.3, 93.9)
Month 9	84.8 (74.7, 91.1)
Month 12	78.4 (67.5, 85.9)
Month 15	75.8 (64.7, 83.8)
Month 18	71.8 (60.3, 80.4)
Month 21	70.4 (58.9, 79.2)

Mixed-lineage leukemia rearrangement: No	
	All patients N=79
Month 24	69.0 (57.4, 78.1)
Month 27	69.0 (57.4, 78.1)
Month 30	66.1 (54.3, 75.6)
Month 33	64.6 (52.7, 74.3)
Month 36	64.6 (52.7, 74.3)
Month 39	64.6 (52.7, 74.3)
Month 42	64.6 (52.7, 74.3)
Month 45	63.1 (51.1, 72.9)
Month 48	60.0 (47.9, 70.2)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194h
Overall survival (OS) by Hypodiploidy
Full analysis set

Hypodiploidy: Yes

	All patients N=1
Events/Total (%)	0/1 (0.0)
Maximum follow-up (months)	59.9
Median follow-up (months)	59.89
Percentiles (95% CI) [1]	
25th	NE
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Hypodiploidy: Yes	
	All patients N=1
Month 24	100 (100, 100)
Month 27	100 (100, 100)
Month 30	100 (100, 100)
Month 33	100 (100, 100)
Month 36	100 (100, 100)
Month 39	100 (100, 100)
Month 42	100 (100, 100)
Month 45	100 (100, 100)
Month 48	100 (100, 100)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194h
Overall survival (OS) by Hypodiploidy
Full analysis set

Hypodiploidy: No

	All patients N=79
Events/Total (%)	33/79 (41.8)
Maximum follow-up (months)	86.5
Median follow-up (months)	45.60
Percentiles (95% CI) [1]	
25th	14.0 (8.6, 28.3)
50th	NE (44.3, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.4 (83.9, 96.5)
Month 6	88.6 (79.3, 93.9)
Month 9	84.8 (74.7, 91.1)
Month 12	77.1 (66.1, 84.9)
Month 15	74.5 (63.3, 82.7)
Month 18	70.5 (59.0, 79.3)
Month 21	69.1 (57.5, 78.1)

Hypodiploidy: No	
	All patients N=79
Month 24	67.7 (56.0, 76.9)
Month 27	67.7 (56.0, 76.9)
Month 30	64.8 (53.0, 74.4)
Month 33	63.3 (51.4, 73.1)
Month 36	63.3 (51.4, 73.1)
Month 39	63.3 (51.4, 73.1)
Month 42	63.3 (51.4, 73.1)
Month 45	61.8 (49.8, 71.7)
Month 48	58.7 (46.6, 69.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194i
Overall survival (OS) by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	All patients N=1
Events/Total (%)	0/1 (0.0)
Maximum follow-up (months)	18.2
Median follow-up (months)	18.17
Percentiles (95% CI) [1]	
25th	NE
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	NE

BCR-ABL1-like: Yes

	All patients N=1
Month 24	NE
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194i
Overall survival (OS) by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	All patients N=79
Events/Total (%)	33/79 (41.8)
Maximum follow-up (months)	86.5
Median follow-up (months)	46.75
Percentiles (95% CI) [1]	
25th	14.0 (8.6, 28.3)
50th	NE (44.3, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.4 (83.9, 96.5)
Month 6	88.6 (79.3, 93.9)
Month 9	84.8 (74.7, 91.1)
Month 12	77.1 (66.1, 84.9)
Month 15	74.5 (63.3, 82.7)
Month 18	70.5 (59.0, 79.3)
Month 21	69.1 (57.5, 78.1)

BCR-ABL1-like: No

	All patients N=79
Month 24	67.8 (56.1, 77.0)
Month 27	67.8 (56.1, 77.0)
Month 30	64.9 (53.1, 74.5)
Month 33	63.5 (51.6, 73.2)
Month 36	63.5 (51.6, 73.2)
Month 39	63.5 (51.6, 73.2)
Month 42	63.5 (51.6, 73.2)
Month 45	62.0 (50.0, 71.9)
Month 48	58.9 (46.9, 69.2)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194j
Overall survival (OS) by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	**All patients N=27**
Events/Total (%)	14/27 (51.9)
Maximum follow-up (months)	86.5
Median follow-up (months)	37.95
Percentiles (95% CI) [1]	
25th	11.8 (2.3, 32.2)
50th	53.6 (14.0, NE)
75th	NE (57.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	92.6 (73.5, 98.1)
Month 6	88.9 (69.4, 96.3)
Month 9	88.9 (69.4, 96.3)
Month 12	74.1 (53.2, 86.7)
Month 15	70.4 (49.4, 83.9)
Month 18	70.4 (49.4, 83.9)
Month 21	70.4 (49.4, 83.9)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	
	All patients N=27
Month 24	66.5 (45.4, 80.9)
Month 27	66.5 (45.4, 80.9)
Month 30	62.6 (41.5, 77.8)
Month 33	58.4 (37.4, 74.5)
Month 36	58.4 (37.4, 74.5)
Month 39	58.4 (37.4, 74.5)
Month 42	58.4 (37.4, 74.5)
Month 45	53.9 (33.1, 70.8)
Month 48	53.9 (33.1, 70.8)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194j
Overall survival (OS) by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No	**All patients N=53**
Events/Total (%)	19/53 (35.8)
Maximum follow-up (months)	67.1
Median follow-up (months)	48.30
Percentiles (95% CI) [1]	
25th	16.6 (6.8, 46.8)
50th	NE (45.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.5 (81.1, 97.1)
Month 6	88.7 (76.5, 94.7)
Month 9	82.9 (69.8, 90.7)
Month 12	79.1 (65.4, 87.8)
Month 15	77.1 (63.3, 86.3)
Month 18	71.1 (56.7, 81.5)
Month 21	69.0 (54.4, 79.8)

Complex karyotypes II (>=5 unrelated abnormalities) : No	
	All patients N=53
Month 24	69.0 (54.4, 79.8)
Month 27	69.0 (54.4, 79.8)
Month 30	66.8 (52.0, 77.9)
Month 33	66.8 (52.0, 77.9)
Month 36	66.8 (52.0, 77.9)
Month 39	66.8 (52.0, 77.9)
Month 42	66.8 (52.0, 77.9)
Month 45	66.8 (52.0, 77.9)
Month 48	62.2 (47.1, 74.1)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194k
Overall survival (OS) by Region
Full analysis set

Region: Europe

	All patients N=28
Events/Total (%)	9/28 (32.1)
Maximum follow-up (months)	67.1
Median follow-up (months)	58.32
Percentiles (95% CI) [1]	
25th	45.6 (9.1, NE)
50th	NE (53.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	96.4 (77.2, 99.5)
Month 9	96.4 (77.2, 99.5)
Month 12	81.6 (61.3, 91.9)
Month 15	81.6 (61.3, 91.9)
Month 18	81.6 (61.3, 91.9)
Month 21	81.6 (61.3, 91.9)

Region: Europe	
	All patients N=28
Month 24	81.6 (61.3, 91.9)
Month 27	81.6 (61.3, 91.9)
Month 30	81.6 (61.3, 91.9)
Month 33	81.6 (61.3, 91.9)
Month 36	81.6 (61.3, 91.9)
Month 39	81.6 (61.3, 91.9)
Month 42	81.6 (61.3, 91.9)
Month 45	77.1 (55.7, 89.0)
Month 48	72.5 (50.5, 86.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194k
Overall survival (OS) by Region
Full analysis set

Region: US

	All patients N=45
Events/Total (%)	20/45 (44.4)
Maximum follow-up (months)	86.5
Median follow-up (months)	30.69
Percentiles (95% CI) [1]	
25th	13.3 (4.0, 21.2)
50th	NE (19.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	88.9 (75.3, 95.2)
Month 6	84.4 (70.1, 92.3)
Month 9	77.8 (62.6, 87.4)
Month 12	75.6 (60.2, 85.6)
Month 15	73.3 (57.8, 83.9)
Month 18	66.6 (50.8, 78.3)
Month 21	64.3 (48.5, 76.4)

Region: US	
	All patients N=45
Month 24	62.0 (46.2, 74.4)
Month 27	62.0 (46.2, 74.4)
Month 30	57.0 (41.2, 70.1)
Month 33	57.0 (41.2, 70.1)
Month 36	57.0 (41.2, 70.1)
Month 39	57.0 (41.2, 70.1)
Month 42	57.0 (41.2, 70.1)
Month 45	57.0 (41.2, 70.1)
Month 48	54.3 (38.4, 67.8)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194k
Overall survival (OS) by Region
Full analysis set

Region: Rest of World	**All patients N=7**
Events/Total (%)	4/7 (57.1)
Maximum follow-up (months)	60.4
Median follow-up (months)	32.20
Percentiles (95% CI) [1]	
25th	11.6 (2.3, 32.2)
50th	32.2 (2.3, NE)
75th	NE (14.0, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	85.7 (33.4, 97.9)
Month 6	85.7 (33.4, 97.9)
Month 9	85.7 (33.4, 97.9)
Month 12	71.4 (25.8, 92.0)
Month 15	57.1 (17.2, 83.7)
Month 18	57.1 (17.2, 83.7)
Month 21	57.1 (17.2, 83.7)

Region: Rest of World	
	All patients N=7
Month 24	57.1 (17.2, 83.7)
Month 27	57.1 (17.2, 83.7)
Month 30	57.1 (17.2, 83.7)
Month 33	42.9 (9.8, 73.4)
Month 36	42.9 (9.8, 73.4)
Month 39	42.9 (9.8, 73.4)
Month 42	42.9 (9.8, 73.4)
Month 45	42.9 (9.8, 73.4)
Month 48	42.9 (9.8, 73.4)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 19 4l
Overall survival (OS) by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes	**All patients N=48**
Events/Total (%)	20/48 (41.7)
Maximum follow-up (months)	72.9
Median follow-up (months)	50.92
Percentiles (95% CI) [1]	
25th	14.0 (9.1, 46.8)
50th	NE (32.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	97.9 (86.1, 99.7)
Month 6	93.7 (81.9, 97.9)
Month 9	89.5 (76.6, 95.5)
Month 12	78.8 (64.2, 88.0)
Month 15	74.5 (59.5, 84.7)
Month 18	72.3 (57.0, 82.9)
Month 21	70.0 (54.6, 81.0)

Prior SCT therapy: Yes	
	All patients N=48
Month 24	70.0 (54.6, 81.0)
Month 27	70.0 (54.6, 81.0)
Month 30	67.7 (52.1, 79.1)
Month 33	65.2 (49.6, 77.1)
Month 36	65.2 (49.6, 77.1)
Month 39	65.2 (49.6, 77.1)
Month 42	65.2 (49.6, 77.1)
Month 45	62.8 (47.1, 75.1)
Month 48	60.4 (44.6, 73.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194l
Overall survival (OS) by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	All patients N=32
Events/Total (%)	13/32 (40.6)
Maximum follow-up (months)	86.5
Median follow-up (months)	34.32
Percentiles (95% CI) [1]	
25th	13.5 (1.7, 45.6)
50th	NE (17.9, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	84.4 (66.5, 93.2)
Month 6	81.3 (62.9, 91.1)
Month 9	78.1 (59.5, 88.9)
Month 12	75.0 (56.2, 86.6)
Month 15	75.0 (56.2, 86.6)
Month 18	68.6 (49.5, 81.7)
Month 21	68.6 (49.5, 81.7)

Prior SCT therapy: No	
	All patients N=32
Month 24	65.2 (45.9, 79.0)
Month 27	65.2 (45.9, 79.0)
Month 30	61.6 (42.2, 76.1)
Month 33	61.6 (42.2, 76.1)
Month 36	61.6 (42.2, 76.1)
Month 39	61.6 (42.2, 76.1)
Month 42	61.6 (42.2, 76.1)
Month 45	61.6 (42.2, 76.1)
Month 48	57.5 (37.9, 72.9)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194m
Overall survival (OS) by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes	**All patients N=13**
Events/Total (%)	6/13 (46.2)
Maximum follow-up (months)	61.4
Median follow-up (months)	37.95
Percentiles (95% CI) [1]	
25th	17.9 (10.5, NE)
50th	NE (16.6, NE)
75th	NE (32.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	84.6 (51.2, 95.9)
Month 15	84.6 (51.2, 95.9)
Month 18	69.2 (37.3, 87.2)
Month 21	61.5 (30.8, 81.8)

Eligibility for SCT: Yes	
	All patients N=13
Month 24	61.5 (30.8, 81.8)
Month 27	61.5 (30.8, 81.8)
Month 30	61.5 (30.8, 81.8)
Month 33	53.8 (24.8, 76.0)
Month 36	53.8 (24.8, 76.0)
Month 39	53.8 (24.8, 76.0)
Month 42	53.8 (24.8, 76.0)
Month 45	53.8 (24.8, 76.0)
Month 48	53.8 (24.8, 76.0)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194m
Overall survival (OS) by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	All patients N=67
Events/Total (%)	27/67 (40.3)
Maximum follow-up (months)	86.5
Median follow-up (months)	46.75
Percentiles (95% CI) [1]	
25th	13.3 (6.8, 44.3)
50th	NE (45.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	91.0 (81.1, 95.9)
Month 6	86.6 (75.8, 92.8)
Month 9	82.0 (70.5, 89.4)
Month 12	76.0 (63.8, 84.5)
Month 15	72.9 (60.5, 82.0)
Month 18	71.3 (58.8, 80.7)
Month 21	71.3 (58.8, 80.7)

Eligibility for SCT: No	
	All patients N=67
Month 24	69.7 (57.0, 79.3)
Month 27	69.7 (57.0, 79.3)
Month 30	66.2 (53.3, 76.3)
Month 33	66.2 (53.3, 76.3)
Month 36	66.2 (53.3, 76.3)
Month 39	66.2 (53.3, 76.3)
Month 42	66.2 (53.3, 76.3)
Month 45	64.4 (51.3, 74.8)
Month 48	60.7 (47.4, 71.6)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194n
Overall survival (OS) by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low

	All patients N=26
Events/Total (%)	6/26 (23.1)
Maximum follow-up (months)	67.1
Median follow-up (months)	59.99
Percentiles (95% CI) [1]	
25th	46.8 (8.6, NE)
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	96.2 (75.7, 99.4)
Month 6	96.2 (75.7, 99.4)
Month 9	92.3 (72.6, 98.0)
Month 12	92.3 (72.6, 98.0)
Month 15	92.3 (72.6, 98.0)
Month 18	87.9 (66.9, 96.0)
Month 21	87.9 (66.9, 96.0)

Baseline bone marrow tumor burden: Low	
	All patients N=26
Month 24	83.5 (61.7, 93.5)
Month 27	83.5 (61.7, 93.5)
Month 30	83.5 (61.7, 93.5)
Month 33	83.5 (61.7, 93.5)
Month 36	83.5 (61.7, 93.5)
Month 39	83.5 (61.7, 93.5)
Month 42	83.5 (61.7, 93.5)
Month 45	83.5 (61.7, 93.5)
Month 48	73.7 (50.2, 87.3)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194n
Overall survival (OS) by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High

	All patients N=54
Events/Total (%)	27/54 (50.0)
Maximum follow-up (months)	86.5
Median follow-up (months)	30.32
Percentiles (95% CI) [1]	
25th	10.9 (5.3, 16.6)
50th	53.6 (16.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	90.7 (79.2, 96.0)
Month 6	85.2 (72.6, 92.3)
Month 9	81.4 (68.2, 89.6)
Month 12	70.1 (55.9, 80.5)
Month 15	66.3 (51.9, 77.3)
Month 18	62.5 (48.1, 73.9)
Month 21	60.5 (46.1, 72.2)

Baseline bone marrow tumor burden: High	
	All patients N=54
Month 24	60.5 (46.1, 72.2)
Month 27	60.5 (46.1, 72.2)
Month 30	56.5 (42.1, 68.6)
Month 33	54.4 (40.0, 66.7)
Month 36	54.4 (40.0, 66.7)
Month 39	54.4 (40.0, 66.7)
Month 42	54.4 (40.0, 66.7)
Month 45	52.2 (37.9, 64.8)
Month 48	52.2 (37.9, 64.8)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194o
Overall survival (OS) by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	All patients N=11
Events/Total (%)	3/11 (27.3)
Maximum follow-up (months)	67.1
Median follow-up (months)	52.63
Percentiles (95% CI) [1]	
25th	46.8 (9.1, NE)
50th	NE (10.9, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	81.8 (44.7, 95.1)
Month 15	81.8 (44.7, 95.1)
Month 18	81.8 (44.7, 95.1)
Month 21	81.8 (44.7, 95.1)

Baseline extramedullary disease presence: Yes	
	All patients N=11
Month 24	81.8 (44.7, 95.1)
Month 27	81.8 (44.7, 95.1)
Month 30	81.8 (44.7, 95.1)
Month 33	81.8 (44.7, 95.1)
Month 36	81.8 (44.7, 95.1)
Month 39	81.8 (44.7, 95.1)
Month 42	81.8 (44.7, 95.1)
Month 45	81.8 (44.7, 95.1)
Month 48	70.1 (32.3, 89.5)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194o
Overall survival (OS) by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	All patients N=69
Events/Total (%)	30/69 (43.5)
Maximum follow-up (months)	86.5
Median follow-up (months)	44.29
Percentiles (95% CI) [1]	
25th	14.0 (6.8, 28.2)
50th	NE (32.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	91.3 (81.7, 96.0)
Month 6	87.0 (76.4, 93.0)
Month 9	82.6 (71.3, 89.7)
Month 12	76.7 (64.8, 85.0)
Month 15	73.7 (61.6, 82.6)
Month 18	69.2 (56.8, 78.7)
Month 21	67.7 (55.1, 77.4)

Baseline extramedullary disease presence: No	
	All patients N=69
Month 24	66.1 (53.5, 76.0)
Month 27	66.1 (53.5, 76.0)
Month 30	62.9 (50.2, 73.2)
Month 33	61.2 (48.4, 71.7)
Month 36	61.2 (48.4, 71.7)
Month 39	61.2 (48.4, 71.7)
Month 42	61.2 (48.4, 71.7)
Month 45	59.4 (46.6, 70.2)
Month 48	57.7 (44.8, 68.6)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194p
Overall survival (OS) by Down syndrome
Full analysis set

Down syndrome: Yes	**All patients N=6**
Events/Total (%)	3/6 (50.0)
Maximum follow-up (months)	63.2
Median follow-up (months)	46.26
Percentiles (95% CI) [1]	
25th	13.3 (0.5, NE)
50th	NE (0.5, NE)
75th	NE (13.3, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	83.3 (27.3, 97.5)
Month 6	83.3 (27.3, 97.5)
Month 9	83.3 (27.3, 97.5)
Month 12	83.3 (27.3, 97.5)
Month 15	66.7 (19.5, 90.4)
Month 18	66.7 (19.5, 90.4)
Month 21	66.7 (19.5, 90.4)

Down syndrome: Yes	
	All patients N=6
Month 24	66.7 (19.5, 90.4)
Month 27	66.7 (19.5, 90.4)
Month 30	66.7 (19.5, 90.4)
Month 33	50.0 (11.1, 80.4)
Month 36	50.0 (11.1, 80.4)
Month 39	50.0 (11.1, 80.4)
Month 42	50.0 (11.1, 80.4)
Month 45	50.0 (11.1, 80.4)
Month 48	50.0 (11.1, 80.4)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194p
Overall survival (OS) by Down syndrome
Full analysis set

Down syndrome: No

	All patients N=74
Events/Total (%)	30/74 (40.5)
Maximum follow-up (months)	86.5
Median follow-up (months)	46.18
Percentiles (95% CI) [1]	
25th	15.2 (8.6, 28.3)
50th	NE (45.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.2 (84.5, 97.1)
Month 6	89.2 (79.5, 94.4)
Month 9	85.1 (74.7, 91.5)
Month 12	76.9 (65.4, 84.9)
Month 15	75.5 (63.9, 83.8)
Month 18	71.2 (59.3, 80.2)
Month 21	69.7 (57.7, 78.9)

Down syndrome: No	
	All patients N=74
Month 24	68.2 (56.1, 77.6)
Month 27	68.2 (56.1, 77.6)
Month 30	65.1 (52.8, 75.0)
Month 33	65.1 (52.8, 75.0)
Month 36	65.1 (52.8, 75.0)
Month 39	65.1 (52.8, 75.0)
Month 42	65.1 (52.8, 75.0)
Month 45	63.4 (51.0, 73.5)
Month 48	60.1 (47.5, 70.6)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median	**All patients N=40**
Events/Total (%)	15/40 (37.5)
Maximum follow-up (months)	67.1
Median follow-up (months)	55.46
Percentiles (95% CI) [1]	
25th	14.0 (9.1, 57.4)
50th	NE (45.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	95.0 (81.5, 98.7)
Month 6	92.5 (78.5, 97.5)
Month 9	89.9 (75.4, 96.1)
Month 12	79.7 (63.4, 89.3)
Month 15	74.4 (57.7, 85.3)
Month 18	74.4 (57.7, 85.3)
Month 21	74.4 (57.7, 85.3)

Time since enrollment to CTL019 infusion: > Median	
	All patients N=40
Month 24	74.4 (57.7, 85.3)
Month 27	74.4 (57.7, 85.3)
Month 30	71.4 (54.3, 83.1)
Month 33	68.3 (50.9, 80.7)
Month 36	68.3 (50.9, 80.7)
Month 39	68.3 (50.9, 80.7)
Month 42	68.3 (50.9, 80.7)
Month 45	68.3 (50.9, 80.7)
Month 48	65.2 (47.5, 78.2)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40
Events/Total (%)	18/40 (45.0)
Maximum follow-up (months)	86.5
Median follow-up (months)	41.12
Percentiles (95% CI) [1]	
25th	13.1 (4.0, 28.2)
50th	NE (19.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	90.0 (75.5, 96.1)
Month 6	85.0 (69.6, 93.0)
Month 9	80.0 (64.0, 89.5)
Month 12	75.0 (58.5, 85.7)
Month 15	75.0 (58.5, 85.7)
Month 18	67.4 (50.6, 79.6)
Month 21	64.8 (47.9, 77.4)

Time since enrollment to CTL019 infusion: <=Median	**All patients N=40**
Month 24	62.2 (45.3, 75.2)
Month 27	62.2 (45.3, 75.2)
Month 30	59.5 (42.6, 72.9)
Month 33	59.5 (42.6, 72.9)
Month 36	59.5 (42.6, 72.9)
Month 39	59.5 (42.6, 72.9)
Month 42	59.5 (42.6, 72.9)
Month 45	56.5 (39.6, 70.4)
Month 48	53.6 (36.7, 67.8)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: 0	**All patients N=6**
Events/Total (%)	2/6 (33.3)
Maximum follow-up (months)	66.0
Median follow-up (months)	29.50
Percentiles (95% CI) [1]	
25th	28.3 (1.7, NE)
50th	NE (1.7, NE)
75th	NE (28.3, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	83.3 (27.3, 97.5)
Month 6	83.3 (27.3, 97.5)
Month 9	83.3 (27.3, 97.5)
Month 12	83.3 (27.3, 97.5)
Month 15	83.3 (27.3, 97.5)
Month 18	83.3 (27.3, 97.5)
Month 21	83.3 (27.3, 97.5)

Number of previous relapses: 0	
	All patients N=6
Month 24	83.3 (27.3, 97.5)
Month 27	83.3 (27.3, 97.5)
Month 30	62.5 (14.2, 89.3)
Month 33	62.5 (14.2, 89.3)
Month 36	62.5 (14.2, 89.3)
Month 39	62.5 (14.2, 89.3)
Month 42	62.5 (14.2, 89.3)
Month 45	62.5 (14.2, 89.3)
Month 48	62.5 (14.2, 89.3)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	All patients N=22
Events/Total (%)	10/22 (45.5)
Maximum follow-up (months)	65.1
Median follow-up (months)	33.41
Percentiles (95% CI) [1]	
25th	15.2 (0.5, 45.6)
50th	NE (15.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	86.4 (63.4, 95.4)
Month 6	81.8 (58.5, 92.8)
Month 9	81.8 (58.5, 92.8)
Month 12	77.3 (53.7, 89.8)
Month 15	77.3 (53.7, 89.8)
Month 18	62.4 (38.5, 79.2)
Month 21	62.4 (38.5, 79.2)

Number of previous relapses: 1	
	All patients N=22
Month 24	57.2 (33.6, 75.1)
Month 27	57.2 (33.6, 75.1)
Month 30	57.2 (33.6, 75.1)
Month 33	57.2 (33.6, 75.1)
Month 36	57.2 (33.6, 75.1)
Month 39	57.2 (33.6, 75.1)
Month 42	57.2 (33.6, 75.1)
Month 45	57.2 (33.6, 75.1)
Month 48	52.0 (29.0, 70.8)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	All patients N=17
Events/Total (%)	6/17 (35.3)
Maximum follow-up (months)	86.5
Median follow-up (months)	28.45
Percentiles (95% CI) [1]	
25th	11.8 (0.4, NE)
50th	NE (10.9, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	94.1 (65.0, 99.1)
Month 6	94.1 (65.0, 99.1)
Month 9	82.4 (54.7, 93.9)
Month 12	70.6 (43.1, 86.6)
Month 15	70.6 (43.1, 86.6)
Month 18	70.6 (43.1, 86.6)
Month 21	64.2 (36.9, 82.1)

Number of previous relapses: 2	
	All patients N=17
Month 24	64.2 (36.9, 82.1)
Month 27	64.2 (36.9, 82.1)
Month 30	64.2 (36.9, 82.1)
Month 33	64.2 (36.9, 82.1)
Month 36	64.2 (36.9, 82.1)
Month 39	64.2 (36.9, 82.1)
Month 42	64.2 (36.9, 82.1)
Month 45	64.2 (36.9, 82.1)
Month 48	64.2 (36.9, 82.1)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 194r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	All patients N=35
Events/Total (%)	15/35 (42.9)
Maximum follow-up (months)	72.9
Median follow-up (months)	53.55
Percentiles (95% CI) [1]	
25th	14.0 (8.6, 53.6)
50th	NE (32.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	97.1 (81.4, 99.6)
Month 6	91.4 (75.7, 97.2)
Month 9	88.5 (72.1, 95.5)
Month 12	79.6 (61.9, 89.7)
Month 15	73.7 (55.6, 85.4)
Month 18	73.7 (55.6, 85.4)
Month 21	73.7 (55.6, 85.4)

Number of previous relapses: >=3	
	All patients N=35
Month 24	73.7 (55.6, 85.4)
Month 27	73.7 (55.6, 85.4)
Month 30	70.7 (52.3, 83.0)
Month 33	67.6 (49.1, 80.6)
Month 36	67.6 (49.1, 80.6)
Month 39	67.6 (49.1, 80.6)
Month 42	67.6 (49.1, 80.6)
Month 45	64.4 (45.8, 78.0)
Month 48	61.2 (42.5, 75.3)

-Full analysis set (FAS) = All patients who received an infusion of CTL019 [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195a
Overall survival (OS) by Age
Enrolled set

Age: <10 years	**All patients N=41**
Events/Total (%)	24/41 (58.5)
Maximum follow-up (months)	87.5
Median follow-up (months)	18.37
Percentiles (95% CI) [1]	
25th	7.3 (1.9, 12.2)
50th	20.1 (10.6, NE)
75th	NE (55.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	85.4 (70.3, 93.1)
Month 6	75.6 (59.4, 86.1)
Month 9	70.7 (54.3, 82.2)
Month 12	63.4 (46.8, 76.1)
Month 15	58.5 (42.0, 71.8)
Month 18	53.4 (37.1, 67.3)
Month 21	48.1 (32.1, 62.4)

Age: <10 years	
	All patients N=41
Month 24	48.1 (32.1, 62.4)
Month 27	48.1 (32.1, 62.4)
Month 30	48.1 (32.1, 62.4)
Month 33	48.1 (32.1, 62.4)
Month 36	48.1 (32.1, 62.4)
Month 39	48.1 (32.1, 62.4)
Month 42	48.1 (32.1, 62.4)
Month 45	48.1 (32.1, 62.4)
Month 48	42.1 (26.5, 56.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195a
Overall survival (OS) by Age
Enrolled set

Age: >=10 years to <18 years	**All patients N=40**
Events/Total (%)	16/40 (40.0)
Maximum follow-up (months)	68.8
Median follow-up (months)	36.70
Percentiles (95% CI) [1]	
25th	11.2 (1.8, 34.4)
50th	NE (29.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	87.5 (72.5, 94.6)
Month 6	79.8 (63.6, 89.3)
Month 9	77.2 (60.7, 87.4)
Month 12	74.5 (57.8, 85.4)
Month 15	74.5 (57.8, 85.4)
Month 18	74.5 (57.8, 85.4)
Month 21	74.5 (57.8, 85.4)

Age: >=10 years to <18 years	
	All patients N=40
Month 24	71.9 (55.0, 83.4)
Month 27	69.2 (52.2, 81.2)
Month 30	66.5 (49.3, 79.0)
Month 33	63.4 (46.1, 76.5)
Month 36	60.4 (42.9, 74.0)
Month 39	60.4 (42.9, 74.0)
Month 42	60.4 (42.9, 74.0)
Month 45	60.4 (42.9, 74.0)
Month 48	57.2 (39.7, 71.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195a
Overall survival (OS) by Age
Enrolled set

Age: >=18

	All patients N=17
Events/Total (%)	9/17 (52.9)
Maximum follow-up (months)	66.3
Median follow-up (months)	16.56
Percentiles (95% CI) [1]	
25th	12.1 (0.4, 16.6)
50th	59.4 (5.9, NE)
75th	NE (16.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.1 (65.0, 99.1)
Month 6	75.3 (46.8, 89.9)
Month 9	75.3 (46.8, 89.9)
Month 12	75.3 (46.8, 89.9)
Month 15	56.5 (29.7, 76.4)
Month 18	50.2 (24.7, 71.2)
Month 21	50.2 (24.7, 71.2)

Age: >=18	
	All patients N=17
Month 24	50.2 (24.7, 71.2)
Month 27	50.2 (24.7, 71.2)
Month 30	50.2 (24.7, 71.2)
Month 33	50.2 (24.7, 71.2)
Month 36	50.2 (24.7, 71.2)
Month 39	50.2 (24.7, 71.2)
Month 42	50.2 (24.7, 71.2)
Month 45	50.2 (24.7, 71.2)
Month 48	50.2 (24.7, 71.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195b
Overall survival (OS) by Gender
Enrolled set

Gender: Male

	All patients N=55
Events/Total (%)	29/55 (52.7)
Maximum follow-up (months)	87.5
Median follow-up (months)	22.47
Percentiles (95% CI) [1]	
25th	8.2 (1.9, 14.8)
50th	47.6 (14.8, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	85.5 (73.0, 92.4)
Month 6	78.2 (64.8, 87.0)
Month 9	74.5 (60.8, 84.1)
Month 12	70.9 (56.9, 81.0)
Month 15	63.4 (49.2, 74.6)
Month 18	59.6 (45.3, 71.2)
Month 21	57.6 (43.3, 69.5)

Gender: Male	
	All patients N=55
Month 24	55.5 (41.3, 67.6)
Month 27	55.5 (41.3, 67.6)
Month 30	55.5 (41.3, 67.6)
Month 33	55.5 (41.3, 67.6)
Month 36	53.3 (39.0, 65.6)
Month 39	53.3 (39.0, 65.6)
Month 42	53.3 (39.0, 65.6)
Month 45	53.3 (39.0, 65.6)
Month 48	46.6 (32.5, 59.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195b
Overall survival (OS) by Gender
Enrolled set

Gender: Female

	All patients N=43
Events/Total (%)	20/43 (46.5)
Maximum follow-up (months)	68.8
Median follow-up (months)	30.06
Percentiles (95% CI) [1]	
25th	8.0 (3.9, 20.1)
50th	59.4 (12.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	90.5 (76.5, 96.3)
Month 6	75.8 (59.7, 86.2)
Month 9	73.3 (57.0, 84.3)
Month 12	68.5 (51.9, 80.3)
Month 15	66.0 (49.4, 78.3)
Month 18	63.6 (47.0, 76.2)
Month 21	61.0 (44.4, 74.0)

Gender: Female	
	All patients N=43
Month 24	61.0 (44.4, 74.0)
Month 27	58.5 (41.9, 71.8)
Month 30	55.9 (39.5, 69.6)
Month 33	53.1 (36.7, 67.1)
Month 36	53.1 (36.7, 67.1)
Month 39	53.1 (36.7, 67.1)
Month 42	53.1 (36.7, 67.1)
Month 45	53.1 (36.7, 67.1)
Month 48	53.1 (36.7, 67.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195c
Overall survival (OS) by Race
Enrolled set

Race: White

	All patients N=70
Events/Total (%)	31/70 (44.3)
Maximum follow-up (months)	87.5
Median follow-up (months)	35.37
Percentiles (95% CI) [1]	
25th	9.9 (4.0, 19.4)
50th	NE (29.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	88.4 (78.2, 94.0)
Month 6	78.3 (66.6, 86.3)
Month 9	75.4 (63.4, 83.9)
Month 12	69.5 (57.2, 78.9)
Month 15	68.0 (55.6, 77.7)
Month 18	66.5 (54.0, 76.3)
Month 21	64.9 (52.4, 75.0)

Race: White	
	All patients N=70
Month 24	63.3 (50.7, 73.5)
Month 27	63.3 (50.7, 73.5)
Month 30	61.7 (49.0, 72.1)
Month 33	60.0 (47.2, 70.6)
Month 36	60.0 (47.2, 70.6)
Month 39	60.0 (47.2, 70.6)
Month 42	60.0 (47.2, 70.6)
Month 45	60.0 (47.2, 70.6)
Month 48	56.4 (43.6, 67.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195c
Overall survival (OS) by Race
Enrolled set

Race: Asian

	All patients N=15
Events/Total (%)	9/15 (60.0)
Maximum follow-up (months)	63.0
Median follow-up (months)	16.49
Percentiles (95% CI) [1]	
25th	3.9 (1.3, 16.5)
50th	24.9 (3.1, NE)
75th	NE (16.5, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	86.7 (56.4, 96.5)
Month 6	65.0 (35.1, 83.7)
Month 9	65.0 (35.1, 83.7)
Month 12	65.0 (35.1, 83.7)
Month 15	57.8 (29.0, 78.4)
Month 18	50.6 (23.3, 72.7)
Month 21	50.6 (23.3, 72.7)

Race: Asian	
	All patients N=15
Month 24	50.6 (23.3, 72.7)
Month 27	43.3 (18.0, 66.5)
Month 30	43.3 (18.0, 66.5)
Month 33	43.3 (18.0, 66.5)
Month 36	32.5 (9.6, 58.3)
Month 39	32.5 (9.6, 58.3)
Month 42	32.5 (9.6, 58.3)
Month 45	32.5 (9.6, 58.3)
Month 48	32.5 (9.6, 58.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195c
Overall survival (OS) by Race
Enrolled set

Race: Other

	All patients N=13
Events/Total (%)	9/13 (69.2)
Maximum follow-up (months)	61.5
Median follow-up (months)	16.56
Percentiles (95% CI) [1]	
25th	12.1 (0.4, 16.6)
50th	16.6 (8.0, NE)
75th	NE (13.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	84.6 (51.2, 95.9)
Month 6	84.6 (51.2, 95.9)
Month 9	76.9 (44.2, 91.9)
Month 12	76.9 (44.2, 91.9)
Month 15	53.8 (24.8, 76.0)
Month 18	46.2 (19.2, 69.6)
Month 21	38.5 (14.1, 62.8)

Race: Other	
	All patients N=13
Month 24	38.5 (14.1, 62.8)
Month 27	38.5 (14.1, 62.8)
Month 30	38.5 (14.1, 62.8)
Month 33	38.5 (14.1, 62.8)
Month 36	38.5 (14.1, 62.8)
Month 39	38.5 (14.1, 62.8)
Month 42	38.5 (14.1, 62.8)
Month 45	38.5 (14.1, 62.8)
Month 48	30.8 (9.5, 55.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195d
Overall survival (OS) by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino	**All patients N=18**
Events/Total (%)	11/18 (61.1)
Maximum follow-up (months)	68.8
Median follow-up (months)	22.90
Percentiles (95% CI) [1]	
25th	4.8 (0.5, 12.1)
50th	22.9 (4.8, NE)
75th	NE (29.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	83.3 (56.8, 94.3)
Month 6	72.2 (45.6, 87.4)
Month 9	66.7 (40.4, 83.4)
Month 12	61.1 (35.3, 79.2)
Month 15	55.6 (30.5, 74.8)
Month 18	50.0 (25.9, 70.1)
Month 21	50.0 (25.9, 70.1)

Ethnicity: Hispanic or Latino	
	All patients N=18
Month 24	50.0 (25.9, 70.1)
Month 27	50.0 (25.9, 70.1)
Month 30	44.4 (21.6, 65.1)
Month 33	38.9 (17.5, 60.0)
Month 36	38.9 (17.5, 60.0)
Month 39	38.9 (17.5, 60.0)
Month 42	38.9 (17.5, 60.0)
Month 45	38.9 (17.5, 60.0)
Month 48	38.9 (17.5, 60.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195d
Overall survival (OS) by Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80
Events/Total (%)	38/80 (47.5)
Maximum follow-up (months)	87.5
Median follow-up (months)	25.97
Percentiles (95% CI) [1]	
25th	10.6 (3.9, 16.5)
50th	59.4 (20.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	88.6 (79.2, 93.9)
Month 6	78.3 (67.5, 85.9)
Month 9	75.8 (64.7, 83.8)
Month 12	71.8 (60.4, 80.5)
Month 15	66.6 (55.0, 75.9)
Month 18	64.0 (52.2, 73.5)
Month 21	61.2 (49.3, 71.0)

Ethnicity: Other	
	All patients N=80
Month 24	59.7 (47.9, 69.8)
Month 27	58.3 (46.4, 68.5)
Month 30	58.3 (46.4, 68.5)
Month 33	58.3 (46.4, 68.5)
Month 36	56.7 (44.8, 67.1)
Month 39	56.7 (44.8, 67.1)
Month 42	56.7 (44.8, 67.1)
Month 45	56.7 (44.8, 67.1)
Month 48	51.9 (39.8, 62.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195e
Overall survival (OS) by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory	**All patients N=8**
Events/Total (%)	4/8 (50.0)
Maximum follow-up (months)	68.8
Median follow-up (months)	28.98
Percentiles (95% CI) [1]	
25th	2.2 (0.5, 31.7)
50th	31.7 (0.5, NE)
75th	NE (3.0, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	62.5 (22.9, 86.1)
Month 6	62.5 (22.9, 86.1)
Month 9	62.5 (22.9, 86.1)
Month 12	62.5 (22.9, 86.1)
Month 15	62.5 (22.9, 86.1)
Month 18	62.5 (22.9, 86.1)
Month 21	62.5 (22.9, 86.1)

Response status at study entry: Primary refractory	
	All patients N=8
Month 24	62.5 (22.9, 86.1)
Month 27	62.5 (22.9, 86.1)
Month 30	62.5 (22.9, 86.1)
Month 33	41.7 (7.2, 74.7)
Month 36	41.7 (7.2, 74.7)
Month 39	41.7 (7.2, 74.7)
Month 42	41.7 (7.2, 74.7)
Month 45	41.7 (7.2, 74.7)
Month 48	41.7 (7.2, 74.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195e
Overall survival (OS) by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease	**All patients N=90**
Events/Total (%)	45/90 (50.0)
Maximum follow-up (months)	87.5
Median follow-up (months)	25.25
Percentiles (95% CI) [1]	
25th	9.9 (4.0, 13.9)
50th	47.9 (19.4, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	89.9 (81.5, 94.6)
Month 6	78.5 (68.4, 85.7)
Month 9	75.1 (64.7, 82.8)
Month 12	70.5 (59.8, 78.9)
Month 15	64.7 (53.8, 73.7)
Month 18	61.2 (50.1, 70.5)
Month 21	58.7 (47.7, 68.3)

Response status at study entry: Relapsed disease	
	All patients N=90
Month 24	57.5 (46.4, 67.1)
Month 27	56.2 (45.1, 66.0)
Month 30	55.0 (43.8, 64.8)
Month 33	55.0 (43.8, 64.8)
Month 36	53.7 (42.5, 63.6)
Month 39	53.7 (42.5, 63.6)
Month 42	53.7 (42.5, 63.6)
Month 45	53.7 (42.5, 63.6)
Month 48	49.6 (38.5, 59.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive	**All patients N=2**
Events/Total (%)	0/2 (0.0)
Maximum follow-up (months)	63.4
Median follow-up (months)	62.21
Percentiles (95% CI) [1]	
25th	NE
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive	
	All patients N=2
Month 24	100 (100, 100)
Month 27	100 (100, 100)
Month 30	100 (100, 100)
Month 33	100 (100, 100)
Month 36	100 (100, 100)
Month 39	100 (100, 100)
Month 42	100 (100, 100)
Month 45	100 (100, 100)
Month 48	100 (100, 100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive	**All patients N=96**
Events/Total (%)	49/96 (51.0)
Maximum follow-up (months)	87.5
Median follow-up (months)	25.25
Percentiles (95% CI) [1]	
25th	8.0 (3.9, 13.4)
50th	47.6 (17.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	87.4 (78.8, 92.6)
Month 6	76.7 (66.8, 84.0)
Month 9	73.5 (63.4, 81.3)
Month 12	69.2 (58.8, 77.5)
Month 15	63.8 (53.2, 72.6)
Month 18	60.5 (49.8, 69.6)
Month 21	58.2 (47.5, 67.5)

Philadelphia chromosome/BCR-ABL: Non-Positive	
	All patients N=96
Month 24	57.1 (46.3, 66.4)
Month 27	55.9 (45.2, 65.3)
Month 30	54.7 (43.9, 64.2)
Month 33	53.4 (42.7, 63.0)
Month 36	52.1 (41.4, 61.8)
Month 39	52.1 (41.4, 61.8)
Month 42	52.1 (41.4, 61.8)
Month 45	52.1 (41.4, 61.8)
Month 48	48.2 (37.5, 58.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195g
Overall survival (OS) by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1
Events/Total (%)	1/1 (100.0)
Maximum follow-up (months)	11.5
Median follow-up (months)	11.50
Percentiles (95% CI) [1]	
25th	11.5 (NE, NE)
50th	11.5 (NE, NE)
75th	11.5 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	0.0 (NE, NE)
Month 15	0.0 (NE, NE)
Month 18	0.0 (NE, NE)
Month 21	0.0 (NE, NE)

Mixed-lineage leukemia rearrangement: Yes	
	All patients N=1
Month 24	0.0 (NE, NE)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195g
Overall survival (OS) by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97
Events/Total (%)	48/97 (49.5)
Maximum follow-up (months)	87.5
Median follow-up (months)	26.32
Percentiles (95% CI) [1]	
25th	8.0 (3.9, 13.9)
50th	47.9 (20.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	87.5 (79.0, 92.7)
Month 6	77.0 (67.1, 84.2)
Month 9	73.8 (63.7, 81.5)
Month 12	70.6 (60.3, 78.7)
Month 15	65.3 (54.8, 73.9)
Month 18	62.0 (51.4, 70.9)
Month 21	59.7 (49.1, 68.9)

Mixed-lineage leukemia rearrangement: No	
	All patients N=97
Month 24	58.6 (47.9, 67.8)
Month 27	57.4 (46.8, 66.7)
Month 30	56.2 (45.6, 65.6)
Month 33	55.0 (44.3, 64.5)
Month 36	53.7 (43.0, 63.3)
Month 39	53.7 (43.0, 63.3)
Month 42	53.7 (43.0, 63.3)
Month 45	53.7 (43.0, 63.3)
Month 48	49.9 (39.2, 59.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195h
Overall survival (OS) by Hypodiploidy
Enrolled set

Hypodiploidy: Yes	**All patients N=3**
Events/Total (%)	2/3 (66.7)
Maximum follow-up (months)	61.8
Median follow-up (months)	1.81
Percentiles (95% CI) [1]	
25th	1.5 (1.5, NE)
50th	1.8 (1.5, NE)
75th	NE (1.5, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	33.3 (0.9, 77.4)
Month 6	33.3 (0.9, 77.4)
Month 9	33.3 (0.9, 77.4)
Month 12	33.3 (0.9, 77.4)
Month 15	33.3 (0.9, 77.4)
Month 18	33.3 (0.9, 77.4)
Month 21	33.3 (0.9, 77.4)

Hypodiploidy: Yes	
	All patients N=3
Month 24	33.3 (0.9, 77.4)
Month 27	33.3 (0.9, 77.4)
Month 30	33.3 (0.9, 77.4)
Month 33	33.3 (0.9, 77.4)
Month 36	33.3 (0.9, 77.4)
Month 39	33.3 (0.9, 77.4)
Month 42	33.3 (0.9, 77.4)
Month 45	33.3 (0.9, 77.4)
Month 48	33.3 (0.9, 77.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195h
Overall survival (OS) by Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95
Events/Total (%)	47/95 (49.5)
Maximum follow-up (months)	87.5
Median follow-up (months)	26.32
Percentiles (95% CI) [1]	
25th	9.9 (4.0, 14.8)
50th	47.9 (20.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	89.4 (81.1, 94.1)
Month 6	78.6 (68.8, 85.6)
Month 9	75.4 (65.3, 82.9)
Month 12	71.0 (60.6, 79.1)
Month 15	65.6 (54.9, 74.2)
Month 18	62.2 (51.5, 71.2)
Month 21	59.9 (49.2, 69.1)

Hypodiploidy: No	
	All patients N=95
Month 24	58.7 (48.0, 68.0)
Month 27	57.6 (46.8, 66.9)
Month 30	56.3 (45.5, 65.8)
Month 33	55.1 (44.2, 64.6)
Month 36	53.8 (42.9, 63.5)
Month 39	53.8 (42.9, 63.5)
Month 42	53.8 (42.9, 63.5)
Month 45	53.8 (42.9, 63.5)
Month 48	49.8 (39.0, 59.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195i
Overall survival (OS) by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2
Events/Total (%)	1/2 (50.0)
Maximum follow-up (months)	20.6
Median follow-up (months)	12.32
Percentiles (95% CI) [1]	
25th	4.0 (4.0, NE)
50th	NE (4.0, NE)
75th	NE (4.0, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	50.0 (0.6, 91.0)
Month 9	50.0 (0.6, 91.0)
Month 12	50.0 (0.6, 91.0)
Month 15	50.0 (0.6, 91.0)
Month 18	50.0 (0.6, 91.0)
Month 21	NE

BCR-ABL1-like: Yes

	All patients N=2
Month 24	NE
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195i
Overall survival (OS) by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96
Events/Total (%)	48/96 (50.0)
Maximum follow-up (months)	87.5
Median follow-up (months)	27.78
Percentiles (95% CI) [1]	
25th	8.2 (3.9, 13.9)
50th	47.9 (19.4, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	87.4 (78.8, 92.6)
Month 6	77.8 (68.0, 84.9)
Month 9	74.6 (64.5, 82.2)
Month 12	70.3 (59.9, 78.4)
Month 15	64.9 (54.3, 73.6)
Month 18	61.6 (50.9, 70.6)
Month 21	59.3 (48.6, 68.5)

BCR-ABL1-like: No	
	All patients N=96
Month 24	58.2 (47.4, 67.4)
Month 27	57.0 (46.3, 66.4)
Month 30	55.8 (45.1, 65.3)
Month 33	54.6 (43.8, 64.1)
Month 36	53.3 (42.6, 63.0)
Month 39	53.3 (42.6, 63.0)
Month 42	53.3 (42.6, 63.0)
Month 45	53.3 (42.6, 63.0)
Month 48	49.5 (38.8, 59.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195j
Overall survival (OS) by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30
Events/Total (%)	17/30 (56.7)
Maximum follow-up (months)	87.5
Median follow-up (months)	32.23
Percentiles (95% CI) [1]	
25th	12.2 (1.8, 22.5)
50th	45.7 (13.9, NE)
75th	NE (55.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	86.7 (68.3, 94.8)
Month 6	83.3 (64.5, 92.7)
Month 9	80.0 (60.8, 90.5)
Month 12	76.7 (57.2, 88.1)
Month 15	66.7 (46.9, 80.5)
Month 18	63.3 (43.6, 77.8)
Month 21	63.3 (43.6, 77.8)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	
	All patients N=30
Month 24	59.8 (40.2, 74.8)
Month 27	59.8 (40.2, 74.8)
Month 30	56.3 (36.8, 71.8)
Month 33	56.3 (36.8, 71.8)
Month 36	52.5 (33.3, 68.6)
Month 39	52.5 (33.3, 68.6)
Month 42	52.5 (33.3, 68.6)
Month 45	52.5 (33.3, 68.6)
Month 48	48.5 (29.5, 65.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195j
Overall survival (OS) by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No	**All patients N=68**
Events/Total (%)	32/68 (47.1)
Maximum follow-up (months)	68.8
Median follow-up (months)	22.75
Percentiles (95% CI) [1]	
25th	5.9 (3.6, 14.8)
50th	47.9 (16.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	88.1 (77.6, 93.9)
Month 6	74.4 (62.1, 83.3)
Month 9	71.4 (58.9, 80.7)
Month 12	66.8 (54.0, 76.7)
Month 15	63.7 (50.8, 74.0)
Month 18	60.5 (47.6, 71.1)
Month 21	57.2 (44.3, 68.2)

Complex karyotypes II (>=5 unrelated abnormalities) : No	
	All patients N=68
Month 24	57.2 (44.3, 68.2)
Month 27	55.5 (42.6, 66.6)
Month 30	55.5 (42.6, 66.6)
Month 33	53.7 (40.7, 65.0)
Month 36	53.7 (40.7, 65.0)
Month 39	53.7 (40.7, 65.0)
Month 42	53.7 (40.7, 65.0)
Month 45	53.7 (40.7, 65.0)
Month 48	50.0 (37.0, 61.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195k
Overall survival (OS) by Region
Enrolled set

Region: Europe

	All patients N=32
Events/Total (%)	13/32 (40.6)
Maximum follow-up (months)	68.6
Median follow-up (months)	51.75
Percentiles (95% CI) [1]	
25th	12.2 (4.0, 55.9)
50th	NE (45.7, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.8 (77.3, 98.4)
Month 6	87.5 (70.0, 95.1)
Month 9	84.4 (66.5, 93.2)
Month 12	81.1 (62.7, 91.1)
Month 15	71.4 (52.2, 84.0)
Month 18	71.4 (52.2, 84.0)
Month 21	71.4 (52.2, 84.0)

Region: Europe	
	All patients N=32
Month 24	71.4 (52.2, 84.0)
Month 27	71.4 (52.2, 84.0)
Month 30	71.4 (52.2, 84.0)
Month 33	71.4 (52.2, 84.0)
Month 36	71.4 (52.2, 84.0)
Month 39	71.4 (52.2, 84.0)
Month 42	71.4 (52.2, 84.0)
Month 45	71.4 (52.2, 84.0)
Month 48	63.5 (43.5, 78.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195k
Overall survival (OS) by Region
Enrolled set

Region: US	**All patients N=57**
Events/Total (%)	31/57 (54.4)
Maximum follow-up (months)	87.5
Median follow-up (months)	22.47
Percentiles (95% CI) [1]	
25th	4.8 (1.8, 11.5)
50th	24.9 (11.5, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	82.2 (69.4, 90.0)
Month 6	71.5 (57.7, 81.4)
Month 9	67.9 (54.0, 78.4)
Month 12	62.5 (48.5, 73.7)
Month 15	60.8 (46.8, 72.1)
Month 18	57.2 (43.2, 68.9)
Month 21	53.5 (39.6, 65.5)

Region: US	
	All patients N=57
Month 24	51.6 (37.9, 63.8)
Month 27	49.8 (36.1, 62.0)
Month 30	47.8 (34.2, 60.2)
Month 33	45.7 (32.2, 58.2)
Month 36	45.7 (32.2, 58.2)
Month 39	45.7 (32.2, 58.2)
Month 42	45.7 (32.2, 58.2)
Month 45	45.7 (32.2, 58.2)
Month 48	43.6 (30.1, 56.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195k
Overall survival (OS) by Region
Enrolled set

Region: Rest of World

	All patients N=9
Events/Total (%)	5/9 (55.6)
Maximum follow-up (months)	63.0
Median follow-up (months)	16.49
Percentiles (95% CI) [1]	
25th	8.6 (3.1, 34.4)
50th	25.4 (3.1, NE)
75th	NE (13.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	75.0 (31.5, 93.1)
Month 9	75.0 (31.5, 93.1)
Month 12	75.0 (31.5, 93.1)
Month 15	62.5 (22.9, 86.1)
Month 18	50.0 (15.2, 77.5)
Month 21	50.0 (15.2, 77.5)

Region: Rest of World	
	All patients N=9
Month 24	50.0 (15.2, 77.5)
Month 27	50.0 (15.2, 77.5)
Month 30	50.0 (15.2, 77.5)
Month 33	50.0 (15.2, 77.5)
Month 36	37.5 (8.7, 67.4)
Month 39	37.5 (8.7, 67.4)
Month 42	37.5 (8.7, 67.4)
Month 45	37.5 (8.7, 67.4)
Month 48	37.5 (8.7, 67.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195l
Overall survival (OS) by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58
Events/Total (%)	28/58 (48.3)
Maximum follow-up (months)	74.0
Median follow-up (months)	29.65
Percentiles (95% CI) [1]	
25th	11.5 (4.8, 17.6)
50th	55.9 (16.5, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	93.0 (82.4, 97.3)
Month 6	84.0 (71.6, 91.4)
Month 9	80.5 (67.5, 88.7)
Month 12	73.2 (59.5, 82.9)
Month 15	65.9 (51.8, 76.7)
Month 18	62.1 (48.0, 73.4)
Month 21	60.2 (46.0, 71.7)

Prior SCT therapy: Yes	
	All patients N=58
Month 24	60.2 (46.0, 71.7)
Month 27	60.2 (46.0, 71.7)
Month 30	58.2 (44.0, 69.9)
Month 33	58.2 (44.0, 69.9)
Month 36	56.1 (41.9, 68.1)
Month 39	56.1 (41.9, 68.1)
Month 42	56.1 (41.9, 68.1)
Month 45	56.1 (41.9, 68.1)
Month 48	51.9 (37.8, 64.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 19.5l
Overall survival (OS) by Prior SCT therapy
Enrolled set

Prior SCT therapy: No	**All patients N=40**
Events/Total (%)	21/40 (52.5)
Maximum follow-up (months)	87.5
Median follow-up (months)	23.67
Percentiles (95% CI) [1]	
25th	3.9 (1.5, 16.6)
50th	31.7 (8.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	80.0 (64.0, 89.5)
Month 6	67.5 (50.7, 79.7)
Month 9	65.0 (48.2, 77.6)
Month 12	65.0 (48.2, 77.6)
Month 15	62.5 (45.7, 75.4)
Month 18	60.0 (43.2, 73.3)
Month 21	57.4 (40.7, 71.0)

Prior SCT therapy: No	
	All patients N=40
Month 24	54.7 (38.0, 68.6)
Month 27	51.9 (35.4, 66.1)
Month 30	51.9 (35.4, 66.1)
Month 33	48.9 (32.4, 63.4)
Month 36	48.9 (32.4, 63.4)
Month 39	48.9 (32.4, 63.4)
Month 42	48.9 (32.4, 63.4)
Month 45	48.9 (32.4, 63.4)
Month 48	45.6 (29.3, 60.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195m
Overall survival (OS) by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17
Events/Total (%)	9/17 (52.9)
Maximum follow-up (months)	63.7
Median follow-up (months)	20.07
Percentiles (95% CI) [1]	
25th	13.4 (1.8, 20.1)
50th	34.4 (11.5, NE)
75th	NE (20.1, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.1 (65.0, 99.1)
Month 6	81.6 (53.0, 93.7)
Month 9	81.6 (53.0, 93.7)
Month 12	75.3 (46.8, 89.9)
Month 15	69.0 (40.8, 85.8)
Month 18	62.7 (35.1, 81.3)
Month 21	50.2 (24.7, 71.2)

Eligibility for SCT: Yes	
	All patients N=17
Month 24	50.2 (24.7, 71.2)
Month 27	50.2 (24.7, 71.2)
Month 30	50.2 (24.7, 71.2)
Month 33	50.2 (24.7, 71.2)
Month 36	43.9 (19.9, 65.7)
Month 39	43.9 (19.9, 65.7)
Month 42	43.9 (19.9, 65.7)
Month 45	43.9 (19.9, 65.7)
Month 48	43.9 (19.9, 65.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195m
Overall survival (OS) by Eligibility for SCT
Enrolled set

Eligibility for SCT: No	**All patients N=81**
Events/Total (%)	40/81 (49.4)
Maximum follow-up (months)	87.5
Median follow-up (months)	26.32
Percentiles (95% CI) [1]	
25th	8.0 (3.9, 13.9)
50th	55.9 (16.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	86.3 (76.6, 92.2)
Month 6	76.3 (65.4, 84.2)
Month 9	72.5 (61.3, 81.0)
Month 12	68.7 (57.3, 77.7)
Month 15	63.6 (52.1, 73.1)
Month 18	61.0 (49.4, 70.8)
Month 21	61.0 (49.4, 70.8)

Eligibility for SCT: No	
	All patients N=81
Month 24	59.7 (48.0, 69.5)
Month 27	58.3 (46.6, 68.3)
Month 30	56.8 (45.1, 66.9)
Month 33	55.3 (43.5, 65.6)
Month 36	55.3 (43.5, 65.6)
Month 39	55.3 (43.5, 65.6)
Month 42	55.3 (43.5, 65.6)
Month 45	55.3 (43.5, 65.6)
Month 48	50.7 (38.9, 61.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195n
Overall survival (OS) by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28
Events/Total (%)	7/28 (25.0)
Maximum follow-up (months)	68.6
Median follow-up (months)	60.83
Percentiles (95% CI) [1]	
25th	47.9 (9.9, NE)
50th	NE (47.9, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	96.3 (76.5, 99.5)
Month 6	96.3 (76.5, 99.5)
Month 9	96.3 (76.5, 99.5)
Month 12	92.6 (73.5, 98.1)
Month 15	92.6 (73.5, 98.1)
Month 18	92.6 (73.5, 98.1)
Month 21	88.4 (68.1, 96.1)

Baseline bone marrow tumor burden: Low	
	All patients N=28
Month 24	84.2 (63.0, 93.8)
Month 27	80.0 (58.2, 91.2)
Month 30	80.0 (58.2, 91.2)
Month 33	80.0 (58.2, 91.2)
Month 36	80.0 (58.2, 91.2)
Month 39	80.0 (58.2, 91.2)
Month 42	80.0 (58.2, 91.2)
Month 45	80.0 (58.2, 91.2)
Month 48	70.6 (47.7, 84.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195n
Overall survival (OS) by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70
Events/Total (%)	42/70 (60.0)
Maximum follow-up (months)	87.5
Median follow-up (months)	16.53
Percentiles (95% CI) [1]	
25th	4.4 (1.8, 10.6)
50th	17.6 (11.2, 59.4)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	84.1 (73.1, 90.9)
Month 6	69.6 (57.3, 79.0)
Month 9	65.3 (52.8, 75.2)
Month 12	60.8 (48.3, 71.2)
Month 15	53.4 (40.9, 64.3)
Month 18	48.9 (36.7, 60.1)
Month 21	47.5 (35.3, 58.7)

Baseline bone marrow tumor burden: High	
	All patients N=70
Month 24	47.5 (35.3, 58.7)
Month 27	47.5 (35.3, 58.7)
Month 30	45.9 (33.8, 57.2)
Month 33	44.2 (32.2, 55.6)
Month 36	42.6 (30.7, 54.0)
Month 39	42.6 (30.7, 54.0)
Month 42	42.6 (30.7, 54.0)
Month 45	42.6 (30.7, 54.0)
Month 48	40.9 (29.1, 52.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195o
Overall survival (OS) by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11
Events/Total (%)	3/11 (27.3)
Maximum follow-up (months)	68.6
Median follow-up (months)	54.08
Percentiles (95% CI) [1]	
25th	47.9 (11.2, NE)
50th	NE (12.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	90.9 (50.8, 98.7)
Month 15	81.8 (44.7, 95.1)
Month 18	81.8 (44.7, 95.1)
Month 21	81.8 (44.7, 95.1)

Baseline extramedullary disease presence: Yes	
	All patients N=11
Month 24	81.8 (44.7, 95.1)
Month 27	81.8 (44.7, 95.1)
Month 30	81.8 (44.7, 95.1)
Month 33	81.8 (44.7, 95.1)
Month 36	81.8 (44.7, 95.1)
Month 39	81.8 (44.7, 95.1)
Month 42	81.8 (44.7, 95.1)
Month 45	81.8 (44.7, 95.1)
Month 48	70.1 (32.3, 89.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195o
Overall survival (OS) by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No	**All patients N=87**
Events/Total (%)	46/87 (52.9)
Maximum follow-up (months)	87.5
Median follow-up (months)	24.87
Percentiles (95% CI) [1]	
25th	5.9 (3.6, 12.1)
50th	34.4 (16.5, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	86.1 (76.7, 91.8)
Month 6	74.3 (63.6, 82.2)
Month 9	70.7 (59.8, 79.2)
Month 12	67.2 (56.1, 76.0)
Month 15	62.4 (51.1, 71.7)
Month 18	58.8 (47.5, 68.4)
Month 21	56.3 (45.0, 66.1)

Baseline extramedullary disease presence: No	
	All patients N=87
Month 24	55.0 (43.8, 64.9)
Month 27	53.8 (42.5, 63.7)
Month 30	52.4 (41.2, 62.5)
Month 33	51.1 (39.8, 61.2)
Month 36	49.7 (38.5, 59.9)
Month 39	49.7 (38.5, 59.9)
Month 42	49.7 (38.5, 59.9)
Month 45	49.7 (38.5, 59.9)
Month 48	46.8 (35.7, 57.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195p
Overall survival (OS) by Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7
Events/Total (%)	4/7 (57.1)
Maximum follow-up (months)	64.4
Median follow-up (months)	34.40
Percentiles (95% CI) [1]	
25th	3.1 (1.5, 34.4)
50th	34.4 (1.5, NE)
75th	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	85.7 (33.4, 97.9)
Month 6	71.4 (25.8, 92.0)
Month 9	71.4 (25.8, 92.0)
Month 12	71.4 (25.8, 92.0)
Month 15	57.1 (17.2, 83.7)
Month 18	57.1 (17.2, 83.7)
Month 21	57.1 (17.2, 83.7)

Down syndrome: Yes	
	All patients N=7
Month 24	57.1 (17.2, 83.7)
Month 27	57.1 (17.2, 83.7)
Month 30	57.1 (17.2, 83.7)
Month 33	57.1 (17.2, 83.7)
Month 36	42.9 (9.8, 73.4)
Month 39	42.9 (9.8, 73.4)
Month 42	42.9 (9.8, 73.4)
Month 45	42.9 (9.8, 73.4)
Month 48	42.9 (9.8, 73.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195p
Overall survival (OS) by Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91
Events/Total (%)	45/91 (49.5)
Maximum follow-up (months)	87.5
Median follow-up (months)	25.63
Percentiles (95% CI) [1]	
25th	8.2 (4.0, 13.9)
50th	47.9 (19.4, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	87.8 (79.0, 93.0)
Month 6	77.7 (67.5, 85.0)
Month 9	74.3 (63.9, 82.1)
Month 12	69.7 (59.0, 78.1)
Month 15	65.2 (54.3, 74.1)
Month 18	61.7 (50.7, 70.9)
Month 21	59.2 (48.2, 68.7)

Down syndrome: No	
	All patients N=91
Month 24	58.0 (47.0, 67.5)
Month 27	56.8 (45.7, 66.4)
Month 30	55.5 (44.4, 65.2)
Month 33	54.1 (43.0, 64.0)
Month 36	54.1 (43.0, 64.0)
Month 39	54.1 (43.0, 64.0)
Month 42	54.1 (43.0, 64.0)
Month 45	54.1 (43.0, 64.0)
Month 48	50.0 (38.8, 60.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40
Events/Total (%)	15/40 (37.5)
Maximum follow-up (months)	68.8
Median follow-up (months)	57.63
Percentiles (95% CI) [1]	
25th	16.5 (11.2, 59.4)
50th	NE (47.6, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	95.0 (81.5, 98.7)
Month 9	92.5 (78.5, 97.5)
Month 12	87.4 (72.3, 94.5)
Month 15	77.1 (60.6, 87.4)
Month 18	74.4 (57.7, 85.3)
Month 21	74.4 (57.7, 85.3)

Time since enrollment to CTL019 infusion: > Median	
	All patients N=40
Month 24	74.4 (57.7, 85.3)
Month 27	74.4 (57.7, 85.3)
Month 30	74.4 (57.7, 85.3)
Month 33	71.3 (54.1, 83.0)
Month 36	68.2 (50.7, 80.6)
Month 39	68.2 (50.7, 80.6)
Month 42	68.2 (50.7, 80.6)
Month 45	68.2 (50.7, 80.6)
Month 48	65.1 (47.4, 78.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median	**All patients N=40**
Events/Total (%)	18/40 (45.0)
Maximum follow-up (months)	87.5
Median follow-up (months)	42.37
Percentiles (95% CI) [1]	
25th	14.4 (5.2, 29.2)
50th	NE (20.1, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.5 (78.5, 97.5)
Month 6	87.5 (72.5, 94.6)
Month 9	82.5 (66.8, 91.2)
Month 12	77.5 (61.2, 87.6)
Month 15	75.0 (58.5, 85.7)
Month 18	70.0 (53.3, 81.7)
Month 21	64.8 (47.9, 77.4)

Time since enrollment to CTL019 infusion: <=Median	**All patients N=40**
Month 24	62.2 (45.3, 75.2)
Month 27	62.2 (45.3, 75.2)
Month 30	59.5 (42.6, 72.9)
Month 33	59.5 (42.6, 72.9)
Month 36	59.5 (42.6, 72.9)
Month 39	59.5 (42.6, 72.9)
Month 42	59.5 (42.6, 72.9)
Month 45	59.5 (42.6, 72.9)
Month 48	53.6 (36.7, 67.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18
Events/Total (%)	16/18 (88.9)
Maximum follow-up (months)	24.9
Median follow-up (months)	1.81
Percentiles (95% CI) [1]	
25th	1.5 (0.3, 1.8)
50th	1.9 (1.5, 4.0)
75th	4.0 (1.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	46.9 (22.5, 68.1)
Month 6	6.7 (0.4, 26.0)
Month 9	6.7 (0.4, 26.0)
Month 12	6.7 (0.4, 26.0)
Month 15	6.7 (0.4, 26.0)
Month 18	6.7 (0.4, 26.0)
Month 21	6.7 (0.4, 26.0)

Time since enrollment to CTL019 infusion: Missing	
	All patients N=18
Month 24	6.7 (0.4, 26.0)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: 0	**All patients N=8**
Events/Total (%)	4/8 (50.0)
Maximum follow-up (months)	68.8
Median follow-up (months)	28.98
Percentiles (95% CI) [1]	
25th	2.2 (0.5, 31.7)
50th	31.7 (0.5, NE)
75th	NE (3.0, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	62.5 (22.9, 86.1)
Month 6	62.5 (22.9, 86.1)
Month 9	62.5 (22.9, 86.1)
Month 12	62.5 (22.9, 86.1)
Month 15	62.5 (22.9, 86.1)
Month 18	62.5 (22.9, 86.1)
Month 21	62.5 (22.9, 86.1)

Number of previous relapses: 0	
	All patients N=8
Month 24	62.5 (22.9, 86.1)
Month 27	62.5 (22.9, 86.1)
Month 30	62.5 (22.9, 86.1)
Month 33	41.7 (7.2, 74.7)
Month 36	41.7 (7.2, 74.7)
Month 39	41.7 (7.2, 74.7)
Month 42	41.7 (7.2, 74.7)
Month 45	41.7 (7.2, 74.7)
Month 48	41.7 (7.2, 74.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: 1	**All patients N=30**
Events/Total (%)	18/30 (60.0)
Maximum follow-up (months)	66.3
Median follow-up (months)	17.97
Percentiles (95% CI) [1]	
25th	4.0 (1.5, 11.5)
50th	19.4 (5.2, NE)
75th	NE (24.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	86.7 (68.3, 94.8)
Month 6	63.3 (43.6, 77.8)
Month 9	63.3 (43.6, 77.8)
Month 12	60.0 (40.5, 75.0)
Month 15	60.0 (40.5, 75.0)
Month 18	52.9 (33.8, 68.9)
Month 21	49.2 (30.3, 65.6)

Number of previous relapses: 1	
	All patients N=30
Month 24	45.4 (26.9, 62.2)
Month 27	41.6 (23.6, 58.7)
Month 30	41.6 (23.6, 58.7)
Month 33	41.6 (23.6, 58.7)
Month 36	41.6 (23.6, 58.7)
Month 39	41.6 (23.6, 58.7)
Month 42	41.6 (23.6, 58.7)
Month 45	41.6 (23.6, 58.7)
Month 48	37.8 (20.5, 55.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: 2	
	All patients N=18
Events/Total (%)	7/18 (38.9)
Maximum follow-up (months)	87.5
Median follow-up (months)	27.84
Percentiles (95% CI) [1]	
25th	12.2 (1.3, NE)
50th	NE (12.2, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	88.9 (62.4, 97.1)
Month 6	88.9 (62.4, 97.1)
Month 9	83.3 (56.8, 94.3)
Month 12	77.8 (51.1, 91.0)
Month 15	66.7 (40.4, 83.4)
Month 18	66.7 (40.4, 83.4)
Month 21	61.1 (35.3, 79.2)

Number of previous relapses: 2	
	All patients N=18
Month 24	61.1 (35.3, 79.2)
Month 27	61.1 (35.3, 79.2)
Month 30	61.1 (35.3, 79.2)
Month 33	61.1 (35.3, 79.2)
Month 36	61.1 (35.3, 79.2)
Month 39	61.1 (35.3, 79.2)
Month 42	61.1 (35.3, 79.2)
Month 45	61.1 (35.3, 79.2)
Month 48	61.1 (35.3, 79.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 195r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42
Events/Total (%)	20/42 (47.6)
Maximum follow-up (months)	74.0
Median follow-up (months)	42.37
Percentiles (95% CI) [1]	
25th	11.2 (4.4, 34.4)
50th	59.4 (16.5, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	92.7 (79.0, 97.6)
Month 6	85.2 (69.9, 93.0)
Month 9	80.2 (64.2, 89.5)
Month 12	75.0 (58.5, 85.7)
Month 15	67.2 (50.3, 79.5)
Month 18	64.6 (47.7, 77.3)
Month 21	64.6 (47.7, 77.3)

Number of previous relapses: >=3	
	All patients N=42
Month 24	64.6 (47.7, 77.3)
Month 27	64.6 (47.7, 77.3)
Month 30	61.9 (44.9, 75.1)
Month 33	61.9 (44.9, 75.1)
Month 36	59.3 (42.3, 72.8)
Month 39	59.3 (42.3, 72.8)
Month 42	59.3 (42.3, 72.8)
Month 45	59.3 (42.3, 72.8)
Month 48	53.6 (36.7, 67.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility [1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982). [2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 196a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years

	All patients N=33				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (54.5)		19 (57.6)		
CRi	8 (24.2)		7 (21.2)		
No response	3 (9.1)		3 (9.1)		
Unknown (UNK)	4 (12.1)		4 (12.1)		
Overall Remission Rate (ORR: CR+CRi)	26 (78.8)	(61.1,91.0)	26 (78.8)	(61.1,91.0)	0.0005

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	All patients N=33				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	23 (69.7)		23 (69.7)		
CRi	6 (18.2)		6 (18.2)		
No response	2 (6.1)		2 (6.1)		
Unknown (UNK)	2 (6.1)		2 (6.1)		
Overall Remission Rate (ORR: CR+CRi)	29 (87.9)	(71.8,96.6)	29 (87.9)	(71.8,96.6)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18

	All patients N=14				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	8 (57.1)		8 (57.1)		
CRi	3 (21.4)		3 (21.4)		
No response	2 (14.3)		2 (14.3)		
Unknown (UNK)	1 (7.1)		1 (7.1)		
Overall Remission Rate (ORR: CR+CRi)	11 (78.6)	(49.2,95.3)	11 (78.6)	(49.2,95.3)	0.0163

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male

	All patients N=46				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	29 (63.0)		29 (63.0)		
CRi	8 (17.4)		8 (17.4)		
No response	5 (10.9)		5 (10.9)		
Unknown (UNK)	4 (8.7)		4 (8.7)		
Overall Remission Rate (ORR: CR+CRi)	37 (80.4)	(66.1,90.6)	37 (80.4)	(66.1,90.6)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female

	All patients N=34				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	20 (58.8)		21 (61.8)		
CRi	9 (26.5)		8 (23.5)		
No response	2 (5.9)		2 (5.9)		
Unknown (UNK)	3 (8.8)		3 (8.8)		
Overall Remission Rate (ORR: CR+CRi)	29 (85.3)	(68.9,95.0)	29 (85.3)	(68.9,95.0)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White

	All patients N=59				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	36 (61.0)		37 (62.7)		
CRi	14 (23.7)		13 (22.0)		
No response	3 (5.1)		3 (5.1)		
Unknown (UNK)	6 (10.2)		6 (10.2)		
Overall Remission Rate (ORR: CR+CRi)	50 (84.7)	(73.0,92.8)	50 (84.7)	(73.0,92.8)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian

	All patients N=10				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (50.0)		5 (50.0)		
CRi	1 (10.0)		1 (10.0)		
No response	3 (30.0)		3 (30.0)		
Unknown (UNK)	1 (10.0)		1 (10.0)		
Overall Remission Rate (ORR: CR+CRi)	6 (60.0)	(26.2,87.8)	6 (60.0)	(26.2,87.8)	0.2635

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	8 (72.7)		8 (72.7)		
CRi	2 (18.2)		2 (18.2)		
No response	1 (9.1)		1 (9.1)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	10 (90.9)	(58.7,99.8)	10 (90.9)	(58.7,99.8)	0.0033

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	All patients N=15				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	11 (73.3)		11 (73.3)		
CRi	2 (13.3)		2 (13.3)		
No response	1 (6.7)		1 (6.7)		
Unknown (UNK)	1 (6.7)		1 (6.7)		
Overall Remission Rate (ORR: CR+CRi)	13 (86.7)	(59.5,98.3)	13 (86.7)	(59.5,98.3)	0.0023

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other

	All patients N=65				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	38 (58.5)		39 (60.0)		
CRi	15 (23.1)		14 (21.5)		
No response	6 (9.2)		6 (9.2)		
Unknown (UNK)	6 (9.2)		6 (9.2)		
Overall Remission Rate (ORR: CR+CRi)	53 (81.5)	(70.0,90.1)	53 (81.5)	(70.0,90.1)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (83.3)		5 (83.3)		
CRi					
No response					
Unknown (UNK)	1 (16.7)		1 (16.7)		
Overall Remission Rate (ORR: CR+CRi)	5 (83.3)	(35.9,99.6)	5 (83.3)	(35.9,99.6)	0.0512

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease

	All patients N=74				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	44 (59.5)		45 (60.8)		
CRi	17 (23.0)		16 (21.6)		
No response	7 (9.5)		7 (9.5)		
Unknown (UNK)	6 (8.1)		6 (8.1)		
Overall Remission Rate (ORR: CR+CRi)	61 (82.4)	(71.8,90.3)	61 (82.4)	(71.8,90.3)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (50.0)		1 (50.0)		
CRi	1 (50.0)		1 (50.0)		
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	2 (100)	(0.0,84.2)	2 (100)	(15.8, 100)	0.0786

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (61.5)		49 (62.8)		
CRi	16 (20.5)		15 (19.2)		
No response	7 (9.0)		7 (9.0)		
Unknown (UNK)	7 (9.0)		7 (9.0)		
Overall Remission Rate (ORR: CR+CRi)	64 (82.1)	(71.7,89.8)	64 (82.1)	(71.7,89.8)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (100)		1 (100)		
CRi					
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	1 (100)	(0.0,97.5)	1 (100)	(2.5, 100)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	All patients N=79				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (60.8)		49 (62.0)		
CRi	17 (21.5)		16 (20.3)		
No response	7 (8.9)		7 (8.9)		
Unknown (UNK)	7 (8.9)		7 (8.9)		
Overall Remission Rate (ORR: CR+CRi)	65 (82.3)	(72.1,90.0)	65 (82.3)	(72.1,90.0)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (100)		1 (100)		
CRi					
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	1 (100)	(0.0,97.5)	1 (100)	(2.5, 100)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No

	All patients N=79				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (60.8)		49 (62.0)		
CRi	17 (21.5)		16 (20.3)		
No response	7 (8.9)		7 (8.9)		
Unknown (UNK)	7 (8.9)		7 (8.9)		
Overall Remission Rate (ORR: CR+CRi)	65 (82.3)	(72.1,90.0)	65 (82.3)	(72.1,90.0)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (100)		1 (100)		
CRi					
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	1 (100)	(0.0,97.5)	1 (100)	(2.5, 100)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	All patients N=79				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (60.8)		49 (62.0)		
CRi	17 (21.5)		16 (20.3)		
No response	7 (8.9)		7 (8.9)		
Unknown (UNK)	7 (8.9)		7 (8.9)		
Overall Remission Rate (ORR: CR+CRi)	65 (82.3)	(72.1,90.0)	65 (82.3)	(72.1,90.0)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (66.7)		18 (66.7)		
CRi	3 (11.1)		3 (11.1)		
No response	3 (11.1)		3 (11.1)		
Unknown (UNK)	3 (11.1)		3 (11.1)		
Overall Remission Rate (ORR: CR+CRi)	21 (77.8)	(57.7,91.4)	21 (77.8)	(57.7,91.4)	0.0019

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	31 (58.5)		32 (60.4)		
CRi	14 (26.4)		13 (24.5)		
No response	4 (7.5)		4 (7.5)		
Unknown (UNK)	4 (7.5)		4 (7.5)		
Overall Remission Rate (ORR: CR+CRi)	45 (84.9)	(72.4,93.3)	45 (84.9)	(72.4,93.3)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Europe

	All patients N=28				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	14 (50.0)		15 (53.6)		
CRi	11 (39.3)		10 (35.7)		
No response	1 (3.6)		1 (3.6)		
Unknown (UNK)	2 (7.1)		2 (7.1)		
Overall Remission Rate (ORR: CR+CRi)	25 (89.3)	(71.8,97.7)	25 (89.3)	(71.8,97.7)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US

	All patients N=45				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (71.1)		32 (71.1)		
CRi	4 (8.9)		4 (8.9)		
No response	4 (8.9)		4 (8.9)		
Unknown (UNK)	5 (11.1)		5 (11.1)		
Overall Remission Rate (ORR: CR+CRi)	36 (80.0)	(65.4,90.4)	36 (80.0)	(65.4,90.4)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: Rest of World

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (42.9)		3 (42.9)		
CRi	2 (28.6)		2 (28.6)		
No response	2 (28.6)		2 (28.6)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	5 (71.4)	(29.0,96.3)	5 (71.4)	(29.0,96.3)	0.1284

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes

	All patients N=48				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	28 (58.3)		29 (60.4)		
CRi	13 (27.1)		12 (25.0)		
No response	4 (8.3)		4 (8.3)		
Unknown (UNK)	3 (6.3)		3 (6.3)		
Overall Remission Rate (ORR: CR+CRi)	41 (85.4)	(72.2,93.9)	41 (85.4)	(72.2,93.9)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (65.6)		21 (65.6)		
CRi	4 (12.5)		4 (12.5)		
No response	3 (9.4)		3 (9.4)		
Unknown (UNK)	4 (12.5)		4 (12.5)		
Overall Remission Rate (ORR: CR+CRi)	25 (78.1)	(60.0,90.7)	25 (78.1)	(60.0,90.7)	0.0007

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes

	All patients N=13				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	10 (76.9)		10 (76.9)		
CRi	2 (15.4)		2 (15.4)		
No response	1 (7.7)		1 (7.7)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	12 (92.3)	(64.0,99.8)	12 (92.3)	(64.0,99.8)	0.0011

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	All patients N=67				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	39 (58.2)		40 (59.7)		
CRi	15 (22.4)		14 (20.9)		
No response	6 (9.0)		6 (9.0)		
Unknown (UNK)	7 (10.4)		7 (10.4)		
Overall Remission Rate (ORR: CR+CRi)	54 (80.6)	(69.1,89.2)	54 (80.6)	(69.1,89.2)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low

	All patients N=26				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	17 (65.4)		17 (65.4)		
CRi	8 (30.8)		8 (30.8)		
No response					
Unknown (UNK)	1 (3.8)		1 (3.8)		
Overall Remission Rate (ORR: CR+CRi)	25 (96.2)	(80.4,99.9)	25 (96.2)	(80.4,99.9)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High

	All patients N=54				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (59.3)		33 (61.1)		
CRi	9 (16.7)		8 (14.8)		
No response	7 (13.0)		7 (13.0)		
Unknown (UNK)	6 (11.1)		6 (11.1)		
Overall Remission Rate (ORR: CR+CRi)	41 (75.9)	(62.4,86.5)	41 (75.9)	(62.4,86.5)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	7 (63.6)		7 (63.6)		
CRi	4 (36.4)		4 (36.4)		
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	11 (100)	(0.0,28.5)	11 (100)	(71.5, 100)	0.0005

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	All patients N=69				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	42 (60.9)		43 (62.3)		
CRi	13 (18.8)		12 (17.4)		
No response	7 (10.1)		7 (10.1)		
Unknown (UNK)	7 (10.1)		7 (10.1)		
Overall Remission Rate (ORR: CR+CRi)	55 (79.7)	(68.3,88.4)	55 (79.7)	(68.3,88.4)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (16.7)		1 (16.7)		
CRi	4 (66.7)		4 (66.7)		
No response					
Unknown (UNK)	1 (16.7)		1 (16.7)		
Overall Remission Rate (ORR: CR+CRi)	5 (83.3)	(35.9,99.6)	5 (83.3)	(35.9,99.6)	0.0512

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No

	All patients N=74				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (64.9)		49 (66.2)		
CRi	13 (17.6)		12 (16.2)		
No response	7 (9.5)		7 (9.5)		
Unknown (UNK)	6 (8.1)		6 (8.1)		
Overall Remission Rate (ORR: CR+CRi)	61 (82.4)	(71.8,90.3)	61 (82.4)	(71.8,90.3)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (52.5)		22 (55.0)		
CRi	13 (32.5)		12 (30.0)		
No response	4 (10.0)		4 (10.0)		
Unknown (UNK)	2 (5.0)		2 (5.0)		
Overall Remission Rate (ORR: CR+CRi)	34 (85.0)	(70.2,94.3)	34 (85.0)	(70.2,94.3)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	28 (70.0)		28 (70.0)		
CRi	4 (10.0)		4 (10.0)		
No response	3 (7.5)		3 (7.5)		
Unknown (UNK)	5 (12.5)		5 (12.5)		
Overall Remission Rate (ORR: CR+CRi)	32 (80.0)	(64.4,90.9)	32 (80.0)	(64.4,90.9)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (83.3)		5 (83.3)		
CRi					
No response					
Unknown (UNK)	1 (16.7)		1 (16.7)		
Overall Remission Rate (ORR: CR+CRi)	5 (83.3)	(35.9,99.6)	5 (83.3)	(35.9,99.6)	0.0512

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	All patients N=22				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	14 (63.6)		14 (63.6)		
CRi	4 (18.2)		4 (18.2)		
No response	3 (13.6)		3 (13.6)		
Unknown (UNK)	1 (4.5)		1 (4.5)		
Overall Remission Rate (ORR: CR+CRi)	18 (81.8)	(59.7,94.8)	18 (81.8)	(59.7,94.8)	0.0014

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	All patients N=17				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (76.5)		13 (76.5)		
CRi	1 (5.9)		1 (5.9)		
No response	1 (5.9)		1 (5.9)		
Unknown (UNK)	2 (11.8)		2 (11.8)		
Overall Remission Rate (ORR: CR+CRi)	14 (82.4)	(56.6,96.2)	14 (82.4)	(56.6,96.2)	0.0038

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 196r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	All patients N=35				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	17 (48.6)		18 (51.4)		
CRi	12 (34.3)		11 (31.4)		
No response	3 (8.6)		3 (8.6)		
Unknown (UNK)	3 (8.6)		3 (8.6)		
Overall Remission Rate (ORR: CR+CRi)	29 (82.9)	(66.4,93.4)	29 (82.9)	(66.4,93.4)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: <10 years

	All patients N=41				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (43.9)		19 (46.3)		
CRi	8 (19.5)		7 (17.1)		
No response	3 (7.3)		3 (7.3)		
Unknown (UNK)	12 (29.3)		12 (29.3)		
Overall Remission Rate (ORR: CR+CRi)	26 (63.4)	(46.9,77.9)	26 (63.4)	(46.9,77.9)	0.0429

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	23 (57.5)		23 (57.5)		
CRi	6 (15.0)		6 (15.0)		
No response	2 (5.0)		2 (5.0)		
Unknown (UNK)	9 (22.5)		9 (22.5)		
Overall Remission Rate (ORR: CR+CRi)	29 (72.5)	(56.1,85.4)	29 (72.5)	(56.1,85.4)	0.0022

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=18

	All patients N=17				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	8 (47.1)		8 (47.1)		
CRi	3 (17.6)		3 (17.6)		
No response	2 (11.8)		2 (11.8)		
Unknown (UNK)	4 (23.5)		4 (23.5)		
Overall Remission Rate (ORR: CR+CRi)	11 (64.7)	(38.3,85.8)	11 (64.7)	(38.3,85.8)	0.1126

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Male

	All patients N=55				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	29 (52.7)		29 (52.7)		
CRi	8 (14.5)		8 (14.5)		
No response	5 (9.1)		5 (9.1)		
Unknown (UNK)	13 (23.6)		13 (23.6)		
Overall Remission Rate (ORR: CR+CRi)	37 (67.3)	(53.3,79.3)	37 (67.3)	(53.3,79.3)	0.0052

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Female

	All patients N=43				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	20 (46.5)		21 (48.8)		
CRi	9 (20.9)		8 (18.6)		
No response	2 (4.7)		2 (4.7)		
Unknown (UNK)	12 (27.9)		12 (27.9)		
Overall Remission Rate (ORR: CR+CRi)	29 (67.4)	(51.5,80.9)	29 (67.4)	(51.5,80.9)	0.0111

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: White

	All patients N=70				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	36 (51.4)		37 (52.9)		
CRi	14 (20.0)		13 (18.6)		
No response	3 (4.3)		3 (4.3)		
Unknown (UNK)	17 (24.3)		17 (24.3)		
Overall Remission Rate (ORR: CR+CRi)	50 (71.4)	(59.4,81.6)	50 (71.4)	(59.4,81.6)	0.0002

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Asian

	All patients N=15				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (33.3)		5 (33.3)		
CRi	1 (6.7)		1 (6.7)		
No response	3 (20.0)		3 (20.0)		
Unknown (UNK)	6 (40.0)		6 (40.0)		
Overall Remission Rate (ORR: CR+CRi)	6 (40.0)	(16.3,67.7)	6 (40.0)	(16.3,67.7)	0.2193

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Other

	All patients N=13				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	8 (61.5)		8 (61.5)		
CRi	2 (15.4)		2 (15.4)		
No response	1 (7.7)		1 (7.7)		
Unknown (UNK)	2 (15.4)		2 (15.4)		
Overall Remission Rate (ORR: CR+CRi)	10 (76.9)	(46.2,95.0)	10 (76.9)	(46.2,95.0)	0.0261

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	11 (61.1)		11 (61.1)		
CRi	2 (11.1)		2 (11.1)		
No response	1 (5.6)		1 (5.6)		
Unknown (UNK)	4 (22.2)		4 (22.2)		
Overall Remission Rate (ORR: CR+CRi)	13 (72.2)	(46.5,90.3)	13 (72.2)	(46.5,90.3)	0.0297

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	38 (47.5)		39 (48.8)		
CRi	15 (18.8)		14 (17.5)		
No response	6 (7.5)		6 (7.5)		
Unknown (UNK)	21 (26.3)		21 (26.3)		
Overall Remission Rate (ORR: CR+CRi)	53 (66.3)	(54.8,76.4)	53 (66.3)	(54.8,76.4)	0.0018

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (62.5)		5 (62.5)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	3 (37.5)		3 (37.5)		
Overall Remission Rate (ORR: CR+CRi)	5 (62.5)	(24.5,91.5)	5 (62.5)	(24.5,91.5)	0.2398

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	44 (48.9)		45 (50.0)		
CRi	17 (18.9)		16 (17.8)		
No response	7 (7.8)		7 (7.8)		
Unknown (UNK)	22 (24.4)		22 (24.4)		
Overall Remission Rate (ORR: CR+CRi)	61 (67.8)	(57.1,77.2)	61 (67.8)	(57.1,77.2)	0.0004

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (50.0)		1 (50.0)		
CRi	1 (50.0)		1 (50.0)		
No response	0		0		
Unknown (UNK)	0		0		
Overall Remission Rate (ORR: CR+CRi)	2 (100)	(0.0,84.2)	2 (100)	(0.0,84.2)	0.0786

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (50.0)		49 (51.0)		
CRi	16 (16.7)		15 (15.6)		
No response	7 (7.3)		7 (7.3)		
Unknown (UNK)	25 (26.0)		25 (26.0)		
Overall Remission Rate (ORR: CR+CRi)	64 (66.7)	(56.3,76.0)	64 (66.7)	(56.3,76.0)	0.0005

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (100)		1 (100)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	0		0		
Overall Remission Rate (ORR: CR+CRi)	1 (100)	(0.0,97.5)	1 (100)	(0.0,97.5)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (49.5)		49 (50.5)		
CRi	17 (17.5)		16 (16.5)		
No response	7 (7.2)		7 (7.2)		
Unknown (UNK)	25 (25.8)		25 (25.8)		
Overall Remission Rate (ORR: CR+CRi)	65 (67.0)	(56.7,76.2)	65 (67.0)	(56.7,76.2)	0.0004

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (33.3)		1 (33.3)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	2 (66.7)		2 (66.7)		
Overall Remission Rate (ORR: CR+CRi)	1 (33.3)	(0.8,90.6)	1 (33.3)	(0.8,90.6)	0.2819

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (50.5)		49 (51.6)		
CRi	17 (17.9)		16 (16.8)		
No response	7 (7.4)		7 (7.4)		
Unknown (UNK)	23 (24.2)		23 (24.2)		
Overall Remission Rate (ORR: CR+CRi)	65 (68.4)	(58.1,77.6)	65 (68.4)	(58.1,77.6)	0.0002

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (50.0)		1 (50.0)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	1 (50.0)		1 (50.0)		
Overall Remission Rate (ORR: CR+CRi)	1 (50.0)	(1.3,98.7)	1 (50.0)	(1.3,98.7)	0.5000

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (50.0)		49 (51.0)		
CRi	17 (17.7)		16 (16.7)		
No response	7 (7.3)		7 (7.3)		
Unknown (UNK)	24 (25.0)		24 (25.0)		
Overall Remission Rate (ORR: CR+CRi)	65 (67.7)	(57.4,76.9)	65 (67.7)	(57.4,76.9)	0.0003

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (60.0)		18 (60.0)		
CRi	3 (10.0)		3 (10.0)		
No response	3 (10.0)		3 (10.0)		
Unknown (UNK)	6 (20.0)		6 (20.0)		
Overall Remission Rate (ORR: CR+CRi)	21 (70.0)	(50.6,85.3)	21 (70.0)	(50.6,85.3)	0.0142

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	31 (45.6)		32 (47.1)		
CRi	14 (20.6)		13 (19.1)		
No response	4 (5.9)		4 (5.9)		
Unknown (UNK)	19 (27.9)		19 (27.9)		
Overall Remission Rate (ORR: CR+CRi)	45 (66.2)	(53.7,77.2)	45 (66.2)	(53.7,77.2)	0.0038

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: Europe

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	14 (43.8)		15 (46.9)		
CRi	11 (34.4)		10 (31.3)		
No response	1 (3.1)		1 (3.1)		
Unknown (UNK)	6 (18.8)		6 (18.8)		
Overall Remission Rate (ORR: CR+CRi)	25 (78.1)	(60.0,90.7)	25 (78.1)	(60.0,90.7)	0.0007

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: US

	All patients N=57				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (56.1)		32 (56.1)		
CRi	4 (7.0)		4 (7.0)		
No response	4 (7.0)		4 (7.0)		
Unknown (UNK)	17 (29.8)		17 (29.8)		
Overall Remission Rate (ORR: CR+CRi)	36 (63.2)	(49.3,75.6)	36 (63.2)	(49.3,75.6)	0.0235

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: Rest of World

	All patients N=9				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (33.3)		3 (33.3)		
CRi	2 (22.2)		2 (22.2)		
No response	2 (22.2)		2 (22.2)		
Unknown (UNK)	2 (22.2)		2 (22.2)		
Overall Remission Rate (ORR: CR+CRi)	5 (55.6)	(21.2,86.3)	5 (55.6)	(21.2,86.3)	0.3694

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	28 (48.3)		29 (50.0)		
CRi	13 (22.4)		12 (20.7)		
No response	4 (6.9)		4 (6.9)		
Unknown (UNK)	13 (22.4)		13 (22.4)		
Overall Remission Rate (ORR: CR+CRi)	41 (70.7)	(57.3,81.9)	41 (70.7)	(57.3,81.9)	0.0008

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (52.5)		21 (52.5)		
CRi	4 (10.0)		4 (10.0)		
No response	3 (7.5)		3 (7.5)		
Unknown (UNK)	12 (30.0)		12 (30.0)		
Overall Remission Rate (ORR: CR+CRi)	25 (62.5)	(45.8,77.3)	25 (62.5)	(45.8,77.3)	0.0569

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	10 (58.8)		10 (58.8)		
CRi	2 (11.8)		2 (11.8)		
No response	1 (5.9)		1 (5.9)		
Unknown (UNK)	4 (23.5)		4 (23.5)		
Overall Remission Rate (ORR: CR+CRi)	12 (70.6)	(44.0,89.7)	12 (70.6)	(44.0,89.7)	0.0448

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	39 (48.1)		40 (49.4)		
CRi	15 (18.5)		14 (17.3)		
No response	6 (7.4)		6 (7.4)		
Unknown (UNK)	21 (25.9)		21 (25.9)		
Overall Remission Rate (ORR: CR+CRi)	54 (66.7)	(55.3,76.8)	54 (66.7)	(55.3,76.8)	0.0013

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	17 (60.7)		17 (60.7)		
CRi	8 (28.6)		8 (28.6)		
No response	0		0		
Unknown (UNK)	3 (10.7)		3 (10.7)		
Overall Remission Rate (ORR: CR+CRi)	25 (89.3)	(71.8,97.7)	25 (89.3)	(71.8,97.7)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (45.7)		33 (47.1)		
CRi	9 (12.9)		8 (11.4)		
No response	7 (10.0)		7 (10.0)		
Unknown (UNK)	22 (31.4)		22 (31.4)		
Overall Remission Rate (ORR: CR+CRi)	41 (58.6)	(46.2,70.2)	41 (58.6)	(46.2,70.2)	0.0757

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	7 (63.6)		7 (63.6)		
CRi	4 (36.4)		4 (36.4)		
No response	0		0		
Unknown (UNK)	0		0		
Overall Remission Rate (ORR: CR+CRi)	11 (100)	(0.0,28.5)	11 (100)	(0.0,28.5)	0.0005

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	42 (48.3)		43 (49.4)		
CRi	13 (14.9)		12 (13.8)		
No response	7 (8.0)		7 (8.0)		
Unknown (UNK)	25 (28.7)		25 (28.7)		
Overall Remission Rate (ORR: CR+CRi)	55 (63.2)	(52.2,73.3)	55 (63.2)	(52.2,73.3)	0.0068

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (14.3)		1 (14.3)		
CRi	4 (57.1)		4 (57.1)		
No response	0		0		
Unknown (UNK)	2 (28.6)		2 (28.6)		
Overall Remission Rate (ORR: CR+CRi)	5 (71.4)	(29.0,96.3)	5 (71.4)	(29.0,96.3)	0.1284

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	48 (52.7)		49 (53.8)		
CRi	13 (14.3)		12 (13.2)		
No response	7 (7.7)		7 (7.7)		
Unknown (UNK)	23 (25.3)		23 (25.3)		
Overall Remission Rate (ORR: CR+CRi)	61 (67.0)	(56.4,76.5)	61 (67.0)	(56.4,76.5)	0.0006

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (52.5)		22 (55.0)		
CRi	13 (32.5)		12 (30.0)		
No response	4 (10.0)		4 (10.0)		
Unknown (UNK)	2 (5.0)		2 (5.0)		
Overall Remission Rate (ORR: CR+CRi)	34 (85.0)	(70.2,94.3)	34 (85.0)	(70.2,94.3)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	28 (70.0)		28 (70.0)		
CRi	4 (10.0)		4 (10.0)		
No response	3 (7.5)		3 (7.5)		
Unknown (UNK)	5 (12.5)		5 (12.5)		
Overall Remission Rate (ORR: CR+CRi)	32 (80.0)	(64.4,90.9)	32 (80.0)	(64.4,90.9)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	0		0		
CRi	0		0		
No response	0		0		
Unknown (UNK)	18 (100)		18 (100)		
Overall Remission Rate (ORR: CR+CRi)	0	(0.0,18.5)	0	(0.0,18.5)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (62.5)		5 (62.5)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	3 (37.5)		3 (37.5)		
Overall Remission Rate (ORR: CR+CRi)	5 (62.5)	(24.5,91.5)	5 (62.5)	(24.5,91.5)	0.2398

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	14 (46.7)		14 (46.7)		
CRi	4 (13.3)		4 (13.3)		
No response	3 (10.0)		3 (10.0)		
Unknown (UNK)	9 (30.0)		9 (30.0)		
Overall Remission Rate (ORR: CR+CRi)	18 (60.0)	(40.6,77.3)	18 (60.0)	(40.6,77.3)	0.1367

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (72.2)		13 (72.2)		
CRi	1 (5.6)		1 (5.6)		
No response	1 (5.6)		1 (5.6)		
Unknown (UNK)	3 (16.7)		3 (16.7)		
Overall Remission Rate (ORR: CR+CRi)	14 (77.8)	(52.4,93.6)	14 (77.8)	(52.4,93.6)	0.0092

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 197r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	17 (40.5)		18 (42.9)		
CRi	12 (28.6)		11 (26.2)		
No response	3 (7.1)		3 (7.1)		
Unknown (UNK)	10 (23.8)		10 (23.8)		
Overall Remission Rate (ORR: CR+CRi)	29 (69.0)	(52.9,82.4)	29 (69.0)	(52.9,82.4)	0.0068

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 198a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Age
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	13.47	4.127	(5.00, 21.93)	0.003
Month 3	7	19.02	4.667	(9.45, 28.60)	<.001
Month 6	7	15.31	4.667	(5.73, 24.88)	0.003
Month 9	4	20.77	6.194	(8.06, 33.48)	0.002
Month 12	2	11.04	8.769	(-6.95, 29.03)	0.219
Month 18	2	18.54	8.769	(0.55, 36.53)	0.044
Month 24	1	21.05	12.497	(-4.59, 46.69)	0.104
Month 36	2	17.54	8.769	(-0.45, 35.53)	0.056
Month 48	2	20.54	8.769	(2.55, 38.53)	0.027
Month 60	2	18.54	8.769	(0.55, 36.53)	0.044

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Age
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	9.94	2.535	(4.93, 14.95)	<.001
Month 3	24	15.85	2.537	(10.83, 20.86)	<.001
Month 6	21	14.46	2.709	(9.11, 19.82)	<.001
Month 9	19	20.72	2.848	(15.09, 26.35)	<.001
Month 12	16	21.04	3.104	(14.91, 27.18)	<.001
Month 18	13	22.78	3.443	(15.98, 29.59)	<.001
Month 24	14	24.37	3.318	(17.81, 30.93)	<.001
Month 36	12	14.68	3.584	(7.60, 21.76)	<.001
Month 48	8	25.06	4.401	(16.36, 33.75)	<.001
Month 60	9	23.89	4.145	(15.70, 32.08)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Age
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-2.41	4.928	(-12.29, 7.47)	0.627
Month 3	10	14.06	4.933	(4.17, 23.96)	0.006
Month 6	9	22.38	5.178	(11.99, 32.76)	<.001
Month 9	7	15.37	5.850	(3.63, 27.10)	0.011
Month 12	6	24.13	6.316	(11.46, 36.80)	<.001
Month 18	5	18.91	6.935	(5.00, 32.82)	0.009
Month 24	5	18.93	6.951	(4.99, 32.87)	0.009
Month 36	4	28.26	7.803	(12.61, 43.91)	<.001
Month 48	4	27.32	7.795	(11.68, 42.95)	<.001
Month 60	4	29.57	7.795	(13.93, 45.20)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Gender
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	27	5.29	3.059	(-0.76, 11.34)	0.086
Month 3	25	12.73	3.180	(6.45, 19.02)	<.001
Month 6	22	12.21	3.392	(5.51, 18.92)	<.001
Month 9	17	17.37	3.865	(9.73, 25.01)	<.001
Month 12	12	16.82	4.588	(7.75, 25.89)	<.001
Month 18	11	16.94	4.793	(7.47, 26.42)	<.001
Month 24	12	19.99	4.589	(10.92, 29.06)	<.001
Month 36	11	11.13	4.794	(1.66, 20.61)	0.022
Month 48	8	20.80	5.652	(9.63, 31.98)	<.001
Month 60	9	21.09	5.308	(10.60, 31.58)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Gender
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	12.55	2.652	(7.28, 17.81)	<.001
Month 3	16	20.84	2.652	(15.57, 26.10)	<.001
Month 6	15	23.44	2.749	(17.99, 28.90)	<.001
Month 9	13	22.75	2.948	(16.90, 28.60)	<.001
Month 12	12	24.96	3.063	(18.88, 31.04)	<.001
Month 18	9	26.44	3.536	(19.42, 33.46)	<.001
Month 24	8	25.59	3.753	(18.15, 33.04)	<.001
Month 36	7	27.88	4.017	(19.91, 35.85)	<.001
Month 48	6	31.59	4.347	(22.96, 40.22)	<.001
Month 60	6	29.92	4.338	(21.31, 38.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Race
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	12.52	2.245	(8.10, 16.95)	<.001
Month 3	32	18.05	2.280	(13.55, 22.54)	<.001
Month 6	31	17.77	2.316	(13.20, 22.34)	<.001
Month 9	24	22.61	2.632	(17.42, 27.80)	<.001
Month 12	19	21.02	2.958	(15.19, 26.85)	<.001
Month 18	15	22.41	3.329	(15.84, 28.97)	<.001
Month 24	16	24.31	3.223	(17.95, 30.67)	<.001
Month 36	14	15.82	3.446	(9.02, 22.61)	<.001
Month 48	11	24.38	3.890	(16.71, 32.05)	<.001
Month 60	12	23.90	3.723	(16.56, 31.24)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Race
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	-2.11	6.752	(-16.30, 12.07)	0.758
Month 3	5	12.89	7.357	(-2.57, 28.34)	0.097
Month 6	3	20.02	9.245	(0.60, 39.45)	0.044
Month 9	3	18.36	9.245	(-1.07, 37.78)	0.063
Month 12	3	16.69	9.245	(-2.73, 36.11)	0.088
Month 18	3	15.02	9.245	(-4.40, 34.45)	0.122
Month 24	2	6.09	11.399	(-17.86, 30.04)	0.600
Month 36	2	26.09	11.399	(2.14, 50.04)	0.034
Month 48	1	29.30	16.617	(-5.61, 64.21)	0.095
Month 60	1	29.30	16.617	(-5.61, 64.21)	0.095

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Race
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-7.26	8.756	(-25.92, 11.40)	0.420
Month 3	4	6.49	8.756	(-12.17, 25.15)	0.470
Month 6	3	5.45	9.786	(-15.41, 26.31)	0.586
Month 9	3	-2.88	9.786	(-23.74, 17.97)	0.772
Month 12	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 18	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 24	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 36	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 48	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 60	2	20.45	11.962	(-5.05, 45.95)	0.108

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	-0.89	3.589	(-8.11, 6.32)	0.804
Month 3	9	9.67	3.968	(1.69, 17.65)	0.019
Month 6	9	4.40	3.977	(-3.59, 12.40)	0.274
Month 9	6	5.89	4.869	(-3.90, 15.68)	0.232
Month 12	4	10.75	5.952	(-1.21, 22.72)	0.077
Month 18	4	12.00	5.952	(0.04, 23.97)	0.049
Month 24	5	12.93	5.328	(2.22, 23.65)	0.019
Month 36	4	11.25	5.952	(-0.71, 23.22)	0.065
Month 48	3	13.05	6.882	(-0.79, 26.88)	0.064
Month 60	4	10.75	5.952	(-1.21, 22.72)	0.077

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	32	10.79	2.560	(5.74, 15.84)	<.001
Month 3	32	18.00	2.559	(12.95, 23.05)	<.001
Month 6	28	20.66	2.736	(15.27, 26.06)	<.001
Month 9	24	23.66	2.955	(17.83, 29.49)	<.001
Month 12	20	23.26	3.238	(16.88, 29.65)	<.001
Month 18	16	23.68	3.620	(16.54, 30.82)	<.001
Month 24	15	24.81	3.738	(17.44, 32.18)	<.001
Month 36	14	19.53	3.869	(11.89, 27.16)	<.001
Month 48	11	28.45	4.366	(19.83, 37.06)	<.001
Month 60	11	28.61	4.365	(20.00, 37.22)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-5.78	4.803	(-16.08, 4.52)	0.249
Month 3	4	5.47	4.803	(-4.83, 15.77)	0.274
Month 6	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 9	3	6.43	5.548	(-5.47, 18.33)	0.266
Month 12	2	6.67	6.795	(-7.90, 21.24)	0.343
Month 18	2	11.67	6.795	(-2.90, 26.24)	0.108
Month 24	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 36	2	1.17	6.795	(-13.40, 15.74)	0.866
Month 48	1	9.05	9.934	(-12.26, 30.35)	0.378
Month 60	1	2.29	9.845	(-18.82, 23.41)	0.819

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	39	9.77	2.290	(5.26, 14.28)	<.001
Month 3	37	17.21	2.351	(12.58, 21.84)	<.001
Month 6	34	17.77	2.453	(12.93, 22.60)	<.001
Month 9	27	21.14	2.752	(15.72, 26.56)	<.001
Month 12	22	21.66	3.049	(15.65, 27.67)	<.001
Month 18	18	21.91	3.370	(15.27, 28.55)	<.001
Month 24	17	23.58	3.468	(16.75, 30.42)	<.001
Month 36	16	19.53	3.575	(12.48, 26.57)	<.001
Month 48	13	26.59	3.967	(18.78, 34.41)	<.001
Month 60	14	26.31	3.823	(18.78, 33.84)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Response status at study entry: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	8.39	2.156	(4.15, 12.64)	<.001
Month 3	40	16.12	2.209	(11.77, 20.47)	<.001
Month 6	36	17.01	2.329	(12.42, 21.60)	<.001
Month 9	29	19.75	2.595	(14.64, 24.87)	<.001
Month 12	23	20.22	2.913	(14.48, 25.96)	<.001
Month 18	19	20.87	3.205	(14.56, 27.18)	<.001
Month 24	19	22.24	3.205	(15.93, 28.56)	<.001
Month 36	17	17.34	3.389	(10.67, 24.02)	<.001
Month 48	13	24.99	3.876	(17.35, 32.62)	<.001
Month 60	14	24.53	3.734	(17.18, 31.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Philadelphia chromosome/BCR-ABL: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Mixed-lineage leukemia rearrangement: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	43	8.30	2.107	(4.15, 12.44)	<.001
Month 3	41	16.09	2.158	(11.84, 20.34)	<.001
Month 6	37	16.98	2.271	(12.51, 21.46)	<.001
Month 9	30	19.73	2.523	(14.76, 24.70)	<.001
Month 12	24	20.25	2.820	(14.70, 25.80)	<.001
Month 18	20	20.93	3.089	(14.85, 27.02)	<.001
Month 24	20	22.24	3.089	(16.16, 28.33)	<.001
Month 36	18	17.66	3.256	(11.24, 24.07)	<.001
Month 48	14	24.92	3.693	(17.65, 32.19)	<.001
Month 60	15	24.48	3.568	(17.46, 31.51)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Mixed-lineage leukemia rearrangement: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Hypodiploidy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	43	8.30	2.107	(4.15, 12.44)	<.001
Month 3	41	16.09	2.158	(11.84, 20.34)	<.001
Month 6	37	16.98	2.271	(12.51, 21.46)	<.001
Month 9	30	19.73	2.523	(14.76, 24.70)	<.001
Month 12	24	20.25	2.820	(14.70, 25.80)	<.001
Month 18	20	20.93	3.089	(14.85, 27.02)	<.001
Month 24	20	22.24	3.089	(16.16, 28.33)	<.001
Month 36	18	17.66	3.256	(11.24, 24.07)	<.001
Month 48	14	24.92	3.693	(17.65, 32.19)	<.001
Month 60	15	24.48	3.568	(17.46, 31.51)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Hypodiploidy: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Subgroup: BCR-ABL1-like: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Subgroup: BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	43	8.30	2.107	(4.15, 12.44)	<.001
Month 3	41	16.09	2.158	(11.84, 20.34)	<.001
Month 6	37	16.98	2.271	(12.51, 21.46)	<.001
Month 9	30	19.73	2.523	(14.76, 24.70)	<.001
Month 12	24	20.25	2.820	(14.70, 25.80)	<.001
Month 18	20	20.93	3.089	(14.85, 27.02)	<.001
Month 24	20	22.24	3.089	(16.16, 28.33)	<.001
Month 36	18	17.66	3.256	(11.24, 24.07)	<.001
Month 48	14	24.92	3.693	(17.65, 32.19)	<.001
Month 60	15	24.48	3.568	(17.46, 31.51)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Subgroup: BCR-ABL1-like: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	17.23	4.761	(7.74, 26.72)	<.001
Month 3	14	18.23	4.926	(8.40, 28.05)	<.001
Month 6	14	25.57	4.925	(15.75, 35.39)	<.001
Month 9	11	24.30	5.557	(13.22, 35.38)	<.001
Month 12	7	28.17	6.965	(14.28, 42.06)	<.001
Month 18	6	31.10	7.524	(16.10, 46.11)	<.001
Month 24	5	32.45	8.252	(15.99, 48.90)	<.001
Month 36	5	22.45	8.252	(5.99, 38.90)	0.008
Month 48	2	37.78	13.031	(11.80, 63.76)	0.005
Month 60	3	34.43	10.648	(13.20, 55.66)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	3.99	2.139	(-0.23, 8.22)	0.064
Month 3	27	15.35	2.178	(11.05, 19.65)	<.001
Month 6	23	12.39	2.361	(7.73, 17.05)	<.001
Month 9	19	17.66	2.596	(12.53, 22.78)	<.001
Month 12	17	16.80	2.745	(11.38, 22.22)	<.001
Month 18	14	16.51	3.025	(10.53, 22.48)	<.001
Month 24	15	18.12	2.922	(12.35, 23.89)	<.001
Month 36	13	15.32	3.139	(9.12, 21.52)	<.001
Month 48	12	21.32	3.267	(14.87, 27.77)	<.001
Month 60	12	21.15	3.267	(14.70, 27.60)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Region
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	11.99	4.153	(3.73, 20.25)	0.005
Month 3	15	16.47	3.993	(8.53, 24.42)	<.001
Month 6	13	16.59	4.278	(8.08, 25.09)	<.001
Month 9	12	18.39	4.454	(9.53, 27.25)	<.001
Month 12	10	19.26	4.887	(9.54, 28.98)	<.001
Month 18	7	22.68	5.839	(11.07, 34.30)	<.001
Month 24	6	24.86	6.298	(12.33, 37.38)	<.001
Month 36	6	13.11	6.298	(0.59, 25.64)	0.040
Month 48	5	26.20	6.912	(12.45, 39.95)	<.001
Month 60	6	24.60	6.318	(12.03, 37.16)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Region
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	7.39	2.416	(2.61, 12.17)	0.003
Month 3	22	15.64	2.574	(10.55, 20.73)	<.001
Month 6	21	15.29	2.634	(10.08, 20.50)	<.001
Month 9	15	20.32	3.121	(14.15, 26.50)	<.001
Month 12	11	20.92	3.643	(13.71, 28.12)	<.001
Month 18	10	19.01	3.818	(11.46, 26.57)	<.001
Month 24	12	20.02	3.485	(13.13, 26.92)	<.001
Month 36	10	16.50	3.817	(8.94, 24.05)	<.001
Month 48	8	22.79	4.270	(14.34, 31.24)	<.001
Month 60	8	21.45	4.268	(13.00, 29.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Region
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	3.92	7.914	(-12.95, 20.79)	0.628
Month 3	4	21.92	7.914	(5.05, 38.79)	0.014
Month 6	3	27.51	9.004	(8.32, 46.70)	0.008
Month 9	3	23.84	9.004	(4.65, 43.03)	0.018
Month 12	3	25.18	9.004	(5.98, 44.37)	0.014
Month 18	3	26.84	9.004	(7.65, 46.03)	0.009
Month 24	2	22.63	11.068	(-0.96, 46.23)	0.059
Month 36	2	34.63	11.068	(11.04, 58.23)	0.007
Month 48	1	18.01	16.141	(-16.39, 52.42)	0.282
Month 60	1	31.01	16.141	(-3.39, 65.42)	0.074

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	11.49	2.743	(6.08, 16.91)	<.001
Month 3	27	17.76	2.691	(12.45, 23.08)	<.001
Month 6	26	19.62	2.743	(14.20, 25.03)	<.001
Month 9	20	23.57	3.127	(17.40, 29.74)	<.001
Month 12	17	21.24	3.391	(14.54, 27.93)	<.001
Month 18	14	23.59	3.737	(16.21, 30.97)	<.001
Month 24	12	24.40	4.037	(16.43, 32.37)	<.001
Month 36	13	18.43	3.878	(10.78, 26.09)	<.001
Month 48	9	25.53	4.663	(16.33, 34.74)	<.001
Month 60	11	26.24	4.218	(17.91, 34.57)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	2.52	3.168	(-3.79, 8.83)	0.429
Month 3	14	13.04	3.492	(6.08, 19.99)	<.001
Month 6	11	11.92	3.940	(4.07, 19.77)	0.003
Month 9	10	10.95	4.142	(2.70, 19.20)	0.010
Month 12	7	18.51	4.938	(8.68, 28.35)	<.001
Month 18	6	15.69	5.333	(5.07, 26.31)	0.004
Month 24	8	17.98	4.618	(8.79, 27.18)	<.001
Month 36	5	17.54	5.843	(5.91, 29.18)	0.004
Month 48	5	22.97	5.842	(11.34, 34.61)	<.001
Month 60	4	20.46	6.532	(7.45, 33.47)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Prior SCT therapy: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	5.29	6.461	(-8.15, 18.72)	0.422
Month 3	5	14.09	6.461	(0.65, 27.52)	0.041
Month 6	4	19.90	7.116	(5.10, 34.70)	0.011
Month 9	3	13.10	8.295	(-4.15, 30.35)	0.129
Month 12	3	11.10	8.295	(-6.15, 28.35)	0.195
Month 18	3	8.77	8.295	(-8.48, 26.01)	0.303
Month 24	3	17.33	8.217	(0.24, 34.41)	0.047
Month 36	3	24.33	8.217	(7.24, 41.41)	0.007
Month 48	1	37.31	14.457	(7.25, 67.38)	0.017
Month 60	2	24.17	10.066	(3.24, 45.11)	0.026

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	38	9.26	2.188	(4.95, 13.58)	<.001
Month 3	36	16.97	2.249	(12.54, 21.40)	<.001
Month 6	33	16.54	2.348	(11.91, 21.17)	<.001
Month 9	27	20.05	2.596	(14.93, 25.16)	<.001
Month 12	21	20.93	2.944	(15.13, 26.73)	<.001
Month 18	17	22.24	3.272	(15.79, 28.69)	<.001
Month 24	17	22.87	3.272	(16.42, 29.32)	<.001
Month 36	15	16.03	3.483	(9.17, 22.90)	<.001
Month 48	13	24.76	3.742	(17.39, 32.14)	<.001
Month 60	13	24.25	3.742	(16.87, 31.62)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Eligibility for SCT: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	5.32	2.933	(-0.51, 11.14)	0.073
Month 3	15	17.65	2.832	(12.03, 23.28)	<.001
Month 6	12	18.25	3.165	(11.96, 24.53)	<.001
Month 9	12	22.05	3.165	(15.76, 28.33)	<.001
Month 12	11	17.53	3.306	(10.97, 24.09)	<.001
Month 18	9	19.46	3.654	(12.20, 26.71)	<.001
Month 24	8	19.31	3.878	(11.61, 27.01)	<.001
Month 36	8	13.68	3.876	(5.99, 21.38)	<.001
Month 48	8	22.25	3.876	(14.55, 29.94)	<.001
Month 60	7	23.62	4.149	(15.38, 31.85)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	9.56	2.881	(3.86, 15.25)	0.001
Month 3	26	15.03	3.044	(9.02, 21.05)	<.001
Month 6	25	16.30	3.101	(10.17, 22.43)	<.001
Month 9	18	18.18	3.655	(10.96, 25.41)	<.001
Month 12	13	22.51	4.302	(14.01, 31.02)	<.001
Month 18	11	22.30	4.677	(13.06, 31.54)	<.001
Month 24	12	24.33	4.478	(15.49, 33.18)	<.001
Month 36	10	20.93	4.904	(11.24, 30.62)	<.001
Month 48	6	29.01	6.343	(16.47, 41.55)	<.001
Month 60	8	25.75	5.499	(14.88, 36.62)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline bone marrow tumor burden: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	16.92	5.170	(6.47, 27.37)	0.002
Month 3	7	22.08	4.784	(12.41, 31.75)	<.001
Month 6	6	28.54	5.193	(18.04, 39.04)	<.001
Month 9	5	30.68	5.660	(19.23, 42.12)	<.001
Month 12	5	28.48	5.660	(17.03, 39.92)	<.001
Month 18	5	35.08	5.660	(23.63, 46.52)	<.001
Month 24	5	29.08	5.660	(17.63, 40.52)	<.001
Month 36	5	25.28	5.660	(13.83, 36.72)	<.001
Month 48	3	30.58	7.360	(15.71, 45.46)	<.001
Month 60	4	34.25	6.329	(21.46, 47.05)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	5.83	2.321	(1.25, 10.41)	0.013
Month 3	34	14.34	2.421	(9.57, 19.12)	<.001
Month 6	31	14.00	2.536	(9.00, 19.00)	<.001
Month 9	25	16.85	2.825	(11.28, 22.42)	<.001
Month 12	19	18.33	3.238	(11.94, 24.71)	<.001
Month 18	15	17.50	3.645	(10.31, 24.69)	<.001
Month 24	15	21.19	3.645	(14.00, 28.37)	<.001
Month 36	13	16.61	3.915	(8.89, 24.33)	<.001
Month 48	11	24.29	4.267	(15.88, 32.71)	<.001
Month 60	11	22.79	4.262	(14.39, 31.19)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline extramedullary disease presence: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in

PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	7.83	2.140	(3.61, 12.04)	<.001
Month 3	40	16.18	2.193	(11.86, 20.50)	<.001
Month 6	36	16.85	2.312	(12.30, 21.40)	<.001
Month 9	29	19.10	2.576	(14.02, 24.17)	<.001
Month 12	23	19.44	2.892	(13.74, 25.14)	<.001
Month 18	19	20.03	3.182	(13.76, 26.30)	<.001
Month 24	19	21.41	3.182	(15.14, 27.68)	<.001
Month 36	17	16.48	3.364	(9.85, 23.11)	<.001
Month 48	13	23.99	3.849	(16.41, 31.57)	<.001
Month 60	15	24.27	3.582	(17.21, 31.32)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Down syndrome: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	5.73	2.910	(-0.03, 11.49)	0.051
Month 3	22	13.02	2.841	(7.40, 18.64)	<.001
Month 6	19	16.83	3.059	(10.78, 22.88)	<.001
Month 9	16	15.24	3.335	(8.64, 21.84)	<.001
Month 12	14	18.25	3.562	(11.21, 25.30)	<.001
Month 18	11	21.83	4.018	(13.88, 29.78)	<.001
Month 24	11	23.29	4.018	(15.35, 31.24)	<.001
Month 36	10	21.69	4.214	(13.35, 30.02)	<.001
Month 48	7	24.37	5.039	(14.40, 34.34)	<.001
Month 60	10	23.92	4.214	(15.58, 32.25)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	10.72	3.077	(4.62, 16.82)	<.001
Month 3	19	19.64	3.309	(13.09, 26.20)	<.001
Month 6	18	17.18	3.400	(10.44, 23.91)	<.001
Month 9	14	24.94	3.866	(17.28, 32.60)	<.001
Month 12	10	23.06	4.563	(14.02, 32.10)	<.001
Month 18	9	19.84	4.808	(10.31, 29.37)	<.001
Month 24	9	20.95	4.808	(11.42, 30.48)	<.001
Month 36	8	12.61	5.100	(2.51, 22.72)	0.015
Month 48	7	25.38	5.464	(14.55, 36.21)	<.001
Month 60	5	25.47	6.459	(12.67, 38.27)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Time since enrollment to CTL019 infusion: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-5.78	4.803	(-16.08, 4.52)	0.249
Month 3	4	5.47	4.803	(-4.83, 15.77)	0.274
Month 6	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 9	3	6.43	5.548	(-5.47, 18.33)	0.266
Month 12	2	6.67	6.795	(-7.90, 21.24)	0.343
Month 18	2	11.67	6.795	(-2.90, 26.24)	0.108
Month 24	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 36	2	1.17	6.795	(-13.40, 15.74)	0.866
Month 48	1	9.05	9.934	(-12.26, 30.35)	0.378
Month 60	1	2.29	9.845	(-18.82, 23.41)	0.819

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	3.23	4.031	(-4.97, 11.43)	0.429
Month 3	7	14.71	4.554	(5.44, 23.97)	0.003
Month 6	5	14.57	5.373	(3.64, 25.50)	0.011
Month 9	6	17.75	4.915	(7.75, 27.75)	<.001
Month 12	4	15.46	6.007	(3.24, 27.69)	0.015
Month 18	3	1.74	6.966	(-12.44, 15.91)	0.805
Month 24	3	19.80	6.950	(5.66, 33.94)	0.008
Month 36	1	17.39	12.331	(-7.70, 42.48)	0.168
Month 48	3	21.13	6.950	(6.99, 35.27)	0.005
Month 60	3	21.80	6.950	(7.66, 35.94)	0.004

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	5.16	4.047	(-2.94, 13.27)	0.207
Month 3	10	12.29	4.422	(3.43, 21.15)	0.007
Month 6	10	9.29	4.422	(0.43, 18.15)	0.040
Month 9	7	10.66	5.272	(0.10, 21.22)	0.048
Month 12	6	21.52	5.713	(10.08, 32.96)	<.001
Month 18	5	24.09	6.234	(11.60, 36.58)	<.001
Month 24	5	19.09	6.234	(6.60, 31.58)	0.003
Month 36	5	27.09	6.234	(14.60, 39.58)	<.001
Month 48	4	29.97	6.974	(16.00, 43.94)	<.001
Month 60	3	28.09	8.042	(11.98, 44.20)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	18	13.62	3.521	(6.64, 20.59)	<.001
Month 3	20	19.75	3.338	(13.13, 26.36)	<.001
Month 6	19	22.90	3.424	(16.12, 29.68)	<.001
Month 9	14	27.52	3.988	(19.62, 35.42)	<.001
Month 12	12	24.89	4.310	(16.35, 33.43)	<.001
Month 18	10	28.14	4.719	(18.79, 37.48)	<.001
Month 24	9	28.24	4.975	(18.39, 38.10)	<.001
Month 36	10	18.55	4.719	(9.20, 27.90)	<.001
Month 48	6	27.31	6.095	(15.24, 39.39)	<.001
Month 60	8	28.25	5.282	(17.79, 38.71)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 198r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: Missing

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
No records met the criteria					

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	11.14	4.212	(2.38, 19.90)	0.015
Month 3	6	11.82	4.158	(3.17, 20.47)	0.010
Month 6	6	9.15	4.158	(0.50, 17.80)	0.039
Month 9	3	12.54	5.854	(0.37, 24.72)	0.044
Month 12	2	3.50	7.209	(-11.50, 18.49)	0.633
Month 18	2	11.00	7.209	(-4.00, 25.99)	0.142
Month 24	1	11.75	10.356	(-9.79, 33.28)	0.269
Month 36	2	10.00	7.209	(-5.00, 24.99)	0.180
Month 48	2	13.00	7.209	(-2.00, 27.99)	0.086
Month 60	2	11.00	7.209	(-4.00, 25.99)	0.142

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	10.98	2.550	(5.94, 16.02)	<.001
Month 3	23	15.83	2.552	(10.79, 20.87)	<.001
Month 6	20	15.18	2.733	(9.78, 20.59)	<.001
Month 9	19	20.56	2.805	(15.02, 26.10)	<.001
Month 12	16	20.87	3.058	(14.83, 26.91)	<.001
Month 18	13	22.64	3.390	(15.94, 29.34)	<.001
Month 24	14	24.24	3.267	(17.78, 30.69)	<.001
Month 36	12	14.54	3.529	(7.56, 21.51)	<.001
Month 48	8	24.98	4.333	(16.42, 33.54)	<.001
Month 60	9	23.79	4.081	(15.72, 31.85)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	7.00	4.468	(-1.97, 15.98)	0.123
Month 3	9	18.37	4.230	(9.87, 26.86)	<.001
Month 6	9	22.81	4.230	(14.31, 31.31)	<.001
Month 9	7	16.03	4.772	(6.45, 25.62)	0.002
Month 12	6	24.95	5.149	(14.61, 35.29)	<.001
Month 18	5	20.09	5.649	(8.74, 31.43)	<.001
Month 24	5	20.27	5.660	(8.90, 31.64)	<.001
Month 36	4	29.89	6.352	(17.13, 42.64)	<.001
Month 48	4	28.89	6.346	(16.14, 41.64)	<.001
Month 60	4	31.14	6.346	(18.39, 43.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	9.31	2.915	(3.55, 15.08)	0.002
Month 3	22	12.49	2.848	(6.86, 18.12)	<.001
Month 6	20	11.31	2.987	(5.40, 17.22)	<.001
Month 9	16	15.23	3.343	(8.61, 21.84)	<.001
Month 12	12	15.87	3.856	(8.24, 23.50)	<.001
Month 18	11	15.91	4.027	(7.94, 23.87)	<.001
Month 24	12	18.96	3.856	(11.33, 26.59)	<.001
Month 36	11	10.00	4.027	(2.03, 17.97)	0.014
Month 48	8	18.66	4.747	(9.27, 28.05)	<.001
Month 60	9	19.51	4.458	(10.69, 28.33)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	12.55	2.652	(7.28, 17.81)	<.001
Month 3	16	20.84	2.652	(15.57, 26.10)	<.001
Month 6	15	23.44	2.749	(17.99, 28.90)	<.001
Month 9	13	22.75	2.948	(16.90, 28.60)	<.001
Month 12	12	24.96	3.063	(18.88, 31.04)	<.001
Month 18	9	26.44	3.536	(19.42, 33.46)	<.001
Month 24	8	25.59	3.753	(18.15, 33.04)	<.001
Month 36	7	27.88	4.017	(19.91, 35.85)	<.001
Month 48	6	31.59	4.347	(22.96, 40.22)	<.001
Month 60	6	29.92	4.338	(21.31, 38.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	13.11	2.192	(8.79, 17.44)	<.001
Month 3	30	16.70	2.154	(12.45, 20.95)	<.001
Month 6	29	17.11	2.192	(12.79, 21.44)	<.001
Month 9	23	20.93	2.460	(16.08, 25.78)	<.001
Month 12	19	20.34	2.707	(15.00, 25.68)	<.001
Month 18	15	21.67	3.046	(15.66, 27.68)	<.001
Month 24	16	23.61	2.950	(17.79, 29.43)	<.001
Month 36	14	15.14	3.154	(8.92, 21.36)	<.001
Month 48	11	23.51	3.559	(16.49, 30.54)	<.001
Month 60	12	23.09	3.407	(16.37, 29.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	10.46	4.095	(1.73, 19.19)	0.022
Month 3	4	20.46	4.095	(11.73, 29.19)	<.001
Month 6	3	22.04	4.661	(12.10, 31.97)	<.001
Month 9	3	20.37	4.661	(10.44, 30.30)	<.001
Month 12	3	18.70	4.661	(8.77, 28.64)	0.001
Month 18	3	17.04	4.661	(7.10, 26.97)	0.002
Month 24	2	9.51	5.729	(-2.70, 21.72)	0.118
Month 36	2	29.51	5.729	(17.30, 41.72)	<.001
Month 48	1	36.93	8.356	(19.12, 54.74)	<.001
Month 60	1	36.93	8.356	(19.12, 54.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-7.26	8.756	(-25.92, 11.40)	0.420
Month 3	4	6.49	8.756	(-12.17, 25.15)	0.470
Month 6	3	5.45	9.786	(-15.41, 26.31)	0.586
Month 9	3	-2.88	9.786	(-23.74, 17.97)	0.772
Month 12	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 18	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 24	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 36	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 48	2	20.45	11.962	(-5.05, 45.95)	0.108
Month 60	2	20.45	11.962	(-5.05, 45.95)	0.108

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	3.48	3.163	(-2.89, 9.84)	0.277
Month 3	9	9.68	3.335	(2.97, 16.39)	0.006
Month 6	9	4.40	3.343	(-2.32, 11.13)	0.194
Month 9	6	5.90	4.092	(-2.33, 14.14)	0.156
Month 12	4	10.76	5.002	(0.70, 20.83)	0.037
Month 18	4	12.01	5.002	(1.95, 22.08)	0.020
Month 24	5	12.95	4.478	(3.94, 21.96)	0.006
Month 36	4	11.26	5.002	(1.20, 21.33)	0.029
Month 48	3	13.04	5.784	(1.41, 24.68)	0.029
Month 60	4	10.76	5.002	(0.70, 20.83)	0.037

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	27	12.64	2.477	(7.75, 17.53)	<.001
Month 3	29	18.00	2.389	(13.29, 22.71)	<.001
Month 6	26	20.33	2.523	(15.35, 25.30)	<.001
Month 9	23	22.09	2.683	(16.79, 27.38)	<.001
Month 12	20	22.75	2.876	(17.08, 28.43)	<.001
Month 18	16	23.16	3.216	(16.81, 29.50)	<.001
Month 24	15	24.44	3.322	(17.89, 30.99)	<.001
Month 36	14	19.16	3.438	(12.37, 25.94)	<.001
Month 48	11	27.85	3.879	(20.19, 35.50)	<.001
Month 60	11	28.14	3.878	(20.49, 35.79)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-5.78	4.803	(-16.08, 4.52)	0.249
Month 3	4	5.47	4.803	(-4.83, 15.77)	0.274
Month 6	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 9	3	6.43	5.548	(-5.47, 18.33)	0.266
Month 12	2	6.67	6.795	(-7.90, 21.24)	0.343
Month 18	2	11.67	6.795	(-2.90, 26.24)	0.108
Month 24	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 36	2	1.17	6.795	(-13.40, 15.74)	0.866
Month 48	1	9.05	9.934	(-12.26, 30.35)	0.378
Month 60	1	2.29	9.845	(-18.82, 23.41)	0.819

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	12.61	2.172	(8.33, 16.89)	<.001
Month 3	34	17.27	2.139	(13.05, 21.48)	<.001
Month 6	32	17.24	2.207	(12.89, 21.59)	<.001
Month 9	26	19.75	2.446	(14.93, 24.57)	<.001
Month 12	22	21.30	2.660	(16.06, 26.54)	<.001
Month 18	18	21.51	2.940	(15.71, 27.30)	<.001
Month 24	17	23.30	3.026	(17.33, 29.26)	<.001
Month 36	16	19.23	3.119	(13.08, 25.38)	<.001
Month 48	13	26.07	3.460	(19.25, 32.89)	<.001
Month 60	14	25.74	3.334	(19.16, 32.31)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	10.82	2.049	(6.78, 14.85)	<.001
Month 3	37	16.09	2.021	(12.11, 20.07)	<.001
Month 6	34	16.53	2.110	(12.37, 20.69)	<.001
Month 9	28	18.41	2.324	(13.83, 22.99)	<.001
Month 12	23	19.84	2.564	(14.79, 24.90)	<.001
Month 18	19	20.44	2.821	(14.88, 26.00)	<.001
Month 24	19	21.86	2.821	(16.30, 27.42)	<.001
Month 36	17	16.99	2.983	(11.12, 22.87)	<.001
Month 48	13	24.46	3.410	(17.74, 31.18)	<.001
Month 60	14	24.06	3.286	(17.58, 30.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	10.70	1.998	(6.76, 14.63)	<.001
Month 3	38	16.08	1.971	(12.20, 19.97)	<.001
Month 6	35	16.52	2.055	(12.47, 20.57)	<.001
Month 9	29	18.42	2.257	(13.98, 22.87)	<.001
Month 12	24	19.87	2.481	(14.99, 24.76)	<.001
Month 18	20	20.50	2.717	(15.15, 25.85)	<.001
Month 24	20	21.85	2.718	(16.50, 27.21)	<.001
Month 36	18	17.30	2.865	(11.65, 22.94)	<.001
Month 48	14	24.38	3.248	(17.98, 30.78)	<.001
Month 60	15	23.99	3.138	(17.81, 30.17)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	10.70	1.998	(6.76, 14.63)	<.001
Month 3	38	16.08	1.971	(12.20, 19.97)	<.001
Month 6	35	16.52	2.055	(12.47, 20.57)	<.001
Month 9	29	18.42	2.257	(13.98, 22.87)	<.001
Month 12	24	19.87	2.481	(14.99, 24.76)	<.001
Month 18	20	20.50	2.717	(15.15, 25.85)	<.001
Month 24	20	21.85	2.718	(16.50, 27.21)	<.001
Month 36	18	17.30	2.865	(11.65, 22.94)	<.001
Month 48	14	24.38	3.248	(17.98, 30.78)	<.001
Month 60	15	23.99	3.138	(17.81, 30.17)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	10.70	1.998	(6.76, 14.63)	<.001
Month 3	38	16.08	1.971	(12.20, 19.97)	<.001
Month 6	35	16.52	2.055	(12.47, 20.57)	<.001
Month 9	29	18.42	2.257	(13.98, 22.87)	<.001
Month 12	24	19.87	2.481	(14.99, 24.76)	<.001
Month 18	20	20.50	2.717	(15.15, 25.85)	<.001
Month 24	20	21.85	2.718	(16.50, 27.21)	<.001
Month 36	18	17.30	2.865	(11.65, 22.94)	<.001
Month 48	14	24.38	3.248	(17.98, 30.78)	<.001
Month 60	15	23.99	3.138	(17.81, 30.17)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	17.93	4.469	(9.00, 26.86)	<.001
Month 3	12	17.63	4.470	(8.70, 26.56)	<.001
Month 6	13	23.23	4.299	(14.64, 31.82)	<.001
Month 9	10	20.61	4.900	(10.82, 30.40)	<.001
Month 12	7	27.69	5.853	(15.99, 39.38)	<.001
Month 18	6	30.10	6.320	(17.48, 42.73)	<.001
Month 24	5	32.97	6.944	(19.10, 46.84)	<.001
Month 36	5	22.97	6.944	(9.10, 36.84)	0.002
Month 48	2	37.57	10.949	(15.70, 59.45)	0.001
Month 60	3	32.63	8.943	(14.77, 50.50)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	7.42	2.104	(3.27, 11.57)	<.001
Month 3	26	15.45	2.063	(11.38, 19.53)	<.001
Month 6	22	13.09	2.245	(8.66, 17.52)	<.001
Month 9	19	17.52	2.413	(12.76, 22.29)	<.001
Month 12	17	16.66	2.551	(11.62, 21.70)	<.001
Month 18	14	16.37	2.811	(10.82, 21.92)	<.001
Month 24	15	17.98	2.716	(12.62, 23.34)	<.001
Month 36	13	15.18	2.918	(9.42, 20.94)	<.001
Month 48	12	21.19	3.037	(15.19, 27.19)	<.001
Month 60	12	21.01	3.037	(15.01, 27.01)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	10.48	3.846	(2.82, 18.14)	0.008
Month 3	13	12.94	3.680	(5.61, 20.27)	<.001
Month 6	11	14.12	3.999	(6.15, 22.08)	<.001
Month 9	11	13.43	4.000	(5.46, 21.40)	0.001
Month 12	10	17.42	4.191	(9.08, 25.77)	<.001
Month 18	7	20.79	5.010	(10.81, 30.76)	<.001
Month 24	6	23.76	5.414	(12.98, 34.54)	<.001
Month 36	6	11.75	5.410	(0.98, 22.53)	0.033
Month 48	5	24.07	5.930	(12.25, 35.88)	<.001
Month 60	6	22.31	5.418	(11.52, 33.10)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	10.29	2.394	(5.56, 15.03)	<.001
Month 3	22	15.76	2.393	(11.02, 20.49)	<.001
Month 6	21	15.41	2.450	(10.56, 20.25)	<.001
Month 9	15	20.46	2.901	(14.72, 26.20)	<.001
Month 12	11	21.05	3.387	(14.35, 27.76)	<.001
Month 18	10	19.14	3.550	(12.12, 26.16)	<.001
Month 24	12	20.14	3.240	(13.73, 26.55)	<.001
Month 36	10	16.62	3.550	(9.59, 23.64)	<.001
Month 48	8	22.89	3.971	(15.04, 30.75)	<.001
Month 60	8	21.57	3.969	(13.71, 29.42)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	16.42	6.088	(3.27, 29.58)	0.018
Month 3	3	32.09	6.088	(18.94, 45.24)	<.001
Month 6	3	30.09	6.088	(16.94, 43.24)	<.001
Month 9	3	26.42	6.088	(13.27, 39.58)	<.001
Month 12	3	27.76	6.088	(14.60, 40.91)	<.001
Month 18	3	29.42	6.088	(16.27, 42.58)	<.001
Month 24	2	26.58	7.451	(10.48, 42.68)	0.003
Month 36	2	38.58	7.451	(22.48, 54.68)	<.001
Month 48	1	26.04	10.876	(2.55, 49.54)	0.032
Month 60	1	39.04	10.876	(15.55, 62.54)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	14.51	2.448	(9.67, 19.34)	<.001
Month 3	24	17.76	2.344	(13.13, 22.39)	<.001
Month 6	24	18.85	2.345	(14.22, 23.48)	<.001
Month 9	19	21.47	2.634	(16.26, 26.67)	<.001
Month 12	17	20.66	2.785	(15.16, 26.16)	<.001
Month 18	14	22.98	3.069	(16.92, 29.04)	<.001
Month 24	12	23.99	3.316	(17.44, 30.54)	<.001
Month 36	13	17.94	3.185	(11.65, 24.23)	<.001
Month 48	9	24.74	3.828	(17.17, 32.30)	<.001
Month 60	11	25.43	3.463	(18.59, 32.27)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	4.02	3.202	(-2.36, 10.40)	0.213
Month 3	14	13.29	3.315	(6.68, 19.89)	<.001
Month 6	11	12.16	3.741	(4.71, 19.62)	0.002
Month 9	10	11.26	3.930	(3.43, 19.10)	0.005
Month 12	7	18.79	4.686	(9.45, 28.13)	<.001
Month 18	6	15.94	5.062	(5.85, 26.03)	0.002
Month 24	8	18.25	4.383	(9.51, 26.98)	<.001
Month 36	5	17.79	5.547	(6.74, 28.84)	0.002
Month 48	5	23.24	5.544	(12.19, 34.29)	<.001
Month 60	4	20.74	6.200	(8.39, 33.09)	0.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	15.23	5.059	(4.64, 25.81)	0.007
Month 3	4	19.98	5.059	(9.39, 30.56)	<.001
Month 6	4	21.98	5.059	(11.39, 32.56)	<.001
Month 9	3	17.48	5.873	(5.19, 29.77)	0.008
Month 12	3	15.48	5.873	(3.19, 27.77)	0.016
Month 18	3	13.14	5.873	(0.85, 25.44)	0.037
Month 24	3	19.53	5.839	(7.31, 31.76)	0.003
Month 36	3	26.53	5.839	(14.31, 38.76)	<.001
Month 48	1	32.47	10.463	(10.57, 54.37)	0.006
Month 60	2	26.65	7.149	(11.69, 41.62)	0.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	10.19	2.164	(5.92, 14.45)	<.001
Month 3	34	15.66	2.131	(11.46, 19.87)	<.001
Month 6	31	15.85	2.233	(11.45, 20.25)	<.001
Month 9	26	18.41	2.437	(13.61, 23.22)	<.001
Month 12	21	20.35	2.712	(15.00, 25.70)	<.001
Month 18	17	21.60	3.014	(15.66, 27.55)	<.001
Month 24	17	22.30	3.014	(16.36, 28.24)	<.001
Month 36	15	15.49	3.209	(9.16, 21.82)	<.001
Month 48	13	24.10	3.447	(17.30, 30.89)	<.001
Month 60	13	23.59	3.447	(16.79, 30.38)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	5.32	2.933	(-0.51, 11.14)	0.073
Month 3	15	17.65	2.832	(12.03, 23.28)	<.001
Month 6	12	18.25	3.165	(11.96, 24.53)	<.001
Month 9	12	22.05	3.165	(15.76, 28.33)	<.001
Month 12	11	17.53	3.306	(10.97, 24.09)	<.001
Month 18	9	19.46	3.654	(12.20, 26.71)	<.001
Month 24	8	19.31	3.878	(11.61, 27.01)	<.001
Month 36	8	13.68	3.876	(5.99, 21.38)	<.001
Month 48	8	22.25	3.876	(14.55, 29.94)	<.001
Month 60	7	23.62	4.149	(15.38, 31.85)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	14.09	2.674	(8.80, 19.38)	<.001
Month 3	23	15.14	2.670	(9.86, 20.42)	<.001
Month 6	23	15.44	2.670	(10.16, 20.72)	<.001
Month 9	17	15.78	3.104	(9.64, 21.92)	<.001
Month 12	13	22.09	3.553	(15.06, 29.12)	<.001
Month 18	11	21.37	3.859	(13.74, 29.00)	<.001
Month 24	12	23.43	3.694	(16.12, 30.74)	<.001
Month 36	10	20.24	4.047	(12.24, 28.25)	<.001
Month 48	6	27.37	5.233	(17.02, 37.72)	<.001
Month 60	8	24.04	4.537	(15.07, 33.01)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	16.92	5.170	(6.47, 27.37)	0.002
Month 3	7	22.08	4.784	(12.41, 31.75)	<.001
Month 6	6	28.54	5.193	(18.04, 39.04)	<.001
Month 9	5	30.68	5.660	(19.23, 42.12)	<.001
Month 12	5	28.48	5.660	(17.03, 39.92)	<.001
Month 18	5	35.08	5.660	(23.63, 46.52)	<.001
Month 24	5	29.08	5.660	(17.63, 40.52)	<.001
Month 36	5	25.28	5.660	(13.83, 36.72)	<.001
Month 48	3	30.58	7.360	(15.71, 45.46)	<.001
Month 60	4	34.25	6.329	(21.46, 47.05)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	31	8.68	2.185	(4.37, 12.99)	<.001
Month 3	31	14.35	2.184	(10.05, 18.66)	<.001
Month 6	29	13.50	2.258	(9.05, 17.95)	<.001
Month 9	24	15.27	2.482	(10.37, 20.16)	<.001
Month 12	19	17.64	2.790	(12.14, 23.14)	<.001
Month 18	15	16.59	3.139	(10.40, 22.79)	<.001
Month 24	15	20.36	3.139	(14.17, 26.55)	<.001
Month 36	13	15.76	3.372	(9.11, 22.41)	<.001
Month 48	11	22.98	3.674	(15.73, 30.22)	<.001
Month 60	11	21.64	3.669	(14.40, 28.88)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in

PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

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Table 199p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	10.25	2.023	(6.26, 14.23)	<.001
Month 3	37	16.19	1.995	(12.26, 20.12)	<.001
Month 6	34	16.36	2.083	(12.26, 20.47)	<.001
Month 9	28	17.72	2.294	(13.20, 22.23)	<.001
Month 12	23	19.04	2.531	(14.05, 24.03)	<.001
Month 18	19	19.56	2.784	(14.08, 25.05)	<.001
Month 24	19	20.99	2.785	(15.50, 26.48)	<.001
Month 36	17	16.09	2.944	(10.29, 21.89)	<.001
Month 48	13	23.39	3.367	(16.76, 30.03)	<.001
Month 60	15	23.77	3.134	(17.60, 29.95)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	18	11.67	2.704	(6.32, 17.02)	<.001
Month 3	20	15.06	2.562	(9.99, 20.13)	<.001
Month 6	18	17.97	2.703	(12.62, 23.32)	<.001
Month 9	16	15.18	2.866	(9.51, 20.86)	<.001
Month 12	14	18.26	3.061	(12.20, 24.32)	<.001
Month 18	11	21.84	3.454	(15.00, 28.67)	<.001
Month 24	11	23.34	3.454	(16.50, 30.17)	<.001
Month 36	10	21.74	3.622	(14.57, 28.91)	<.001
Month 48	7	24.49	4.331	(15.92, 33.07)	<.001
Month 60	10	23.99	3.623	(16.82, 31.16)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	19	9.52	2.991	(3.58, 15.45)	0.002
Month 3	18	17.12	3.073	(11.03, 23.21)	<.001
Month 6	17	15.04	3.162	(8.77, 21.31)	<.001
Month 9	13	22.68	3.619	(15.50, 29.85)	<.001
Month 12	10	22.38	4.126	(14.20, 30.56)	<.001
Month 18	9	18.98	4.346	(10.37, 27.60)	<.001
Month 24	9	20.10	4.346	(11.48, 28.71)	<.001
Month 36	8	11.82	4.610	(2.68, 20.96)	0.012
Month 48	7	23.89	4.935	(14.10, 33.67)	<.001
Month 60	5	24.06	5.834	(12.49, 35.63)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-5.78	4.803	(-16.08, 4.52)	0.249
Month 3	4	5.47	4.803	(-4.83, 15.77)	0.274
Month 6	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 9	3	6.43	5.548	(-5.47, 18.33)	0.266
Month 12	2	6.67	6.795	(-7.90, 21.24)	0.343
Month 18	2	11.67	6.795	(-2.90, 26.24)	0.108
Month 24	3	10.10	5.548	(-1.80, 22.00)	0.090
Month 36	2	1.17	6.795	(-13.40, 15.74)	0.866
Month 48	1	9.05	9.934	(-12.26, 30.35)	0.378
Month 60	1	2.29	9.845	(-18.82, 23.41)	0.819

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	8.58	3.506	(1.44, 15.72)	0.020
Month 3	7	15.12	3.714	(7.56, 22.69)	<.001
Month 6	5	14.91	4.383	(5.98, 23.83)	0.002
Month 9	6	18.15	4.009	(9.99, 26.32)	<.001
Month 12	4	15.55	4.903	(5.57, 25.54)	0.003
Month 18	3	1.60	5.686	(-9.98, 13.19)	0.780
Month 24	3	19.76	5.672	(8.20, 31.31)	0.001
Month 36	1	16.20	10.072	(-4.32, 36.71)	0.118
Month 48	3	21.09	5.672	(9.54, 32.64)	<.001
Month 60	3	21.76	5.672	(10.20, 33.31)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	6.66	4.347	(-2.05, 15.38)	0.131
Month 3	10	12.46	4.347	(3.75, 21.18)	0.006
Month 6	10	9.46	4.347	(0.75, 18.18)	0.034
Month 9	7	10.75	5.177	(0.37, 21.13)	0.043
Month 12	6	21.58	5.610	(10.34, 32.83)	<.001
Month 18	5	24.18	6.122	(11.90, 36.45)	<.001
Month 24	5	19.18	6.122	(6.90, 31.45)	0.003
Month 36	5	27.18	6.122	(14.90, 39.45)	<.001
Month 48	4	30.05	6.850	(16.31, 43.78)	<.001
Month 60	3	28.18	7.899	(12.34, 44.01)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 199r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in EQVAS total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	16.63	3.114	(10.46, 22.80)	<.001
Month 3	17	20.04	2.922	(14.24, 25.83)	<.001
Month 6	17	22.19	2.923	(16.40, 27.99)	<.001
Month 9	13	24.70	3.343	(18.07, 31.33)	<.001
Month 12	12	23.92	3.477	(17.02, 30.81)	<.001
Month 18	10	27.30	3.808	(19.75, 34.85)	<.001
Month 24	9	27.74	4.017	(19.78, 35.71)	<.001
Month 36	10	17.87	3.809	(10.32, 25.42)	<.001
Month 48	6	26.18	4.918	(16.43, 35.93)	<.001
Month 60	8	27.02	4.260	(18.58, 35.47)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Age
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	2.64	5.190	(-7.99, 13.27)	0.615
Month 3	7	7.50	5.952	(-4.70, 19.69)	0.218
Month 6	7	8.92	5.952	(-3.27, 21.12)	0.145
Month 9	4	4.72	7.807	(-11.27, 20.71)	0.550
Month 12	2	18.03	11.047	(-4.60, 40.66)	0.114
Month 18	2	21.83	11.047	(-0.80, 44.46)	0.058
Month 24	2	16.93	11.047	(-5.70, 39.56)	0.137
Month 36	2	9.33	11.047	(-13.30, 31.96)	0.406
Month 48	2	18.03	11.047	(-4.60, 40.66)	0.114
Month 60	2	20.18	11.047	(-2.45, 42.81)	0.078

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Age
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	5.48	2.631	(0.28, 10.68)	0.039
Month 3	24	14.99	2.633	(9.79, 20.20)	<.001
Month 6	21	16.32	2.812	(10.77, 21.88)	<.001
Month 9	19	20.99	2.955	(15.15, 26.83)	<.001
Month 12	16	24.57	3.222	(18.21, 30.94)	<.001
Month 18	12	25.97	3.719	(18.62, 33.32)	<.001
Month 24	14	27.64	3.445	(20.83, 34.45)	<.001
Month 36	12	23.80	3.732	(16.42, 31.17)	<.001
Month 48	7	27.64	4.872	(18.01, 37.27)	<.001
Month 60	9	27.33	4.304	(18.82, 35.83)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Age
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-1.97	5.427	(-12.90, 8.95)	0.718
Month 3	9	12.53	5.423	(1.61, 23.44)	0.025
Month 6	10	11.92	5.119	(1.62, 22.22)	0.024
Month 9	7	13.47	6.125	(1.14, 25.80)	0.033
Month 12	5	24.18	7.237	(9.62, 38.75)	0.002
Month 18	4	13.56	8.096	(-2.73, 29.86)	0.101
Month 24	4	21.37	8.130	(5.01, 37.74)	0.012
Month 36	3	20.42	9.416	(1.46, 39.37)	0.035
Month 48	3	26.62	9.416	(7.66, 45.57)	0.007
Month 60	3	26.58	9.416	(7.63, 45.54)	0.007

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Gender
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	3.57	2.829	(-2.02, 9.17)	0.209
Month 3	24	14.98	2.944	(9.16, 20.80)	<.001
Month 6	22	14.37	3.079	(8.28, 20.45)	<.001
Month 9	17	16.09	3.498	(9.18, 23.01)	<.001
Month 12	12	21.60	4.163	(13.37, 29.83)	<.001
Month 18	10	21.46	4.560	(12.44, 30.48)	<.001
Month 24	12	21.97	4.165	(13.74, 30.21)	<.001
Month 36	11	18.94	4.356	(10.33, 27.55)	<.001
Month 48	8	22.95	5.107	(12.85, 33.04)	<.001
Month 60	9	26.49	4.821	(16.96, 36.02)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Gender
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	3.56	3.340	(-3.08, 10.19)	0.290
Month 3	16	11.61	3.355	(4.95, 18.28)	<.001
Month 6	16	14.04	3.336	(7.41, 20.66)	<.001
Month 9	13	18.20	3.706	(10.84, 25.56)	<.001
Month 12	11	25.74	4.021	(17.75, 33.73)	<.001
Month 18	8	23.71	4.717	(14.34, 33.08)	<.001
Month 24	8	28.91	4.722	(19.53, 38.29)	<.001
Month 36	6	23.13	5.487	(12.23, 34.03)	<.001
Month 48	4	30.61	6.717	(17.27, 43.95)	<.001
Month 60	5	25.36	5.988	(13.47, 37.26)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Race
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	5.68	2.397	(0.96, 10.41)	0.019
Month 3	32	14.37	2.433	(9.57, 19.17)	<.001
Month 6	31	16.39	2.472	(11.52, 21.27)	<.001
Month 9	24	19.02	2.810	(13.48, 24.56)	<.001
Month 12	19	25.40	3.159	(19.17, 31.63)	<.001
Month 18	14	23.62	3.680	(16.36, 30.87)	<.001
Month 24	17	26.32	3.339	(19.73, 32.90)	<.001
Month 36	14	20.80	3.685	(13.53, 28.07)	<.001
Month 48	9	26.71	4.590	(17.66, 35.77)	<.001
Month 60	11	28.17	4.157	(19.97, 36.36)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Race
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	0.62	2.586	(-5.34, 6.59)	0.815
Month 3	3	-0.55	3.031	(-7.54, 6.44)	0.862
Month 6	2	-1.14	3.643	(-9.54, 7.26)	0.762
Month 9	2	-3.19	3.643	(-11.59, 5.21)	0.407
Month 12	2	1.06	3.643	(-7.34, 9.46)	0.778
Month 18	2	3.26	3.643	(-5.14, 11.66)	0.397
Month 24	1	-3.56	5.274	(-15.72, 8.60)	0.519
Month 36	1	8.44	5.274	(-3.72, 20.60)	0.148
Month 48	1	19.34	5.274	(7.18, 31.50)	0.006
Month 60	1	13.84	5.274	(1.68, 26.00)	0.030

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Race
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-9.84	7.424	(-25.32, 5.65)	0.200
Month 3	5	14.72	7.424	(-0.76, 30.21)	0.061
Month 6	5	5.62	7.594	(-10.22, 21.46)	0.468
Month 9	4	13.54	8.315	(-3.81, 30.88)	0.119
Month 12	2	24.15	11.719	(-0.30, 48.60)	0.053
Month 18	2	29.30	11.719	(4.85, 53.75)	0.021
Month 24	2	32.00	11.719	(7.55, 56.45)	0.013
Month 36	2	31.75	11.719	(7.30, 56.20)	0.014
Month 48	2	29.05	11.719	(4.60, 53.50)	0.022
Month 60	2	26.85	11.719	(2.40, 51.30)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	-7.23	4.205	(-15.67, 1.20)	0.091
Month 3	10	13.40	4.609	(4.15, 22.64)	0.005
Month 6	11	4.96	4.410	(-3.88, 13.81)	0.265
Month 9	7	14.30	5.508	(3.25, 25.34)	0.012
Month 12	4	20.03	7.283	(5.42, 34.64)	0.008
Month 18	4	20.15	7.283	(5.54, 34.76)	0.008
Month 24	5	19.53	6.514	(6.47, 32.60)	0.004
Month 36	4	20.28	7.283	(5.67, 34.89)	0.007
Month 48	3	18.22	8.434	(1.30, 35.13)	0.035
Month 60	4	15.10	7.283	(0.49, 29.71)	0.043

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	7.61	2.497	(2.68, 12.54)	0.003
Month 3	30	13.55	2.496	(8.63, 18.48)	<.001
Month 6	27	17.34	2.631	(12.15, 22.53)	<.001
Month 9	23	17.48	2.852	(11.85, 23.11)	<.001
Month 12	19	24.54	3.135	(18.35, 30.72)	<.001
Month 18	14	23.27	3.652	(16.06, 30.48)	<.001
Month 24	15	26.86	3.533	(19.88, 33.83)	<.001
Month 36	13	21.52	3.805	(14.01, 29.03)	<.001
Month 48	9	29.11	4.555	(20.13, 38.10)	<.001
Month 60	10	30.79	4.324	(22.26, 39.33)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	4.095	(-3.77, 13.92)	0.237
Month 3	4	17.37	4.095	(8.53, 26.22)	<.001
Month 6	3	20.89	4.590	(10.97, 30.80)	<.001
Month 9	3	32.45	4.590	(22.54, 42.37)	<.001
Month 12	2	40.03	5.702	(27.71, 52.35)	<.001
Month 18	1	23.58	7.943	(6.42, 40.74)	0.011
Month 24	3	21.59	4.590	(11.67, 31.50)	<.001
Month 36	2	25.88	5.702	(13.56, 38.20)	<.001
Month 48	1	22.77	8.145	(5.18, 40.37)	0.015
Month 60	1	12.68	7.943	(-4.48, 29.84)	0.134

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	38	3.31	2.311	(-1.25, 7.86)	0.154
Month 3	36	12.91	2.373	(8.23, 17.59)	<.001
Month 6	35	13.50	2.408	(8.75, 18.24)	<.001
Month 9	27	15.08	2.741	(9.68, 20.49)	<.001
Month 12	21	21.82	3.107	(15.70, 27.94)	<.001
Month 18	17	22.24	3.454	(15.43, 29.05)	<.001
Month 24	17	25.58	3.456	(18.77, 32.39)	<.001
Month 36	15	20.42	3.683	(13.16, 27.68)	<.001
Month 48	11	26.70	4.295	(18.23, 35.16)	<.001
Month 60	13	27.63	3.952	(19.84, 35.42)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	3.70	2.166	(-0.57, 7.96)	0.089
Month 3	39	12.94	2.219	(8.57, 17.32)	<.001
Month 6	37	13.47	2.278	(8.98, 17.95)	<.001
Month 9	29	16.23	2.573	(11.16, 21.30)	<.001
Month 12	22	22.87	2.954	(17.05, 28.69)	<.001
Month 18	17	21.62	3.360	(15.00, 28.24)	<.001
Month 24	19	24.12	3.181	(17.85, 30.39)	<.001
Month 36	16	19.74	3.472	(12.90, 26.58)	<.001
Month 48	11	25.27	4.178	(17.04, 33.50)	<.001
Month 60	13	25.85	3.845	(18.27, 33.42)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.61	2.149	(-0.63, 7.84)	0.095
Month 3	40	13.49	2.200	(9.15, 17.82)	<.001
Month 6	38	14.09	2.258	(9.64, 18.53)	<.001
Month 9	30	16.78	2.541	(11.77, 21.78)	<.001
Month 12	23	23.29	2.901	(17.58, 29.01)	<.001
Month 18	18	22.36	3.279	(15.90, 28.82)	<.001
Month 24	20	24.87	3.113	(18.74, 31.00)	<.001
Month 36	17	20.88	3.382	(14.22, 27.54)	<.001
Month 48	12	26.16	4.016	(18.25, 34.07)	<.001
Month 60	14	26.56	3.720	(19.24, 33.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.61	2.149	(-0.63, 7.84)	0.095
Month 3	40	13.49	2.200	(9.15, 17.82)	<.001
Month 6	38	14.09	2.258	(9.64, 18.53)	<.001
Month 9	30	16.78	2.541	(11.77, 21.78)	<.001
Month 12	23	23.29	2.901	(17.58, 29.01)	<.001
Month 18	18	22.36	3.279	(15.90, 28.82)	<.001
Month 24	20	24.87	3.113	(18.74, 31.00)	<.001
Month 36	17	20.88	3.382	(14.22, 27.54)	<.001
Month 48	12	26.16	4.016	(18.25, 34.07)	<.001
Month 60	14	26.56	3.720	(19.24, 33.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment

Subgroup: BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.61	2.149	(-0.63, 7.84)	0.095
Month 3	40	13.49	2.200	(9.15, 17.82)	<.001
Month 6	38	14.09	2.258	(9.64, 18.53)	<.001
Month 9	30	16.78	2.541	(11.77, 21.78)	<.001
Month 12	23	23.29	2.901	(17.58, 29.01)	<.001
Month 18	18	22.36	3.279	(15.90, 28.82)	<.001
Month 24	20	24.87	3.113	(18.74, 31.00)	<.001
Month 36	17	20.88	3.382	(14.22, 27.54)	<.001
Month 48	12	26.16	4.016	(18.25, 34.07)	<.001
Month 60	14	26.56	3.720	(19.24, 33.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	11.90	4.026	(3.87, 19.94)	0.004
Month 3	13	16.13	4.178	(7.79, 24.47)	<.001
Month 6	14	17.20	4.026	(9.17, 25.24)	<.001
Month 9	11	15.56	4.543	(6.50, 24.63)	0.001
Month 12	7	30.76	5.695	(19.40, 42.13)	<.001
Month 18	6	29.55	6.147	(17.28, 41.81)	<.001
Month 24	5	37.96	6.758	(24.48, 51.45)	<.001
Month 36	5	28.14	6.758	(14.66, 41.63)	<.001
Month 48	1	40.57	15.085	(10.46, 70.67)	0.009
Month 60	3	37.37	8.699	(20.01, 54.73)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	-0.40	2.542	(-5.42, 4.62)	0.876
Month 3	27	12.28	2.585	(7.18, 17.38)	<.001
Month 6	24	12.74	2.744	(7.32, 18.16)	<.001
Month 9	19	17.91	3.082	(11.83, 24.00)	<.001
Month 12	16	20.05	3.357	(13.42, 26.67)	<.001
Month 18	12	19.00	3.876	(11.35, 26.65)	<.001
Month 24	15	20.17	3.469	(13.32, 27.02)	<.001
Month 36	12	17.88	3.885	(10.21, 25.56)	<.001
Month 48	11	23.46	4.049	(15.47, 31.46)	<.001
Month 60	11	22.83	4.049	(14.84, 30.83)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Region
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	2.80	3.155	(-3.47, 9.08)	0.377
Month 3	15	12.63	3.047	(6.57, 18.69)	<.001
Month 6	14	12.35	3.160	(6.07, 18.63)	<.001
Month 9	12	11.09	3.410	(4.31, 17.88)	0.002
Month 12	10	18.95	3.732	(11.52, 26.37)	<.001
Month 18	7	22.93	4.462	(14.05, 31.80)	<.001
Month 24	7	24.60	4.461	(15.73, 33.48)	<.001
Month 36	6	15.35	4.829	(5.75, 24.96)	0.002
Month 48	4	25.25	5.932	(13.46, 37.05)	<.001
Month 60	6	26.03	4.834	(16.41, 35.64)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Region
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	4.47	2.933	(-1.33, 10.27)	0.130
Month 3	23	13.73	3.108	(7.58, 19.87)	<.001
Month 6	22	14.74	3.179	(8.45, 21.03)	<.001
Month 9	16	19.47	3.726	(12.10, 26.84)	<.001
Month 12	11	24.97	4.501	(16.07, 33.87)	<.001
Month 18	9	22.66	4.969	(12.83, 32.49)	<.001
Month 24	12	24.72	4.304	(16.21, 33.23)	<.001
Month 36	10	24.86	4.718	(15.52, 34.19)	<.001
Month 48	7	25.78	5.633	(14.64, 36.93)	<.001
Month 60	7	25.83	5.640	(14.67, 36.98)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Region
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	9.07	9.047	(-14.18, 32.33)	0.362
Month 3	2	17.77	9.047	(-5.48, 41.03)	0.107
Month 6	2	22.67	9.047	(-0.58, 45.93)	0.054
Month 9	2	25.92	9.047	(2.67, 49.18)	0.035
Month 12	2	34.12	9.047	(10.87, 57.38)	0.013
Month 18	2	21.62	9.047	(-1.63, 44.88)	0.062
Month 24	1	23.28	13.023	(-10.19, 56.76)	0.134
Month 36	1	13.48	13.023	(-19.99, 46.96)	0.348
Month 48	1	21.18	13.023	(-12.29, 54.66)	0.165
Month 60	1	26.58	13.023	(-6.89, 60.06)	0.097

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	3.55	2.669	(-1.72, 8.82)	0.186
Month 3	26	12.56	2.617	(7.39, 17.73)	<.001
Month 6	27	13.95	2.569	(8.88, 19.02)	<.001
Month 9	20	14.01	2.987	(8.11, 19.91)	<.001
Month 12	17	20.02	3.236	(13.63, 26.41)	<.001
Month 18	14	21.96	3.566	(14.92, 29.00)	<.001
Month 24	13	23.38	3.704	(16.06, 30.69)	<.001
Month 36	13	18.78	3.704	(11.46, 26.09)	<.001
Month 48	8	25.98	4.721	(16.65, 35.30)	<.001
Month 60	11	28.61	4.024	(20.67, 36.56)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	4.24	3.662	(-3.06, 11.55)	0.251
Month 3	14	15.62	4.014	(7.62, 23.63)	<.001
Month 6	11	14.38	4.514	(5.37, 23.38)	0.002
Month 9	10	21.74	4.736	(12.29, 31.19)	<.001
Month 12	6	32.24	6.117	(20.04, 44.45)	<.001
Month 18	4	22.98	7.508	(8.00, 37.96)	0.003
Month 24	7	27.63	5.657	(16.35, 38.92)	<.001
Month 36	4	26.69	7.574	(11.58, 41.80)	<.001
Month 48	4	25.69	7.490	(10.74, 40.63)	0.001
Month 60	3	20.22	8.679	(2.91, 37.54)	0.023

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	16.85	4.578	(6.77, 26.93)	0.004
Month 3	3	18.55	4.578	(8.47, 28.63)	0.002
Month 6	3	21.82	4.578	(11.74, 31.89)	<.001
Month 9	2	18.79	5.622	(6.42, 31.17)	0.007
Month 12	2	31.29	5.622	(18.92, 43.67)	<.001
Month 18	2	28.59	5.622	(16.22, 40.97)	<.001
Month 24	2	30.37	5.674	(17.88, 42.86)	<.001
Month 36	2	35.27	5.674	(22.78, 47.76)	<.001
Month 48	1	35.46	7.917	(18.04, 52.89)	<.001
Month 60	2	35.27	5.674	(22.78, 47.76)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	39	2.69	2.202	(-1.65, 7.02)	0.224
Month 3	37	13.19	2.259	(8.74, 17.64)	<.001
Month 6	35	13.59	2.323	(9.01, 18.17)	<.001
Month 9	28	16.83	2.596	(11.72, 21.95)	<.001
Month 12	21	22.78	2.998	(16.87, 28.68)	<.001
Month 18	16	21.81	3.435	(15.04, 28.58)	<.001
Month 24	18	23.83	3.239	(17.45, 30.21)	<.001
Month 36	15	18.44	3.553	(11.44, 25.44)	<.001
Month 48	11	25.21	4.142	(17.04, 33.37)	<.001
Month 60	12	24.16	3.971	(16.34, 31.99)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	1.90	3.297	(-4.65, 8.45)	0.566
Month 3	15	12.77	3.186	(6.45, 19.10)	<.001
Month 6	12	14.77	3.560	(7.70, 21.84)	<.001
Month 9	12	19.13	3.559	(12.06, 26.20)	<.001
Month 12	11	18.95	3.718	(11.57, 26.33)	<.001
Month 18	8	17.83	4.359	(9.17, 26.49)	<.001
Month 24	9	16.59	4.113	(8.42, 24.75)	<.001
Month 36	8	12.55	4.373	(3.87, 21.23)	0.005
Month 48	8	21.31	4.359	(12.65, 29.96)	<.001
Month 60	7	22.71	4.661	(13.46, 31.97)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	4.60	2.784	(-0.91, 10.10)	0.101
Month 3	25	14.05	2.941	(8.23, 19.86)	<.001
Month 6	26	14.10	2.884	(8.39, 19.80)	<.001
Month 9	18	15.08	3.469	(8.22, 21.94)	<.001
Month 12	12	27.31	4.253	(18.90, 35.72)	<.001
Month 18	10	26.04	4.653	(16.84, 35.24)	<.001
Month 24	11	31.54	4.437	(22.77, 40.31)	<.001
Month 36	9	28.09	4.911	(18.37, 37.80)	<.001
Month 48	4	33.91	7.353	(19.38, 48.45)	<.001
Month 60	7	29.92	5.560	(18.93, 40.91)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	7.26	4.824	(-2.49, 17.01)	0.140
Month 3	7	14.32	4.473	(5.28, 23.36)	0.003
Month 6	6	17.40	4.826	(7.65, 27.16)	<.001
Month 9	5	18.44	5.284	(7.76, 29.12)	0.001
Month 12	5	19.50	5.284	(8.82, 30.18)	<.001
Month 18	5	18.40	5.284	(7.72, 29.08)	0.001
Month 24	5	15.78	5.284	(5.10, 26.46)	0.005
Month 36	5	13.60	5.284	(2.92, 24.28)	0.014
Month 48	3	21.51	6.833	(7.70, 35.32)	0.003
Month 60	4	23.52	5.909	(11.58, 35.46)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	2.88	2.376	(-1.81, 7.56)	0.228
Month 3	33	13.20	2.480	(8.31, 18.09)	<.001
Month 6	32	13.24	2.521	(8.27, 18.21)	<.001
Month 9	25	16.43	2.850	(10.81, 22.05)	<.001
Month 12	18	24.41	3.358	(17.78, 31.03)	<.001
Month 18	13	24.17	3.951	(16.38, 31.96)	<.001
Month 24	15	28.01	3.681	(20.75, 35.27)	<.001
Month 36	12	24.08	4.124	(15.95, 32.22)	<.001
Month 48	9	28.13	4.752	(18.76, 37.50)	<.001
Month 60	10	28.09	4.509	(19.20, 36.98)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate

with an Variance Component covariance structure.

Table 200p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment

Subgroup: Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	2.18	2.128	(-2.01, 6.37)	0.307
Month 3	39	13.45	2.181	(9.16, 17.75)	<.001
Month 6	37	13.82	2.240	(9.41, 18.24)	<.001
Month 9	29	16.44	2.529	(11.46, 21.42)	<.001
Month 12	22	22.14	2.903	(16.42, 27.86)	<.001
Month 18	17	21.66	3.303	(15.16, 28.17)	<.001
Month 24	19	23.30	3.126	(17.15, 29.46)	<.001
Month 36	16	19.30	3.411	(12.57, 26.02)	<.001
Month 48	11	24.86	4.107	(16.77, 32.95)	<.001
Month 60	14	26.16	3.640	(18.99, 33.33)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	19	4.83	2.795	(-0.70, 10.37)	0.086
Month 3	20	14.17	2.723	(8.78, 19.56)	<.001
Month 6	19	15.78	2.799	(10.24, 21.32)	<.001
Month 9	15	17.21	3.154	(10.97, 23.45)	<.001
Month 12	13	23.81	3.380	(17.12, 30.51)	<.001
Month 18	10	23.55	3.852	(15.93, 31.18)	<.001
Month 24	11	26.29	3.673	(19.02, 33.56)	<.001
Month 36	9	24.39	4.068	(16.34, 32.44)	<.001
Month 48	6	28.14	4.973	(18.30, 37.99)	<.001
Month 60	10	28.43	3.853	(20.80, 36.06)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	2.98	3.283	(-3.53, 9.48)	0.367
Month 3	20	13.01	3.515	(6.04, 19.97)	<.001
Month 6	19	12.61	3.602	(5.47, 19.74)	<.001
Month 9	15	16.10	4.055	(8.06, 24.13)	<.001
Month 12	10	22.02	4.976	(12.16, 31.88)	<.001
Month 18	8	20.43	5.557	(9.42, 31.44)	<.001
Month 24	9	22.79	5.245	(12.39, 33.18)	<.001
Month 36	8	16.81	5.566	(5.78, 27.84)	0.003
Month 48	6	24.32	6.411	(11.61, 37.02)	<.001
Month 60	4	21.75	7.891	(6.11, 37.39)	0.007

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	4.095	(-3.77, 13.92)	0.237
Month 3	4	17.37	4.095	(8.53, 26.22)	<.001
Month 6	3	20.89	4.590	(10.97, 30.80)	<.001
Month 9	3	32.45	4.590	(22.54, 42.37)	<.001
Month 12	2	40.03	5.702	(27.71, 52.35)	<.001
Month 18	1	23.58	7.943	(6.42, 40.74)	0.011
Month 24	3	21.59	4.590	(11.67, 31.50)	<.001
Month 36	2	25.88	5.702	(13.56, 38.20)	<.001
Month 48	1	22.77	8.145	(5.18, 40.37)	0.015
Month 60	1	12.68	7.943	(-4.48, 29.84)	0.134

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-8.69	5.294	(-19.43, 2.06)	0.110
Month 3	8	0.19	5.878	(-11.74, 12.12)	0.974
Month 6	6	1.33	6.770	(-12.42, 15.07)	0.846
Month 9	7	9.16	6.265	(-3.56, 21.88)	0.153
Month 12	4	15.81	8.317	(-1.07, 32.69)	0.066
Month 18	3	8.89	9.599	(-10.60, 28.38)	0.361
Month 24	3	13.62	9.569	(-5.81, 33.04)	0.164
Month 36	1	1.01	16.746	(-32.99, 35.00)	0.952
Month 48	2	9.54	11.810	(-14.43, 33.52)	0.425
Month 60	2	12.24	11.810	(-11.73, 36.22)	0.307

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	7.15	4.807	(-2.51, 16.82)	0.143
Month 3	9	15.16	5.261	(4.58, 25.74)	0.006
Month 6	9	11.63	5.261	(1.05, 22.21)	0.032
Month 9	6	13.00	6.497	(-0.06, 26.07)	0.051
Month 12	5	19.75	7.112	(5.45, 34.05)	0.008
Month 18	4	25.46	7.884	(9.61, 41.32)	0.002
Month 24	4	29.51	7.884	(13.66, 45.37)	<.001
Month 36	4	30.74	7.884	(14.88, 46.59)	<.001
Month 48	4	30.49	7.884	(14.63, 46.34)	<.001
Month 60	3	24.64	9.117	(6.31, 42.97)	0.009

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 200r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Subgroup: Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	5.05	3.139	(-1.17, 11.26)	0.111
Month 3	19	16.19	2.969	(10.31, 22.07)	<.001
Month 6	20	18.59	2.895	(12.85, 24.32)	<.001
Month 9	14	17.21	3.464	(10.35, 24.07)	<.001
Month 12	12	25.48	3.736	(18.08, 32.88)	<.001
Month 18	10	26.18	4.093	(18.07, 34.29)	<.001
Month 24	10	28.62	4.096	(20.51, 36.74)	<.001
Month 36	10	21.55	4.096	(13.44, 29.67)	<.001
Month 48	5	31.43	5.792	(19.95, 42.90)	<.001
Month 60	8	33.83	4.579	(24.76, 42.90)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	0.62	5.930	(-11.53, 12.76)	0.918
Month 3	7	11.05	6.863	(-3.00, 25.11)	0.118
Month 6	7	10.34	6.863	(-3.72, 24.40)	0.143
Month 9	4	0.33	8.897	(-17.89, 18.56)	0.970
Month 12	2	7.78	12.671	(-18.17, 33.74)	0.544
Month 18	2	5.28	12.671	(-20.67, 31.24)	0.680
Month 24	2	7.78	12.671	(-18.17, 33.74)	0.544
Month 36	2	5.28	12.671	(-20.67, 31.24)	0.680
Month 48	2	12.78	12.671	(-13.17, 38.74)	0.322
Month 60	2	17.78	12.671	(-8.17, 43.74)	0.172

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	9.66	3.599	(2.55, 16.77)	0.008
Month 3	24	19.45	3.603	(12.33, 26.57)	<.001
Month 6	21	19.78	3.841	(12.18, 27.37)	<.001
Month 9	19	23.21	4.043	(15.22, 31.19)	<.001
Month 12	16	28.56	4.404	(19.86, 37.26)	<.001
Month 18	12	31.18	5.090	(21.12, 41.24)	<.001
Month 24	14	30.76	4.711	(21.45, 40.07)	<.001
Month 36	12	18.51	5.117	(8.40, 28.62)	<.001
Month 48	7	28.55	6.660	(15.39, 41.71)	<.001
Month 60	9	25.18	5.868	(13.58, 36.78)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	6.85	6.311	(-5.85, 19.55)	0.283
Month 3	9	8.89	6.268	(-3.72, 21.51)	0.163
Month 6	10	9.73	5.925	(-2.20, 21.65)	0.107
Month 9	7	7.57	7.080	(-6.68, 21.82)	0.290
Month 12	5	16.39	8.379	(-0.48, 33.25)	0.057
Month 18	4	11.09	9.366	(-7.77, 29.94)	0.243
Month 24	4	18.04	9.372	(-0.83, 36.90)	0.060
Month 36	3	17.46	10.888	(-4.46, 39.37)	0.116
Month 48	3	24.12	10.888	(2.21, 46.04)	0.032
Month 60	3	10.79	10.888	(-11.12, 32.71)	0.327

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	6.05	5.783	(-5.80, 17.90)	0.304
Month 3	7	12.48	6.570	(-0.98, 25.94)	0.068
Month 6	7	18.29	6.570	(4.84, 31.75)	0.010
Month 9	4	6.09	8.698	(-11.73, 23.91)	0.490
Month 12	2	22.76	12.241	(-2.32, 47.83)	0.074
Month 18	2	29.01	12.241	(3.93, 54.08)	0.025
Month 24	2	24.31	12.241	(-0.77, 49.38)	0.057
Month 36	2	-0.74	12.241	(-25.82, 24.33)	0.952
Month 48	2	24.31	12.241	(-0.77, 49.38)	0.057
Month 60	2	27.41	12.241	(2.33, 52.48)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	4.13	3.966	(-3.71, 11.96)	0.300
Month 3	24	18.31	3.969	(10.47, 26.15)	<.001
Month 6	21	20.15	4.239	(11.77, 28.53)	<.001
Month 9	19	28.30	4.456	(19.49, 37.11)	<.001
Month 12	16	29.44	4.859	(19.83, 39.04)	<.001
Month 18	12	31.69	5.608	(20.61, 42.78)	<.001
Month 24	14	35.79	5.195	(25.53, 46.06)	<.001
Month 36	12	32.27	5.620	(21.16, 43.38)	<.001
Month 48	7	37.12	7.350	(22.59, 51.64)	<.001
Month 60	9	38.70	6.492	(25.87, 51.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-3.17	7.690	(-18.64, 12.31)	0.683
Month 3	9	22.00	7.701	(6.50, 37.50)	0.006
Month 6	10	21.43	7.258	(6.82, 36.04)	0.005
Month 9	7	25.60	8.705	(8.08, 43.12)	0.005
Month 12	5	39.08	10.247	(18.46, 59.71)	<.001
Month 18	4	25.73	11.508	(2.56, 48.89)	0.030
Month 24	4	36.28	11.624	(12.88, 59.67)	0.003
Month 36	3	38.03	13.339	(11.18, 64.88)	0.007
Month 48	3	43.23	13.339	(16.38, 70.08)	0.002
Month 60	3	44.30	13.339	(17.45, 71.15)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	0.62	5.101	(-9.83, 11.06)	0.905
Month 3	7	4.60	5.871	(-7.43, 16.63)	0.440
Month 6	7	4.10	5.871	(-7.93, 16.13)	0.491
Month 9	4	3.89	7.661	(-11.80, 19.58)	0.615
Month 12	2	14.18	10.874	(-8.09, 36.46)	0.203
Month 18	2	16.63	10.874	(-5.64, 38.91)	0.137
Month 24	2	11.68	10.874	(-10.59, 33.96)	0.292
Month 36	2	13.33	10.874	(-8.94, 35.61)	0.230
Month 48	2	13.33	10.874	(-8.94, 35.61)	0.230
Month 60	2	14.98	10.874	(-7.29, 37.26)	0.179

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	6.09	2.448	(1.25, 10.93)	0.014
Month 3	24	13.22	2.450	(8.38, 18.07)	<.001
Month 6	21	14.01	2.616	(8.84, 19.18)	<.001
Month 9	19	16.87	2.750	(11.44, 22.31)	<.001
Month 12	16	21.80	2.998	(15.88, 27.72)	<.001
Month 18	12	22.76	3.461	(15.92, 29.60)	<.001
Month 24	14	23.04	3.206	(16.71, 29.38)	<.001
Month 36	12	18.92	3.474	(12.06, 25.79)	<.001
Month 48	7	22.83	4.532	(13.87, 31.78)	<.001
Month 60	9	21.62	4.001	(13.71, 29.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-1.48	4.922	(-11.39, 8.43)	0.765
Month 3	9	7.56	4.915	(-2.33, 17.45)	0.131
Month 6	10	7.26	4.652	(-2.11, 16.62)	0.126
Month 9	7	7.73	5.561	(-3.46, 18.92)	0.171
Month 12	5	16.02	6.582	(2.77, 29.26)	0.019
Month 18	4	6.77	7.357	(-8.04, 21.58)	0.362
Month 24	4	12.84	7.358	(-1.97, 27.65)	0.088
Month 36	3	11.88	8.537	(-5.31, 29.06)	0.171
Month 48	3	18.54	8.537	(1.36, 35.73)	0.035
Month 60	3	17.98	8.537	(0.79, 35.16)	0.041

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-10.72	15.342	(-53.32, 31.88)	0.523
Month 3	2	0.65	23.096	(-63.47, 64.78)	0.979
Month 6	2	10.65	23.096	(-53.47, 74.78)	0.669
Month 9	1	-1.92	30.996	(-87.98, 84.14)	0.954
Month 12	1	-1.92	30.996	(-87.98, 84.14)	0.954
Month 18	1	-1.92	30.996	(-87.98, 84.14)	0.954
Month 24	1	-21.92	30.996	(-107.98, 64.14)	0.519
Month 36	1	-11.92	30.996	(-97.98, 74.14)	0.720
Month 48	1	-16.92	30.996	(-102.98, 69.14)	0.614
Month 60	1	-16.92	30.996	(-102.98, 69.14)	0.614

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	4.27	3.557	(-2.77, 11.31)	0.232
Month 3	21	11.18	3.199	(4.86, 17.51)	<.001
Month 6	19	13.18	3.365	(6.52, 19.83)	<.001
Month 9	17	12.94	3.556	(5.90, 19.97)	<.001
Month 12	15	19.24	3.785	(11.75, 26.73)	<.001
Month 18	11	16.33	4.424	(7.58, 25.09)	<.001
Month 24	13	18.66	4.066	(10.62, 26.71)	<.001
Month 36	11	20.12	4.424	(11.37, 28.88)	<.001
Month 48	7	23.15	5.542	(12.19, 34.12)	<.001
Month 60	9	21.80	4.894	(12.12, 31.48)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter: SCHOOL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-8.31	6.373	(-21.18, 4.56)	0.200
Month 3	8	4.75	6.753	(-8.88, 18.39)	0.485
Month 6	9	4.33	6.367	(-8.53, 17.19)	0.500
Month 9	6	14.78	7.812	(-1.00, 30.55)	0.066
Month 12	4	22.64	9.550	(3.36, 41.93)	0.023
Month 18	3	4.26	11.030	(-18.01, 26.54)	0.701
Month 24	4	8.74	9.571	(-10.59, 28.07)	0.366
Month 36	3	13.42	11.034	(-8.86, 35.71)	0.231
Month 48	3	18.42	11.034	(-3.86, 40.71)	0.103
Month 60	3	23.42	11.034	(1.14, 45.71)	0.040

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	8.92	5.511	(-2.39, 20.22)	0.117
Month 3	7	3.32	5.951	(-8.89, 15.54)	0.581
Month 6	7	6.18	5.951	(-6.03, 18.39)	0.308
Month 9	4	5.76	7.810	(-10.27, 21.78)	0.467
Month 12	2	23.26	11.026	(0.63, 45.88)	0.044
Month 18	2	25.76	11.026	(3.13, 48.38)	0.027
Month 24	2	18.26	11.026	(-4.37, 40.88)	0.109
Month 36	2	18.26	11.026	(-4.37, 40.88)	0.109
Month 48	2	18.26	11.026	(-4.37, 40.88)	0.109
Month 60	2	23.26	11.026	(0.63, 45.88)	0.044

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	2.48	2.678	(-2.81, 7.78)	0.355
Month 3	24	8.14	2.679	(2.84, 13.43)	0.003
Month 6	21	7.25	2.862	(1.59, 12.90)	0.012
Month 9	19	12.93	3.008	(6.98, 18.87)	<.001
Month 12	16	15.23	3.279	(8.75, 21.71)	<.001
Month 18	12	18.63	3.786	(11.15, 26.11)	<.001
Month 24	14	17.63	3.505	(10.71, 24.56)	<.001
Month 36	12	16.21	3.793	(8.71, 23.71)	<.001
Month 48	7	16.01	4.956	(6.21, 25.80)	0.002
Month 60	9	17.55	4.380	(8.89, 26.20)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment

Parameter: SOCIAL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-1.48	4.991	(-11.54, 8.57)	0.768
Month 3	9	8.59	4.975	(-1.43, 18.61)	0.091
Month 6	10	8.37	4.693	(-1.09, 17.82)	0.081
Month 9	7	1.99	5.636	(-9.36, 13.34)	0.726
Month 12	5	10.37	6.636	(-3.00, 23.73)	0.125
Month 18	3	10.64	8.599	(-6.68, 27.96)	0.222
Month 24	4	11.76	7.474	(-3.29, 26.81)	0.123
Month 36	3	4.18	8.645	(-13.23, 21.59)	0.631
Month 48	3	12.52	8.645	(-4.89, 29.93)	0.155
Month 60	3	19.18	8.645	(1.77, 36.59)	0.032

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	8.68	3.439	(1.88, 15.48)	0.013
Month 3	24	19.30	3.570	(12.24, 26.35)	<.001
Month 6	22	17.41	3.732	(10.03, 24.79)	<.001
Month 9	17	18.33	4.242	(9.95, 26.72)	<.001
Month 12	12	26.69	5.049	(16.71, 36.67)	<.001
Month 18	10	25.28	5.532	(14.34, 36.21)	<.001
Month 24	12	27.94	5.056	(17.95, 37.94)	<.001
Month 36	11	16.73	5.290	(6.27, 27.19)	0.002
Month 48	8	24.40	6.197	(12.15, 36.65)	<.001
Month 60	9	32.11	5.834	(20.57, 43.64)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	5.89	4.400	(-2.85, 14.63)	0.184
Month 3	16	9.84	4.410	(1.08, 18.60)	0.028
Month 6	16	12.35	4.388	(3.64, 21.07)	0.006
Month 9	13	14.17	4.881	(4.48, 23.87)	0.005
Month 12	11	20.94	5.295	(10.42, 31.45)	<.001
Month 18	8	21.88	6.218	(9.53, 34.23)	<.001
Month 24	8	22.33	6.205	(10.00, 34.65)	<.001
Month 36	6	15.88	7.221	(1.54, 30.22)	0.030
Month 48	4	26.21	8.793	(8.74, 43.67)	0.004
Month 60	5	0.97	7.898	(-14.72, 16.66)	0.903

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	4.05	3.953	(-3.77, 11.86)	0.308
Month 3	24	18.40	4.114	(10.26, 26.53)	<.001
Month 6	22	17.32	4.299	(8.82, 25.82)	<.001
Month 9	17	19.45	4.889	(9.79, 29.12)	<.001
Month 12	12	22.66	5.818	(11.15, 34.16)	<.001
Month 18	10	24.41	6.373	(11.81, 37.01)	<.001
Month 24	12	27.73	5.823	(16.21, 39.24)	<.001
Month 36	11	22.27	6.090	(10.23, 34.31)	<.001
Month 48	8	29.61	7.132	(15.51, 43.71)	<.001
Month 60	9	32.02	6.735	(18.71, 45.34)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	2.49	4.938	(-7.32, 12.30)	0.615
Month 3	16	19.06	4.959	(9.21, 28.91)	<.001
Month 6	16	25.40	4.935	(15.60, 35.20)	<.001
Month 9	13	30.79	5.481	(19.90, 41.67)	<.001
Month 12	11	39.55	5.947	(27.73, 51.36)	<.001
Month 18	8	36.97	6.979	(23.11, 50.83)	<.001
Month 24	8	43.50	7.008	(29.58, 57.42)	<.001
Month 36	6	38.38	8.095	(22.30, 54.46)	<.001
Month 48	4	48.97	9.894	(29.32, 68.62)	<.001
Month 60	5	48.99	8.846	(31.42, 66.56)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	3.19	2.623	(-1.99, 8.38)	0.225
Month 3	24	12.90	2.729	(7.50, 18.29)	<.001
Month 6	22	12.62	2.855	(6.97, 18.26)	<.001
Month 9	17	14.21	3.242	(7.80, 20.62)	<.001
Month 12	12	20.92	3.859	(13.29, 28.55)	<.001
Month 18	10	19.70	4.227	(11.35, 28.06)	<.001
Month 24	12	18.80	3.860	(11.17, 26.43)	<.001
Month 36	11	17.11	4.036	(9.13, 25.09)	<.001
Month 48	8	19.25	4.734	(9.89, 28.61)	<.001
Month 60	9	23.50	4.467	(14.67, 32.33)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	4.09	3.079	(-2.03, 10.21)	0.187
Month 3	16	7.56	3.089	(1.43, 13.70)	0.016
Month 6	16	8.00	3.076	(1.89, 14.10)	0.011
Month 9	13	11.52	3.416	(4.74, 18.31)	0.001
Month 12	11	18.30	3.709	(10.94, 25.67)	<.001
Month 18	8	16.60	4.349	(7.96, 25.24)	<.001
Month 24	8	20.62	4.349	(11.98, 29.25)	<.001
Month 36	6	15.01	5.055	(4.97, 25.05)	0.004
Month 48	4	20.96	6.198	(8.65, 33.27)	0.001
Month 60	5	12.66	5.519	(1.70, 23.62)	0.024

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	-7.09	4.318	(-15.65, 1.47)	0.103
Month 3	17	9.96	4.063	(1.90, 18.01)	0.016
Month 6	16	15.10	4.196	(6.78, 23.41)	<.001
Month 9	13	10.48	4.634	(1.29, 19.66)	0.026
Month 12	11	19.14	5.040	(9.15, 29.13)	<.001
Month 18	9	14.37	5.581	(3.31, 25.44)	0.011
Month 24	11	10.57	5.037	(0.58, 20.55)	0.038
Month 36	10	18.54	5.283	(8.06, 29.01)	<.001
Month 48	8	19.97	5.910	(8.25, 31.68)	0.001
Month 60	9	20.49	5.581	(9.42, 31.55)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	4.69	4.057	(-3.39, 12.76)	0.251
Month 3	14	7.27	4.199	(-1.09, 15.63)	0.087
Month 6	14	4.60	4.197	(-3.76, 12.95)	0.277
Month 9	11	15.73	4.736	(6.30, 25.16)	0.001
Month 12	9	18.79	5.237	(8.36, 29.22)	<.001
Month 18	6	10.49	6.413	(-2.28, 23.26)	0.106
Month 24	7	21.12	5.940	(9.29, 32.94)	<.001
Month 36	5	12.97	7.033	(-1.04, 26.97)	0.069
Month 48	3	10.68	9.140	(-7.52, 28.88)	0.246
Month 60	4	14.28	7.856	(-1.36, 29.92)	0.073

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	0.91	2.671	(-4.37, 6.19)	0.735
Month 3	24	8.58	2.780	(3.09, 14.08)	0.002
Month 6	22	7.55	2.907	(1.81, 13.30)	0.010
Month 9	17	11.82	3.302	(5.29, 18.35)	<.001
Month 12	12	14.41	3.930	(6.64, 22.18)	<.001
Month 18	10	16.71	4.305	(8.20, 25.22)	<.001
Month 24	12	15.08	3.931	(7.31, 22.85)	<.001
Month 36	11	14.96	4.108	(6.84, 23.09)	<.001
Month 48	8	12.65	4.816	(3.13, 22.17)	0.010
Month 60	9	16.84	4.548	(7.85, 25.83)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	5.99	3.585	(-1.13, 13.11)	0.098
Month 3	16	6.58	3.485	(-0.35, 13.50)	0.062
Month 6	16	8.08	3.460	(1.21, 14.96)	0.022
Month 9	13	6.07	3.839	(-1.55, 13.70)	0.117
Month 12	11	15.33	4.171	(7.04, 23.61)	<.001
Month 18	7	19.20	5.246	(8.78, 29.63)	<.001
Month 24	8	18.07	4.897	(8.34, 27.80)	<.001
Month 36	6	11.54	5.688	(0.24, 22.84)	0.045
Month 48	4	20.46	6.973	(6.61, 34.32)	0.004
Month 60	5	21.84	6.201	(9.52, 34.15)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	8.24	3.125	(2.08, 14.41)	0.009
Month 3	32	15.36	3.169	(9.11, 21.61)	<.001
Month 6	31	16.80	3.219	(10.45, 23.15)	<.001
Month 9	24	18.41	3.660	(11.19, 25.63)	<.001
Month 12	19	24.35	4.114	(16.23, 32.46)	<.001
Month 18	14	24.71	4.797	(15.24, 34.17)	<.001
Month 24	17	25.71	4.348	(17.14, 34.29)	<.001
Month 36	14	14.41	4.807	(4.93, 23.89)	0.003
Month 48	9	21.13	5.985	(9.33, 32.94)	<.001
Month 60	11	21.93	5.404	(11.28, 32.59)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.55	1.753	(1.51, 9.59)	0.013
Month 3	3	3.89	2.029	(-0.79, 8.57)	0.092
Month 6	2	0.53	2.435	(-5.08, 6.15)	0.832
Month 9	2	-3.22	2.435	(-8.83, 2.40)	0.223
Month 12	2	3.03	2.435	(-2.58, 8.65)	0.248
Month 18	2	-1.97	2.435	(-7.58, 3.65)	0.443
Month 24	1	-4.53	3.542	(-12.70, 3.64)	0.237
Month 36	1	5.47	3.542	(-2.70, 13.64)	0.161
Month 48	1	30.47	3.542	(22.30, 38.64)	<.001
Month 60	1	-4.53	3.542	(-12.70, 3.64)	0.237

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	2.33	9.018	(-16.48, 21.14)	0.799
Month 3	5	22.33	9.018	(3.52, 41.14)	0.022
Month 6	5	10.60	9.213	(-8.62, 29.81)	0.264
Month 9	4	15.37	10.087	(-5.67, 36.41)	0.143
Month 12	2	37.69	14.228	(8.01, 67.36)	0.015
Month 18	2	40.19	14.228	(10.51, 69.86)	0.010
Month 24	2	45.19	14.228	(15.51, 74.86)	0.005
Month 36	2	42.69	14.228	(13.01, 72.36)	0.007
Month 48	2	42.69	14.228	(13.01, 72.36)	0.007
Month 60	2	32.69	14.228	(3.01, 62.36)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	7.08	3.351	(0.47, 13.69)	0.036
Month 3	32	20.04	3.403	(13.33, 26.75)	<.001
Month 6	31	23.50	3.456	(16.68, 30.31)	<.001
Month 9	24	26.86	3.929	(19.11, 34.61)	<.001
Month 12	19	33.41	4.417	(24.70, 42.12)	<.001
Month 18	14	30.75	5.147	(20.60, 40.90)	<.001
Month 24	17	37.01	4.671	(27.79, 46.22)	<.001
Month 36	14	29.69	5.150	(19.54, 39.85)	<.001
Month 48	9	40.47	6.420	(27.81, 53.13)	<.001
Month 60	11	41.48	5.813	(30.01, 52.94)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	1.19	4.979	(-10.29, 12.67)	0.817
Month 3	3	-0.07	5.819	(-13.49, 13.35)	0.991
Month 6	2	-2.59	6.976	(-18.67, 13.50)	0.720
Month 9	2	-8.84	6.976	(-24.92, 7.25)	0.241
Month 12	2	0.51	6.976	(-15.57, 16.60)	0.943
Month 18	2	14.61	6.976	(-1.47, 30.70)	0.069
Month 24	1	8.66	10.122	(-14.68, 32.00)	0.417
Month 36	1	21.16	10.122	(-2.18, 44.50)	0.070
Month 48	1	27.36	10.122	(4.02, 50.70)	0.027
Month 60	1	33.66	10.122	(10.32, 57.00)	0.010

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-20.02	10.781	(-42.51, 2.47)	0.078
Month 3	5	16.86	10.781	(-5.63, 39.35)	0.134
Month 6	5	7.30	10.854	(-15.35, 29.94)	0.509
Month 9	4	24.35	12.099	(-0.89, 49.59)	0.058
Month 12	2	25.24	17.028	(-10.28, 60.76)	0.154
Month 18	2	33.49	17.028	(-2.03, 69.01)	0.063
Month 24	2	33.29	17.028	(-2.23, 68.81)	0.065
Month 36	2	33.04	17.028	(-2.48, 68.56)	0.067
Month 48	2	31.49	17.028	(-4.03, 67.01)	0.079
Month 60	2	33.04	17.028	(-2.48, 68.56)	0.067

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	4.81	2.254	(0.36, 9.25)	0.034
Month 3	32	11.11	2.287	(6.60, 15.62)	<.001
Month 6	31	12.46	2.324	(7.87, 17.04)	<.001
Month 9	24	14.68	2.641	(9.47, 19.89)	<.001
Month 12	19	20.98	2.968	(15.13, 26.83)	<.001
Month 18	14	19.61	3.458	(12.79, 26.43)	<.001
Month 24	17	20.40	3.138	(14.21, 26.59)	<.001
Month 36	14	16.05	3.465	(9.21, 22.88)	<.001
Month 48	9	19.36	4.313	(10.85, 27.87)	<.001
Month 60	11	21.04	3.905	(13.34, 28.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	0.47	3.206	(-6.92, 7.86)	0.887
Month 3	3	-0.74	3.765	(-9.42, 7.94)	0.848
Month 6	2	-0.37	4.538	(-10.84, 10.09)	0.937
Month 9	2	0.58	4.538	(-9.89, 11.04)	0.902
Month 12	2	1.28	4.538	(-9.19, 11.74)	0.785
Month 18	2	-2.07	4.538	(-12.54, 8.39)	0.660
Month 24	1	-10.09	6.551	(-25.20, 5.01)	0.162
Month 36	1	1.51	6.551	(-13.60, 16.61)	0.824
Month 48	1	14.91	6.551	(-0.20, 30.01)	0.052
Month 60	1	3.21	6.551	(-11.90, 18.31)	0.638

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-4.14	6.779	(-18.28, 10.00)	0.548
Month 3	5	13.84	6.779	(-0.30, 27.98)	0.055
Month 6	5	5.15	6.909	(-9.27, 19.56)	0.465
Month 9	4	8.84	7.577	(-6.97, 24.64)	0.257
Month 12	2	22.86	10.720	(0.50, 45.22)	0.046
Month 18	2	26.16	10.720	(3.80, 48.52)	0.024
Month 24	2	30.36	10.720	(8.00, 52.72)	0.010
Month 36	2	30.36	10.720	(8.00, 52.72)	0.010
Month 48	2	27.01	10.720	(4.65, 49.37)	0.020
Month 60	2	22.86	10.720	(0.50, 45.22)	0.046

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	2.05	3.477	(-4.82, 8.93)	0.556
Month 3	23	8.56	3.326	(1.98, 15.13)	0.011
Month 6	23	12.77	3.325	(6.20, 19.34)	<.001
Month 9	18	14.24	3.754	(6.82, 21.66)	<.001
Month 12	16	21.20	3.982	(13.33, 29.07)	<.001
Month 18	11	13.10	4.805	(3.60, 22.59)	0.007
Month 24	15	15.68	4.115	(7.55, 23.81)	<.001
Month 36	12	16.30	4.598	(7.21, 25.39)	<.001
Month 48	8	18.71	5.631	(7.58, 29.84)	0.001
Month 60	10	21.46	5.045	(11.49, 31.44)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-12.19	9.970	(-35.18, 10.80)	0.256
Month 3	3	-6.49	11.692	(-33.45, 20.48)	0.594
Month 6	2	0.11	14.157	(-32.53, 32.76)	0.994
Month 9	2	7.61	14.157	(-25.03, 40.26)	0.605
Month 12	2	2.61	14.157	(-30.03, 35.26)	0.858
Month 18	2	2.61	14.157	(-30.03, 35.26)	0.858
Month 24	1	-15.35	20.323	(-62.21, 31.52)	0.472
Month 36	1	-0.35	20.323	(-47.21, 46.52)	0.987
Month 48	1	-0.35	20.323	(-47.21, 46.52)	0.987
Month 60	1	-0.35	20.323	(-47.21, 46.52)	0.987

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-8.15	8.062	(-24.96, 8.67)	0.324
Month 3	5	13.85	8.062	(-2.96, 30.67)	0.101
Month 6	5	1.31	8.113	(-15.62, 18.23)	0.874
Month 9	4	9.41	9.046	(-9.46, 28.28)	0.311
Month 12	2	13.11	12.770	(-13.53, 39.74)	0.317
Month 18	2	18.11	12.770	(-8.53, 44.74)	0.172
Month 24	2	25.61	12.770	(-1.03, 52.24)	0.059
Month 36	2	33.11	12.770	(6.47, 59.74)	0.017
Month 48	2	30.61	12.770	(3.97, 57.24)	0.026
Month 60	2	23.11	12.770	(-3.53, 49.74)	0.085

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter: SOCIAL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	32	3.45	2.516	(-1.51, 8.41)	0.172
Month 3	32	8.44	2.513	(3.48, 13.39)	<.001
Month 6	31	9.65	2.554	(4.61, 14.69)	<.001
Month 9	24	11.21	2.902	(5.48, 16.93)	<.001
Month 12	19	16.20	3.261	(9.77, 22.63)	<.001
Month 18	14	18.68	3.801	(11.19, 26.18)	<.001
Month 24	17	17.97	3.449	(11.17, 24.77)	<.001
Month 36	14	15.17	3.807	(7.67, 22.68)	<.001
Month 48	9	17.28	4.739	(7.94, 26.63)	<.001
Month 60	11	20.45	4.289	(11.99, 28.91)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment

Parameter: SOCIAL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	6.32	2.967	(-0.70, 13.33)	0.071
Month 3	3	-0.11	3.446	(-8.25, 8.04)	0.976
Month 6	2	-2.57	4.182	(-12.46, 7.31)	0.558
Month 9	2	-5.07	4.182	(-14.96, 4.81)	0.264
Month 12	2	-2.57	4.182	(-12.46, 7.31)	0.558
Month 18	1	-0.36	6.197	(-15.01, 14.30)	0.955
Month 24	1	-9.79	5.996	(-23.97, 4.39)	0.147
Month 36	1	0.21	5.996	(-13.97, 14.39)	0.973
Month 48	1	15.21	5.996	(1.03, 29.39)	0.039
Month 60	1	15.21	5.996	(1.03, 29.39)	0.039

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-5.11	5.656	(-16.91, 6.69)	0.377
Month 3	5	6.89	5.656	(-4.91, 18.69)	0.237
Month 6	5	0.04	5.748	(-11.95, 12.03)	0.995
Month 9	4	4.34	6.388	(-8.98, 17.67)	0.505
Month 12	2	16.96	8.910	(-1.62, 35.55)	0.071
Month 18	2	19.46	8.910	(0.88, 38.05)	0.041
Month 24	2	19.46	8.910	(0.88, 38.05)	0.041
Month 36	2	14.46	8.910	(-4.12, 33.05)	0.120
Month 48	2	6.96	8.910	(-11.62, 25.55)	0.444
Month 60	2	11.96	8.910	(-6.62, 30.55)	0.194

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	-0.28	5.095	(-10.50, 9.94)	0.957
Month 3	10	19.61	5.585	(8.41, 30.81)	<.001
Month 6	11	9.51	5.328	(-1.18, 20.19)	0.080
Month 9	7	15.93	6.670	(2.55, 29.31)	0.020
Month 12	4	25.54	8.824	(7.84, 43.24)	0.006
Month 18	4	21.79	8.824	(4.09, 39.49)	0.017
Month 24	5	21.02	7.902	(5.17, 36.87)	0.010
Month 36	4	21.79	8.824	(4.09, 39.49)	0.017
Month 48	3	27.47	10.189	(7.04, 47.91)	0.009
Month 60	4	6.79	8.824	(-10.91, 24.49)	0.445

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	10.43	3.305	(3.90, 16.95)	0.002
Month 3	30	14.10	3.295	(7.60, 20.60)	<.001
Month 6	27	17.26	3.473	(10.41, 24.11)	<.001
Month 9	23	16.57	3.766	(9.14, 24.00)	<.001
Month 12	19	23.95	4.139	(15.79, 32.12)	<.001
Month 18	14	24.57	4.824	(15.05, 34.09)	<.001
Month 24	15	27.57	4.667	(18.36, 36.78)	<.001
Month 36	13	15.43	5.032	(5.50, 25.36)	0.002
Month 48	9	24.39	6.017	(12.52, 36.27)	<.001
Month 60	10	26.68	5.705	(15.43, 37.94)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	-13.03	5.804	(-24.68, -1.39)	0.029
Month 3	10	15.40	6.361	(2.64, 28.16)	0.019
Month 6	11	8.99	6.073	(-3.19, 21.17)	0.145
Month 9	7	23.61	7.601	(8.36, 38.85)	0.003
Month 12	4	27.49	10.051	(7.34, 47.65)	0.008
Month 18	4	30.84	10.051	(10.69, 51.00)	0.003
Month 24	5	26.68	8.994	(8.64, 44.72)	0.005
Month 36	4	26.69	10.051	(6.54, 46.85)	0.010
Month 48	3	26.75	11.661	(3.36, 50.14)	0.026
Month 60	4	29.82	10.051	(9.66, 49.98)	0.005

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	9.91	3.565	(2.87, 16.94)	0.006
Month 3	30	19.46	3.566	(12.43, 26.50)	<.001
Month 6	27	24.29	3.756	(16.88, 31.70)	<.001
Month 9	23	23.63	4.074	(15.59, 31.66)	<.001
Month 12	19	31.20	4.478	(22.36, 40.03)	<.001
Month 18	14	29.89	5.218	(19.59, 40.18)	<.001
Month 24	15	37.26	5.049	(27.30, 47.22)	<.001
Month 36	13	30.30	5.429	(19.59, 41.02)	<.001
Month 48	9	41.98	6.505	(29.14, 54.81)	<.001
Month 60	10	42.15	6.176	(29.97, 54.34)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	-3.82	3.940	(-11.72, 4.09)	0.337
Month 3	10	12.45	4.317	(3.79, 21.11)	0.006
Month 6	11	2.61	4.135	(-5.69, 10.90)	0.531
Month 9	7	9.18	5.160	(-1.17, 19.53)	0.081
Month 12	4	15.97	6.825	(2.28, 29.66)	0.023
Month 18	4	14.29	6.825	(0.61, 27.98)	0.041
Month 24	5	15.21	6.109	(2.96, 27.46)	0.016
Month 36	4	16.79	6.825	(3.11, 30.48)	0.017
Month 48	3	14.65	7.885	(-1.16, 30.47)	0.069
Month 60	4	7.22	6.825	(-6.47, 20.91)	0.295

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	6.17	2.326	(1.59, 10.76)	0.009
Month 3	30	10.14	2.323	(5.56, 14.73)	<.001
Month 6	27	13.48	2.450	(8.64, 18.31)	<.001
Month 9	23	14.09	2.655	(8.85, 19.33)	<.001
Month 12	19	20.81	2.919	(15.05, 26.57)	<.001
Month 18	14	19.65	3.401	(12.94, 26.36)	<.001
Month 24	15	21.22	3.288	(14.73, 27.70)	<.001
Month 36	13	16.90	3.542	(9.91, 23.89)	<.001
Month 48	9	22.07	4.242	(13.70, 30.44)	<.001
Month 60	10	24.64	4.025	(16.69, 32.58)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-10.85	5.509	(-21.92, 0.23)	0.055
Month 3	9	12.26	5.810	(0.58, 23.94)	0.040
Month 6	10	-2.11	5.541	(-13.24, 9.03)	0.705
Month 9	7	3.60	6.585	(-9.64, 16.83)	0.588
Month 12	4	7.76	8.726	(-9.77, 25.30)	0.378
Month 18	4	6.51	8.726	(-11.02, 24.05)	0.459
Month 24	5	10.38	7.795	(-5.28, 26.05)	0.189
Month 36	4	14.01	8.726	(-3.52, 31.55)	0.115
Month 48	3	12.64	10.058	(-7.57, 32.86)	0.215
Month 60	4	2.76	8.726	(-14.77, 20.30)	0.753

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	2.63	3.545	(-4.38, 9.64)	0.460
Month 3	22	6.74	3.380	(0.05, 13.42)	0.048
Month 6	20	15.00	3.549	(7.98, 22.02)	<.001
Month 9	17	16.26	3.843	(8.66, 23.86)	<.001
Month 12	16	22.88	3.962	(15.04, 30.71)	<.001
Month 18	11	15.61	4.785	(6.15, 25.08)	0.001
Month 24	13	16.43	4.395	(7.73, 25.12)	<.001
Month 36	11	19.10	4.781	(9.65, 28.56)	<.001
Month 48	8	21.15	5.602	(10.07, 32.23)	<.001
Month 60	9	26.87	5.285	(16.42, 37.32)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	-4.89	3.362	(-11.63, 1.86)	0.152
Month 3	10	6.99	3.688	(-0.41, 14.38)	0.064
Month 6	11	1.61	3.528	(-5.47, 8.68)	0.651
Month 9	7	7.79	4.404	(-1.05, 16.62)	0.083
Month 12	4	14.86	5.821	(3.18, 26.54)	0.014
Month 18	4	14.86	5.821	(3.18, 26.54)	0.014
Month 24	5	14.31	5.207	(3.87, 24.75)	0.008
Month 36	4	14.86	5.821	(3.18, 26.54)	0.014
Month 48	3	2.86	6.752	(-10.68, 16.41)	0.673
Month 60	4	12.36	5.821	(0.68, 24.04)	0.038

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	5.74	2.647	(0.52, 10.97)	0.031
Month 3	30	8.01	2.600	(2.88, 13.15)	0.002
Month 6	27	9.89	2.741	(4.49, 15.30)	<.001
Month 9	23	9.76	2.972	(3.89, 15.62)	0.001
Month 12	19	15.07	3.266	(8.63, 21.52)	<.001
Month 18	13	18.80	3.950	(11.00, 26.59)	<.001
Month 24	15	17.04	3.679	(9.78, 24.30)	<.001
Month 36	13	13.82	3.959	(6.00, 21.63)	<.001
Month 48	9	19.90	4.748	(10.53, 29.27)	<.001
Month 60	10	21.14	4.504	(12.25, 30.03)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	5.836	(-7.54, 17.67)	0.401
Month 3	4	18.82	5.836	(6.21, 31.42)	0.007
Month 6	3	13.51	6.590	(-0.73, 27.74)	0.061
Month 9	3	30.17	6.590	(15.94, 44.41)	<.001
Month 12	2	37.47	8.230	(19.69, 55.25)	<.001
Month 18	1	13.09	11.430	(-11.60, 37.79)	0.273
Month 24	3	15.17	6.590	(0.94, 29.41)	0.038
Month 36	2	-7.53	8.230	(-25.31, 10.25)	0.377
Month 48	1	-3.15	11.709	(-28.45, 22.14)	0.792
Month 60	1	-36.91	11.430	(-61.60, -12.21)	0.007

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	38	7.80	2.877	(2.13, 13.47)	0.007
Month 3	36	14.99	2.951	(9.17, 20.80)	<.001
Month 6	35	15.43	2.994	(9.53, 21.33)	<.001
Month 9	27	14.87	3.409	(8.15, 21.59)	<.001
Month 12	21	22.64	3.863	(15.03, 30.26)	<.001
Month 18	17	24.49	4.296	(16.03, 32.96)	<.001
Month 24	17	27.44	4.298	(18.97, 35.91)	<.001
Month 36	15	19.97	4.585	(10.93, 29.00)	<.001
Month 48	11	27.95	5.346	(17.41, 38.49)	<.001
Month 60	13	25.74	4.910	(16.07, 35.42)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	6.99	6.062	(-6.11, 20.08)	0.270
Month 3	4	24.16	6.062	(11.07, 37.26)	0.002
Month 6	3	39.93	6.742	(25.36, 54.50)	<.001
Month 9	3	48.23	6.742	(33.66, 62.80)	<.001
Month 12	2	59.34	8.317	(41.37, 77.31)	<.001
Month 18	1	53.78	11.788	(28.32, 79.25)	<.001
Month 24	3	46.13	6.742	(31.56, 60.70)	<.001
Month 36	2	57.79	8.317	(39.82, 75.76)	<.001
Month 48	1	46.20	11.656	(21.02, 71.38)	0.002
Month 60	1	53.78	11.788	(28.32, 79.25)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	38	2.83	3.307	(-3.69, 9.35)	0.393
Month 3	36	17.40	3.398	(10.70, 24.09)	<.001
Month 6	35	18.72	3.446	(11.93, 25.51)	<.001
Month 9	27	21.35	3.925	(13.61, 29.09)	<.001
Month 12	21	27.36	4.449	(18.60, 36.13)	<.001
Month 18	17	28.31	4.945	(18.56, 38.05)	<.001
Month 24	17	32.97	4.950	(23.22, 42.73)	<.001
Month 36	15	25.52	5.271	(15.13, 35.91)	<.001
Month 48	11	36.57	6.147	(24.45, 48.68)	<.001
Month 60	13	38.15	5.658	(27.00, 49.30)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	3.38	5.094	(-7.62, 14.39)	0.518
Month 3	4	13.16	5.094	(2.15, 24.16)	0.023
Month 6	3	10.90	5.790	(-1.61, 23.41)	0.082
Month 9	3	24.23	5.790	(11.72, 36.74)	0.001
Month 12	2	30.08	7.181	(14.57, 45.60)	0.001
Month 18	1	8.03	10.046	(-13.68, 29.73)	0.439
Month 24	3	8.67	5.790	(-3.84, 21.17)	0.158
Month 36	2	9.23	7.181	(-6.28, 24.75)	0.221
Month 48	1	10.54	10.441	(-12.02, 33.10)	0.331
Month 60	1	-8.67	10.046	(-30.38, 13.03)	0.404

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	38	3.49	2.110	(-0.67, 7.65)	0.100
Month 3	36	10.33	2.166	(6.06, 14.60)	<.001
Month 6	35	10.60	2.199	(6.27, 14.93)	<.001
Month 9	27	11.72	2.502	(6.78, 16.65)	<.001
Month 12	21	18.67	2.837	(13.08, 24.26)	<.001
Month 18	17	18.88	3.153	(12.67, 25.10)	<.001
Month 24	17	21.43	3.154	(15.21, 27.64)	<.001
Month 36	15	17.64	3.362	(11.01, 24.26)	<.001
Month 48	11	21.24	3.922	(13.51, 28.97)	<.001
Month 60	13	22.02	3.606	(14.91, 29.13)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	10.98	10.858	(-12.68, 34.64)	0.332
Month 3	4	8.73	9.137	(-11.18, 28.64)	0.358
Month 6	3	1.17	10.565	(-21.85, 24.19)	0.914
Month 9	3	16.17	10.565	(-6.85, 39.19)	0.152
Month 12	2	19.20	12.956	(-9.03, 47.43)	0.164
Month 18	1	-3.58	18.666	(-44.25, 37.09)	0.851
Month 24	3	-0.50	10.565	(-23.52, 22.52)	0.963
Month 36	2	1.70	12.956	(-26.53, 29.93)	0.898
Month 48	1	11.98	19.264	(-29.99, 53.95)	0.546
Month 60	1	-13.58	18.666	(-54.25, 27.09)	0.481

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	27	-2.82	3.156	(-9.04, 3.41)	0.374
Month 3	27	8.24	3.159	(2.00, 14.47)	0.010
Month 6	27	10.73	3.160	(4.49, 16.96)	<.001
Month 9	21	12.12	3.578	(5.06, 19.19)	<.001
Month 12	18	19.17	3.866	(11.54, 26.80)	<.001
Month 18	14	14.32	4.386	(5.66, 22.97)	0.001
Month 24	15	17.52	4.236	(9.16, 25.89)	<.001
Month 36	13	19.51	4.548	(10.53, 28.48)	<.001
Month 48	10	19.49	5.188	(9.25, 29.73)	<.001
Month 60	12	22.25	4.735	(12.91, 31.60)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-3.44	6.096	(-16.61, 9.73)	0.582
Month 3	4	11.56	6.096	(-1.61, 24.73)	0.080
Month 6	3	16.68	6.837	(1.91, 31.45)	0.030
Month 9	3	25.01	6.837	(10.24, 39.78)	0.003
Month 12	2	32.13	8.547	(13.67, 50.60)	0.002
Month 18	1	19.63	11.965	(-6.21, 45.48)	0.125
Month 24	3	10.01	6.837	(-4.76, 24.78)	0.167
Month 36	2	32.13	8.547	(13.67, 50.60)	0.002
Month 48	1	14.63	11.965	(-11.21, 40.48)	0.243
Month 60	1	29.63	11.965	(3.79, 55.48)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	3.25	2.228	(-1.14, 7.64)	0.146
Month 3	36	7.03	2.256	(2.58, 11.48)	0.002
Month 6	35	6.89	2.289	(2.38, 11.40)	0.003
Month 9	27	7.49	2.606	(2.36, 12.63)	0.004
Month 12	21	13.27	2.954	(7.45, 19.09)	<.001
Month 18	16	17.77	3.385	(11.09, 24.44)	<.001
Month 24	17	17.49	3.285	(11.01, 23.96)	<.001
Month 36	15	11.91	3.500	(5.01, 18.81)	<.001
Month 48	11	15.85	4.082	(7.81, 23.90)	<.001
Month 60	13	18.17	3.757	(10.77, 25.58)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	7.62	2.806	(2.10, 13.15)	0.007
Month 3	39	14.80	2.871	(9.14, 20.46)	<.001
Month 6	37	14.59	2.947	(8.78, 20.40)	<.001
Month 9	29	15.58	3.329	(9.02, 22.14)	<.001
Month 12	22	23.34	3.822	(15.81, 30.87)	<.001
Month 18	17	22.84	4.349	(14.28, 31.41)	<.001
Month 24	19	25.01	4.114	(16.90, 33.11)	<.001
Month 36	16	15.61	4.498	(6.75, 24.48)	<.001
Month 48	11	24.29	5.406	(13.64, 34.94)	<.001
Month 60	13	20.54	4.970	(10.75, 30.33)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	3.29	3.106	(-2.83, 9.40)	0.291
Month 3	39	17.61	3.185	(11.34, 23.89)	<.001
Month 6	37	19.26	3.268	(12.82, 25.70)	<.001
Month 9	29	22.71	3.692	(15.43, 29.98)	<.001
Month 12	22	28.93	4.239	(20.58, 37.28)	<.001
Month 18	17	28.09	4.822	(18.59, 37.59)	<.001
Month 24	19	33.03	4.567	(24.03, 42.03)	<.001
Month 36	16	26.90	4.978	(17.09, 36.71)	<.001
Month 48	11	35.33	5.994	(23.52, 47.14)	<.001
Month 60	13	37.48	5.516	(26.61, 48.35)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	3.84	2.036	(-0.17, 7.85)	0.061
Month 3	39	10.28	2.085	(6.17, 14.38)	<.001
Month 6	37	10.25	2.142	(6.04, 14.47)	<.001
Month 9	29	12.73	2.418	(7.97, 17.50)	<.001
Month 12	22	19.47	2.776	(14.00, 24.94)	<.001
Month 18	17	18.05	3.158	(11.82, 24.27)	<.001
Month 24	19	19.13	2.988	(13.24, 25.02)	<.001
Month 36	16	15.87	3.263	(9.44, 22.30)	<.001
Month 48	11	19.87	3.926	(12.14, 27.61)	<.001
Month 60	13	19.62	3.612	(12.50, 26.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	-0.57	3.115	(-6.72, 5.57)	0.855
Month 3	30	7.68	3.063	(1.63, 13.72)	0.013
Month 6	29	9.62	3.118	(3.47, 15.77)	0.002
Month 9	23	13.23	3.496	(6.34, 20.13)	<.001
Month 12	19	19.63	3.847	(12.04, 27.22)	<.001
Month 18	14	13.55	4.487	(4.70, 22.40)	0.003
Month 24	17	14.28	4.068	(6.25, 22.30)	<.001
Month 36	14	16.52	4.483	(7.68, 25.37)	<.001
Month 48	10	18.45	5.303	(7.99, 28.91)	<.001
Month 60	12	19.27	4.844	(9.71, 28.83)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	40	2.97	2.170	(-1.30, 7.25)	0.172
Month 3	39	7.60	2.195	(3.27, 11.92)	<.001
Month 6	37	7.41	2.253	(2.97, 11.85)	0.001
Month 9	29	8.90	2.545	(3.89, 13.92)	<.001
Month 12	22	14.41	2.921	(8.65, 20.16)	<.001
Month 18	16	17.54	3.427	(10.79, 24.29)	<.001
Month 24	19	16.05	3.145	(9.85, 22.25)	<.001
Month 36	16	13.44	3.433	(6.67, 20.20)	<.001
Month 48	11	15.85	4.132	(7.71, 23.99)	<.001
Month 60	13	18.99	3.801	(11.50, 26.48)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	7.57	2.767	(2.12, 13.02)	0.007
Month 3	40	15.44	2.829	(9.86, 21.01)	<.001
Month 6	38	15.27	2.902	(9.55, 20.98)	<.001
Month 9	30	16.39	3.266	(9.96, 22.83)	<.001
Month 12	23	23.85	3.729	(16.50, 31.19)	<.001
Month 18	18	23.79	4.217	(15.49, 32.10)	<.001
Month 24	20	25.75	4.001	(17.87, 33.63)	<.001
Month 36	17	16.75	4.353	(8.17, 25.32)	<.001
Month 48	12	25.17	5.164	(14.99, 35.34)	<.001
Month 60	14	21.20	4.779	(11.79, 30.61)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.63	3.091	(-2.46, 9.72)	0.242
Month 3	40	18.46	3.167	(12.23, 24.70)	<.001
Month 6	38	20.39	3.248	(13.99, 26.79)	<.001
Month 9	30	23.89	3.656	(16.69, 31.09)	<.001
Month 12	23	29.93	4.175	(21.71, 38.16)	<.001
Month 18	18	29.70	4.720	(20.40, 39.00)	<.001
Month 24	20	34.38	4.483	(25.54, 43.21)	<.001
Month 36	17	28.80	4.864	(19.22, 38.38)	<.001
Month 48	12	37.35	5.780	(25.96, 48.73)	<.001
Month 60	14	39.12	5.353	(28.57, 49.66)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.54	1.999	(-0.40, 7.47)	0.078
Month 3	40	10.69	2.046	(6.66, 14.72)	<.001
Month 6	38	10.62	2.101	(6.48, 14.76)	<.001
Month 9	30	12.95	2.363	(8.30, 17.61)	<.001
Month 12	23	19.58	2.698	(14.27, 24.90)	<.001
Month 18	18	18.29	3.050	(12.28, 24.30)	<.001
Month 24	20	19.54	2.894	(13.84, 25.24)	<.001
Month 36	17	16.58	3.146	(10.39, 22.78)	<.001
Month 48	12	20.13	3.736	(12.77, 27.49)	<.001
Month 60	14	19.83	3.460	(13.02, 26.65)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	-1.46	3.029	(-7.43, 4.52)	0.631
Month 3	31	8.34	2.980	(2.46, 14.21)	0.006
Month 6	30	9.75	3.032	(3.77, 15.73)	0.002
Month 9	24	12.65	3.385	(5.98, 19.33)	<.001
Month 12	20	19.15	3.708	(11.84, 26.47)	<.001
Month 18	15	13.04	4.287	(4.59, 21.50)	0.003
Month 24	18	14.62	3.909	(6.91, 22.33)	<.001
Month 36	15	17.17	4.282	(8.73, 25.62)	<.001
Month 48	11	18.77	4.999	(8.91, 28.63)	<.001
Month 60	13	19.43	4.602	(10.36, 28.51)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	2.83	2.118	(-1.35, 7.00)	0.183
Month 3	40	7.72	2.142	(3.50, 11.94)	<.001
Month 6	38	7.70	2.198	(3.37, 12.03)	<.001
Month 9	30	9.24	2.474	(4.37, 14.11)	<.001
Month 12	23	14.67	2.824	(9.10, 20.23)	<.001
Month 18	17	17.77	3.286	(11.29, 24.24)	<.001
Month 24	20	16.30	3.030	(10.33, 22.27)	<.001
Month 36	17	13.92	3.292	(7.44, 20.41)	<.001
Month 48	12	15.53	3.910	(7.82, 23.23)	<.001
Month 60	14	18.81	3.622	(11.67, 25.94)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	7.57	2.767	(2.12, 13.02)	0.007
Month 3	40	15.44	2.829	(9.86, 21.01)	<.001
Month 6	38	15.27	2.902	(9.55, 20.98)	<.001
Month 9	30	16.39	3.266	(9.96, 22.83)	<.001
Month 12	23	23.85	3.729	(16.50, 31.19)	<.001
Month 18	18	23.79	4.217	(15.49, 32.10)	<.001
Month 24	20	25.75	4.001	(17.87, 33.63)	<.001
Month 36	17	16.75	4.353	(8.17, 25.32)	<.001
Month 48	12	25.17	5.164	(14.99, 35.34)	<.001
Month 60	14	21.20	4.779	(11.79, 30.61)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.63	3.091	(-2.46, 9.72)	0.242
Month 3	40	18.46	3.167	(12.23, 24.70)	<.001
Month 6	38	20.39	3.248	(13.99, 26.79)	<.001
Month 9	30	23.89	3.656	(16.69, 31.09)	<.001
Month 12	23	29.93	4.175	(21.71, 38.16)	<.001
Month 18	18	29.70	4.720	(20.40, 39.00)	<.001
Month 24	20	34.38	4.483	(25.54, 43.21)	<.001
Month 36	17	28.80	4.864	(19.22, 38.38)	<.001
Month 48	12	37.35	5.780	(25.96, 48.73)	<.001
Month 60	14	39.12	5.353	(28.57, 49.66)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.54	1.999	(-0.40, 7.47)	0.078
Month 3	40	10.69	2.046	(6.66, 14.72)	<.001
Month 6	38	10.62	2.101	(6.48, 14.76)	<.001
Month 9	30	12.95	2.363	(8.30, 17.61)	<.001
Month 12	23	19.58	2.698	(14.27, 24.90)	<.001
Month 18	18	18.29	3.050	(12.28, 24.30)	<.001
Month 24	20	19.54	2.894	(13.84, 25.24)	<.001
Month 36	17	16.58	3.146	(10.39, 22.78)	<.001
Month 48	12	20.13	3.736	(12.77, 27.49)	<.001
Month 60	14	19.83	3.460	(13.02, 26.65)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Table 201h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	-1.46	3.029	(-7.43, 4.52)	0.631
Month 3	31	8.34	2.980	(2.46, 14.21)	0.006
Month 6	30	9.75	3.032	(3.77, 15.73)	0.002
Month 9	24	12.65	3.385	(5.98, 19.33)	<.001
Month 12	20	19.15	3.708	(11.84, 26.47)	<.001
Month 18	15	13.04	4.287	(4.59, 21.50)	0.003
Month 24	18	14.62	3.909	(6.91, 22.33)	<.001
Month 36	15	17.17	4.282	(8.73, 25.62)	<.001
Month 48	11	18.77	4.999	(8.91, 28.63)	<.001
Month 60	13	19.43	4.602	(10.36, 28.51)	<.001

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Table 201h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	2.83	2.118	(-1.35, 7.00)	0.183
Month 3	40	7.72	2.142	(3.50, 11.94)	<.001
Month 6	38	7.70	2.198	(3.37, 12.03)	<.001
Month 9	30	9.24	2.474	(4.37, 14.11)	<.001
Month 12	23	14.67	2.824	(9.10, 20.23)	<.001
Month 18	17	17.77	3.286	(11.29, 24.24)	<.001
Month 24	20	16.30	3.030	(10.33, 22.27)	<.001
Month 36	17	13.92	3.292	(7.44, 20.41)	<.001
Month 48	12	15.53	3.910	(7.82, 23.23)	<.001
Month 60	14	18.81	3.622	(11.67, 25.94)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	7.57	2.767	(2.12, 13.02)	0.007
Month 3	40	15.44	2.829	(9.86, 21.01)	<.001
Month 6	38	15.27	2.902	(9.55, 20.98)	<.001
Month 9	30	16.39	3.266	(9.96, 22.83)	<.001
Month 12	23	23.85	3.729	(16.50, 31.19)	<.001
Month 18	18	23.79	4.217	(15.49, 32.10)	<.001
Month 24	20	25.75	4.001	(17.87, 33.63)	<.001
Month 36	17	16.75	4.353	(8.17, 25.32)	<.001
Month 48	12	25.17	5.164	(14.99, 35.34)	<.001
Month 60	14	21.20	4.779	(11.79, 30.61)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.63	3.091	(-2.46, 9.72)	0.242
Month 3	40	18.46	3.167	(12.23, 24.70)	<.001
Month 6	38	20.39	3.248	(13.99, 26.79)	<.001
Month 9	30	23.89	3.656	(16.69, 31.09)	<.001
Month 12	23	29.93	4.175	(21.71, 38.16)	<.001
Month 18	18	29.70	4.720	(20.40, 39.00)	<.001
Month 24	20	34.38	4.483	(25.54, 43.21)	<.001
Month 36	17	28.80	4.864	(19.22, 38.38)	<.001
Month 48	12	37.35	5.780	(25.96, 48.73)	<.001
Month 60	14	39.12	5.353	(28.57, 49.66)	<.001

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Table 201i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	42	3.54	1.999	(-0.40, 7.47)	0.078
Month 3	40	10.69	2.046	(6.66, 14.72)	<.001
Month 6	38	10.62	2.101	(6.48, 14.76)	<.001
Month 9	30	12.95	2.363	(8.30, 17.61)	<.001
Month 12	23	19.58	2.698	(14.27, 24.90)	<.001
Month 18	18	18.29	3.050	(12.28, 24.30)	<.001
Month 24	20	19.54	2.894	(13.84, 25.24)	<.001
Month 36	17	16.58	3.146	(10.39, 22.78)	<.001
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Table 201i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	-1.46	3.029	(-7.43, 4.52)	0.631
Month 3	31	8.34	2.980	(2.46, 14.21)	0.006
Month 6	30	9.75	3.032	(3.77, 15.73)	0.002
Month 9	24	12.65	3.385	(5.98, 19.33)	<.001
Month 12	20	19.15	3.708	(11.84, 26.47)	<.001
Month 18	15	13.04	4.287	(4.59, 21.50)	0.003
Month 24	18	14.62	3.909	(6.91, 22.33)	<.001
Month 36	15	17.17	4.282	(8.73, 25.62)	<.001
Month 48	11	18.77	4.999	(8.91, 28.63)	<.001
Month 60	13	19.43	4.602	(10.36, 28.51)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	2.83	2.118	(-1.35, 7.00)	0.183
Month 3	40	7.72	2.142	(3.50, 11.94)	<.001
Month 6	38	7.70	2.198	(3.37, 12.03)	<.001
Month 9	30	9.24	2.474	(4.37, 14.11)	<.001
Month 12	23	14.67	2.824	(9.10, 20.23)	<.001
Month 18	17	17.77	3.286	(11.29, 24.24)	<.001
Month 24	20	16.30	3.030	(10.33, 22.27)	<.001
Month 36	17	13.92	3.292	(7.44, 20.41)	<.001
Month 48	12	15.53	3.910	(7.82, 23.23)	<.001
Month 60	14	18.81	3.622	(11.67, 25.94)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	16.28	5.487	(5.33, 27.23)	0.004
Month 3	13	18.18	5.668	(6.87, 29.49)	0.002
Month 6	14	23.36	5.461	(12.46, 34.25)	<.001
Month 9	11	17.39	6.144	(5.13, 29.65)	0.006
Month 12	7	36.25	7.732	(20.82, 51.68)	<.001
Month 18	6	40.87	8.352	(24.21, 57.54)	<.001
Month 24	5	48.61	9.220	(30.21, 67.00)	<.001
Month 36	5	29.61	9.220	(11.21, 48.00)	0.002
Month 48	1	50.69	20.330	(10.12, 91.26)	0.015
Month 60	3	42.29	11.803	(18.73, 65.84)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	3.04	3.080	(-3.04, 9.12)	0.325
Month 3	27	14.12	3.130	(7.94, 20.30)	<.001
Month 6	24	11.54	3.327	(4.97, 18.11)	<.001
Month 9	19	16.25	3.734	(8.87, 23.62)	<.001
Month 12	16	18.41	4.066	(10.38, 26.44)	<.001
Month 18	12	15.66	4.695	(6.39, 24.93)	0.001
Month 24	15	17.71	4.199	(9.42, 26.00)	<.001
Month 36	12	11.95	4.707	(2.66, 21.25)	0.012
Month 48	11	20.82	4.905	(11.14, 30.51)	<.001
Month 60	11	14.52	4.903	(4.84, 24.20)	0.004

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	14.63	5.078	(4.50, 24.77)	0.005
Month 3	13	20.02	5.272	(9.50, 30.54)	<.001
Month 6	14	23.96	5.079	(13.83, 34.10)	<.001
Month 9	11	21.02	5.740	(9.57, 32.48)	<.001
Month 12	7	34.26	7.188	(19.91, 48.60)	<.001
Month 18	6	29.68	7.757	(14.20, 45.16)	<.001
Month 24	5	42.28	8.514	(25.29, 59.27)	<.001
Month 36	5	32.90	8.514	(15.91, 49.89)	<.001
Month 48	1	50.77	19.092	(12.67, 88.87)	0.010
Month 60	3	46.45	10.986	(24.53, 68.37)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	-1.68	3.915	(-9.41, 6.06)	0.669
Month 3	27	17.80	3.985	(9.93, 25.67)	<.001
Month 6	24	18.63	4.224	(10.29, 26.96)	<.001
Month 9	19	25.78	4.747	(16.41, 35.15)	<.001
Month 12	16	28.08	5.173	(17.87, 38.29)	<.001
Month 18	12	29.79	5.976	(17.99, 41.59)	<.001
Month 24	15	31.44	5.352	(20.87, 42.01)	<.001
Month 36	12	27.05	5.984	(15.24, 38.87)	<.001
Month 48	11	35.26	6.239	(22.94, 47.58)	<.001
Month 60	11	36.49	6.238	(24.18, 48.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	10.11	3.787	(2.55, 17.67)	0.009
Month 3	13	13.42	3.928	(5.58, 21.26)	0.001
Month 6	14	13.06	3.785	(5.50, 20.61)	<.001
Month 9	11	12.48	4.265	(3.97, 20.99)	0.005
Month 12	7	28.92	5.352	(18.24, 39.60)	<.001
Month 18	6	29.64	5.778	(18.11, 41.17)	<.001
Month 24	5	35.94	6.359	(23.25, 48.63)	<.001
Month 36	5	25.94	6.359	(13.25, 38.63)	<.001
Month 48	1	34.57	14.153	(6.33, 62.81)	0.017
Month 60	3	32.50	8.168	(16.20, 48.80)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	0.30	2.297	(-4.24, 4.83)	0.898
Month 3	27	9.39	2.336	(4.78, 14.01)	<.001
Month 6	24	9.67	2.482	(4.77, 14.58)	<.001
Month 9	19	13.66	2.787	(8.16, 19.16)	<.001
Month 12	16	15.55	3.035	(9.56, 21.54)	<.001
Month 18	12	12.89	3.505	(5.97, 19.82)	<.001
Month 24	15	13.82	3.134	(7.63, 20.01)	<.001
Month 36	12	12.88	3.510	(5.95, 19.81)	<.001
Month 48	11	17.42	3.661	(10.19, 24.65)	<.001
Month 60	11	15.58	3.660	(8.36, 22.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	6.65	6.159	(-5.79, 19.08)	0.287
Month 3	7	11.09	6.596	(-2.23, 24.41)	0.100
Month 6	9	10.09	5.804	(-1.63, 21.81)	0.090
Month 9	7	9.01	6.578	(-4.28, 22.29)	0.178
Month 12	5	31.30	7.785	(15.58, 47.03)	<.001
Month 18	4	26.49	8.701	(8.92, 44.06)	0.004
Month 24	4	33.99	8.701	(16.42, 51.56)	<.001
Month 36	4	33.99	8.701	(16.42, 51.56)	<.001
Month 48	1	22.64	17.415	(-12.53, 57.81)	0.201
Month 60	3	36.11	10.052	(15.81, 56.41)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	-4.33	3.422	(-11.09, 2.43)	0.208
Month 3	24	7.40	3.277	(0.92, 13.88)	0.025
Month 6	21	10.09	3.510	(3.15, 17.03)	0.005
Month 9	17	14.52	3.891	(6.83, 22.21)	<.001
Month 12	15	15.10	4.143	(6.91, 23.29)	<.001
Month 18	11	8.19	4.849	(-1.40, 17.77)	0.094
Month 24	14	8.83	4.289	(0.35, 17.30)	0.041
Month 36	11	11.22	4.839	(1.65, 20.78)	0.022
Month 48	10	17.33	5.076	(7.29, 27.36)	<.001
Month 60	10	14.18	5.078	(4.14, 24.21)	0.006

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	6.75	3.921	(-1.08, 14.57)	0.090
Month 3	13	7.82	4.071	(-0.30, 15.94)	0.059
Month 6	14	6.16	3.921	(-1.66, 13.98)	0.121
Month 9	11	6.18	4.423	(-2.65, 15.00)	0.167
Month 12	7	17.62	5.546	(6.55, 28.69)	0.002
Month 18	6	21.97	5.989	(10.02, 33.92)	<.001
Month 24	5	23.32	6.574	(10.20, 36.44)	<.001
Month 36	5	15.32	6.574	(2.20, 28.44)	0.023
Month 48	1	27.64	14.716	(-1.73, 57.00)	0.065
Month 60	3	18.33	8.507	(1.36, 35.31)	0.035

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	27	1.16	2.537	(-3.85, 6.17)	0.648
Month 3	27	7.78	2.526	(2.79, 12.76)	0.002
Month 6	24	8.89	2.681	(3.59, 14.18)	0.001
Month 9	19	11.53	3.015	(5.57, 17.48)	<.001
Month 12	16	13.36	3.280	(6.88, 19.83)	<.001
Month 18	11	15.69	3.957	(7.88, 23.51)	<.001
Month 24	15	13.52	3.390	(6.83, 20.22)	<.001
Month 36	12	13.05	3.798	(5.55, 20.55)	<.001
Month 48	11	13.21	3.958	(5.40, 21.03)	0.001
Month 60	11	18.21	3.958	(10.40, 26.03)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	3.91	4.971	(-5.97, 13.80)	0.434
Month 3	15	15.93	4.804	(6.38, 25.49)	0.001
Month 6	14	17.89	4.987	(7.97, 27.81)	<.001
Month 9	12	14.21	5.375	(3.52, 24.90)	0.010
Month 12	10	21.70	5.882	(10.01, 33.40)	<.001
Month 18	7	27.71	7.043	(13.71, 41.72)	<.001
Month 24	7	31.25	7.032	(17.27, 45.24)	<.001
Month 36	6	14.11	7.621	(-1.05, 29.26)	0.068
Month 48	4	26.74	9.465	(7.92, 45.56)	0.006
Month 60	6	33.15	7.606	(18.02, 48.27)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	9.47	3.533	(2.48, 16.46)	0.008
Month 3	23	14.91	3.733	(7.53, 22.30)	<.001
Month 6	22	14.12	3.815	(6.57, 21.66)	<.001
Month 9	16	18.29	4.473	(9.45, 27.14)	<.001
Month 12	11	25.26	5.400	(14.58, 35.94)	<.001
Month 18	9	22.99	5.968	(11.19, 34.80)	<.001
Month 24	12	24.08	5.167	(13.86, 34.30)	<.001
Month 36	10	19.63	5.677	(8.40, 30.86)	<.001
Month 48	7	28.33	6.768	(14.95, 41.72)	<.001
Month 60	7	15.93	6.763	(2.55, 29.31)	0.020

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	9.27	6.440	(-7.28, 25.82)	0.210
Month 3	2	19.27	6.440	(2.72, 35.82)	0.030
Month 6	2	9.27	6.440	(-7.28, 25.82)	0.210
Month 9	2	16.77	6.440	(0.22, 33.32)	0.048
Month 12	2	29.27	6.440	(12.72, 45.82)	0.006
Month 18	2	14.27	6.440	(-2.28, 30.82)	0.078
Month 24	1	2.19	9.270	(-21.64, 26.02)	0.823
Month 36	1	-2.81	9.270	(-26.64, 21.02)	0.774
Month 48	1	-7.81	9.270	(-31.64, 16.02)	0.438
Month 60	1	-12.81	9.270	(-36.64, 11.02)	0.225

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	5.35	4.266	(-3.13, 13.83)	0.213
Month 3	15	15.20	4.122	(7.00, 23.40)	<.001
Month 6	14	15.89	4.269	(7.40, 24.38)	<.001
Month 9	12	12.97	4.617	(3.79, 22.15)	0.006
Month 12	10	21.31	5.046	(11.27, 31.34)	<.001
Month 18	7	23.43	6.033	(11.44, 35.43)	<.001
Month 24	7	27.57	6.032	(15.58, 39.57)	<.001
Month 36	6	13.83	6.529	(0.84, 26.81)	0.037
Month 48	4	30.38	7.998	(14.48, 46.29)	<.001
Month 60	6	31.18	6.524	(18.20, 44.15)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	3.30	4.316	(-5.23, 11.84)	0.445
Month 3	23	20.42	4.578	(11.37, 29.48)	<.001
Month 6	22	22.95	4.678	(13.70, 32.21)	<.001
Month 9	16	28.48	5.486	(17.63, 39.34)	<.001
Month 12	11	33.68	6.634	(20.56, 46.80)	<.001
Month 18	9	33.28	7.325	(18.79, 47.77)	<.001
Month 24	12	37.21	6.342	(24.66, 49.75)	<.001
Month 36	10	36.62	6.942	(22.88, 50.35)	<.001
Month 48	7	37.60	8.299	(21.18, 54.01)	<.001
Month 60	7	41.81	8.304	(25.38, 58.23)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	10.72	15.987	(-30.38, 51.81)	0.532
Month 3	2	20.12	15.987	(-20.98, 61.21)	0.264
Month 6	2	31.07	15.987	(-10.03, 72.16)	0.110
Month 9	2	43.57	15.987	(2.47, 84.66)	0.042
Month 12	2	48.22	15.987	(7.12, 89.31)	0.030
Month 18	2	37.32	15.987	(-3.78, 78.41)	0.067
Month 24	1	45.85	23.013	(-13.31, 105.01)	0.103
Month 36	1	45.85	23.013	(-13.31, 105.01)	0.103
Month 48	1	55.25	23.013	(-3.91, 114.41)	0.062
Month 60	1	52.15	23.013	(-7.01, 111.31)	0.073

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	1.28	2.965	(-4.61, 7.18)	0.666
Month 3	15	10.97	2.863	(5.28, 16.66)	<.001
Month 6	14	10.40	2.971	(4.50, 16.31)	<.001
Month 9	12	10.22	3.202	(3.85, 16.59)	0.002
Month 12	10	17.54	3.506	(10.56, 24.51)	<.001
Month 18	7	22.44	4.192	(14.11, 30.78)	<.001
Month 24	7	22.80	4.191	(14.46, 31.13)	<.001
Month 36	6	15.82	4.535	(6.80, 24.84)	<.001
Month 48	4	22.30	5.586	(11.20, 33.41)	<.001
Month 60	6	23.17	4.548	(14.12, 32.21)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	5.05	2.697	(-0.28, 10.39)	0.063
Month 3	23	10.00	2.858	(4.35, 15.66)	<.001
Month 6	22	10.15	2.925	(4.37, 15.94)	<.001
Month 9	16	14.56	3.427	(7.78, 21.34)	<.001
Month 12	11	20.27	4.135	(12.09, 28.45)	<.001
Month 18	9	17.04	4.569	(8.00, 26.07)	<.001
Month 24	12	17.97	3.957	(10.14, 25.79)	<.001
Month 36	10	18.58	4.341	(9.99, 27.16)	<.001
Month 48	7	19.42	5.182	(9.17, 29.67)	<.001
Month 60	7	17.18	5.184	(6.92, 27.43)	0.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	8.23	5.444	(-5.76, 22.23)	0.191
Month 3	2	16.53	5.444	(2.54, 30.53)	0.029
Month 6	2	18.23	5.444	(4.24, 32.23)	0.020
Month 9	2	16.58	5.444	(2.59, 30.58)	0.029
Month 12	2	26.53	5.444	(12.54, 40.53)	0.005
Month 18	2	13.23	5.444	(-0.76, 27.23)	0.059
Month 24	1	11.31	7.837	(-8.84, 31.45)	0.209
Month 36	1	-3.69	7.837	(-23.84, 16.45)	0.657
Month 48	1	2.91	7.837	(-17.24, 23.05)	0.726
Month 60	1	12.91	7.837	(-7.24, 33.05)	0.160

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	2.55	5.476	(-8.45, 13.54)	0.644
Month 3	9	11.23	5.099	(0.99, 21.48)	0.032
Month 6	9	9.14	5.108	(-1.12, 19.40)	0.080
Month 9	7	9.17	5.711	(-2.30, 20.64)	0.115
Month 12	7	15.32	5.719	(3.83, 26.81)	0.010
Month 18	4	13.41	7.608	(-1.88, 28.69)	0.084
Month 24	5	14.11	6.847	(0.36, 27.86)	0.045
Month 36	4	14.66	7.608	(-0.63, 29.94)	0.060
Month 48	3	19.92	8.866	(2.11, 37.73)	0.029
Month 60	5	20.11	6.847	(6.36, 33.86)	0.005

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	-1.36	3.906	(-9.10, 6.37)	0.728
Month 3	20	7.31	3.883	(-0.38, 15.00)	0.062
Month 6	19	9.07	3.989	(1.17, 16.97)	0.025
Month 9	15	13.12	4.483	(4.25, 22.00)	0.004
Month 12	11	18.09	5.238	(7.72, 28.47)	<.001
Month 18	9	11.55	5.790	(0.08, 23.01)	0.048
Month 24	12	12.08	5.012	(2.16, 22.00)	0.017
Month 36	10	17.49	5.496	(6.61, 28.37)	0.002
Month 48	7	15.42	6.566	(2.42, 28.43)	0.020
Month 60	7	14.62	6.569	(1.62, 27.63)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	5.10	10.228	(-21.19, 31.40)	0.639
Month 3	2	15.10	10.228	(-11.19, 41.40)	0.200
Month 6	2	27.60	10.228	(1.31, 53.90)	0.043
Month 9	2	22.60	10.228	(-3.69, 48.90)	0.078
Month 12	2	35.10	10.228	(8.81, 61.40)	0.019
Month 18	2	17.60	10.228	(-8.69, 43.90)	0.146
Month 24	1	24.69	14.724	(-13.16, 62.54)	0.154
Month 36	1	4.69	14.724	(-33.16, 42.54)	0.763
Month 48	1	19.69	14.724	(-18.16, 57.54)	0.239
Month 60	1	34.69	14.724	(-3.16, 72.54)	0.065

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	13	1.50	3.666	(-5.80, 8.79)	0.684
Month 3	15	7.58	3.415	(0.79, 14.37)	0.029
Month 6	14	6.30	3.534	(-0.73, 13.32)	0.078
Month 9	12	6.97	3.818	(-0.62, 14.57)	0.071
Month 12	10	12.02	4.179	(3.70, 20.33)	0.005
Month 18	7	19.72	5.000	(9.77, 29.66)	<.001
Month 24	7	16.15	5.000	(6.20, 26.09)	0.002
Month 36	6	11.22	5.413	(0.46, 21.99)	0.041
Month 48	4	22.87	6.608	(9.73, 36.01)	<.001
Month 60	6	17.50	5.407	(6.75, 28.25)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	3.20	2.636	(-2.02, 8.41)	0.227
Month 3	23	6.90	2.797	(1.37, 12.44)	0.015
Month 6	22	7.28	2.864	(1.61, 12.94)	0.012
Month 9	16	10.68	3.354	(4.05, 17.32)	0.002
Month 12	11	17.07	4.045	(9.06, 25.07)	<.001
Month 18	8	19.10	4.744	(9.71, 28.48)	<.001
Month 24	12	17.24	3.872	(9.58, 24.90)	<.001
Month 36	10	18.36	4.244	(9.97, 26.76)	<.001
Month 48	7	14.15	5.070	(4.12, 24.18)	0.006
Month 60	7	20.47	5.074	(10.43, 30.51)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	10.21	5.429	(-3.75, 24.16)	0.119
Month 3	2	15.21	5.429	(1.25, 29.16)	0.038
Month 6	2	17.71	5.429	(3.75, 31.66)	0.022
Month 9	2	10.21	5.429	(-3.75, 24.16)	0.119
Month 12	2	15.21	5.429	(1.25, 29.16)	0.038
Month 18	2	7.71	5.429	(-6.25, 21.66)	0.215
Month 24	1	6.87	7.815	(-13.21, 26.96)	0.419
Month 36	1	-13.13	7.815	(-33.21, 6.96)	0.154
Month 48	1	-3.13	7.815	(-23.21, 16.96)	0.706
Month 60	1	16.88	7.815	(-3.21, 36.96)	0.083

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	7.61	3.535	(0.63, 14.59)	0.033
Month 3	26	15.34	3.464	(8.50, 22.18)	<.001
Month 6	27	16.14	3.400	(9.43, 22.86)	<.001
Month 9	20	14.83	3.954	(7.02, 22.63)	<.001
Month 12	17	20.34	4.283	(11.88, 28.79)	<.001
Month 18	14	23.06	4.720	(13.74, 32.38)	<.001
Month 24	13	25.51	4.907	(15.82, 35.20)	<.001
Month 36	13	16.66	4.907	(6.97, 26.35)	<.001
Month 48	8	24.01	6.260	(11.65, 36.37)	<.001
Month 60	11	25.64	5.325	(15.13, 36.16)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	7.36	4.609	(-1.84, 16.55)	0.115
Month 3	14	15.60	5.041	(5.54, 25.65)	0.003
Month 6	11	13.28	5.667	(1.98, 24.59)	0.022
Month 9	10	19.25	5.946	(7.39, 31.11)	0.002
Month 12	6	33.99	7.687	(18.66, 49.33)	<.001
Month 18	4	26.79	9.433	(7.98, 45.61)	0.006
Month 24	7	26.21	7.104	(12.04, 40.38)	<.001
Month 36	4	17.13	9.550	(-1.92, 36.18)	0.077
Month 48	4	26.79	9.433	(7.98, 45.61)	0.006
Month 60	3	5.89	10.853	(-15.76, 27.54)	0.589

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	4.18	3.741	(-3.20, 11.57)	0.265
Month 3	26	16.79	3.669	(9.54, 24.03)	<.001
Month 6	27	19.48	3.599	(12.37, 26.59)	<.001
Month 9	20	18.58	4.187	(10.31, 26.85)	<.001
Month 12	17	25.05	4.536	(16.09, 34.01)	<.001
Month 18	14	28.71	4.998	(18.84, 38.58)	<.001
Month 24	13	30.86	5.194	(20.60, 41.12)	<.001
Month 36	13	24.35	5.194	(14.10, 34.61)	<.001
Month 48	8	38.50	6.613	(25.44, 51.55)	<.001
Month 60	11	40.47	5.639	(29.34, 51.61)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	4.16	5.259	(-6.34, 14.65)	0.432
Month 3	14	22.43	5.781	(10.90, 33.97)	<.001
Month 6	11	22.26	6.504	(9.28, 35.23)	0.001
Month 9	10	33.36	6.822	(19.75, 46.97)	<.001
Month 12	6	42.58	8.821	(24.99, 60.18)	<.001
Month 18	4	29.73	10.869	(8.04, 51.41)	0.008
Month 24	7	40.58	8.168	(24.28, 56.87)	<.001
Month 36	4	42.09	10.833	(20.48, 63.70)	<.001
Month 48	4	35.77	10.788	(14.25, 57.29)	0.001
Month 60	3	36.06	12.507	(11.11, 61.01)	0.005

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	3.29	2.470	(-1.59, 8.17)	0.185
Month 3	26	10.16	2.422	(5.38, 14.94)	<.001
Month 6	27	10.99	2.378	(6.29, 15.68)	<.001
Month 9	20	11.62	2.764	(6.16, 17.07)	<.001
Month 12	17	17.20	2.995	(11.29, 23.12)	<.001
Month 18	14	18.35	3.301	(11.83, 24.87)	<.001
Month 24	13	19.35	3.428	(12.58, 26.12)	<.001
Month 36	13	15.75	3.428	(8.98, 22.52)	<.001
Month 48	8	18.95	4.373	(10.31, 27.58)	<.001
Month 60	11	22.17	3.725	(14.82, 29.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	4.11	3.543	(-2.96, 11.18)	0.250
Month 3	14	11.87	3.883	(4.13, 19.62)	0.003
Month 6	11	9.82	4.372	(1.10, 18.54)	0.028
Month 9	10	15.26	4.587	(6.11, 24.41)	0.001
Month 12	6	26.30	5.920	(14.49, 38.11)	<.001
Month 18	4	18.18	7.250	(3.72, 32.64)	0.015
Month 24	7	19.99	5.478	(9.06, 30.92)	<.001
Month 36	4	18.60	7.351	(3.94, 33.27)	0.014
Month 48	4	21.30	7.293	(6.75, 35.85)	0.005
Month 60	3	12.14	8.389	(-4.60, 28.87)	0.152

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	-2.35	3.783	(-9.84, 5.14)	0.535
Month 3	18	7.04	3.685	(-0.25, 14.34)	0.058
Month 6	20	11.97	3.493	(5.06, 18.89)	<.001
Month 9	15	13.75	4.028	(5.78, 21.73)	<.001
Month 12	14	18.78	4.169	(10.52, 27.03)	<.001
Month 18	11	14.80	4.707	(5.49, 24.12)	0.002
Month 24	11	13.75	4.704	(4.44, 23.06)	0.004
Month 36	11	17.39	4.704	(8.08, 26.70)	<.001
Month 48	7	16.40	5.906	(4.71, 28.09)	0.006
Month 60	10	21.91	4.934	(12.14, 31.67)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	13	-0.43	5.354	(-11.13, 10.28)	0.937
Month 3	13	10.02	5.339	(-0.65, 20.69)	0.065
Month 6	10	5.34	6.097	(-6.84, 17.53)	0.384
Month 9	9	10.92	6.422	(-1.91, 23.76)	0.094
Month 12	6	20.01	7.859	(4.30, 35.72)	0.013
Month 18	4	8.16	9.648	(-11.13, 27.44)	0.401
Month 24	7	15.94	7.277	(1.39, 30.49)	0.032
Month 36	4	16.92	9.671	(-2.41, 36.25)	0.085
Month 48	4	23.35	9.697	(3.97, 42.74)	0.019
Month 60	3	11.07	11.155	(-11.23, 33.37)	0.325

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	3.41	2.755	(-2.03, 8.85)	0.217
Month 3	26	6.45	2.646	(1.23, 11.68)	0.016
Month 6	27	6.95	2.599	(1.82, 12.08)	0.008
Month 9	20	6.88	3.020	(0.91, 12.84)	0.024
Month 12	17	11.14	3.274	(4.68, 17.61)	<.001
Month 18	13	17.43	3.743	(10.04, 24.82)	<.001
Month 24	13	15.69	3.744	(8.30, 23.09)	<.001
Month 36	13	11.46	3.744	(4.07, 18.85)	0.003
Month 48	8	16.01	4.771	(6.58, 25.43)	<.001
Month 60	11	19.03	4.070	(11.00, 27.07)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	2.61	3.224	(-3.83, 9.04)	0.422
Month 3	14	10.63	3.532	(3.58, 17.67)	0.004
Month 6	11	10.03	3.968	(2.12, 17.95)	0.014
Month 9	10	13.56	4.161	(5.26, 21.86)	0.002
Month 12	6	23.81	5.390	(13.05, 34.56)	<.001
Month 18	4	17.70	6.623	(4.49, 30.91)	0.009
Month 24	7	17.10	4.978	(7.16, 27.03)	0.001
Month 36	4	20.52	6.672	(7.21, 33.83)	0.003
Month 48	4	13.63	6.592	(0.48, 26.78)	0.042
Month 60	3	18.65	7.603	(3.49, 33.82)	0.017

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	26.08	5.306	(14.40, 37.76)	<.001
Month 3	3	24.42	5.306	(12.74, 36.09)	<.001
Month 6	3	21.08	5.306	(9.40, 32.76)	0.002
Month 9	2	17.07	6.540	(2.68, 31.46)	0.024
Month 12	2	32.07	6.540	(17.68, 46.46)	<.001
Month 18	2	27.07	6.540	(12.68, 41.46)	0.002
Month 24	2	34.79	6.597	(20.27, 49.31)	<.001
Month 36	2	32.29	6.597	(17.77, 46.81)	<.001
Month 48	1	34.11	9.199	(13.86, 54.36)	0.003
Month 60	2	32.29	6.597	(17.77, 46.81)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	39	6.20	2.873	(0.54, 11.86)	0.032
Month 3	37	14.81	2.942	(9.01, 20.60)	<.001
Month 6	35	14.94	3.025	(8.98, 20.90)	<.001
Month 9	28	16.60	3.381	(9.94, 23.27)	<.001
Month 12	21	23.42	3.906	(15.72, 31.11)	<.001
Month 18	16	23.78	4.478	(14.95, 32.60)	<.001
Month 24	18	24.24	4.217	(15.93, 32.55)	<.001
Month 36	15	14.12	4.633	(4.99, 23.25)	0.003
Month 48	11	24.04	5.398	(13.40, 34.68)	<.001
Month 60	12	18.37	5.164	(8.20, 28.55)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	15.68	5.589	(3.38, 27.98)	0.017
Month 3	3	21.91	5.589	(9.61, 34.22)	0.002
Month 6	3	27.11	5.589	(14.81, 39.42)	<.001
Month 9	2	27.48	6.896	(12.30, 42.66)	0.002
Month 12	2	33.68	6.896	(18.50, 48.86)	<.001
Month 18	2	38.38	6.896	(23.20, 53.56)	<.001
Month 24	2	36.37	6.955	(21.06, 51.67)	<.001
Month 36	2	39.52	6.955	(24.21, 54.82)	<.001
Month 48	1	42.08	9.700	(20.73, 63.43)	0.001
Month 60	2	42.62	6.955	(27.31, 57.92)	<.001

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Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	39	2.88	3.256	(-3.54, 9.30)	0.377
Month 3	37	18.34	3.343	(11.76, 24.93)	<.001
Month 6	35	19.98	3.435	(13.21, 26.75)	<.001
Month 9	28	23.99	3.842	(16.42, 31.57)	<.001
Month 12	21	29.91	4.437	(21.17, 38.66)	<.001
Month 18	16	28.90	5.085	(18.88, 38.92)	<.001
Month 24	18	33.57	4.795	(24.12, 43.02)	<.001
Month 36	15	26.57	5.255	(16.21, 36.92)	<.001
Month 48	11	36.64	6.129	(24.56, 48.72)	<.001
Month 60	12	37.31	5.873	(25.74, 48.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	18.43	5.129	(7.14, 29.72)	0.004
Month 3	3	17.00	5.129	(5.71, 28.29)	0.007
Month 6	3	19.23	5.129	(7.94, 30.52)	0.003
Month 9	2	14.63	6.288	(0.79, 28.47)	0.040
Month 12	2	30.43	6.288	(16.59, 44.27)	<.001
Month 18	2	23.78	6.288	(9.94, 37.62)	0.003
Month 24	2	27.35	6.345	(13.39, 41.32)	0.001
Month 36	2	33.20	6.345	(19.24, 47.17)	<.001
Month 48	1	31.84	8.866	(12.32, 51.35)	0.004
Month 60	2	31.50	6.345	(17.54, 45.47)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	39	2.44	2.015	(-1.53, 6.42)	0.226
Month 3	37	10.28	2.067	(6.20, 14.35)	<.001
Month 6	35	10.07	2.127	(5.88, 14.26)	<.001
Month 9	28	12.97	2.376	(8.29, 17.65)	<.001
Month 12	21	18.75	2.744	(13.34, 24.15)	<.001
Month 18	16	17.80	3.143	(11.61, 24.00)	<.001
Month 24	18	18.27	2.963	(12.43, 24.11)	<.001
Month 36	15	13.97	3.251	(7.56, 20.37)	<.001
Month 48	11	19.04	3.791	(11.57, 26.51)	<.001
Month 60	12	17.05	3.634	(9.89, 24.21)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	14.29	8.870	(-5.47, 34.06)	0.138
Month 3	3	10.45	7.028	(-5.21, 26.11)	0.168
Month 6	3	17.12	7.028	(1.46, 32.78)	0.035
Month 9	2	5.00	8.598	(-14.16, 24.16)	0.574
Month 12	2	35.00	8.598	(15.84, 54.16)	0.002
Month 18	2	20.00	8.598	(0.84, 39.16)	0.042
Month 24	2	17.06	8.683	(-2.29, 36.41)	0.078
Month 36	2	37.06	8.683	(17.71, 56.41)	0.002
Month 48	1	31.35	12.198	(4.17, 58.53)	0.028
Month 60	2	34.56	8.683	(15.21, 53.91)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	-2.23	3.122	(-8.39, 3.93)	0.476
Month 3	28	8.25	3.125	(2.09, 14.42)	0.009
Month 6	27	9.11	3.187	(2.82, 15.40)	0.005
Month 9	22	13.39	3.522	(6.44, 20.34)	<.001
Month 12	18	17.39	3.894	(9.70, 25.07)	<.001
Month 18	13	11.77	4.590	(2.71, 20.83)	0.011
Month 24	16	13.93	4.134	(5.77, 22.08)	<.001
Month 36	13	13.70	4.582	(4.66, 22.74)	0.003
Month 48	10	17.76	5.225	(7.45, 28.08)	<.001
Month 60	11	15.98	4.993	(6.12, 25.83)	0.002

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	13.65	4.557	(3.62, 23.68)	0.012
Month 3	3	15.31	4.557	(5.28, 25.34)	0.006
Month 6	3	18.65	4.557	(8.62, 28.68)	0.002
Month 9	2	22.04	5.608	(9.70, 34.38)	0.002
Month 12	2	24.54	5.608	(12.20, 36.88)	0.001
Month 18	2	24.54	5.608	(12.20, 36.88)	0.001
Month 24	2	28.01	5.659	(15.56, 40.47)	<.001
Month 36	2	28.01	5.659	(15.56, 40.47)	<.001
Month 48	1	26.86	7.890	(9.49, 44.22)	0.006
Month 60	2	25.51	5.659	(13.06, 37.97)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	38	2.02	2.182	(-2.28, 6.32)	0.355
Month 3	37	7.18	2.208	(2.83, 11.53)	0.001
Month 6	35	6.88	2.271	(2.40, 11.35)	0.003
Month 9	28	8.49	2.539	(3.48, 13.49)	<.001
Month 12	21	13.94	2.931	(8.17, 19.72)	<.001
Month 18	15	17.15	3.470	(10.31, 23.99)	<.001
Month 24	18	14.64	3.166	(8.40, 20.88)	<.001
Month 36	15	11.63	3.473	(4.79, 18.48)	<.001
Month 48	11	14.37	4.050	(6.39, 22.35)	<.001
Month 60	12	17.01	3.881	(9.36, 24.66)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	3.80	3.573	(-3.30, 10.89)	0.290
Month 3	15	16.97	3.452	(10.12, 23.83)	<.001
Month 6	12	13.65	3.858	(5.98, 21.31)	<.001
Month 9	12	19.34	3.857	(11.68, 27.00)	<.001
Month 12	11	16.27	4.029	(8.27, 24.27)	<.001
Month 18	8	13.81	4.726	(4.43, 23.20)	0.004
Month 24	9	14.60	4.457	(5.75, 23.46)	0.001
Month 36	8	4.28	4.738	(-5.13, 13.68)	0.369
Month 48	8	15.35	4.725	(5.96, 24.73)	0.002
Month 60	7	15.15	5.053	(5.11, 25.18)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	9.91	3.760	(2.48, 17.35)	0.009
Month 3	25	14.67	3.952	(6.86, 22.49)	<.001
Month 6	26	16.69	3.871	(9.04, 24.35)	<.001
Month 9	18	14.52	4.660	(5.31, 23.73)	0.002
Month 12	12	30.10	5.713	(18.81, 41.40)	<.001
Month 18	10	31.33	6.266	(18.94, 43.72)	<.001
Month 24	11	34.72	5.958	(22.94, 46.50)	<.001
Month 36	9	27.72	6.625	(14.62, 40.82)	<.001
Month 48	4	41.46	9.873	(21.94, 60.98)	<.001
Month 60	7	26.20	7.472	(11.43, 40.98)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	0.51	5.654	(-10.72, 11.73)	0.929
Month 3	15	15.96	5.465	(5.10, 26.81)	0.004
Month 6	12	21.02	6.103	(8.91, 33.14)	<.001
Month 9	12	25.63	6.103	(13.51, 37.75)	<.001
Month 12	11	25.14	6.376	(12.48, 37.80)	<.001
Month 18	8	27.44	7.476	(12.60, 42.29)	<.001
Month 24	9	28.50	7.056	(14.49, 42.51)	<.001
Month 36	8	22.30	7.504	(7.39, 37.20)	0.004
Month 48	8	35.26	7.474	(20.41, 50.10)	<.001
Month 60	7	35.66	7.992	(19.79, 51.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	5.40	3.726	(-1.97, 12.77)	0.150
Month 3	25	20.04	3.942	(12.24, 27.83)	<.001
Month 6	26	20.35	3.864	(12.71, 27.99)	<.001
Month 9	18	22.86	4.649	(13.67, 32.05)	<.001
Month 12	12	33.81	5.704	(22.53, 45.08)	<.001
Month 18	10	31.36	6.233	(19.04, 43.69)	<.001
Month 24	11	39.04	5.952	(27.28, 50.81)	<.001
Month 36	9	34.58	6.572	(21.58, 47.57)	<.001
Month 48	4	40.26	9.853	(20.78, 59.74)	<.001
Month 60	7	42.29	7.452	(27.55, 57.02)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	2.39	2.685	(-2.94, 7.72)	0.376
Month 3	15	10.63	2.594	(5.48, 15.78)	<.001
Month 6	12	11.14	2.900	(5.38, 16.90)	<.001
Month 9	12	15.44	2.899	(9.69, 21.20)	<.001
Month 12	11	15.35	3.028	(9.34, 21.36)	<.001
Month 18	8	12.46	3.552	(5.40, 19.51)	<.001
Month 24	9	10.20	3.349	(3.55, 16.85)	0.003
Month 36	8	7.43	3.558	(0.36, 14.49)	0.040
Month 48	8	13.73	3.551	(6.68, 20.78)	<.001
Month 60	7	15.46	3.796	(7.92, 22.99)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	4.26	2.674	(-1.02, 9.55)	0.113
Month 3	25	10.86	2.823	(5.28, 16.44)	<.001
Month 6	26	10.74	2.769	(5.26, 16.21)	<.001
Month 9	18	11.24	3.329	(4.65, 17.82)	<.001
Month 12	12	23.31	4.078	(15.25, 31.37)	<.001
Month 18	10	22.98	4.465	(14.15, 31.81)	<.001
Month 24	11	27.02	4.256	(18.61, 35.44)	<.001
Month 36	9	24.59	4.718	(15.26, 33.91)	<.001
Month 48	4	30.91	7.057	(16.96, 44.87)	<.001
Month 60	7	23.74	5.336	(13.19, 34.29)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	2.31	4.218	(-6.09, 10.71)	0.586
Month 3	12	9.84	3.648	(2.57, 17.11)	0.009
Month 6	9	12.30	4.211	(3.91, 20.69)	0.005
Month 9	10	14.39	3.993	(6.43, 22.35)	<.001
Month 12	10	17.89	3.993	(9.93, 25.85)	<.001
Month 18	7	11.23	4.778	(1.71, 20.75)	0.021
Month 24	8	5.26	4.469	(-3.64, 14.16)	0.243
Month 36	7	6.27	4.786	(-3.27, 15.80)	0.194
Month 48	7	13.63	4.776	(4.12, 23.15)	0.006
Month 60	6	15.45	5.157	(5.17, 25.72)	0.004

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Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	-2.90	4.061	(-10.95, 5.14)	0.476
Month 3	19	7.35	4.285	(-1.15, 15.84)	0.089
Month 6	21	8.71	4.070	(0.65, 16.78)	0.035
Month 9	14	11.40	4.973	(1.55, 21.26)	0.024
Month 12	10	20.28	5.884	(8.62, 31.94)	<.001
Month 18	8	14.66	6.588	(1.61, 27.72)	0.028
Month 24	10	22.14	5.899	(10.45, 33.83)	<.001
Month 36	8	26.61	6.581	(13.57, 39.65)	<.001
Month 48	4	27.24	9.305	(8.80, 45.67)	0.004
Month 60	7	22.88	7.042	(8.92, 36.83)	0.002

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	13	4.49	3.284	(-2.03, 11.02)	0.175
Month 3	15	9.13	3.052	(3.06, 15.19)	0.004
Month 6	12	10.90	3.414	(4.12, 17.68)	0.002
Month 9	12	11.25	3.412	(4.47, 18.03)	0.001
Month 12	11	11.96	3.567	(4.87, 19.04)	0.001
Month 18	7	12.86	4.467	(3.98, 21.73)	0.005
Month 24	9	7.57	3.941	(-0.26, 15.39)	0.058
Month 36	8	7.65	4.186	(-0.67, 15.96)	0.071
Month 48	8	10.39	4.180	(2.08, 18.69)	0.015
Month 60	7	15.71	4.467	(6.84, 24.59)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	2.32	2.718	(-3.05, 7.70)	0.394
Month 3	25	6.97	2.872	(1.29, 12.65)	0.016
Month 6	26	6.50	2.815	(0.94, 12.07)	0.022
Month 9	18	7.84	3.386	(1.14, 14.53)	0.022
Month 12	12	17.05	4.148	(8.85, 25.26)	<.001
Month 18	10	21.28	4.542	(12.30, 30.26)	<.001
Month 24	11	23.30	4.332	(14.73, 31.86)	<.001
Month 36	9	19.25	4.797	(9.77, 28.74)	<.001
Month 48	4	23.88	7.179	(9.68, 38.07)	0.001
Month 60	7	21.34	5.429	(10.60, 32.07)	<.001

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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	14.51	7.633	(-0.92, 29.94)	0.065
Month 3	7	27.08	7.109	(12.71, 41.45)	<.001
Month 6	6	24.05	7.614	(8.67, 39.44)	0.003
Month 9	5	25.32	8.346	(8.45, 42.19)	0.004
Month 12	5	24.82	8.346	(7.95, 41.69)	0.005
Month 18	5	24.82	8.346	(7.95, 41.69)	0.005
Month 24	5	17.82	8.346	(0.95, 34.69)	0.039
Month 36	5	14.82	8.346	(-2.05, 31.69)	0.083
Month 48	3	18.86	10.767	(-2.90, 40.63)	0.087
Month 60	4	20.51	9.326	(1.66, 39.36)	0.034

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	6.21	2.966	(0.36, 12.06)	0.038
Month 3	33	13.15	3.092	(7.05, 19.25)	<.001
Month 6	32	13.59	3.144	(7.39, 19.79)	<.001
Month 9	25	14.20	3.555	(7.19, 21.21)	<.001
Month 12	18	23.47	4.187	(15.21, 31.73)	<.001
Month 18	13	23.58	4.927	(13.86, 33.30)	<.001
Month 24	15	28.46	4.588	(19.42, 37.51)	<.001
Month 36	12	18.00	5.146	(7.85, 28.15)	<.001
Month 48	9	27.71	5.925	(16.02, 39.39)	<.001
Month 60	10	21.64	5.618	(10.56, 32.72)	<.001

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n = number of subjects with measurements at both baseline and the post-baseline visits.
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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	3.95	8.763	(-13.76, 21.66)	0.655
Month 3	7	16.28	8.118	(-0.13, 32.68)	0.052
Month 6	6	20.44	8.764	(2.72, 38.15)	0.025
Month 9	5	19.97	9.600	(0.57, 39.37)	0.044
Month 12	5	24.33	9.600	(4.93, 43.73)	0.015
Month 18	5	27.47	9.600	(8.07, 46.87)	0.007
Month 24	5	24.35	9.600	(4.95, 43.75)	0.015
Month 36	5	24.33	9.600	(4.93, 43.73)	0.015
Month 48	3	37.92	12.400	(12.86, 62.98)	0.004
Month 60	4	36.46	10.759	(14.71, 58.20)	0.002

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	3.38	3.225	(-2.98, 9.74)	0.296
Month 3	33	18.83	3.369	(12.18, 25.47)	<.001
Month 6	32	19.86	3.420	(13.12, 26.61)	<.001
Month 9	25	24.71	3.870	(17.08, 32.34)	<.001
Month 12	18	31.52	4.560	(22.53, 40.51)	<.001
Month 18	13	31.15	5.365	(20.57, 41.74)	<.001
Month 24	15	37.69	5.003	(27.82, 47.56)	<.001
Month 36	12	30.96	5.595	(19.93, 42.00)	<.001
Month 48	9	38.24	6.452	(25.51, 50.96)	<.001
Month 60	10	40.65	6.119	(28.58, 52.71)	<.001

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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	8.74	3.897	(0.86, 16.61)	0.031
Month 3	7	13.22	3.612	(5.92, 20.52)	<.001
Month 6	6	15.65	3.894	(7.78, 23.52)	<.001
Month 9	5	18.01	4.262	(9.40, 26.63)	<.001
Month 12	5	16.95	4.262	(8.34, 25.57)	<.001
Month 18	5	13.97	4.262	(5.36, 22.59)	0.002
Month 24	5	11.33	4.262	(2.72, 19.95)	0.011
Month 36	5	7.97	4.262	(-0.64, 16.59)	0.069
Month 48	3	12.94	5.519	(1.79, 24.10)	0.024
Month 60	4	16.79	4.764	(7.16, 26.41)	0.001

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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	2.61	2.243	(-1.82, 7.03)	0.246
Month 3	33	10.07	2.341	(5.45, 14.69)	<.001
Month 6	32	9.56	2.381	(4.86, 14.25)	<.001
Month 9	25	11.95	2.691	(6.65, 17.26)	<.001
Month 12	18	20.36	3.170	(14.10, 26.61)	<.001
Month 18	13	20.09	3.730	(12.73, 27.45)	<.001
Month 24	15	22.35	3.473	(15.50, 29.20)	<.001
Month 36	12	20.22	3.893	(12.54, 27.90)	<.001
Month 48	9	22.78	4.486	(13.93, 31.62)	<.001
Month 60	10	21.25	4.257	(12.86, 29.65)	<.001

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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	5.41	5.043	(-4.80, 15.62)	0.290
Month 3	6	4.11	4.600	(-5.20, 13.42)	0.377
Month 6	6	16.87	4.607	(7.54, 26.19)	<.001
Month 9	5	24.38	5.038	(14.18, 34.58)	<.001
Month 12	5	22.38	5.038	(12.18, 32.58)	<.001
Month 18	5	14.38	5.038	(4.18, 24.58)	0.007
Month 24	5	11.38	5.038	(1.18, 21.58)	0.030
Month 36	5	9.38	5.038	(-0.82, 19.58)	0.070
Month 48	3	14.43	6.529	(1.22, 27.65)	0.033
Month 60	4	18.13	5.634	(6.73, 29.53)	0.003

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	-3.11	3.565	(-10.16, 3.93)	0.384
Month 3	25	9.19	3.566	(2.15, 16.24)	0.011
Month 6	24	7.90	3.651	(0.68, 15.11)	0.032
Month 9	19	9.47	4.086	(1.40, 17.55)	0.022
Month 12	15	18.14	4.599	(9.05, 27.23)	<.001
Month 18	10	12.78	5.649	(1.62, 23.95)	0.025
Month 24	13	16.04	4.941	(6.27, 25.80)	0.001
Month 36	10	21.52	5.634	(10.38, 32.65)	<.001
Month 48	8	20.41	6.298	(7.97, 32.86)	0.001
Month 60	9	20.31	5.946	(8.56, 32.06)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	7.81	3.454	(0.82, 14.79)	0.029
Month 3	7	5.73	3.193	(-0.73, 12.19)	0.080
Month 6	6	8.12	3.448	(1.15, 15.09)	0.024
Month 9	5	2.84	3.774	(-4.79, 10.48)	0.456
Month 12	5	2.84	3.774	(-4.79, 10.48)	0.456
Month 18	4	5.32	4.224	(-3.23, 13.86)	0.215
Month 24	5	3.84	3.774	(-3.79, 11.48)	0.315
Month 36	5	-1.16	3.774	(-8.79, 6.48)	0.761
Month 48	3	5.59	4.907	(-4.34, 15.52)	0.262
Month 60	4	11.09	4.219	(2.56, 19.63)	0.012

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	35	2.05	2.350	(-2.59, 6.68)	0.385
Month 3	33	8.16	2.417	(3.39, 12.92)	<.001
Month 6	32	7.67	2.456	(2.83, 12.52)	0.002
Month 9	25	10.61	2.778	(5.13, 16.09)	<.001
Month 12	18	17.92	3.272	(11.46, 24.37)	<.001
Month 18	13	21.58	3.851	(13.98, 29.18)	<.001
Month 24	15	20.32	3.588	(13.24, 27.40)	<.001
Month 36	12	19.93	4.023	(12.00, 27.87)	<.001
Month 48	9	18.99	4.628	(9.86, 28.12)	<.001
Month 60	10	21.68	4.392	(13.02, 30.34)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in

PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

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Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	6.79	2.790	(1.29, 12.28)	0.016
Month 3	39	15.50	2.854	(9.87, 21.12)	<.001
Month 6	37	14.70	2.930	(8.93, 20.47)	<.001
Month 9	29	16.06	3.310	(9.54, 22.58)	<.001
Month 12	22	22.73	3.799	(15.24, 30.21)	<.001
Month 18	17	22.40	4.323	(13.88, 30.92)	<.001
Month 24	19	24.59	4.090	(16.54, 32.65)	<.001
Month 36	16	14.90	4.471	(6.09, 23.71)	0.001
Month 48	11	23.14	5.376	(12.55, 33.73)	<.001
Month 60	14	21.02	4.762	(11.64, 30.40)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	1.74	3.095	(-4.36, 7.84)	0.575
Month 3	39	18.49	3.174	(12.24, 24.74)	<.001
Month 6	37	20.04	3.257	(13.62, 26.46)	<.001
Month 9	29	23.36	3.679	(16.11, 30.61)	<.001
Month 12	22	28.62	4.224	(20.30, 36.94)	<.001
Month 18	17	29.63	4.805	(20.16, 39.09)	<.001
Month 24	19	32.56	4.551	(23.60, 41.53)	<.001
Month 36	16	26.41	4.960	(16.64, 36.18)	<.001
Month 48	11	35.89	5.975	(24.12, 47.66)	<.001
Month 60	14	38.49	5.295	(28.05, 48.92)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	41	2.36	1.984	(-1.55, 6.27)	0.235
Month 3	39	10.62	2.032	(6.62, 14.62)	<.001
Month 6	37	10.39	2.088	(6.28, 14.51)	<.001
Month 9	29	12.73	2.357	(8.09, 17.38)	<.001
Month 12	22	18.49	2.705	(13.16, 23.82)	<.001
Month 18	17	17.25	3.078	(11.19, 23.32)	<.001
Month 24	19	18.08	2.912	(12.34, 23.81)	<.001
Month 36	16	15.40	3.179	(9.13, 21.66)	<.001
Month 48	11	18.95	3.827	(11.41, 26.49)	<.001
Month 60	14	19.55	3.392	(12.87, 26.23)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	-3.34	3.036	(-9.33, 2.65)	0.273
Month 3	30	8.23	2.986	(2.34, 14.12)	0.006
Month 6	29	9.90	3.041	(3.90, 15.90)	0.001
Month 9	23	12.32	3.408	(5.60, 19.05)	<.001
Month 12	19	18.10	3.750	(10.70, 25.50)	<.001
Month 18	14	11.58	4.376	(2.95, 20.21)	0.009
Month 24	17	12.31	3.965	(4.49, 20.14)	0.002
Month 36	14	16.11	4.369	(7.50, 24.73)	<.001
Month 48	10	18.55	5.169	(8.35, 28.74)	<.001
Month 60	13	19.05	4.536	(10.10, 28.00)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	40	1.34	2.112	(-2.82, 5.50)	0.526
Month 3	39	7.52	2.137	(3.31, 11.73)	<.001
Month 6	37	7.43	2.195	(3.11, 11.76)	<.001
Month 9	29	9.16	2.478	(4.27, 14.04)	<.001
Month 12	22	13.38	2.844	(7.78, 18.99)	<.001
Month 18	16	17.30	3.336	(10.73, 23.88)	<.001
Month 24	19	15.00	3.062	(8.97, 21.04)	<.001
Month 36	16	12.98	3.341	(6.40, 19.56)	<.001
Month 48	11	14.33	4.023	(6.40, 22.25)	<.001
Month 60	14	18.38	3.566	(11.35, 25.40)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	19	9.23	4.245	(0.82, 17.63)	0.032
Month 3	20	17.56	4.133	(9.38, 25.75)	<.001
Month 6	19	13.51	4.252	(5.10, 21.93)	0.002
Month 9	15	18.11	4.788	(8.64, 27.59)	<.001
Month 12	13	24.44	5.126	(14.29, 34.59)	<.001
Month 18	10	25.53	5.845	(13.96, 37.11)	<.001
Month 24	11	27.31	5.572	(16.28, 38.35)	<.001
Month 36	9	21.30	6.181	(9.06, 33.54)	<.001
Month 48	6	22.50	7.564	(7.52, 37.47)	0.004
Month 60	10	21.97	5.849	(10.39, 33.56)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	6.05	3.726	(-1.34, 13.43)	0.107
Month 3	20	13.16	3.987	(5.26, 21.06)	0.001
Month 6	19	16.78	4.083	(8.69, 24.87)	<.001
Month 9	15	14.92	4.596	(5.81, 24.03)	0.002
Month 12	10	23.32	5.635	(12.15, 34.48)	<.001
Month 18	8	21.79	6.301	(9.30, 34.28)	<.001
Month 24	9	24.12	5.949	(12.34, 35.91)	<.001
Month 36	8	11.66	6.320	(-0.86, 24.18)	0.068
Month 48	6	28.12	7.265	(13.73, 42.52)	<.001
Month 60	4	18.98	8.911	(1.33, 36.64)	0.035

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	19	5.89	3.749	(-1.54, 13.31)	0.119
Month 3	20	18.95	3.655	(11.71, 26.18)	<.001
Month 6	19	23.93	3.751	(16.51, 31.36)	<.001
Month 9	15	25.58	4.231	(17.20, 33.95)	<.001
Month 12	13	30.80	4.535	(21.82, 39.78)	<.001
Month 18	10	31.44	5.168	(21.20, 41.67)	<.001
Month 24	11	34.39	4.931	(24.62, 44.15)	<.001
Month 36	9	32.11	5.459	(21.30, 42.92)	<.001
Month 48	6	40.36	6.671	(27.16, 53.57)	<.001
Month 60	10	40.21	5.170	(29.98, 50.45)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	2.43	4.875	(-7.23, 12.09)	0.619
Month 3	20	18.28	5.220	(7.94, 28.63)	<.001
Month 6	19	17.00	5.348	(6.40, 27.59)	0.002
Month 9	15	22.49	6.019	(10.56, 34.41)	<.001
Month 12	10	28.20	7.401	(13.53, 42.87)	<.001
Month 18	8	27.03	8.263	(10.65, 43.40)	0.001
Month 24	9	33.78	7.794	(18.34, 49.23)	<.001
Month 36	8	24.67	8.256	(8.31, 41.03)	0.003
Month 48	6	34.61	9.521	(15.75, 53.48)	<.001
Month 60	4	33.46	11.705	(10.26, 56.65)	0.005

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	19	4.20	2.795	(-1.33, 9.73)	0.136
Month 3	20	11.70	2.723	(6.31, 17.09)	<.001
Month 6	19	11.54	2.801	(5.99, 17.08)	<.001
Month 9	15	12.81	3.153	(6.57, 19.05)	<.001
Month 12	13	20.10	3.379	(13.41, 26.79)	<.001
Month 18	10	19.27	3.852	(11.64, 26.90)	<.001
Month 24	11	21.62	3.672	(14.35, 28.89)	<.001
Month 36	9	20.06	4.066	(12.01, 28.11)	<.001
Month 48	6	21.46	4.972	(11.62, 31.31)	<.001
Month 60	10	21.97	3.852	(14.34, 29.59)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	3.17	2.905	(-2.59, 8.93)	0.277
Month 3	20	9.87	3.110	(3.71, 16.04)	0.002
Month 6	19	10.00	3.189	(3.68, 16.32)	0.002
Month 9	15	12.64	3.591	(5.53, 19.76)	<.001
Month 12	10	18.49	4.400	(9.77, 27.20)	<.001
Month 18	8	16.78	4.916	(7.04, 26.52)	<.001
Month 24	9	16.68	4.639	(7.49, 25.87)	<.001
Month 36	8	12.60	4.930	(2.83, 22.36)	0.012
Month 48	6	18.77	5.675	(7.52, 30.01)	0.001
Month 60	4	15.31	6.981	(1.48, 29.15)	0.030

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	-0.84	4.507	(-9.78, 8.11)	0.853
Month 3	16	9.32	4.227	(0.93, 17.71)	0.030
Month 6	16	10.24	4.228	(1.85, 18.63)	0.017
Month 9	12	11.18	4.866	(1.52, 20.84)	0.024
Month 12	11	22.61	5.086	(12.52, 32.71)	<.001
Month 18	8	15.21	5.968	(3.37, 27.06)	0.012
Month 24	10	19.24	5.337	(8.65, 29.83)	<.001
Month 36	8	20.84	5.961	(9.01, 32.67)	<.001
Month 48	5	24.94	7.544	(9.97, 39.91)	0.001
Month 60	9	24.45	5.625	(13.29, 35.61)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	-1.46	4.131	(-9.67, 6.75)	0.724
Month 3	15	7.72	4.245	(-0.71, 16.16)	0.072
Month 6	14	9.47	4.393	(0.73, 18.20)	0.034
Month 9	12	13.81	4.746	(4.38, 23.24)	0.005
Month 12	9	14.45	5.484	(3.55, 25.35)	0.010
Month 18	7	10.73	6.220	(-1.63, 23.10)	0.088
Month 24	8	8.48	5.812	(-3.07, 20.03)	0.148
Month 36	7	12.07	6.235	(-0.32, 24.46)	0.056
Month 48	6	12.40	6.729	(-0.98, 25.77)	0.069
Month 60	4	9.35	8.230	(-7.01, 25.70)	0.259

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	18	4.63	3.005	(-1.32, 10.58)	0.126
Month 3	20	8.31	2.846	(2.68, 13.95)	0.004
Month 6	19	11.17	2.922	(5.39, 16.96)	<.001
Month 9	15	12.26	3.298	(5.73, 18.79)	<.001
Month 12	13	15.18	3.531	(8.19, 22.17)	<.001
Month 18	10	17.55	4.024	(9.58, 25.51)	<.001
Month 24	11	18.13	3.838	(10.53, 25.73)	<.001
Month 36	9	15.36	4.255	(6.94, 23.79)	<.001
Month 48	6	18.97	5.206	(8.67, 29.28)	<.001
Month 60	10	20.47	4.028	(12.50, 28.45)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	1.42	3.040	(-4.61, 7.44)	0.642
Month 3	20	7.14	3.257	(0.68, 13.59)	0.031
Month 6	19	4.29	3.341	(-2.33, 10.92)	0.201
Month 9	15	5.96	3.761	(-1.49, 13.42)	0.116
Month 12	10	13.79	4.608	(4.66, 22.92)	0.003
Month 18	7	17.89	5.511	(6.97, 28.81)	0.002
Month 24	9	14.03	4.858	(4.40, 23.66)	0.005
Month 36	8	12.46	5.155	(2.24, 22.67)	0.017
Month 48	6	12.45	5.949	(0.66, 24.24)	0.039
Month 60	4	15.26	7.332	(0.73, 29.79)	0.040

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	5.836	(-7.54, 17.67)	0.401
Month 3	4	18.82	5.836	(6.21, 31.42)	0.007
Month 6	3	13.51	6.590	(-0.73, 27.74)	0.061
Month 9	3	30.17	6.590	(15.94, 44.41)	<.001
Month 12	2	37.47	8.230	(19.69, 55.25)	<.001
Month 18	1	13.09	11.430	(-11.60, 37.79)	0.273
Month 24	3	15.17	6.590	(0.94, 29.41)	0.038
Month 36	2	-7.53	8.230	(-25.31, 10.25)	0.377
Month 48	1	-3.15	11.709	(-28.45, 22.14)	0.792
Month 60	1	-36.91	11.430	(-61.60, -12.21)	0.007

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-1.95	5.365	(-12.84, 8.94)	0.718
Month 3	8	-0.21	5.947	(-12.28, 11.87)	0.973
Month 6	6	-0.63	6.830	(-14.50, 13.23)	0.927
Month 9	7	5.32	6.322	(-7.51, 18.15)	0.406
Month 12	4	12.89	8.408	(-4.18, 29.96)	0.134
Month 18	3	3.51	9.715	(-16.21, 23.23)	0.720
Month 24	3	11.03	9.660	(-8.58, 30.64)	0.261
Month 36	1	3.48	16.924	(-30.87, 37.84)	0.838
Month 48	2	9.76	11.914	(-14.43, 33.94)	0.418
Month 60	2	12.26	11.914	(-11.93, 36.44)	0.311

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	9.33	5.673	(-2.08, 20.73)	0.107
Month 3	9	18.97	6.043	(6.82, 31.12)	0.003
Month 6	9	16.19	6.043	(4.04, 28.34)	0.010
Month 9	6	12.88	7.493	(-2.19, 27.94)	0.092
Month 12	5	23.45	8.169	(7.03, 39.87)	0.006
Month 18	4	32.82	9.063	(14.60, 51.05)	<.001
Month 24	4	34.07	9.063	(15.85, 52.30)	<.001
Month 36	4	35.32	9.063	(17.10, 53.55)	<.001
Month 48	4	41.57	9.063	(23.35, 59.80)	<.001
Month 60	3	21.26	10.438	(0.27, 42.25)	0.047

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	9.45	4.518	(0.50, 18.40)	0.039
Month 3	19	18.68	4.273	(10.21, 27.14)	<.001
Month 6	20	20.54	4.166	(12.29, 28.79)	<.001
Month 9	14	19.26	4.985	(9.39, 29.14)	<.001
Month 12	12	26.26	5.375	(15.61, 36.90)	<.001
Month 18	10	28.50	5.896	(16.82, 40.18)	<.001
Month 24	10	30.77	5.899	(19.09, 42.46)	<.001
Month 36	10	18.77	5.899	(7.09, 30.46)	0.002
Month 48	5	24.38	8.374	(7.79, 40.97)	0.004
Month 60	8	32.07	6.584	(19.03, 45.11)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	6.99	6.062	(-6.11, 20.08)	0.270
Month 3	4	24.16	6.062	(11.07, 37.26)	0.002
Month 6	3	39.93	6.742	(25.36, 54.50)	<.001
Month 9	3	48.23	6.742	(33.66, 62.80)	<.001
Month 12	2	59.34	8.317	(41.37, 77.31)	<.001
Month 18	1	53.78	11.788	(28.32, 79.25)	<.001
Month 24	3	46.13	6.742	(31.56, 60.70)	<.001
Month 36	2	57.79	8.317	(39.82, 75.76)	<.001
Month 48	1	46.20	11.656	(21.02, 71.38)	0.002
Month 60	1	53.78	11.788	(28.32, 79.25)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-14.17	7.409	(-29.21, 0.87)	0.064
Month 3	8	2.20	8.253	(-14.55, 18.96)	0.791
Month 6	6	3.76	9.523	(-15.58, 23.09)	0.696
Month 9	7	18.64	8.814	(0.75, 36.53)	0.042
Month 12	4	23.50	11.666	(-0.19, 47.18)	0.052
Month 18	3	18.29	13.464	(-9.05, 45.62)	0.183
Month 24	3	23.59	13.474	(-3.77, 50.94)	0.089
Month 36	1	1.32	23.515	(-46.41, 49.06)	0.955
Month 48	2	17.13	16.624	(-16.62, 50.88)	0.310
Month 60	2	20.23	16.624	(-13.52, 53.98)	0.232

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	10.24	7.150	(-4.13, 24.62)	0.158
Month 3	9	19.09	7.869	(3.27, 34.91)	0.019
Month 6	9	15.95	7.869	(0.13, 31.77)	0.048
Month 9	6	16.75	9.645	(-2.64, 36.14)	0.089
Month 12	5	22.42	10.614	(1.08, 43.76)	0.040
Month 18	4	31.51	11.786	(7.81, 55.21)	0.010
Month 24	4	36.89	11.786	(13.19, 60.59)	0.003
Month 36	4	39.89	11.786	(16.19, 63.59)	0.001
Month 48	4	37.54	11.786	(13.84, 61.24)	0.003
Month 60	3	37.12	13.599	(9.78, 64.47)	0.009

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	5.41	4.356	(-3.22, 14.03)	0.217
Month 3	19	21.92	4.121	(13.75, 30.08)	<.001
Month 6	20	25.24	4.017	(17.28, 33.20)	<.001
Month 9	14	22.28	4.809	(12.76, 31.81)	<.001
Month 12	12	31.04	5.185	(20.77, 41.32)	<.001
Month 18	10	30.83	5.681	(19.57, 42.08)	<.001
Month 24	10	35.00	5.686	(23.74, 46.27)	<.001
Month 36	10	26.23	5.686	(14.97, 37.50)	<.001
Month 48	5	45.52	8.034	(29.60, 61.43)	<.001
Month 60	8	44.66	6.355	(32.07, 57.25)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	3.38	5.094	(-7.62, 14.39)	0.518
Month 3	4	13.16	5.094	(2.15, 24.16)	0.023
Month 6	3	10.90	5.790	(-1.61, 23.41)	0.082
Month 9	3	24.23	5.790	(11.72, 36.74)	0.001
Month 12	2	30.08	7.181	(14.57, 45.60)	0.001
Month 18	1	8.03	10.046	(-13.68, 29.73)	0.439
Month 24	3	8.67	5.790	(-3.84, 21.17)	0.158
Month 36	2	9.23	7.181	(-6.28, 24.75)	0.221
Month 48	1	10.54	10.441	(-12.02, 33.10)	0.331
Month 60	1	-8.67	10.046	(-30.38, 13.03)	0.404

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-5.91	4.526	(-15.10, 3.28)	0.200
Month 3	8	-1.03	5.008	(-11.19, 9.14)	0.839
Month 6	6	-0.28	5.752	(-11.96, 11.40)	0.961
Month 9	7	3.85	5.325	(-6.96, 14.66)	0.474
Month 12	4	10.84	7.104	(-3.58, 25.26)	0.136
Month 18	3	2.70	8.225	(-14.00, 19.40)	0.745
Month 24	3	7.48	8.142	(-9.05, 24.01)	0.365
Month 36	1	-0.10	14.235	(-29.00, 28.80)	0.994
Month 48	2	5.08	10.014	(-15.25, 25.41)	0.615
Month 60	2	7.58	10.014	(-12.75, 27.91)	0.454

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	6.35	4.341	(-2.38, 15.08)	0.150
Month 3	9	13.42	4.758	(3.85, 22.98)	0.007
Month 6	9	9.59	4.758	(0.03, 19.16)	0.049
Month 9	6	10.65	5.890	(-1.20, 22.49)	0.077
Month 12	5	17.44	6.413	(4.55, 30.34)	0.009
Month 18	4	22.13	7.135	(7.78, 36.47)	0.003
Month 24	4	25.08	7.135	(10.73, 39.42)	<.001
Month 36	4	25.48	7.135	(11.13, 39.82)	<.001
Month 48	4	26.30	7.135	(11.96, 40.65)	<.001
Month 60	3	18.34	8.264	(1.72, 34.95)	0.031

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	4.86	2.999	(-1.08, 10.80)	0.108
Month 3	19	12.90	2.837	(7.28, 18.52)	<.001
Month 6	20	14.99	2.767	(9.50, 20.47)	<.001
Month 9	14	14.50	3.308	(7.95, 21.05)	<.001
Month 12	12	22.35	3.569	(15.28, 29.42)	<.001
Month 18	10	23.61	3.911	(15.87, 31.36)	<.001
Month 24	10	25.14	3.912	(17.39, 32.89)	<.001
Month 36	10	18.97	3.912	(11.22, 26.72)	<.001
Month 48	5	23.57	5.536	(12.60, 34.53)	<.001
Month 60	8	27.96	4.374	(19.30, 36.63)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	10.98	10.858	(-12.68, 34.64)	0.332
Month 3	4	8.73	9.137	(-11.18, 28.64)	0.358
Month 6	3	1.17	10.565	(-21.85, 24.19)	0.914
Month 9	3	16.17	10.565	(-6.85, 39.19)	0.152
Month 12	2	19.20	12.956	(-9.03, 47.43)	0.164
Month 18	1	-3.58	18.666	(-44.25, 37.09)	0.851
Month 24	3	-0.50	10.565	(-23.52, 22.52)	0.963
Month 36	2	1.70	12.956	(-26.53, 29.93)	0.898
Month 48	1	11.98	19.264	(-29.99, 53.95)	0.546
Month 60	1	-13.58	18.666	(-54.25, 27.09)	0.481

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	-12.52	6.755	(-26.31, 1.28)	0.074
Month 3	7	-3.07	7.031	(-17.43, 11.29)	0.665
Month 6	5	2.06	8.248	(-14.78, 18.91)	0.804
Month 9	6	-2.88	7.532	(-18.26, 12.50)	0.705
Month 12	4	5.44	9.368	(-13.69, 24.57)	0.566
Month 18	3	-8.55	10.981	(-30.98, 13.88)	0.442
Month 24	3	-1.50	10.697	(-23.35, 20.35)	0.889
Month 36	1	-10.95	18.582	(-48.90, 27.00)	0.560
Month 48	2	0.73	13.047	(-25.92, 27.37)	0.956
Month 60	2	0.73	13.047	(-25.92, 27.37)	0.956

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-2.59	6.254	(-15.20, 10.01)	0.680
Month 3	8	17.63	6.641	(4.25, 31.01)	0.011
Month 6	8	10.13	6.641	(-3.25, 23.51)	0.134
Month 9	6	16.67	7.732	(1.08, 32.25)	0.037
Month 12	5	16.95	8.390	(0.04, 33.86)	0.049
Month 18	4	20.79	9.394	(1.85, 39.72)	0.032
Month 24	4	23.29	9.394	(4.35, 42.22)	0.017
Month 36	4	25.79	9.394	(6.85, 44.72)	0.009
Month 48	4	22.04	9.394	(3.10, 40.97)	0.024
Month 60	3	16.75	10.888	(-5.20, 38.69)	0.131

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SCHOOL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	1.92	4.710	(-7.46, 11.30)	0.685
Month 3	12	7.82	4.319	(-0.78, 16.42)	0.074
Month 6	14	15.52	3.986	(7.58, 23.46)	<.001
Month 9	9	17.78	4.966	(7.89, 27.66)	<.001
Month 12	9	26.51	4.965	(16.63, 36.40)	<.001
Month 18	7	20.25	5.630	(9.04, 31.46)	<.001
Month 24	8	21.98	5.271	(11.48, 32.47)	<.001
Month 36	8	23.23	5.271	(12.73, 33.72)	<.001
Month 48	4	26.43	7.460	(11.57, 41.28)	<.001
Month 60	7	31.46	5.635	(20.24, 42.68)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-3.44	6.096	(-16.61, 9.73)	0.582
Month 3	4	11.56	6.096	(-1.61, 24.73)	0.080
Month 6	3	16.68	6.837	(1.91, 31.45)	0.030
Month 9	3	25.01	6.837	(10.24, 39.78)	0.003
Month 12	2	32.13	8.547	(13.67, 50.60)	0.002
Month 18	1	19.63	11.965	(-6.21, 45.48)	0.125
Month 24	3	10.01	6.837	(-4.76, 24.78)	0.167
Month 36	2	32.13	8.547	(13.67, 50.60)	0.002
Month 48	1	14.63	11.965	(-11.21, 40.48)	0.243
Month 60	1	29.63	11.965	(3.79, 55.48)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	10	-5.21	4.147	(-13.63, 3.21)	0.217
Month 3	8	0.68	4.620	(-8.70, 10.06)	0.884
Month 6	6	-3.50	5.326	(-14.31, 7.31)	0.515
Month 9	7	5.09	4.930	(-4.92, 15.10)	0.309
Month 12	4	11.37	6.534	(-1.90, 24.63)	0.091
Month 18	3	9.61	7.544	(-5.70, 24.93)	0.211
Month 24	3	10.31	7.530	(-4.97, 25.60)	0.179
Month 36	1	4.52	13.130	(-22.13, 31.18)	0.733
Month 48	2	3.08	9.264	(-15.73, 21.88)	0.742
Month 60	2	8.08	9.264	(-10.73, 26.88)	0.389

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	6.44	3.799	(-1.21, 14.08)	0.097
Month 3	9	6.18	4.186	(-2.24, 14.61)	0.146
Month 6	9	5.63	4.186	(-2.79, 14.05)	0.185
Month 9	6	3.79	5.132	(-6.53, 14.12)	0.463
Month 12	5	12.54	5.642	(1.19, 23.89)	0.031
Month 18	3	20.56	7.275	(5.92, 35.19)	0.007
Month 24	4	17.94	6.279	(5.31, 30.57)	0.006
Month 36	4	15.44	6.279	(2.81, 28.07)	0.018
Month 48	4	15.44	6.279	(2.81, 28.07)	0.018
Month 60	3	16.84	7.293	(2.17, 31.51)	0.025

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 201r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment
Parameter: SOCIAL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	3.73	3.581	(-3.36, 10.83)	0.300
Month 3	19	9.39	3.286	(2.88, 15.90)	0.005
Month 6	20	11.12	3.205	(4.77, 17.47)	<.001
Month 9	14	9.03	3.831	(1.43, 16.62)	0.020
Month 12	12	14.56	4.138	(6.36, 22.76)	<.001
Month 18	10	20.35	4.530	(11.38, 29.33)	<.001
Month 24	10	20.21	4.532	(11.24, 29.19)	<.001
Month 36	10	13.71	4.532	(4.74, 22.69)	0.003
Month 48	5	22.05	6.409	(9.36, 34.75)	<.001
Month 60	8	22.69	5.067	(12.65, 32.72)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	6.23	6.162	(-6.55, 19.01)	0.323
Month 3	6	6.99	6.230	(-5.93, 19.91)	0.274
Month 6	6	11.72	6.230	(-1.20, 24.64)	0.073
Month 9	3	12.03	8.774	(-6.16, 30.23)	0.184
Month 12	2	17.71	10.689	(-4.46, 39.87)	0.112
Month 18	2	21.51	10.689	(-0.66, 43.67)	0.057
Month 24	2	16.61	10.689	(-5.56, 38.77)	0.135
Month 36	2	9.01	10.689	(-13.16, 31.17)	0.408
Month 48	2	17.71	10.689	(-4.46, 39.87)	0.112
Month 60	2	19.86	10.689	(-2.31, 42.02)	0.077

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	6.49	2.678	(1.20, 11.79)	0.017
Month 3	23	15.34	2.680	(10.04, 20.64)	<.001
Month 6	20	16.51	2.871	(10.83, 22.18)	<.001
Month 9	19	20.97	2.945	(15.15, 26.79)	<.001
Month 12	16	24.55	3.210	(18.21, 30.90)	<.001
Month 18	12	25.95	3.706	(18.62, 33.27)	<.001
Month 24	14	27.62	3.433	(20.83, 34.40)	<.001
Month 36	12	23.77	3.719	(16.42, 31.12)	<.001
Month 48	7	27.63	4.855	(18.04, 37.23)	<.001
Month 60	9	27.32	4.288	(18.85, 35.80)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	3.24	5.309	(-7.45, 13.93)	0.545
Month 3	9	12.51	5.029	(2.38, 22.64)	0.017
Month 6	10	12.07	4.743	(2.52, 21.62)	0.014
Month 9	7	13.55	5.676	(2.12, 24.98)	0.021
Month 12	5	24.35	6.703	(10.85, 37.85)	<.001
Month 18	4	13.92	7.497	(-1.18, 29.02)	0.070
Month 24	4	21.93	7.526	(6.77, 37.09)	0.006
Month 36	3	21.13	8.717	(3.58, 38.69)	0.019
Month 48	3	27.33	8.717	(9.78, 44.89)	0.003
Month 60	3	27.30	8.717	(9.74, 44.86)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	8.23	2.921	(2.45, 14.01)	0.006
Month 3	22	15.73	2.853	(10.08, 21.37)	<.001
Month 6	20	15.79	2.996	(9.86, 21.71)	<.001
Month 9	16	17.94	3.347	(11.32, 24.56)	<.001
Month 12	12	21.56	3.864	(13.92, 29.21)	<.001
Month 18	10	21.42	4.232	(13.05, 29.80)	<.001
Month 24	12	21.94	3.866	(14.29, 29.59)	<.001
Month 36	11	18.91	4.043	(10.91, 26.91)	<.001
Month 48	8	22.90	4.740	(13.52, 32.28)	<.001
Month 60	9	26.44	4.474	(17.59, 35.29)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	3.56	3.340	(-3.08, 10.19)	0.290
Month 3	16	11.61	3.355	(4.95, 18.28)	<.001
Month 6	16	14.04	3.336	(7.41, 20.66)	<.001
Month 9	13	18.20	3.706	(10.84, 25.56)	<.001
Month 12	11	25.74	4.021	(17.75, 33.73)	<.001
Month 18	8	23.71	4.717	(14.34, 33.08)	<.001
Month 24	8	28.91	4.722	(19.53, 38.29)	<.001
Month 36	6	23.13	5.487	(12.23, 34.03)	<.001
Month 48	4	30.61	6.717	(17.27, 43.95)	<.001
Month 60	5	25.36	5.988	(13.47, 37.26)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	8.73	2.422	(3.95, 13.50)	<.001
Month 3	30	14.82	2.381	(10.12, 19.51)	<.001
Month 6	29	17.46	2.422	(12.68, 22.24)	<.001
Month 9	23	20.42	2.720	(15.05, 25.79)	<.001
Month 12	19	25.51	2.992	(19.61, 31.41)	<.001
Month 18	14	23.74	3.486	(16.86, 30.61)	<.001
Month 24	17	26.43	3.163	(20.19, 32.67)	<.001
Month 36	14	20.95	3.491	(14.06, 27.84)	<.001
Month 48	9	26.76	4.349	(18.18, 35.34)	<.001
Month 60	11	28.19	3.939	(20.42, 35.96)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	3.99	2.049	(-0.85, 8.84)	0.092
Month 3	3	-0.34	2.049	(-5.18, 4.51)	0.873
Month 6	2	-1.13	2.465	(-6.96, 4.69)	0.659
Month 9	2	-3.18	2.465	(-9.01, 2.64)	0.237
Month 12	2	1.07	2.465	(-4.76, 6.89)	0.679
Month 18	2	3.27	2.465	(-2.56, 9.09)	0.227
Month 24	1	-4.27	3.582	(-12.74, 4.20)	0.272
Month 36	1	7.73	3.582	(-0.74, 16.20)	0.068
Month 48	1	18.63	3.582	(10.16, 27.10)	0.001
Month 60	1	13.13	3.582	(4.66, 21.60)	0.008

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-9.84	7.424	(-25.32, 5.65)	0.200
Month 3	5	14.72	7.424	(-0.76, 30.21)	0.061
Month 6	5	5.62	7.594	(-10.22, 21.46)	0.468
Month 9	4	13.54	8.315	(-3.81, 30.88)	0.119
Month 12	2	24.15	11.719	(-0.30, 48.60)	0.053
Month 18	2	29.30	11.719	(4.85, 53.75)	0.021
Month 24	2	32.00	11.719	(7.55, 56.45)	0.013
Month 36	2	31.75	11.719	(7.30, 56.20)	0.014
Month 48	2	29.05	11.719	(4.60, 53.50)	0.022
Month 60	2	26.85	11.719	(2.40, 51.30)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	-3.32	4.043	(-11.43, 4.79)	0.415
Month 3	10	13.46	4.243	(4.95, 21.98)	0.003
Month 6	11	5.20	4.057	(-2.94, 13.34)	0.205
Month 9	7	14.47	5.070	(4.29, 24.64)	0.006
Month 12	4	20.12	6.704	(6.67, 33.57)	0.004
Month 18	4	20.25	6.704	(6.79, 33.70)	0.004
Month 24	5	19.63	5.996	(7.60, 31.67)	0.002
Month 36	4	20.37	6.704	(6.92, 33.82)	0.004
Month 48	3	18.13	7.765	(2.55, 33.72)	0.023
Month 60	4	15.20	6.704	(1.74, 28.65)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	9.64	2.644	(4.43, 14.86)	<.001
Month 3	28	13.92	2.548	(8.89, 18.95)	<.001
Month 6	25	18.57	2.696	(13.24, 23.89)	<.001
Month 9	22	18.85	2.876	(13.17, 24.53)	<.001
Month 12	19	24.62	3.091	(18.51, 30.72)	<.001
Month 18	14	23.35	3.602	(16.24, 30.46)	<.001
Month 24	15	26.94	3.484	(20.06, 33.82)	<.001
Month 36	13	21.61	3.751	(14.20, 29.01)	<.001
Month 48	9	29.19	4.492	(20.33, 38.06)	<.001
Month 60	10	30.87	4.264	(22.45, 39.29)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	4.095	(-3.77, 13.92)	0.237
Month 3	4	17.37	4.095	(8.53, 26.22)	<.001
Month 6	3	20.89	4.590	(10.97, 30.80)	<.001
Month 9	3	32.45	4.590	(22.54, 42.37)	<.001
Month 12	2	40.03	5.702	(27.71, 52.35)	<.001
Month 18	1	23.58	7.943	(6.42, 40.74)	0.011
Month 24	3	21.59	4.590	(11.67, 31.50)	<.001
Month 36	2	25.88	5.702	(13.56, 38.20)	<.001
Month 48	1	22.77	8.145	(5.18, 40.37)	0.015
Month 60	1	12.68	7.943	(-4.48, 29.84)	0.134

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	6.04	2.397	(1.31, 10.76)	0.013
Month 3	34	13.25	2.362	(8.59, 17.90)	<.001
Month 6	33	14.29	2.398	(9.56, 19.02)	<.001
Month 9	26	16.18	2.702	(10.85, 21.51)	<.001
Month 12	21	21.88	3.005	(15.95, 27.80)	<.001
Month 18	17	22.30	3.340	(15.72, 28.88)	<.001
Month 24	17	25.66	3.342	(19.07, 32.24)	<.001
Month 36	15	20.51	3.562	(13.49, 27.53)	<.001
Month 48	11	26.73	4.154	(18.54, 34.92)	<.001
Month 60	13	27.66	3.822	(20.12, 35.19)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	6.24	2.229	(1.84, 10.63)	0.006
Month 3	37	13.25	2.199	(8.92, 17.58)	<.001
Month 6	35	14.21	2.261	(9.75, 18.66)	<.001
Month 9	28	17.29	2.528	(12.31, 22.28)	<.001
Month 12	22	22.93	2.851	(17.31, 28.55)	<.001
Month 18	17	21.69	3.243	(15.30, 28.08)	<.001
Month 24	19	24.19	3.070	(18.15, 30.24)	<.001
Month 36	16	19.83	3.351	(13.23, 26.43)	<.001
Month 48	11	25.32	4.032	(17.37, 33.26)	<.001
Month 60	13	25.88	3.711	(18.57, 33.19)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	6.07	2.211	(1.71, 10.42)	0.007
Month 3	38	13.81	2.182	(9.51, 18.11)	<.001
Month 6	36	14.84	2.242	(10.42, 19.26)	<.001
Month 9	29	17.82	2.498	(12.90, 22.74)	<.001
Month 12	23	23.35	2.804	(17.83, 28.88)	<.001
Month 18	18	22.42	3.170	(16.17, 28.66)	<.001
Month 24	20	24.94	3.009	(19.02, 30.87)	<.001
Month 36	17	20.97	3.269	(14.53, 27.41)	<.001
Month 48	12	26.20	3.882	(18.55, 33.85)	<.001
Month 60	14	26.60	3.596	(19.51, 33.68)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	6.07	2.211	(1.71, 10.42)	0.007
Month 3	38	13.81	2.182	(9.51, 18.11)	<.001
Month 6	36	14.84	2.242	(10.42, 19.26)	<.001
Month 9	29	17.82	2.498	(12.90, 22.74)	<.001
Month 12	23	23.35	2.804	(17.83, 28.88)	<.001
Month 18	18	22.42	3.170	(16.17, 28.66)	<.001
Month 24	20	24.94	3.009	(19.02, 30.87)	<.001
Month 36	17	20.97	3.269	(14.53, 27.41)	<.001
Month 48	12	26.20	3.882	(18.55, 33.85)	<.001
Month 60	14	26.60	3.596	(19.51, 33.68)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	6.07	2.211	(1.71, 10.42)	0.007
Month 3	38	13.81	2.182	(9.51, 18.11)	<.001
Month 6	36	14.84	2.242	(10.42, 19.26)	<.001
Month 9	29	17.82	2.498	(12.90, 22.74)	<.001
Month 12	23	23.35	2.804	(17.83, 28.88)	<.001
Month 18	18	22.42	3.170	(16.17, 28.66)	<.001
Month 24	20	24.94	3.009	(19.02, 30.87)	<.001
Month 36	17	20.97	3.269	(14.53, 27.41)	<.001
Month 48	12	26.20	3.882	(18.55, 33.85)	<.001
Month 60	14	26.60	3.596	(19.51, 33.68)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	13.72	4.304	(5.12, 22.32)	0.002
Month 3	12	16.59	4.309	(7.98, 25.20)	<.001
Month 6	13	19.15	4.139	(10.88, 27.42)	<.001
Month 9	10	18.27	4.720	(8.84, 27.70)	<.001
Month 12	7	31.12	5.639	(19.85, 42.39)	<.001
Month 18	6	29.88	6.088	(17.72, 42.05)	<.001
Month 24	5	38.38	6.689	(25.02, 51.75)	<.001
Month 36	5	28.56	6.689	(15.20, 41.93)	<.001
Month 48	1	41.06	14.940	(11.21, 70.92)	0.008
Month 60	3	37.61	8.620	(20.39, 54.83)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	2.59	2.585	(-2.52, 7.69)	0.319
Month 3	26	12.57	2.532	(7.57, 17.57)	<.001
Month 6	23	12.88	2.693	(7.56, 18.20)	<.001
Month 9	19	17.88	2.962	(12.03, 23.73)	<.001
Month 12	16	20.03	3.226	(13.66, 26.40)	<.001
Month 18	12	18.98	3.725	(11.63, 26.34)	<.001
Month 24	15	20.17	3.334	(13.58, 26.75)	<.001
Month 36	12	17.90	3.734	(10.52, 25.27)	<.001
Month 48	11	23.45	3.891	(15.77, 31.13)	<.001
Month 60	11	22.81	3.891	(15.13, 30.49)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	5.22	3.292	(-1.34, 11.77)	0.117
Month 3	13	13.21	3.163	(6.92, 19.51)	<.001
Month 6	12	13.99	3.298	(7.43, 20.56)	<.001
Month 9	11	13.18	3.442	(6.32, 20.03)	<.001
Month 12	10	18.88	3.606	(11.70, 26.06)	<.001
Month 18	7	22.85	4.312	(14.27, 31.44)	<.001
Month 24	7	24.54	4.310	(15.95, 33.12)	<.001
Month 36	6	15.26	4.667	(5.97, 24.55)	0.002
Month 48	4	25.26	5.730	(13.85, 36.67)	<.001
Month 60	6	26.01	4.670	(16.71, 35.31)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	6.89	3.011	(0.93, 12.85)	0.024
Month 3	23	13.91	3.008	(7.95, 19.86)	<.001
Month 6	22	14.97	3.075	(8.88, 21.05)	<.001
Month 9	16	19.68	3.605	(12.54, 26.81)	<.001
Month 12	11	25.24	4.354	(16.62, 33.85)	<.001
Month 18	9	22.89	4.808	(13.38, 32.40)	<.001
Month 24	12	24.95	4.164	(16.71, 33.19)	<.001
Month 36	10	25.12	4.565	(16.09, 34.15)	<.001
Month 48	7	25.96	5.451	(15.18, 36.75)	<.001
Month 60	7	25.94	5.459	(15.14, 36.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	9.07	9.047	(-14.18, 32.33)	0.362
Month 3	2	17.77	9.047	(-5.48, 41.03)	0.107
Month 6	2	22.67	9.047	(-0.58, 45.93)	0.054
Month 9	2	25.92	9.047	(2.67, 49.18)	0.035
Month 12	2	34.12	9.047	(10.87, 57.38)	0.013
Month 18	2	21.62	9.047	(-1.63, 44.88)	0.062
Month 24	1	23.28	13.023	(-10.19, 56.76)	0.134
Month 36	1	13.48	13.023	(-19.99, 46.96)	0.348
Month 48	1	21.18	13.023	(-12.29, 54.66)	0.165
Month 60	1	26.58	13.023	(-6.89, 60.06)	0.097

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	5.36	2.814	(-0.20, 10.92)	0.058
Month 3	24	12.89	2.695	(7.57, 18.21)	<.001
Month 6	25	14.89	2.641	(9.67, 20.11)	<.001
Month 9	19	15.37	3.032	(9.38, 21.36)	<.001
Month 12	17	19.99	3.202	(13.67, 26.32)	<.001
Month 18	14	21.94	3.528	(14.97, 28.91)	<.001
Month 24	13	23.34	3.665	(16.10, 30.58)	<.001
Month 36	13	18.74	3.665	(11.50, 25.98)	<.001
Month 48	8	25.96	4.670	(16.73, 35.19)	<.001
Month 60	11	28.59	3.981	(20.73, 36.46)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	7.36	3.603	(0.16, 14.55)	0.045
Month 3	14	15.76	3.736	(8.30, 23.22)	<.001
Month 6	11	14.73	4.194	(6.36, 23.10)	<.001
Month 9	10	22.12	4.400	(13.34, 30.90)	<.001
Month 12	6	32.67	5.683	(21.33, 44.01)	<.001
Month 18	4	23.54	6.975	(9.62, 37.46)	0.001
Month 24	7	27.99	5.257	(17.49, 38.48)	<.001
Month 36	4	27.48	7.034	(13.44, 41.52)	<.001
Month 48	4	26.13	6.959	(12.24, 40.02)	<.001
Month 60	3	20.15	8.073	(4.04, 36.27)	0.015

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	16.85	4.578	(6.77, 26.93)	0.004
Month 3	3	18.55	4.578	(8.47, 28.63)	0.002
Month 6	3	21.82	4.578	(11.74, 31.89)	<.001
Month 9	2	18.79	5.622	(6.42, 31.17)	0.007
Month 12	2	31.29	5.622	(18.92, 43.67)	<.001
Month 18	2	28.59	5.622	(16.22, 40.97)	<.001
Month 24	2	30.37	5.674	(17.88, 42.86)	<.001
Month 36	2	35.27	5.674	(22.78, 47.76)	<.001
Month 48	1	35.46	7.917	(18.04, 52.89)	<.001
Month 60	2	35.27	5.674	(22.78, 47.76)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	34	5.22	2.273	(0.74, 9.70)	0.023
Month 3	35	13.51	2.240	(9.10, 17.93)	<.001
Month 6	33	14.38	2.307	(9.83, 18.93)	<.001
Month 9	27	17.96	2.550	(12.93, 22.98)	<.001
Month 12	21	22.86	2.892	(17.16, 28.56)	<.001
Month 18	16	21.89	3.313	(15.36, 28.42)	<.001
Month 24	18	23.91	3.123	(17.76, 30.07)	<.001
Month 36	15	18.55	3.426	(11.80, 25.30)	<.001
Month 48	11	25.26	3.995	(17.38, 33.13)	<.001
Month 60	12	24.19	3.830	(16.64, 31.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	1.90	3.297	(-4.65, 8.45)	0.566
Month 3	15	12.77	3.186	(6.45, 19.10)	<.001
Month 6	12	14.77	3.560	(7.70, 21.84)	<.001
Month 9	12	19.13	3.559	(12.06, 26.20)	<.001
Month 12	11	18.95	3.718	(11.57, 26.33)	<.001
Month 18	8	17.83	4.359	(9.17, 26.49)	<.001
Month 24	9	16.59	4.113	(8.42, 24.75)	<.001
Month 36	8	12.55	4.373	(3.87, 21.23)	0.005
Month 48	8	21.31	4.359	(12.65, 29.96)	<.001
Month 60	7	22.71	4.661	(13.46, 31.97)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	8.74	2.903	(3.00, 14.48)	0.003
Month 3	23	14.59	2.903	(8.84, 20.33)	<.001
Month 6	24	15.20	2.841	(9.58, 20.82)	<.001
Month 9	17	16.71	3.380	(10.03, 23.40)	<.001
Month 12	12	27.53	4.024	(19.57, 35.49)	<.001
Month 18	10	26.22	4.403	(17.51, 34.94)	<.001
Month 24	11	31.73	4.199	(23.42, 40.04)	<.001
Month 36	9	28.32	4.648	(19.13, 37.52)	<.001
Month 48	4	34.00	6.960	(20.23, 47.77)	<.001
Month 60	7	29.99	5.263	(19.58, 40.40)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	7.26	4.824	(-2.49, 17.01)	0.140
Month 3	7	14.32	4.473	(5.28, 23.36)	0.003
Month 6	6	17.40	4.826	(7.65, 27.16)	<.001
Month 9	5	18.44	5.284	(7.76, 29.12)	0.001
Month 12	5	19.50	5.284	(8.82, 30.18)	<.001
Month 18	5	18.40	5.284	(7.72, 29.08)	0.001
Month 24	5	15.78	5.284	(5.10, 26.46)	0.005
Month 36	5	13.60	5.284	(2.92, 24.28)	0.014
Month 48	3	21.51	6.833	(7.70, 35.32)	0.003
Month 60	4	23.52	5.909	(11.58, 35.46)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	31	5.72	2.460	(0.87, 10.58)	0.021
Month 3	31	13.61	2.460	(8.75, 18.46)	<.001
Month 6	30	14.12	2.502	(9.18, 19.05)	<.001
Month 9	24	17.68	2.797	(12.16, 23.20)	<.001
Month 12	18	24.46	3.228	(18.09, 30.83)	<.001
Month 18	13	24.22	3.798	(16.73, 31.71)	<.001
Month 24	15	28.07	3.538	(21.09, 35.06)	<.001
Month 36	12	24.17	3.964	(16.35, 31.99)	<.001
Month 48	9	28.15	4.568	(19.14, 37.16)	<.001
Month 60	10	28.11	4.334	(19.56, 36.66)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate

with an Variance Component covariance structure.

Table 202p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	4.57	2.190	(0.25, 8.88)	0.038
Month 3	37	13.79	2.160	(9.53, 18.04)	<.001
Month 6	35	14.58	2.221	(10.21, 18.96)	<.001
Month 9	28	17.50	2.483	(12.61, 22.40)	<.001
Month 12	22	22.18	2.800	(16.66, 27.70)	<.001
Month 18	17	21.71	3.186	(15.43, 27.98)	<.001
Month 24	19	23.36	3.015	(17.42, 29.30)	<.001
Month 36	16	19.37	3.290	(12.88, 25.85)	<.001
Month 48	11	24.88	3.962	(17.07, 32.69)	<.001
Month 60	14	26.19	3.511	(19.27, 33.11)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	6.88	2.928	(1.09, 12.68)	0.020
Month 3	19	14.59	2.769	(9.11, 20.08)	<.001
Month 6	18	16.00	2.849	(10.36, 21.64)	<.001
Month 9	15	17.18	3.125	(10.99, 23.37)	<.001
Month 12	13	23.78	3.348	(17.14, 30.41)	<.001
Month 18	10	23.51	3.817	(15.95, 31.07)	<.001
Month 24	11	26.24	3.639	(19.03, 33.45)	<.001
Month 36	9	24.32	4.032	(16.33, 32.30)	<.001
Month 48	6	28.10	4.927	(18.34, 37.86)	<.001
Month 60	10	28.37	3.818	(20.81, 35.93)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	5.67	3.360	(-0.99, 12.34)	0.094
Month 3	19	13.25	3.449	(6.41, 20.09)	<.001
Month 6	18	13.91	3.538	(6.89, 20.92)	<.001
Month 9	14	18.29	4.012	(10.34, 26.25)	<.001
Month 12	10	22.32	4.756	(12.89, 31.75)	<.001
Month 18	8	20.71	5.311	(10.17, 31.24)	<.001
Month 24	9	23.09	5.013	(13.15, 33.02)	<.001
Month 36	8	17.13	5.320	(6.58, 27.68)	0.002
Month 48	6	24.48	6.130	(12.33, 36.64)	<.001
Month 60	4	21.73	7.548	(6.77, 36.70)	0.005

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	4.095	(-3.77, 13.92)	0.237
Month 3	4	17.37	4.095	(8.53, 26.22)	<.001
Month 6	3	20.89	4.590	(10.97, 30.80)	<.001
Month 9	3	32.45	4.590	(22.54, 42.37)	<.001
Month 12	2	40.03	5.702	(27.71, 52.35)	<.001
Month 18	1	23.58	7.943	(6.42, 40.74)	0.011
Month 24	3	21.59	4.590	(11.67, 31.50)	<.001
Month 36	2	25.88	5.702	(13.56, 38.20)	<.001
Month 48	1	22.77	8.145	(5.18, 40.37)	0.015
Month 60	1	12.68	7.943	(-4.48, 29.84)	0.134

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-3.29	4.879	(-13.20, 6.63)	0.505
Month 3	8	0.28	5.133	(-10.15, 10.71)	0.957
Month 6	6	1.38	5.912	(-10.63, 13.40)	0.817
Month 9	7	9.20	5.471	(-1.92, 20.32)	0.102
Month 12	4	15.71	7.263	(0.95, 30.47)	0.038
Month 18	3	8.77	8.383	(-8.26, 25.81)	0.303
Month 24	3	13.61	8.356	(-3.37, 30.59)	0.113
Month 36	1	0.63	14.624	(-29.09, 30.35)	0.966
Month 48	2	9.31	10.314	(-11.65, 30.27)	0.373
Month 60	2	12.01	10.314	(-8.95, 32.97)	0.252

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	8.79	5.347	(-1.98, 19.55)	0.107
Month 3	9	15.34	5.347	(4.58, 26.10)	0.006
Month 6	9	11.81	5.347	(1.05, 22.57)	0.032
Month 9	6	13.27	6.583	(0.02, 26.52)	0.050
Month 12	5	20.02	7.208	(5.51, 34.53)	0.008
Month 18	4	25.69	7.998	(9.59, 41.79)	0.002
Month 24	4	29.74	7.998	(13.64, 45.84)	<.001
Month 36	4	30.96	7.998	(14.86, 47.06)	<.001
Month 48	4	30.71	7.998	(14.61, 46.81)	<.001
Month 60	3	24.80	9.261	(6.15, 43.44)	0.010

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 202r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL total score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Subgroup: Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	7.15	3.246	(0.72, 13.59)	0.030
Month 3	17	16.94	3.049	(10.90, 22.98)	<.001
Month 6	18	20.30	2.965	(14.43, 26.18)	<.001
Month 9	13	19.36	3.492	(12.44, 26.28)	<.001
Month 12	12	25.54	3.629	(18.35, 32.73)	<.001
Month 18	10	26.26	3.976	(18.38, 34.14)	<.001
Month 24	10	28.71	3.979	(20.82, 36.60)	<.001
Month 36	10	21.64	3.979	(13.75, 29.53)	<.001
Month 48	5	31.47	5.627	(20.31, 42.62)	<.001
Month 60	8	33.87	4.448	(25.06, 42.69)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	4.27	7.598	(-11.49, 20.03)	0.580
Month 3	6	10.47	7.736	(-5.57, 26.51)	0.190
Month 6	6	8.80	7.736	(-7.24, 24.85)	0.267
Month 9	3	5.27	10.780	(-17.08, 27.63)	0.630
Month 12	2	7.74	13.222	(-19.68, 35.16)	0.564
Month 18	2	5.24	13.222	(-22.18, 32.66)	0.696
Month 24	2	7.74	13.222	(-19.68, 35.16)	0.564
Month 36	2	5.24	13.222	(-22.18, 32.66)	0.696
Month 48	2	12.74	13.222	(-14.68, 40.16)	0.346
Month 60	2	17.74	13.222	(-9.68, 45.16)	0.193

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	10.94	3.667	(3.69, 18.18)	0.003
Month 3	23	19.64	3.671	(12.38, 26.89)	<.001
Month 6	20	20.22	3.924	(12.47, 27.98)	<.001
Month 9	19	23.11	4.029	(15.14, 31.07)	<.001
Month 12	16	28.40	4.390	(19.72, 37.08)	<.001
Month 18	12	31.00	5.075	(20.96, 41.03)	<.001
Month 24	14	30.58	4.697	(21.30, 39.87)	<.001
Month 36	12	18.27	5.103	(8.18, 28.36)	<.001
Month 48	7	28.47	6.638	(15.35, 41.59)	<.001
Month 60	9	25.04	5.850	(13.47, 36.60)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	10.29	6.529	(-2.86, 23.44)	0.122
Month 3	9	8.84	6.167	(-3.58, 21.27)	0.158
Month 6	10	9.91	5.819	(-1.81, 21.63)	0.096
Month 9	7	7.70	6.956	(-6.31, 21.71)	0.274
Month 12	5	16.46	8.234	(-0.13, 33.04)	0.052
Month 18	4	11.25	9.201	(-7.28, 29.78)	0.228
Month 24	4	18.29	9.205	(-0.25, 36.83)	0.053
Month 36	3	18.02	10.690	(-3.51, 39.55)	0.099
Month 48	3	24.69	10.690	(3.16, 46.22)	0.026
Month 60	3	11.35	10.690	(-10.18, 32.88)	0.294

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	8.95	6.833	(-5.22, 23.12)	0.204
Month 3	6	11.42	6.861	(-2.80, 25.65)	0.110
Month 6	6	20.81	6.861	(6.58, 35.04)	0.006
Month 9	3	16.61	9.692	(-3.49, 36.71)	0.101
Month 12	2	23.06	11.805	(-1.43, 47.54)	0.064
Month 18	2	29.31	11.805	(4.82, 53.79)	0.021
Month 24	2	24.61	11.805	(0.12, 49.09)	0.049
Month 36	2	-0.44	11.805	(-24.93, 24.04)	0.970
Month 48	2	24.61	11.805	(0.12, 49.09)	0.049
Month 60	2	27.71	11.805	(3.22, 52.19)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	4.81	4.066	(-3.22, 12.85)	0.238
Month 3	23	18.93	4.068	(10.89, 26.97)	<.001
Month 6	20	21.27	4.361	(12.66, 29.89)	<.001
Month 9	19	28.43	4.473	(19.59, 37.27)	<.001
Month 12	16	29.58	4.876	(19.94, 39.22)	<.001
Month 18	12	31.83	5.628	(20.71, 42.96)	<.001
Month 24	14	35.94	5.214	(25.64, 46.25)	<.001
Month 36	12	32.44	5.640	(21.29, 43.59)	<.001
Month 48	7	37.20	7.379	(22.62, 51.79)	<.001
Month 60	9	38.78	6.518	(25.89, 51.66)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	2.71	7.805	(-13.01, 18.43)	0.730
Month 3	9	22.09	7.405	(7.18, 37.01)	0.005
Month 6	10	21.67	6.976	(7.62, 35.72)	0.003
Month 9	7	25.72	8.368	(8.86, 42.57)	0.004
Month 12	5	39.41	9.843	(19.59, 59.24)	<.001
Month 18	4	26.35	11.049	(4.10, 48.60)	0.021
Month 24	4	37.13	11.157	(14.65, 59.60)	0.002
Month 36	3	38.81	12.806	(13.02, 64.61)	0.004
Month 48	3	44.01	12.806	(18.22, 69.81)	0.001
Month 60	3	45.08	12.806	(19.29, 70.87)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	4.61	6.162	(-8.17, 17.38)	0.463
Month 3	6	4.23	6.249	(-8.73, 17.19)	0.505
Month 6	6	6.45	6.249	(-6.51, 19.41)	0.313
Month 9	3	8.57	8.781	(-9.64, 26.78)	0.340
Month 12	2	13.79	10.703	(-8.41, 35.98)	0.211
Month 18	2	16.24	10.703	(-5.96, 38.43)	0.143
Month 24	2	11.29	10.703	(-10.91, 33.48)	0.303
Month 36	2	12.94	10.703	(-9.26, 35.13)	0.240
Month 48	2	12.94	10.703	(-9.26, 35.13)	0.240
Month 60	2	14.59	10.703	(-7.61, 36.78)	0.187

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	7.27	2.472	(2.39, 12.16)	0.004
Month 3	23	13.41	2.474	(8.52, 18.30)	<.001
Month 6	20	13.67	2.649	(8.44, 18.91)	<.001
Month 9	19	16.80	2.718	(11.43, 22.17)	<.001
Month 12	16	21.70	2.963	(15.85, 27.56)	<.001
Month 18	12	22.66	3.420	(15.90, 29.42)	<.001
Month 24	14	22.94	3.168	(16.68, 29.20)	<.001
Month 36	12	18.79	3.434	(12.00, 25.58)	<.001
Month 48	7	22.76	4.478	(13.91, 31.61)	<.001
Month 60	9	21.57	3.953	(13.76, 29.39)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	3.69	4.723	(-5.82, 13.20)	0.438
Month 3	9	7.53	4.461	(-1.46, 16.52)	0.098
Month 6	10	7.37	4.221	(-1.13, 15.87)	0.088
Month 9	7	7.82	5.045	(-2.34, 17.98)	0.128
Month 12	5	16.05	5.972	(4.03, 28.08)	0.010
Month 18	4	6.84	6.674	(-6.61, 20.28)	0.311
Month 24	4	13.03	6.674	(-0.41, 26.47)	0.057
Month 36	3	12.37	7.741	(-3.22, 27.96)	0.117
Month 48	3	19.04	7.741	(3.45, 34.63)	0.018
Month 60	3	18.47	7.741	(2.88, 34.06)	0.021

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	12.23	13.644	(-46.47, 70.94)	0.465
Month 3	2	-2.88	14.857	(-66.81, 61.04)	0.864
Month 6	2	7.12	14.857	(-56.81, 71.04)	0.679
Month 9	1	-0.42	19.594	(-84.73, 83.89)	0.985
Month 12	1	-0.42	19.594	(-84.73, 83.89)	0.985
Month 18	1	-0.42	19.594	(-84.73, 83.89)	0.985
Month 24	1	-20.42	19.594	(-104.73, 63.89)	0.407
Month 36	1	-10.42	19.594	(-94.73, 73.89)	0.648
Month 48	1	-15.42	19.594	(-99.73, 68.89)	0.514
Month 60	1	-15.42	19.594	(-99.73, 68.89)	0.514

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	6.78	3.520	(-0.19, 13.74)	0.057
Month 3	20	10.98	3.145	(4.75, 17.20)	<.001
Month 6	18	11.40	3.316	(4.84, 17.97)	<.001
Month 9	17	12.76	3.411	(6.01, 19.51)	<.001
Month 12	15	19.05	3.632	(11.86, 26.24)	<.001
Month 18	11	16.17	4.245	(7.77, 24.57)	<.001
Month 24	13	18.47	3.902	(10.75, 26.19)	<.001
Month 36	11	19.91	4.246	(11.51, 28.32)	<.001
Month 48	7	22.95	5.318	(12.43, 33.48)	<.001
Month 60	9	21.64	4.695	(12.35, 30.93)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	-2.01	6.170	(-14.48, 10.46)	0.746
Month 3	8	4.86	6.170	(-7.61, 17.33)	0.435
Month 6	9	4.47	5.816	(-7.29, 16.22)	0.447
Month 9	6	15.02	7.135	(0.60, 29.45)	0.042
Month 12	4	22.77	8.725	(5.13, 40.40)	0.013
Month 18	3	4.34	10.077	(-16.03, 24.70)	0.669
Month 24	4	8.72	8.747	(-8.96, 26.40)	0.325
Month 36	3	13.65	10.080	(-6.72, 34.02)	0.183
Month 48	3	18.65	10.080	(-1.72, 39.02)	0.072
Month 60	3	23.65	10.080	(3.28, 44.02)	0.024

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Age: <10 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	11.98	5.927	(-0.35, 24.31)	0.056
Month 3	6	5.95	5.469	(-5.42, 17.32)	0.289
Month 6	6	10.95	5.469	(-0.42, 22.32)	0.058
Month 9	3	15.98	7.714	(-0.06, 32.02)	0.051
Month 12	2	23.40	9.388	(3.87, 42.92)	0.021
Month 18	2	25.90	9.388	(6.37, 45.42)	0.012
Month 24	2	18.40	9.388	(-1.13, 37.92)	0.063
Month 36	2	18.40	9.388	(-1.13, 37.92)	0.063
Month 48	2	18.40	9.388	(-1.13, 37.92)	0.063
Month 60	2	23.40	9.388	(3.87, 42.92)	0.021

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Age: >=10 years to <18 years

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	3.12	2.732	(-2.28, 8.52)	0.255
Month 3	23	8.81	2.734	(3.41, 14.22)	0.002
Month 6	20	7.46	2.928	(1.67, 13.25)	0.012
Month 9	19	12.85	3.004	(6.92, 18.79)	<.001
Month 12	16	15.16	3.274	(8.68, 21.63)	<.001
Month 18	12	18.55	3.780	(11.08, 26.02)	<.001
Month 24	14	17.55	3.500	(10.63, 24.47)	<.001
Month 36	12	16.11	3.788	(8.62, 23.60)	<.001
Month 48	7	15.95	4.949	(6.17, 25.73)	0.002
Month 60	9	17.52	4.373	(8.87, 26.16)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203a
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Age
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Age: >=18

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	8	3.87	4.713	(-5.63, 13.37)	0.416
Month 3	9	8.48	4.460	(-0.51, 17.47)	0.064
Month 6	10	8.48	4.202	(0.01, 16.95)	0.050
Month 9	7	1.87	5.050	(-8.31, 12.05)	0.713
Month 12	5	10.48	5.941	(-1.50, 22.45)	0.085
Month 18	3	11.19	7.694	(-4.32, 26.69)	0.153
Month 24	4	12.38	6.686	(-1.09, 25.86)	0.071
Month 36	3	4.94	7.734	(-10.65, 20.52)	0.527
Month 48	3	13.27	7.734	(-2.32, 28.85)	0.093
Month 60	3	19.94	7.734	(4.35, 35.52)	0.013

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	13.15	3.736	(5.76, 20.54)	<.001
Month 3	22	19.97	3.646	(12.76, 27.19)	<.001
Month 6	20	17.94	3.825	(10.37, 25.50)	<.001
Month 9	16	20.28	4.275	(11.82, 28.74)	<.001
Month 12	12	26.61	4.936	(16.84, 36.38)	<.001
Month 18	10	25.19	5.408	(14.49, 35.88)	<.001
Month 24	12	27.82	4.943	(18.04, 37.60)	<.001
Month 36	11	16.57	5.173	(6.34, 26.81)	0.002
Month 48	8	24.41	6.058	(12.43, 36.39)	<.001
Month 60	9	32.08	5.703	(20.80, 43.36)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	5.89	4.400	(-2.85, 14.63)	0.184
Month 3	16	9.84	4.410	(1.08, 18.60)	0.028
Month 6	16	12.35	4.388	(3.64, 21.07)	0.006
Month 9	13	14.17	4.881	(4.48, 23.87)	0.005
Month 12	11	20.94	5.295	(10.42, 31.45)	<.001
Month 18	8	21.88	6.218	(9.53, 34.23)	<.001
Month 24	8	22.33	6.205	(10.00, 34.65)	<.001
Month 36	6	15.88	7.221	(1.54, 30.22)	0.030
Month 48	4	26.21	8.793	(8.74, 43.67)	0.004
Month 60	5	0.97	7.898	(-14.72, 16.66)	0.903

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	8.22	4.227	(-0.14, 16.58)	0.054
Month 3	22	19.25	4.129	(11.08, 27.42)	<.001
Month 6	20	19.25	4.334	(10.68, 27.83)	<.001
Month 9	16	22.32	4.843	(12.73, 31.90)	<.001
Month 12	12	22.93	5.591	(11.87, 34.00)	<.001
Month 18	10	24.69	6.125	(12.57, 36.81)	<.001
Month 24	12	28.06	5.595	(16.99, 39.13)	<.001
Month 36	11	22.64	5.851	(11.06, 34.22)	<.001
Month 48	8	29.81	6.855	(16.25, 43.37)	<.001
Month 60	9	32.18	6.475	(19.37, 44.99)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	2.49	4.938	(-7.32, 12.30)	0.615
Month 3	16	19.06	4.959	(9.21, 28.91)	<.001
Month 6	16	25.40	4.935	(15.60, 35.20)	<.001
Month 9	13	30.79	5.481	(19.90, 41.67)	<.001
Month 12	11	39.55	5.947	(27.73, 51.36)	<.001
Month 18	8	36.97	6.979	(23.11, 50.83)	<.001
Month 24	8	43.50	7.008	(29.58, 57.42)	<.001
Month 36	6	38.38	8.095	(22.30, 54.46)	<.001
Month 48	4	48.97	9.894	(29.32, 68.62)	<.001
Month 60	5	48.99	8.846	(31.42, 66.56)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	8.06	2.685	(2.75, 13.37)	0.003
Month 3	22	13.59	2.622	(8.40, 18.78)	<.001
Month 6	20	13.60	2.754	(8.15, 19.05)	<.001
Month 9	16	15.41	3.075	(9.33, 21.50)	<.001
Month 12	12	20.74	3.551	(13.71, 27.76)	<.001
Month 18	10	19.53	3.890	(11.83, 27.22)	<.001
Month 24	12	18.59	3.553	(11.56, 25.62)	<.001
Month 36	11	16.88	3.715	(9.53, 24.23)	<.001
Month 48	8	19.13	4.356	(10.51, 27.75)	<.001
Month 60	9	23.39	4.109	(15.26, 31.52)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	4.09	3.079	(-2.03, 10.21)	0.187
Month 3	16	7.56	3.089	(1.43, 13.70)	0.016
Month 6	16	8.00	3.076	(1.89, 14.10)	0.011
Month 9	13	11.52	3.416	(4.74, 18.31)	0.001
Month 12	11	18.30	3.709	(10.94, 25.67)	<.001
Month 18	8	16.60	4.349	(7.96, 25.24)	<.001
Month 24	8	20.62	4.349	(11.98, 29.25)	<.001
Month 36	6	15.01	5.055	(4.97, 25.05)	0.004
Month 48	4	20.96	6.198	(8.65, 33.27)	0.001
Month 60	5	12.66	5.519	(1.70, 23.62)	0.024

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	5.04	4.414	(-3.71, 13.80)	0.256
Month 3	16	9.57	3.661	(2.31, 16.83)	0.010
Month 6	15	13.02	3.788	(5.51, 20.54)	<.001
Month 9	13	10.30	4.054	(2.26, 18.34)	0.013
Month 12	11	19.00	4.408	(10.26, 27.74)	<.001
Month 18	9	14.26	4.880	(4.58, 23.94)	0.004
Month 24	11	10.40	4.406	(1.66, 19.14)	0.020
Month 36	10	18.35	4.622	(9.18, 27.52)	<.001
Month 48	8	19.83	5.169	(9.58, 30.08)	<.001
Month 60	9	20.37	4.880	(10.69, 30.05)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	4.69	4.057	(-3.39, 12.76)	0.251
Month 3	14	7.27	4.199	(-1.09, 15.63)	0.087
Month 6	14	4.60	4.197	(-3.76, 12.95)	0.277
Month 9	11	15.73	4.736	(6.30, 25.16)	0.001
Month 12	9	18.79	5.237	(8.36, 29.22)	<.001
Month 18	6	10.49	6.413	(-2.28, 23.26)	0.106
Month 24	7	21.12	5.940	(9.29, 32.94)	<.001
Month 36	5	12.97	7.033	(-1.04, 26.97)	0.069
Month 48	3	10.68	9.140	(-7.52, 28.88)	0.246
Month 60	4	14.28	7.856	(-1.36, 29.92)	0.073

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Gender: Male

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	3.66	2.707	(-1.69, 9.02)	0.179
Month 3	22	10.37	2.645	(5.14, 15.60)	<.001
Month 6	20	9.42	2.776	(3.93, 14.91)	<.001
Month 9	16	13.96	3.103	(7.82, 20.09)	<.001
Month 12	12	14.33	3.581	(7.24, 21.41)	<.001
Month 18	10	16.63	3.923	(8.87, 24.39)	<.001
Month 24	12	14.99	3.582	(7.90, 22.07)	<.001
Month 36	11	14.86	3.744	(7.46, 22.27)	<.001
Month 48	8	12.58	4.388	(3.90, 21.27)	0.005
Month 60	9	16.78	4.144	(8.59, 24.98)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203b
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Gender
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Gender: Female

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	5.99	3.585	(-1.13, 13.11)	0.098
Month 3	16	6.58	3.485	(-0.35, 13.50)	0.062
Month 6	16	8.08	3.460	(1.21, 14.96)	0.022
Month 9	13	6.07	3.839	(-1.55, 13.70)	0.117
Month 12	11	15.33	4.171	(7.04, 23.61)	<.001
Month 18	7	19.20	5.246	(8.78, 29.63)	<.001
Month 24	8	18.07	4.897	(8.34, 27.80)	<.001
Month 36	6	11.54	5.688	(0.24, 22.84)	0.045
Month 48	4	20.46	6.973	(6.61, 34.32)	0.004
Month 60	5	21.84	6.201	(9.52, 34.15)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	11.63	3.298	(5.12, 18.14)	<.001
Month 3	30	15.50	3.242	(9.11, 21.90)	<.001
Month 6	29	17.04	3.295	(10.54, 23.54)	<.001
Month 9	23	19.72	3.702	(12.41, 27.02)	<.001
Month 12	19	24.30	4.074	(16.26, 32.34)	<.001
Month 18	14	24.65	4.751	(15.28, 34.02)	<.001
Month 24	17	25.67	4.305	(17.17, 34.16)	<.001
Month 36	14	14.35	4.760	(4.96, 23.75)	0.003
Month 48	9	21.11	5.926	(9.42, 32.80)	<.001
Month 60	11	21.90	5.351	(11.34, 32.46)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	3.86	1.748	(-0.27, 7.99)	0.063
Month 3	3	3.86	1.748	(-0.27, 7.99)	0.063
Month 6	2	0.55	2.096	(-4.41, 5.51)	0.801
Month 9	2	-3.20	2.096	(-8.16, 1.76)	0.171
Month 12	2	3.05	2.096	(-1.91, 8.01)	0.189
Month 18	2	-1.95	2.096	(-6.91, 3.01)	0.383
Month 24	1	-4.39	3.048	(-11.60, 2.82)	0.193
Month 36	1	5.61	3.048	(-1.60, 12.82)	0.108
Month 48	1	30.61	3.048	(23.40, 37.82)	<.001
Month 60	1	-4.39	3.048	(-11.60, 2.82)	0.193

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	2.33	9.018	(-16.48, 21.14)	0.799
Month 3	5	22.33	9.018	(3.52, 41.14)	0.022
Month 6	5	10.60	9.213	(-8.62, 29.81)	0.264
Month 9	4	15.37	10.087	(-5.67, 36.41)	0.143
Month 12	2	37.69	14.228	(8.01, 67.36)	0.015
Month 18	2	40.19	14.228	(10.51, 69.86)	0.010
Month 24	2	45.19	14.228	(15.51, 74.86)	0.005
Month 36	2	42.69	14.228	(13.01, 72.36)	0.007
Month 48	2	42.69	14.228	(13.01, 72.36)	0.007
Month 60	2	32.69	14.228	(3.01, 62.36)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	9.52	3.466	(2.68, 16.36)	0.007
Month 3	30	20.65	3.408	(13.92, 27.37)	<.001
Month 6	29	25.13	3.466	(18.30, 31.97)	<.001
Month 9	23	29.20	3.892	(21.52, 36.88)	<.001
Month 12	19	33.94	4.283	(25.49, 42.39)	<.001
Month 18	14	31.31	4.991	(21.47, 41.16)	<.001
Month 24	17	37.56	4.529	(28.63, 46.50)	<.001
Month 36	14	30.28	4.993	(20.43, 40.13)	<.001
Month 48	9	40.83	6.229	(28.55, 53.12)	<.001
Month 60	11	41.81	5.641	(30.68, 52.94)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	4.25	5.781	(-9.43, 17.92)	0.487
Month 3	3	0.08	5.781	(-13.59, 13.75)	0.989
Month 6	2	-2.61	6.935	(-19.00, 13.79)	0.718
Month 9	2	-8.86	6.935	(-25.25, 7.54)	0.242
Month 12	2	0.49	6.935	(-15.90, 16.89)	0.945
Month 18	2	14.59	6.935	(-1.80, 30.99)	0.073
Month 24	1	8.14	10.085	(-15.70, 31.99)	0.446
Month 36	1	20.64	10.085	(-3.20, 44.49)	0.080
Month 48	1	26.84	10.085	(3.00, 50.69)	0.032
Month 60	1	33.14	10.085	(9.30, 56.99)	0.013

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-20.02	10.781	(-42.51, 2.47)	0.078
Month 3	5	16.86	10.781	(-5.63, 39.35)	0.134
Month 6	5	7.30	10.854	(-15.35, 29.94)	0.509
Month 9	4	24.35	12.099	(-0.89, 49.59)	0.058
Month 12	2	25.24	17.028	(-10.28, 60.76)	0.154
Month 18	2	33.49	17.028	(-2.03, 69.01)	0.063
Month 24	2	33.29	17.028	(-2.23, 68.81)	0.065
Month 36	2	33.04	17.028	(-2.48, 68.56)	0.067
Month 48	2	31.49	17.028	(-4.03, 67.01)	0.079
Month 60	2	33.04	17.028	(-2.48, 68.56)	0.067

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	29	8.11	2.266	(3.64, 12.58)	<.001
Month 3	30	11.47	2.228	(7.08, 15.87)	<.001
Month 6	29	13.10	2.266	(8.63, 17.57)	<.001
Month 9	23	15.51	2.545	(10.49, 20.54)	<.001
Month 12	19	20.90	2.800	(15.37, 26.42)	<.001
Month 18	14	19.53	3.262	(13.09, 25.96)	<.001
Month 24	17	20.31	2.959	(14.47, 26.15)	<.001
Month 36	14	15.96	3.268	(9.51, 22.41)	<.001
Month 48	9	19.28	4.068	(11.25, 27.31)	<.001
Month 60	11	20.97	3.682	(13.70, 28.23)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	3.97	3.052	(-3.24, 11.19)	0.234
Month 3	3	-0.49	3.052	(-7.71, 6.72)	0.876
Month 6	2	-0.33	3.684	(-9.04, 8.38)	0.931
Month 9	2	0.62	3.684	(-8.09, 9.33)	0.871
Month 12	2	1.32	3.684	(-7.39, 10.03)	0.731
Month 18	2	-2.03	3.684	(-10.74, 6.68)	0.599
Month 24	1	-11.00	5.349	(-23.65, 1.65)	0.079
Month 36	1	0.60	5.349	(-12.05, 13.25)	0.914
Month 48	1	14.00	5.349	(1.35, 26.65)	0.035
Month 60	1	2.30	5.349	(-10.35, 14.95)	0.680

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-4.14	6.779	(-18.28, 10.00)	0.548
Month 3	5	13.84	6.779	(-0.30, 27.98)	0.055
Month 6	5	5.15	6.909	(-9.27, 19.56)	0.465
Month 9	4	8.84	7.577	(-6.97, 24.64)	0.257
Month 12	2	22.86	10.720	(0.50, 45.22)	0.046
Month 18	2	26.16	10.720	(3.80, 48.52)	0.024
Month 24	2	30.36	10.720	(8.00, 52.72)	0.010
Month 36	2	30.36	10.720	(8.00, 52.72)	0.010
Month 48	2	27.01	10.720	(4.65, 49.37)	0.020
Month 60	2	22.86	10.720	(0.50, 45.22)	0.046

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	18	8.19	3.445	(1.38, 15.00)	0.019
Month 3	22	8.34	3.119	(2.18, 14.51)	0.008
Month 6	22	11.38	3.118	(5.21, 17.54)	<.001
Month 9	18	14.16	3.444	(7.35, 20.97)	<.001
Month 12	16	21.13	3.654	(13.90, 28.35)	<.001
Month 18	11	13.00	4.408	(4.28, 21.71)	0.004
Month 24	15	15.59	3.774	(8.12, 23.05)	<.001
Month 36	12	16.23	4.219	(7.89, 24.57)	<.001
Month 48	8	18.63	5.166	(8.42, 28.85)	<.001
Month 60	10	21.35	4.628	(12.20, 30.50)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	1.80	7.028	(-14.82, 18.41)	0.806
Month 3	3	-4.87	7.028	(-21.49, 11.75)	0.511
Month 6	2	0.99	8.524	(-19.17, 21.14)	0.911
Month 9	2	8.49	8.524	(-11.67, 28.64)	0.353
Month 12	2	3.49	8.524	(-16.67, 23.64)	0.695
Month 18	2	3.49	8.524	(-16.67, 23.64)	0.695
Month 24	1	-19.67	12.355	(-48.88, 9.54)	0.155
Month 36	1	-4.67	12.355	(-33.88, 24.54)	0.717
Month 48	1	-4.67	12.355	(-33.88, 24.54)	0.717
Month 60	1	-4.67	12.355	(-33.88, 24.54)	0.717

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-8.15	8.062	(-24.96, 8.67)	0.324
Month 3	5	13.85	8.062	(-2.96, 30.67)	0.101
Month 6	5	1.31	8.113	(-15.62, 18.23)	0.874
Month 9	4	9.41	9.046	(-9.46, 28.28)	0.311
Month 12	2	13.11	12.770	(-13.53, 39.74)	0.317
Month 18	2	18.11	12.770	(-8.53, 44.74)	0.172
Month 24	2	25.61	12.770	(-1.03, 52.24)	0.059
Month 36	2	33.11	12.770	(6.47, 59.74)	0.017
Month 48	2	30.61	12.770	(3.97, 57.24)	0.026
Month 60	2	23.11	12.770	(-3.53, 49.74)	0.085

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Race: White

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	28	5.81	2.551	(0.77, 10.84)	0.024
Month 3	30	9.69	2.465	(4.83, 14.55)	<.001
Month 6	29	11.04	2.506	(6.10, 15.99)	<.001
Month 9	23	12.66	2.815	(7.10, 18.21)	<.001
Month 12	19	16.24	3.096	(10.13, 22.35)	<.001
Month 18	14	18.74	3.608	(11.62, 25.86)	<.001
Month 24	17	18.02	3.274	(11.56, 24.48)	<.001
Month 36	14	15.25	3.614	(8.12, 22.38)	<.001
Month 48	9	17.33	4.499	(8.45, 26.21)	<.001
Month 60	11	20.47	4.072	(12.43, 28.50)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Race: Asian

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	6.64	3.696	(-2.41, 15.68)	0.123
Month 3	3	-0.03	3.696	(-9.07, 9.02)	0.994
Month 6	2	-2.52	4.495	(-13.51, 8.48)	0.596
Month 9	2	-5.02	4.495	(-16.01, 5.98)	0.307
Month 12	2	-2.52	4.495	(-13.51, 8.48)	0.596
Month 18	1	-0.12	6.737	(-16.61, 16.36)	0.986
Month 24	1	-9.91	6.573	(-25.99, 6.18)	0.183
Month 36	1	0.09	6.573	(-15.99, 16.18)	0.989
Month 48	1	15.09	6.573	(-0.99, 31.18)	0.061
Month 60	1	15.09	6.573	(-0.99, 31.18)	0.061

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203c
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Race
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Race: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	-5.11	5.656	(-16.91, 6.69)	0.377
Month 3	5	6.89	5.656	(-4.91, 18.69)	0.237
Month 6	5	0.04	5.748	(-11.95, 12.03)	0.995
Month 9	4	4.34	6.388	(-8.98, 17.67)	0.505
Month 12	2	16.96	8.910	(-1.62, 35.55)	0.071
Month 18	2	19.46	8.910	(0.88, 38.05)	0.041
Month 24	2	19.46	8.910	(0.88, 38.05)	0.041
Month 36	2	14.46	8.910	(-4.12, 33.05)	0.120
Month 48	2	6.96	8.910	(-11.62, 25.55)	0.444
Month 60	2	11.96	8.910	(-6.62, 30.55)	0.194

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	1.90	5.277	(-8.69, 12.49)	0.720
Month 3	10	19.70	5.540	(8.58, 30.81)	<.001
Month 6	11	9.64	5.284	(-0.96, 20.25)	0.074
Month 9	7	16.05	6.616	(2.77, 29.33)	0.019
Month 12	4	25.66	8.752	(8.10, 43.22)	0.005
Month 18	4	21.91	8.752	(4.35, 39.47)	0.015
Month 24	5	21.09	7.839	(5.36, 36.82)	0.010
Month 36	4	21.91	8.752	(4.35, 39.47)	0.015
Month 48	3	27.56	10.107	(7.28, 47.85)	0.009
Month 60	4	6.91	8.752	(-10.65, 24.47)	0.433

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	12.94	3.539	(5.95, 19.92)	<.001
Month 3	28	14.15	3.407	(7.43, 20.88)	<.001
Month 6	25	17.54	3.602	(10.43, 24.65)	<.001
Month 9	22	17.88	3.844	(10.29, 25.47)	<.001
Month 12	19	23.95	4.131	(15.80, 32.11)	<.001
Month 18	14	24.55	4.815	(15.04, 34.05)	<.001
Month 24	15	27.53	4.659	(18.33, 36.73)	<.001
Month 36	13	15.36	5.024	(5.44, 25.27)	0.003
Month 48	9	24.43	6.007	(12.57, 36.29)	<.001
Month 60	10	26.68	5.695	(15.44, 37.92)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	-8.84	5.805	(-20.49, 2.81)	0.134
Month 3	10	15.55	6.093	(3.32, 27.77)	0.014
Month 6	11	9.23	5.816	(-2.44, 20.90)	0.118
Month 9	7	23.82	7.280	(9.21, 38.43)	0.002
Month 12	4	27.67	9.627	(8.35, 46.99)	0.006
Month 18	4	31.02	9.627	(11.70, 50.34)	0.002
Month 24	5	26.91	8.614	(9.62, 44.19)	0.003
Month 36	4	26.87	9.627	(7.55, 46.19)	0.007
Month 48	3	26.75	11.172	(4.33, 49.17)	0.020
Month 60	4	30.00	9.627	(10.68, 49.32)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	11.07	3.825	(3.51, 18.62)	0.004
Month 3	28	20.03	3.688	(12.75, 27.31)	<.001
Month 6	25	26.19	3.901	(18.48, 33.89)	<.001
Month 9	22	25.88	4.163	(17.66, 34.09)	<.001
Month 12	19	31.63	4.475	(22.80, 40.46)	<.001
Month 18	14	30.34	5.214	(20.04, 40.63)	<.001
Month 24	15	37.75	5.044	(27.79, 47.71)	<.001
Month 36	13	30.82	5.423	(20.11, 41.52)	<.001
Month 48	9	42.40	6.501	(29.57, 55.23)	<.001
Month 60	10	42.51	6.174	(30.32, 54.70)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	-0.07	3.772	(-7.64, 7.50)	0.984
Month 3	10	12.51	3.957	(4.57, 20.45)	0.003
Month 6	11	2.84	3.788	(-4.76, 10.45)	0.456
Month 9	7	9.32	4.729	(-0.16, 18.81)	0.054
Month 12	4	16.02	6.255	(3.47, 28.58)	0.013
Month 18	4	14.35	6.255	(1.80, 26.90)	0.026
Month 24	5	15.21	5.600	(3.97, 26.45)	0.009
Month 36	4	16.85	6.255	(4.30, 29.40)	0.009
Month 48	3	14.65	7.227	(0.15, 29.15)	0.048
Month 60	4	7.27	6.255	(-5.28, 19.83)	0.250

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	8.61	2.441	(3.79, 13.43)	<.001
Month 3	28	10.41	2.351	(5.77, 15.05)	<.001
Month 6	25	14.23	2.488	(9.32, 19.14)	<.001
Month 9	22	14.93	2.654	(9.69, 20.16)	<.001
Month 12	19	20.73	2.853	(15.10, 26.36)	<.001
Month 18	14	19.57	3.324	(13.01, 26.13)	<.001
Month 24	15	21.10	3.214	(14.75, 27.44)	<.001
Month 36	13	16.74	3.463	(9.90, 23.58)	<.001
Month 48	9	22.00	4.146	(13.81, 30.18)	<.001
Month 60	10	24.58	3.934	(16.81, 32.34)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-5.07	5.256	(-15.64, 5.49)	0.339
Month 3	9	12.33	5.258	(1.76, 22.90)	0.023
Month 6	10	-1.99	5.014	(-12.08, 8.09)	0.693
Month 9	7	3.66	5.960	(-8.33, 15.64)	0.543
Month 12	4	7.75	7.898	(-8.13, 23.63)	0.331
Month 18	4	6.50	7.898	(-9.38, 22.38)	0.415
Month 24	5	10.40	7.055	(-3.79, 24.58)	0.147
Month 36	4	14.00	7.898	(-1.88, 29.88)	0.083
Month 48	3	12.70	9.103	(-5.60, 31.01)	0.169
Month 60	4	2.75	7.898	(-13.13, 18.63)	0.729

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	8.57	3.561	(1.53, 15.62)	0.017
Month 3	21	6.25	3.204	(-0.09, 12.59)	0.053
Month 6	19	13.32	3.371	(6.65, 19.99)	<.001
Month 9	17	16.19	3.559	(9.15, 23.23)	<.001
Month 12	16	22.81	3.669	(15.55, 30.07)	<.001
Month 18	11	15.56	4.431	(6.80, 24.33)	<.001
Month 24	13	16.36	4.071	(8.31, 24.41)	<.001
Month 36	11	19.02	4.428	(10.26, 27.78)	<.001
Month 48	8	21.08	5.188	(10.81, 31.34)	<.001
Month 60	9	26.81	4.894	(17.13, 36.49)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Ethnicity: Hispanic or Latino

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	-0.97	3.037	(-7.06, 5.13)	0.752
Month 3	10	6.97	3.192	(0.56, 13.37)	0.034
Month 6	11	1.95	3.049	(-4.17, 8.07)	0.525
Month 9	7	8.02	3.809	(0.38, 15.66)	0.040
Month 12	4	15.00	5.036	(4.90, 25.10)	0.004
Month 18	4	15.00	5.036	(4.90, 25.10)	0.004
Month 24	5	14.39	4.505	(5.35, 23.43)	0.002
Month 36	4	15.00	5.036	(4.90, 25.10)	0.004
Month 48	3	2.58	5.844	(-9.15, 14.30)	0.661
Month 60	4	12.50	5.036	(2.40, 22.60)	0.016

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203d
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Ethnicity
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Ethnicity: Other

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	6.75	2.788	(1.24, 12.25)	0.017
Month 3	28	9.29	2.633	(4.09, 14.49)	<.001
Month 6	25	11.45	2.786	(5.95, 16.95)	<.001
Month 9	22	11.19	2.973	(5.32, 17.06)	<.001
Month 12	19	15.07	3.196	(8.76, 21.38)	<.001
Month 18	13	18.76	3.865	(11.13, 26.39)	<.001
Month 24	15	16.99	3.600	(9.88, 24.09)	<.001
Month 36	13	13.74	3.874	(6.09, 21.39)	<.001
Month 48	9	19.85	4.646	(10.68, 29.03)	<.001
Month 60	10	21.15	4.407	(12.45, 29.85)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	5.836	(-7.54, 17.67)	0.401
Month 3	4	18.82	5.836	(6.21, 31.42)	0.007
Month 6	3	13.51	6.590	(-0.73, 27.74)	0.061
Month 9	3	30.17	6.590	(15.94, 44.41)	<.001
Month 12	2	37.47	8.230	(19.69, 55.25)	<.001
Month 18	1	13.09	11.430	(-11.60, 37.79)	0.273
Month 24	3	15.17	6.590	(0.94, 29.41)	0.038
Month 36	2	-7.53	8.230	(-25.31, 10.25)	0.377
Month 48	1	-3.15	11.709	(-28.45, 22.14)	0.792
Month 60	1	-36.91	11.430	(-61.60, -12.21)	0.007

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	10.39	3.069	(4.34, 16.44)	<.001
Month 3	34	15.16	3.022	(9.20, 21.11)	<.001
Month 6	33	15.62	3.067	(9.57, 21.66)	<.001
Month 9	26	15.94	3.457	(9.13, 22.76)	<.001
Month 12	21	22.64	3.844	(15.06, 30.22)	<.001
Month 18	17	24.48	4.275	(16.06, 32.91)	<.001
Month 24	17	27.42	4.277	(18.99, 35.86)	<.001
Month 36	15	19.94	4.563	(10.94, 28.93)	<.001
Month 48	11	27.98	5.320	(17.49, 38.46)	<.001
Month 60	13	25.75	4.886	(16.11, 35.38)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	6.99	6.062	(-6.11, 20.08)	0.270
Month 3	4	24.16	6.062	(11.07, 37.26)	0.002
Month 6	3	39.93	6.742	(25.36, 54.50)	<.001
Month 9	3	48.23	6.742	(33.66, 62.80)	<.001
Month 12	2	59.34	8.317	(41.37, 77.31)	<.001
Month 18	1	53.78	11.788	(28.32, 79.25)	<.001
Month 24	3	46.13	6.742	(31.56, 60.70)	<.001
Month 36	2	57.79	8.317	(39.82, 75.76)	<.001
Month 48	1	46.20	11.656	(21.02, 71.38)	0.002
Month 60	1	53.78	11.788	(28.32, 79.25)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	4.86	3.498	(-2.03, 11.76)	0.166
Month 3	34	17.81	3.447	(11.02, 24.61)	<.001
Month 6	33	19.91	3.499	(13.02, 26.81)	<.001
Month 9	26	23.20	3.944	(15.42, 30.97)	<.001
Month 12	21	27.75	4.385	(19.10, 36.39)	<.001
Month 18	17	28.70	4.875	(19.09, 38.31)	<.001
Month 24	17	33.39	4.878	(23.78, 43.01)	<.001
Month 36	15	25.96	5.195	(15.72, 36.20)	<.001
Month 48	11	36.90	6.061	(24.95, 48.85)	<.001
Month 60	13	38.46	5.579	(27.46, 49.46)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	3.38	5.094	(-7.62, 14.39)	0.518
Month 3	4	13.16	5.094	(2.15, 24.16)	0.023
Month 6	3	10.90	5.790	(-1.61, 23.41)	0.082
Month 9	3	24.23	5.790	(11.72, 36.74)	0.001
Month 12	2	30.08	7.181	(14.57, 45.60)	0.001
Month 18	1	8.03	10.046	(-13.68, 29.73)	0.439
Month 24	3	8.67	5.790	(-3.84, 21.17)	0.158
Month 36	2	9.23	7.181	(-6.28, 24.75)	0.221
Month 48	1	10.54	10.441	(-12.02, 33.10)	0.331
Month 60	1	-8.67	10.046	(-30.38, 13.03)	0.404

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	6.54	2.166	(2.27, 10.81)	0.003
Month 3	34	10.63	2.134	(6.42, 14.84)	<.001
Month 6	33	11.08	2.166	(6.81, 15.35)	<.001
Month 9	26	12.36	2.441	(7.55, 17.17)	<.001
Month 12	21	18.59	2.715	(13.24, 23.94)	<.001
Month 18	17	18.80	3.017	(12.85, 24.74)	<.001
Month 24	17	21.34	3.018	(15.39, 27.29)	<.001
Month 36	15	17.54	3.218	(11.19, 23.88)	<.001
Month 48	11	21.16	3.753	(13.76, 28.56)	<.001
Month 60	13	21.94	3.451	(15.13, 28.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	10.98	10.858	(-12.68, 34.64)	0.332
Month 3	4	8.73	9.137	(-11.18, 28.64)	0.358
Month 6	3	1.17	10.565	(-21.85, 24.19)	0.914
Month 9	3	16.17	10.565	(-6.85, 39.19)	0.152
Month 12	2	19.20	12.956	(-9.03, 47.43)	0.164
Month 18	1	-3.58	18.666	(-44.25, 37.09)	0.851
Month 24	3	-0.50	10.565	(-23.52, 22.52)	0.963
Month 36	2	1.70	12.956	(-26.53, 29.93)	0.898
Month 48	1	11.98	19.264	(-29.99, 53.95)	0.546
Month 60	1	-13.58	18.666	(-54.25, 27.09)	0.481

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	3.48	3.137	(-2.72, 9.67)	0.269
Month 3	26	8.00	2.953	(2.17, 13.83)	0.007
Month 6	26	9.43	2.954	(3.60, 15.26)	0.002
Month 9	21	12.05	3.283	(5.57, 18.53)	<.001
Month 12	18	19.09	3.546	(12.09, 26.09)	<.001
Month 18	14	14.23	4.023	(6.28, 22.17)	<.001
Month 24	15	17.44	3.886	(9.77, 25.11)	<.001
Month 36	13	19.44	4.173	(11.20, 27.68)	<.001
Month 48	10	19.40	4.760	(10.01, 28.80)	<.001
Month 60	12	22.17	4.344	(13.59, 30.74)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Response status at study entry: Primary refractory

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-3.44	6.096	(-16.61, 9.73)	0.582
Month 3	4	11.56	6.096	(-1.61, 24.73)	0.080
Month 6	3	16.68	6.837	(1.91, 31.45)	0.030
Month 9	3	25.01	6.837	(10.24, 39.78)	0.003
Month 12	2	32.13	8.547	(13.67, 50.60)	0.002
Month 18	1	19.63	11.965	(-6.21, 45.48)	0.125
Month 24	3	10.01	6.837	(-4.76, 24.78)	0.167
Month 36	2	32.13	8.547	(13.67, 50.60)	0.002
Month 48	1	14.63	11.965	(-11.21, 40.48)	0.243
Month 60	1	29.63	11.965	(3.79, 55.48)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203e
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Response status at study entry
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Response status at study entry: Relapsed disease

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	32	5.32	2.280	(0.82, 9.81)	0.021
Month 3	34	8.09	2.212	(3.73, 12.46)	<.001
Month 6	33	7.98	2.245	(3.55, 12.40)	<.001
Month 9	26	8.64	2.530	(3.65, 13.63)	<.001
Month 12	21	13.25	2.814	(7.71, 18.80)	<.001
Month 18	16	17.75	3.225	(11.39, 24.11)	<.001
Month 24	17	17.47	3.129	(11.30, 23.64)	<.001
Month 36	15	11.89	3.334	(5.32, 18.47)	<.001
Month 48	11	15.84	3.888	(8.17, 23.50)	<.001
Month 60	13	18.15	3.579	(11.10, 25.21)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	10.02	2.979	(4.15, 15.89)	<.001
Month 3	37	14.94	2.937	(9.16, 20.73)	<.001
Month 6	35	14.71	3.017	(8.77, 20.66)	<.001
Month 9	28	16.60	3.374	(9.95, 23.25)	<.001
Month 12	22	23.33	3.806	(15.83, 30.83)	<.001
Month 18	17	22.82	4.331	(14.29, 31.36)	<.001
Month 24	19	24.98	4.097	(16.91, 33.06)	<.001
Month 36	16	15.57	4.480	(6.74, 24.40)	<.001
Month 48	11	24.30	5.384	(13.69, 34.91)	<.001
Month 60	13	20.53	4.949	(10.77, 30.28)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	5.18	3.261	(-1.25, 11.61)	0.114
Month 3	37	18.00	3.218	(11.66, 24.34)	<.001
Month 6	35	20.42	3.307	(13.90, 26.93)	<.001
Month 9	28	24.49	3.698	(17.20, 31.78)	<.001
Month 12	22	29.31	4.171	(21.09, 37.53)	<.001
Month 18	17	28.48	4.745	(19.12, 37.83)	<.001
Month 24	19	33.45	4.493	(24.60, 42.31)	<.001
Month 36	16	27.33	4.898	(17.68, 36.98)	<.001
Month 48	11	35.65	5.900	(24.02, 47.28)	<.001
Month 60	13	37.78	5.430	(27.08, 48.48)	<.001

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
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Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	6.68	2.082	(2.58, 10.78)	0.002
Month 3	37	10.55	2.054	(6.50, 14.60)	<.001
Month 6	35	10.68	2.111	(6.52, 14.84)	<.001
Month 9	28	13.37	2.360	(8.71, 18.02)	<.001
Month 12	22	19.39	2.662	(14.14, 24.64)	<.001
Month 18	17	17.96	3.028	(12.00, 23.93)	<.001
Month 24	19	19.04	2.866	(13.40, 24.69)	<.001
Month 36	16	15.77	3.130	(9.60, 21.94)	<.001
Month 48	11	19.80	3.765	(12.38, 27.22)	<.001
Month 60	13	19.55	3.464	(12.72, 26.37)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	5.57	3.085	(-0.52, 11.66)	0.073
Month 3	29	7.43	2.864	(1.78, 13.08)	0.010
Month 6	28	8.37	2.917	(2.62, 14.13)	0.005
Month 9	23	13.16	3.215	(6.82, 19.51)	<.001
Month 12	19	19.56	3.537	(12.58, 26.54)	<.001
Month 18	14	13.47	4.126	(5.33, 21.61)	0.001
Month 24	17	14.21	3.740	(6.83, 21.59)	<.001
Month 36	14	16.46	4.122	(8.32, 24.59)	<.001
Month 48	10	18.38	4.876	(8.76, 28.00)	<.001
Month 60	12	19.19	4.454	(10.40, 27.98)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE
Month 60	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203f
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Philadelphia chromosome/BCR-ABL
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Philadelphia chromosome/BCR-ABL: Non-Positive

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	35	4.79	2.219	(0.42, 9.17)	0.032
Month 3	37	8.60	2.157	(4.35, 12.86)	<.001
Month 6	35	8.46	2.217	(4.09, 12.83)	<.001
Month 9	28	10.02	2.480	(5.14, 14.91)	<.001
Month 12	22	14.40	2.796	(8.89, 19.92)	<.001
Month 18	16	17.54	3.280	(11.07, 24.00)	<.001
Month 24	19	16.05	3.011	(10.11, 21.98)	<.001
Month 36	16	13.43	3.286	(6.96, 19.91)	<.001
Month 48	11	15.85	3.955	(8.05, 23.64)	<.001
Month 60	13	18.99	3.639	(11.82, 26.16)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	9.89	2.931	(4.12, 15.67)	<.001
Month 3	38	15.61	2.891	(9.91, 21.31)	<.001
Month 6	36	15.42	2.967	(9.57, 21.27)	<.001
Month 9	29	17.41	3.308	(10.89, 23.92)	<.001
Month 12	23	23.83	3.713	(16.52, 31.15)	<.001
Month 18	18	23.77	4.199	(15.50, 32.04)	<.001
Month 24	20	25.73	3.984	(17.88, 33.58)	<.001
Month 36	17	16.70	4.335	(8.16, 25.24)	<.001
Month 48	12	25.18	5.142	(15.05, 35.31)	<.001
Month 60	14	21.19	4.758	(11.82, 30.57)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	5.47	3.242	(-0.91, 11.86)	0.093
Month 3	38	18.87	3.201	(12.57, 25.18)	<.001
Month 6	36	21.56	3.286	(15.09, 28.04)	<.001
Month 9	29	25.65	3.663	(18.43, 32.86)	<.001
Month 12	23	30.31	4.112	(22.21, 38.41)	<.001
Month 18	18	30.09	4.648	(20.93, 39.25)	<.001
Month 24	20	34.80	4.414	(26.10, 43.49)	<.001
Month 36	17	29.23	4.789	(19.80, 38.67)	<.001
Month 48	12	37.68	5.693	(26.46, 48.89)	<.001
Month 60	14	39.42	5.273	(29.03, 49.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	6.28	2.044	(2.25, 10.30)	0.002
Month 3	38	10.97	2.017	(7.00, 14.95)	<.001
Month 6	36	11.06	2.072	(6.98, 15.14)	<.001
Month 9	29	13.57	2.308	(9.02, 18.12)	<.001
Month 12	23	19.50	2.591	(14.39, 24.61)	<.001
Month 18	18	18.21	2.929	(12.44, 23.98)	<.001
Month 24	20	19.46	2.780	(13.98, 24.93)	<.001
Month 36	17	16.49	3.021	(10.53, 22.44)	<.001
Month 48	12	20.05	3.588	(12.98, 27.12)	<.001
Month 60	14	19.76	3.322	(13.22, 26.31)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	4.34	3.009	(-1.59, 10.28)	0.151
Month 3	30	8.12	2.801	(2.60, 13.65)	0.004
Month 6	29	8.55	2.851	(2.92, 14.17)	0.003
Month 9	24	12.58	3.130	(6.41, 18.76)	<.001
Month 12	20	19.08	3.429	(12.32, 25.85)	<.001
Month 18	15	12.96	3.965	(5.14, 20.78)	0.001
Month 24	18	14.55	3.615	(7.42, 21.68)	<.001
Month 36	15	17.10	3.961	(9.29, 24.92)	<.001
Month 48	11	18.70	4.624	(9.58, 27.82)	<.001
Month 60	13	19.36	4.257	(10.96, 27.75)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203g
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by MLL rearrangement
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Mixed-lineage leukemia rearrangement: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	4.60	2.161	(0.34, 8.86)	0.034
Month 3	38	8.71	2.103	(4.56, 12.85)	<.001
Month 6	36	8.74	2.160	(4.48, 12.99)	<.001
Month 9	29	10.33	2.407	(5.59, 15.07)	<.001
Month 12	23	14.66	2.702	(9.33, 19.98)	<.001
Month 18	17	17.76	3.143	(11.56, 23.95)	<.001
Month 24	20	16.29	2.899	(10.58, 22.00)	<.001
Month 36	17	13.91	3.149	(7.71, 20.12)	<.001
Month 48	12	15.52	3.741	(8.15, 22.89)	<.001
Month 60	14	18.80	3.464	(11.97, 25.62)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	9.89	2.931	(4.12, 15.67)	<.001
Month 3	38	15.61	2.891	(9.91, 21.31)	<.001
Month 6	36	15.42	2.967	(9.57, 21.27)	<.001
Month 9	29	17.41	3.308	(10.89, 23.92)	<.001
Month 12	23	23.83	3.713	(16.52, 31.15)	<.001
Month 18	18	23.77	4.199	(15.50, 32.04)	<.001
Month 24	20	25.73	3.984	(17.88, 33.58)	<.001
Month 36	17	16.70	4.335	(8.16, 25.24)	<.001
Month 48	12	25.18	5.142	(15.05, 35.31)	<.001
Month 60	14	21.19	4.758	(11.82, 30.57)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	5.47	3.242	(-0.91, 11.86)	0.093
Month 3	38	18.87	3.201	(12.57, 25.18)	<.001
Month 6	36	21.56	3.286	(15.09, 28.04)	<.001
Month 9	29	25.65	3.663	(18.43, 32.86)	<.001
Month 12	23	30.31	4.112	(22.21, 38.41)	<.001
Month 18	18	30.09	4.648	(20.93, 39.25)	<.001
Month 24	20	34.80	4.414	(26.10, 43.49)	<.001
Month 36	17	29.23	4.789	(19.80, 38.67)	<.001
Month 48	12	37.68	5.693	(26.46, 48.89)	<.001
Month 60	14	39.42	5.273	(29.03, 49.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	6.28	2.044	(2.25, 10.30)	0.002
Month 3	38	10.97	2.017	(7.00, 14.95)	<.001
Month 6	36	11.06	2.072	(6.98, 15.14)	<.001
Month 9	29	13.57	2.308	(9.02, 18.12)	<.001
Month 12	23	19.50	2.591	(14.39, 24.61)	<.001
Month 18	18	18.21	2.929	(12.44, 23.98)	<.001
Month 24	20	19.46	2.780	(13.98, 24.93)	<.001
Month 36	17	16.49	3.021	(10.53, 22.44)	<.001
Month 48	12	20.05	3.588	(12.98, 27.12)	<.001
Month 60	14	19.76	3.322	(13.22, 26.31)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	4.34	3.009	(-1.59, 10.28)	0.151
Month 3	30	8.12	2.801	(2.60, 13.65)	0.004
Month 6	29	8.55	2.851	(2.92, 14.17)	0.003
Month 9	24	12.58	3.130	(6.41, 18.76)	<.001
Month 12	20	19.08	3.429	(12.32, 25.85)	<.001
Month 18	15	12.96	3.965	(5.14, 20.78)	0.001
Month 24	18	14.55	3.615	(7.42, 21.68)	<.001
Month 36	15	17.10	3.961	(9.29, 24.92)	<.001
Month 48	11	18.70	4.624	(9.58, 27.82)	<.001
Month 60	13	19.36	4.257	(10.96, 27.75)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203h
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Hypodiploidy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Hypodiploidy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	4.60	2.161	(0.34, 8.86)	0.034
Month 3	38	8.71	2.103	(4.56, 12.85)	<.001
Month 6	36	8.74	2.160	(4.48, 12.99)	<.001
Month 9	29	10.33	2.407	(5.59, 15.07)	<.001
Month 12	23	14.66	2.702	(9.33, 19.98)	<.001
Month 18	17	17.76	3.143	(11.56, 23.95)	<.001
Month 24	20	16.29	2.899	(10.58, 22.00)	<.001
Month 36	17	13.91	3.149	(7.71, 20.12)	<.001
Month 48	12	15.52	3.741	(8.15, 22.89)	<.001
Month 60	14	18.80	3.464	(11.97, 25.62)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	9.89	2.931	(4.12, 15.67)	<.001
Month 3	38	15.61	2.891	(9.91, 21.31)	<.001
Month 6	36	15.42	2.967	(9.57, 21.27)	<.001
Month 9	29	17.41	3.308	(10.89, 23.92)	<.001
Month 12	23	23.83	3.713	(16.52, 31.15)	<.001
Month 18	18	23.77	4.199	(15.50, 32.04)	<.001
Month 24	20	25.73	3.984	(17.88, 33.58)	<.001
Month 36	17	16.70	4.335	(8.16, 25.24)	<.001
Month 48	12	25.18	5.142	(15.05, 35.31)	<.001
Month 60	14	21.19	4.758	(11.82, 30.57)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	5.47	3.242	(-0.91, 11.86)	0.093
Month 3	38	18.87	3.201	(12.57, 25.18)	<.001
Month 6	36	21.56	3.286	(15.09, 28.04)	<.001
Month 9	29	25.65	3.663	(18.43, 32.86)	<.001
Month 12	23	30.31	4.112	(22.21, 38.41)	<.001
Month 18	18	30.09	4.648	(20.93, 39.25)	<.001
Month 24	20	34.80	4.414	(26.10, 43.49)	<.001
Month 36	17	29.23	4.789	(19.80, 38.67)	<.001
Month 48	12	37.68	5.693	(26.46, 48.89)	<.001
Month 60	14	39.42	5.273	(29.03, 49.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	37	6.28	2.044	(2.25, 10.30)	0.002
Month 3	38	10.97	2.017	(7.00, 14.95)	<.001
Month 6	36	11.06	2.072	(6.98, 15.14)	<.001
Month 9	29	13.57	2.308	(9.02, 18.12)	<.001
Month 12	23	19.50	2.591	(14.39, 24.61)	<.001
Month 18	18	18.21	2.929	(12.44, 23.98)	<.001
Month 24	20	19.46	2.780	(13.98, 24.93)	<.001
Month 36	17	16.49	3.021	(10.53, 22.44)	<.001
Month 48	12	20.05	3.588	(12.98, 27.12)	<.001
Month 60	14	19.76	3.322	(13.22, 26.31)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	26	4.34	3.009	(-1.59, 10.28)	0.151
Month 3	30	8.12	2.801	(2.60, 13.65)	0.004
Month 6	29	8.55	2.851	(2.92, 14.17)	0.003
Month 9	24	12.58	3.130	(6.41, 18.76)	<.001
Month 12	20	19.08	3.429	(12.32, 25.85)	<.001
Month 18	15	12.96	3.965	(5.14, 20.78)	0.001
Month 24	18	14.55	3.615	(7.42, 21.68)	<.001
Month 36	15	17.10	3.961	(9.29, 24.92)	<.001
Month 48	11	18.70	4.624	(9.58, 27.82)	<.001
Month 60	13	19.36	4.257	(10.96, 27.75)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203i
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by BCR-ABL1-like
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | BCR-ABL1-like: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	4.60	2.161	(0.34, 8.86)	0.034
Month 3	38	8.71	2.103	(4.56, 12.85)	<.001
Month 6	36	8.74	2.160	(4.48, 12.99)	<.001
Month 9	29	10.33	2.407	(5.59, 15.07)	<.001
Month 12	23	14.66	2.702	(9.33, 19.98)	<.001
Month 18	17	17.76	3.143	(11.56, 23.95)	<.001
Month 24	20	16.29	2.899	(10.58, 22.00)	<.001
Month 36	17	13.91	3.149	(7.71, 20.12)	<.001
Month 48	12	15.52	3.741	(8.15, 22.89)	<.001
Month 60	14	18.80	3.464	(11.97, 25.62)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	20.42	5.898	(8.63, 32.20)	<.001
Month 3	12	18.42	5.915	(6.60, 30.24)	0.003
Month 6	13	23.62	5.682	(12.26, 34.97)	<.001
Month 9	10	20.10	6.455	(7.20, 33.00)	0.003
Month 12	7	36.86	7.730	(21.41, 52.30)	<.001
Month 18	6	41.50	8.351	(24.81, 58.19)	<.001
Month 24	5	49.40	9.217	(30.98, 67.82)	<.001
Month 36	5	30.40	9.217	(11.98, 48.82)	0.002
Month 48	1	51.00	20.353	(10.33, 91.67)	0.015
Month 60	3	43.00	11.807	(19.40, 66.59)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	4.67	3.243	(-1.73, 11.08)	0.152
Month 3	26	14.14	3.176	(7.86, 20.41)	<.001
Month 6	23	11.63	3.380	(4.95, 18.30)	<.001
Month 9	19	16.19	3.716	(8.85, 23.53)	<.001
Month 12	16	18.34	4.047	(10.34, 26.33)	<.001
Month 18	12	15.59	4.673	(6.36, 24.82)	0.001
Month 24	15	17.62	4.180	(9.36, 25.87)	<.001
Month 36	12	11.81	4.686	(2.56, 21.07)	0.013
Month 48	11	20.72	4.882	(11.08, 30.36)	<.001
Month 60	11	14.44	4.881	(4.80, 24.07)	0.004

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	14.95	5.475	(4.01, 25.89)	0.008
Month 3	12	20.15	5.475	(9.21, 31.09)	<.001
Month 6	13	25.65	5.259	(15.15, 36.16)	<.001
Month 9	10	25.47	6.005	(13.47, 37.47)	<.001
Month 12	7	35.10	7.168	(20.77, 49.42)	<.001
Month 18	6	30.46	7.741	(14.99, 45.93)	<.001
Month 24	5	43.16	8.489	(26.19, 60.12)	<.001
Month 36	5	33.78	8.489	(16.81, 50.74)	<.001
Month 48	1	51.89	19.043	(13.84, 89.94)	0.008
Month 60	3	47.12	10.971	(25.20, 69.05)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	1.19	4.089	(-6.88, 9.27)	0.771
Month 3	26	18.38	4.010	(10.46, 26.30)	<.001
Month 6	23	19.62	4.260	(11.21, 28.03)	<.001
Month 9	19	25.94	4.687	(16.68, 35.19)	<.001
Month 12	16	28.27	5.107	(18.18, 38.36)	<.001
Month 18	12	30.00	5.900	(18.35, 41.66)	<.001
Month 24	15	31.68	5.283	(21.24, 42.11)	<.001
Month 36	12	27.30	5.907	(15.63, 38.96)	<.001
Month 48	11	35.41	6.161	(23.24, 47.58)	<.001
Month 60	11	36.65	6.160	(24.48, 48.82)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	12.67	4.008	(4.67, 20.68)	0.002
Month 3	12	14.13	4.015	(6.10, 22.15)	<.001
Month 6	13	14.97	3.857	(7.27, 22.68)	<.001
Month 9	10	14.07	4.391	(5.30, 22.85)	0.002
Month 12	7	29.00	5.251	(18.50, 39.49)	<.001
Month 18	6	29.72	5.669	(18.39, 41.05)	<.001
Month 24	5	36.03	6.239	(23.56, 48.50)	<.001
Month 36	5	26.03	6.239	(13.56, 38.50)	<.001
Month 48	1	34.66	13.888	(6.91, 62.41)	0.015
Month 60	3	32.57	8.016	(16.55, 48.59)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	3.30	2.312	(-1.27, 7.86)	0.156
Month 3	26	9.49	2.264	(5.02, 13.96)	<.001
Month 6	23	9.30	2.410	(4.54, 14.06)	<.001
Month 9	19	13.57	2.650	(8.34, 18.81)	<.001
Month 12	16	15.46	2.886	(9.76, 21.16)	<.001
Month 18	12	12.81	3.333	(6.22, 19.39)	<.001
Month 24	15	13.74	2.981	(7.85, 19.63)	<.001
Month 36	12	12.80	3.339	(6.20, 19.39)	<.001
Month 48	11	17.34	3.483	(10.46, 24.22)	<.001
Month 60	11	15.50	3.480	(8.62, 22.37)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	7	8.74	6.602	(-4.60, 22.08)	0.193
Month 3	7	11.29	6.617	(-2.08, 24.67)	0.096
Month 6	9	10.22	5.826	(-1.55, 22.00)	0.087
Month 9	7	9.17	6.601	(-4.18, 22.51)	0.173
Month 12	5	31.48	7.812	(15.69, 47.27)	<.001
Month 18	4	26.64	8.733	(8.99, 44.29)	0.004
Month 24	4	34.14	8.733	(16.49, 51.79)	<.001
Month 36	4	34.14	8.733	(16.49, 51.79)	<.001
Month 48	1	22.86	17.477	(-12.46, 58.18)	0.198
Month 60	3	36.23	10.090	(15.84, 56.62)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	19	2.83	3.277	(-3.65, 9.31)	0.389
Month 3	23	7.05	2.977	(1.16, 12.93)	0.019
Month 6	20	8.34	3.198	(2.01, 14.66)	0.010
Month 9	17	14.35	3.461	(7.51, 21.19)	<.001
Month 12	15	14.93	3.685	(7.65, 22.22)	<.001
Month 18	11	8.05	4.312	(-0.48, 16.57)	0.064
Month 24	14	8.66	3.814	(1.12, 16.20)	0.025
Month 36	11	11.03	4.305	(2.52, 19.55)	0.011
Month 48	10	17.14	4.515	(8.21, 26.07)	<.001
Month 60	10	14.02	4.516	(5.09, 22.95)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	7.43	4.118	(-0.80, 15.66)	0.076
Month 3	12	9.45	4.122	(1.22, 17.69)	0.025
Month 6	13	8.33	3.958	(0.42, 16.23)	0.039
Month 9	10	8.94	4.512	(-0.08, 17.95)	0.052
Month 12	7	17.81	5.393	(7.03, 28.59)	0.002
Month 18	6	22.16	5.824	(10.52, 33.80)	<.001
Month 24	5	23.51	6.392	(10.74, 36.28)	<.001
Month 36	5	15.51	6.392	(2.74, 28.28)	0.018
Month 48	1	27.82	14.310	(-0.77, 56.42)	0.056
Month 60	3	18.52	8.277	(1.98, 35.06)	0.029

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203j
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Complex Karyotypes
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Complex karyotypes II (>=5 unrelated abnormalities) : No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	3.55	2.580	(-1.54, 8.65)	0.170
Month 3	26	8.47	2.470	(3.59, 13.35)	<.001
Month 6	23	9.30	2.626	(4.12, 14.49)	<.001
Month 9	19	11.46	2.892	(5.75, 17.17)	<.001
Month 12	16	13.30	3.147	(7.08, 19.51)	<.001
Month 18	11	15.64	3.796	(8.14, 23.14)	<.001
Month 24	15	13.47	3.252	(7.05, 19.90)	<.001
Month 36	12	13.01	3.644	(5.82, 20.21)	<.001
Month 48	11	13.16	3.797	(5.66, 20.66)	<.001
Month 60	11	18.16	3.797	(10.66, 25.66)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	7.36	5.423	(-3.44, 18.16)	0.179
Month 3	13	15.97	5.213	(5.59, 26.35)	0.003
Month 6	12	18.18	5.439	(7.35, 29.01)	0.001
Month 9	11	16.28	5.669	(5.00, 27.57)	0.005
Month 12	10	21.48	5.941	(9.65, 33.31)	<.001
Month 18	7	27.44	7.117	(13.26, 41.61)	<.001
Month 24	7	31.01	7.103	(16.87, 45.16)	<.001
Month 36	6	13.80	7.701	(-1.53, 29.13)	0.077
Month 48	4	26.77	9.554	(7.75, 45.80)	0.006
Month 60	6	32.99	7.680	(17.70, 48.29)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	11.24	3.724	(3.87, 18.61)	0.003
Month 3	23	15.11	3.718	(7.76, 22.47)	<.001
Month 6	22	14.35	3.797	(6.83, 21.86)	<.001
Month 9	16	18.51	4.454	(9.69, 27.32)	<.001
Month 12	11	25.53	5.375	(14.89, 36.16)	<.001
Month 18	9	23.26	5.941	(11.50, 35.01)	<.001
Month 24	12	24.33	5.143	(14.15, 34.50)	<.001
Month 36	10	19.93	5.649	(8.76, 31.11)	<.001
Month 48	7	28.60	6.736	(15.28, 41.93)	<.001
Month 60	7	16.16	6.732	(2.84, 29.48)	0.018

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	9.27	6.440	(-7.28, 25.82)	0.210
Month 3	2	19.27	6.440	(2.72, 35.82)	0.030
Month 6	2	9.27	6.440	(-7.28, 25.82)	0.210
Month 9	2	16.77	6.440	(0.22, 33.32)	0.048
Month 12	2	29.27	6.440	(12.72, 45.82)	0.006
Month 18	2	14.27	6.440	(-2.28, 30.82)	0.078
Month 24	1	2.19	9.270	(-21.64, 26.02)	0.823
Month 36	1	-2.81	9.270	(-26.64, 21.02)	0.774
Month 48	1	-7.81	9.270	(-31.64, 16.02)	0.438
Month 60	1	-12.81	9.270	(-36.64, 11.02)	0.225

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	7.66	4.476	(-1.25, 16.57)	0.091
Month 3	13	16.14	4.298	(7.58, 24.69)	<.001
Month 6	12	18.93	4.481	(10.01, 27.85)	<.001
Month 9	11	16.52	4.681	(7.20, 25.85)	<.001
Month 12	10	21.52	4.899	(11.76, 31.27)	<.001
Month 18	7	23.67	5.857	(12.01, 35.34)	<.001
Month 24	7	27.80	5.856	(16.14, 39.47)	<.001
Month 36	6	14.14	6.336	(1.53, 26.76)	0.028
Month 48	4	30.42	7.769	(14.95, 45.89)	<.001
Month 60	6	31.27	6.338	(18.65, 43.89)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	5.06	4.494	(-3.83, 13.95)	0.262
Month 3	23	20.64	4.492	(11.75, 29.52)	<.001
Month 6	22	23.20	4.589	(14.12, 32.27)	<.001
Month 9	16	28.73	5.381	(18.09, 39.38)	<.001
Month 12	11	33.98	6.506	(21.11, 46.86)	<.001
Month 18	9	33.57	7.184	(19.36, 47.79)	<.001
Month 24	12	37.49	6.220	(25.18, 49.79)	<.001
Month 36	10	36.88	6.809	(23.41, 50.36)	<.001
Month 48	7	37.79	8.142	(21.68, 53.90)	<.001
Month 60	7	41.99	8.148	(25.87, 58.11)	<.001

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P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	10.72	15.987	(-30.38, 51.81)	0.532
Month 3	2	20.12	15.987	(-20.98, 61.21)	0.264
Month 6	2	31.07	15.987	(-10.03, 72.16)	0.110
Month 9	2	43.57	15.987	(2.47, 84.66)	0.042
Month 12	2	48.22	15.987	(7.12, 89.31)	0.030
Month 18	2	37.32	15.987	(-3.78, 78.41)	0.067
Month 24	1	45.85	23.013	(-13.31, 105.01)	0.103
Month 36	1	45.85	23.013	(-13.31, 105.01)	0.103
Month 48	1	55.25	23.013	(-3.91, 114.41)	0.062
Month 60	1	52.15	23.013	(-7.01, 111.31)	0.073

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	3.62	3.083	(-2.52, 9.76)	0.244
Month 3	13	11.43	2.963	(5.53, 17.33)	<.001
Month 6	12	11.15	3.089	(5.00, 17.30)	<.001
Month 9	11	11.37	3.221	(4.95, 17.78)	<.001
Month 12	10	17.35	3.377	(10.62, 24.07)	<.001
Month 18	7	22.21	4.039	(14.16, 30.25)	<.001
Month 24	7	22.59	4.037	(14.55, 30.62)	<.001
Month 36	6	15.52	4.372	(6.81, 24.22)	<.001
Month 48	4	22.36	5.374	(11.66, 33.06)	<.001
Month 60	6	23.14	4.376	(14.42, 31.85)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	7.85	2.759	(2.39, 13.31)	0.005
Month 3	23	10.17	2.756	(4.71, 15.62)	<.001
Month 6	22	10.36	2.819	(4.78, 15.94)	<.001
Month 9	16	14.73	3.304	(8.19, 21.27)	<.001
Month 12	11	20.48	3.986	(12.60, 28.37)	<.001
Month 18	9	17.20	4.406	(8.48, 25.91)	<.001
Month 24	12	18.14	3.815	(10.60, 25.69)	<.001
Month 36	10	18.82	4.184	(10.54, 27.10)	<.001
Month 48	7	19.62	4.996	(9.74, 29.50)	<.001
Month 60	7	17.29	4.999	(7.40, 27.18)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	8.23	5.444	(-5.76, 22.23)	0.191
Month 3	2	16.53	5.444	(2.54, 30.53)	0.029
Month 6	2	18.23	5.444	(4.24, 32.23)	0.020
Month 9	2	16.58	5.444	(2.59, 30.58)	0.029
Month 12	2	26.53	5.444	(12.54, 40.53)	0.005
Month 18	2	13.23	5.444	(-0.76, 27.23)	0.059
Month 24	1	11.31	7.837	(-8.84, 31.45)	0.209
Month 36	1	-3.69	7.837	(-23.84, 16.45)	0.657
Month 48	1	2.91	7.837	(-17.24, 23.05)	0.726
Month 60	1	12.91	7.837	(-7.24, 33.05)	0.160

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	7	7.48	5.135	(-2.85, 17.81)	0.152
Month 3	8	10.34	4.745	(0.80, 19.89)	0.034
Month 6	8	4.25	4.753	(-5.31, 13.81)	0.376
Month 9	7	9.10	5.022	(-1.00, 19.21)	0.076
Month 12	7	15.21	5.023	(5.11, 25.31)	0.004
Month 18	4	13.23	6.678	(-0.20, 26.67)	0.053
Month 24	5	13.91	6.007	(1.83, 26.00)	0.025
Month 36	4	14.48	6.678	(1.05, 27.92)	0.035
Month 48	3	19.67	7.780	(4.02, 35.32)	0.015
Month 60	5	19.91	6.007	(7.83, 32.00)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	5.68	3.862	(-1.97, 13.33)	0.144
Month 3	20	7.35	3.540	(0.34, 14.37)	0.040
Month 6	19	9.10	3.636	(1.90, 16.30)	0.014
Month 9	15	13.17	4.087	(5.08, 21.27)	0.002
Month 12	11	18.13	4.775	(8.67, 27.59)	<.001
Month 18	9	11.62	5.279	(1.16, 22.07)	0.030
Month 24	12	12.13	4.569	(3.08, 21.18)	0.009
Month 36	10	17.52	5.010	(7.59, 27.44)	<.001
Month 48	7	15.46	5.985	(3.60, 27.31)	0.011
Month 60	7	14.71	5.989	(2.84, 26.57)	0.016

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	5.10	10.228	(-21.19, 31.40)	0.639
Month 3	2	15.10	10.228	(-11.19, 41.40)	0.200
Month 6	2	27.60	10.228	(1.31, 53.90)	0.043
Month 9	2	22.60	10.228	(-3.69, 48.90)	0.078
Month 12	2	35.10	10.228	(8.81, 61.40)	0.019
Month 18	2	17.60	10.228	(-8.69, 43.90)	0.146
Month 24	1	24.69	14.724	(-13.16, 62.54)	0.154
Month 36	1	4.69	14.724	(-33.16, 42.54)	0.763
Month 48	1	19.69	14.724	(-18.16, 57.54)	0.239
Month 60	1	34.69	14.724	(-3.16, 72.54)	0.065

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Region: Europe

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	2.94	3.760	(-4.55, 10.43)	0.436
Month 3	13	10.12	3.460	(3.23, 17.01)	0.005
Month 6	12	8.76	3.598	(1.59, 15.92)	0.017
Month 9	11	9.44	3.760	(1.95, 16.93)	0.014
Month 12	10	11.84	3.941	(3.99, 19.69)	0.004
Month 18	7	19.48	4.716	(10.08, 28.87)	<.001
Month 24	7	15.91	4.716	(6.51, 25.30)	0.001
Month 36	6	10.91	5.108	(0.73, 21.08)	0.036
Month 48	4	22.72	6.231	(10.31, 35.13)	<.001
Month 60	6	17.44	5.096	(7.29, 27.59)	0.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Region: US

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	4.86	2.717	(-0.51, 10.24)	0.076
Month 3	23	7.12	2.716	(1.74, 12.49)	0.010
Month 6	22	7.54	2.780	(2.04, 13.04)	0.008
Month 9	16	10.89	3.257	(4.45, 17.34)	0.001
Month 12	11	17.31	3.928	(9.53, 25.08)	<.001
Month 18	8	19.34	4.606	(10.23, 28.46)	<.001
Month 24	12	17.46	3.760	(10.02, 24.90)	<.001
Month 36	10	18.62	4.120	(10.47, 26.77)	<.001
Month 48	7	14.34	4.924	(4.60, 24.08)	0.004
Month 60	7	20.61	4.928	(10.86, 30.36)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
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LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203k
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Region
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Region: Rest of World

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	10.21	5.429	(-3.75, 24.16)	0.119
Month 3	2	15.21	5.429	(1.25, 29.16)	0.038
Month 6	2	17.71	5.429	(3.75, 31.66)	0.022
Month 9	2	10.21	5.429	(-3.75, 24.16)	0.119
Month 12	2	15.21	5.429	(1.25, 29.16)	0.038
Month 18	2	7.71	5.429	(-6.25, 21.66)	0.215
Month 24	1	6.87	7.815	(-13.21, 26.96)	0.419
Month 36	1	-13.13	7.815	(-33.21, 6.96)	0.154
Month 48	1	-3.13	7.815	(-23.21, 16.96)	0.706
Month 60	1	16.88	7.815	(-3.21, 36.96)	0.083

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	9.45	3.764	(2.01, 16.88)	0.013
Month 3	24	15.44	3.603	(8.32, 22.56)	<.001
Month 6	25	16.26	3.530	(9.29, 23.23)	<.001
Month 9	19	16.18	4.053	(8.17, 24.19)	<.001
Month 12	17	20.20	4.280	(11.75, 28.66)	<.001
Month 18	14	22.92	4.717	(13.61, 32.24)	<.001
Month 24	13	25.31	4.904	(15.62, 35.00)	<.001
Month 36	13	16.46	4.904	(6.78, 26.15)	<.001
Month 48	8	24.00	6.254	(11.65, 36.36)	<.001
Month 60	11	25.51	5.321	(15.00, 36.02)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	10.27	4.832	(0.63, 19.92)	0.037
Month 3	14	15.75	5.007	(5.76, 25.74)	0.002
Month 6	11	13.59	5.618	(2.37, 24.80)	0.018
Month 9	10	19.59	5.894	(7.82, 31.35)	0.001
Month 12	6	34.41	7.618	(19.20, 49.61)	<.001
Month 18	4	27.31	9.348	(8.66, 45.97)	0.005
Month 24	7	26.45	7.046	(12.39, 40.52)	<.001
Month 36	4	17.91	9.461	(-0.98, 36.79)	0.063
Month 48	4	27.31	9.348	(8.66, 45.97)	0.005
Month 60	3	6.10	10.763	(-15.38, 27.58)	0.573

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	5.51	3.998	(-2.38, 13.41)	0.170
Month 3	24	17.22	3.828	(9.66, 24.79)	<.001
Month 6	25	21.02	3.751	(13.61, 28.43)	<.001
Month 9	19	20.86	4.307	(12.35, 29.37)	<.001
Month 12	17	25.39	4.548	(16.40, 34.37)	<.001
Month 18	14	29.03	5.012	(19.13, 38.93)	<.001
Month 24	13	31.24	5.206	(20.95, 41.52)	<.001
Month 36	13	24.73	5.206	(14.44, 35.01)	<.001
Month 48	8	38.81	6.630	(25.72, 51.91)	<.001
Month 60	11	40.79	5.655	(29.61, 51.96)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	6.44	5.331	(-4.21, 17.08)	0.232
Month 3	14	22.76	5.527	(11.73, 33.79)	<.001
Month 6	11	22.69	6.211	(10.30, 35.09)	<.001
Month 9	10	33.80	6.515	(20.80, 46.81)	<.001
Month 12	6	43.09	8.423	(26.28, 59.90)	<.001
Month 18	4	30.37	10.376	(9.66, 51.08)	0.005
Month 24	7	41.08	7.799	(25.51, 56.64)	<.001
Month 36	4	42.68	10.343	(22.04, 63.32)	<.001
Month 48	4	36.10	10.307	(15.53, 56.68)	<.001
Month 60	3	36.26	11.952	(12.40, 60.12)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	22	5.29	2.578	(0.20, 10.38)	0.042
Month 3	24	10.45	2.468	(5.57, 15.32)	<.001
Month 6	25	11.50	2.419	(6.72, 16.28)	<.001
Month 9	19	12.42	2.776	(6.94, 17.91)	<.001
Month 12	17	17.01	2.932	(11.22, 22.80)	<.001
Month 18	14	18.17	3.231	(11.79, 24.56)	<.001
Month 24	13	19.11	3.356	(12.48, 25.74)	<.001
Month 36	13	15.51	3.356	(8.88, 22.14)	<.001
Month 48	8	18.84	4.280	(10.39, 27.30)	<.001
Month 60	11	22.01	3.646	(14.81, 29.21)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	7.71	3.497	(0.73, 14.69)	0.031
Month 3	14	11.96	3.623	(4.73, 19.19)	0.002
Month 6	11	10.10	4.073	(1.97, 18.23)	0.016
Month 9	10	15.57	4.273	(7.04, 24.10)	<.001
Month 12	6	26.62	5.516	(15.62, 37.63)	<.001
Month 18	4	18.51	6.755	(5.02, 31.99)	0.008
Month 24	7	20.19	5.106	(10.00, 30.38)	<.001
Month 36	4	19.42	6.844	(5.76, 33.09)	0.006
Month 48	4	21.92	6.791	(8.36, 35.47)	0.002
Month 60	3	12.07	7.821	(-3.54, 27.68)	0.128

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	3.08	3.727	(-4.30, 10.46)	0.411
Month 3	17	6.50	3.507	(-0.45, 13.44)	0.066
Month 6	19	10.15	3.315	(3.59, 16.71)	0.003
Month 9	15	13.57	3.727	(6.19, 20.95)	<.001
Month 12	14	18.58	3.857	(10.94, 26.22)	<.001
Month 18	11	14.63	4.354	(6.01, 23.25)	0.001
Month 24	11	13.56	4.352	(4.95, 22.18)	0.002
Month 36	11	17.20	4.352	(8.58, 25.82)	<.001
Month 48	7	16.24	5.463	(5.42, 27.06)	0.004
Month 60	10	21.72	4.565	(12.68, 30.76)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	11	5.98	5.366	(-4.75, 16.71)	0.270
Month 3	13	10.13	4.929	(0.27, 19.99)	0.044
Month 6	10	5.54	5.628	(-5.72, 16.79)	0.329
Month 9	9	11.10	5.928	(-0.75, 22.96)	0.066
Month 12	6	20.10	7.257	(5.59, 34.62)	0.007
Month 18	4	8.16	8.910	(-9.66, 25.99)	0.363
Month 24	7	16.03	6.720	(2.59, 29.48)	0.020
Month 36	4	17.22	8.926	(-0.64, 35.07)	0.058
Month 48	4	23.69	8.950	(5.79, 41.59)	0.010
Month 60	3	11.03	10.301	(-9.58, 31.64)	0.289

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Prior SCT therapy: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	4.25	2.873	(-1.43, 9.92)	0.141
Month 3	24	7.75	2.687	(2.45, 13.06)	0.004
Month 6	25	8.21	2.634	(3.00, 13.41)	0.002
Month 9	19	8.32	3.022	(2.35, 14.29)	0.007
Month 12	17	11.04	3.193	(4.74, 17.35)	<.001
Month 18	13	17.32	3.651	(10.10, 24.53)	<.001
Month 24	13	15.55	3.653	(8.33, 22.76)	<.001
Month 36	13	11.32	3.653	(4.10, 18.53)	0.002
Month 48	8	15.90	4.654	(6.71, 25.10)	<.001
Month 60	11	18.95	3.970	(11.10, 26.79)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203l
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Prior SCT therapy
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Prior SCT therapy: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	5.29	3.168	(-1.03, 11.61)	0.100
Month 3	14	10.79	3.288	(4.23, 17.35)	0.002
Month 6	11	10.33	3.689	(2.96, 17.69)	0.007
Month 9	10	13.93	3.866	(6.21, 21.65)	<.001
Month 12	6	24.37	5.006	(14.38, 34.36)	<.001
Month 18	4	18.43	6.150	(6.15, 30.70)	0.004
Month 24	7	17.55	4.624	(8.32, 26.78)	<.001
Month 36	4	21.43	6.195	(9.06, 33.79)	<.001
Month 48	4	14.18	6.123	(1.96, 26.40)	0.024
Month 60	3	18.82	7.068	(4.72, 32.93)	0.010

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	26.08	5.306	(14.40, 37.76)	<.001
Month 3	3	24.42	5.306	(12.74, 36.09)	<.001
Month 6	3	21.08	5.306	(9.40, 32.76)	0.002
Month 9	2	17.07	6.540	(2.68, 31.46)	0.024
Month 12	2	32.07	6.540	(17.68, 46.46)	<.001
Month 18	2	27.07	6.540	(12.68, 41.46)	0.002
Month 24	2	34.79	6.597	(20.27, 49.31)	<.001
Month 36	2	32.29	6.597	(17.77, 46.81)	<.001
Month 48	1	34.11	9.199	(13.86, 54.36)	0.003
Month 60	2	32.29	6.597	(17.77, 46.81)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	34	8.53	3.065	(2.49, 14.57)	0.006
Month 3	35	14.94	3.019	(8.99, 20.89)	<.001
Month 6	33	15.07	3.107	(8.94, 21.19)	<.001
Month 9	27	17.69	3.435	(10.92, 24.46)	<.001
Month 12	21	23.41	3.896	(15.73, 31.09)	<.001
Month 18	16	23.76	4.467	(14.96, 32.57)	<.001
Month 24	18	24.24	4.206	(15.95, 32.53)	<.001
Month 36	15	14.09	4.622	(4.98, 23.20)	0.003
Month 48	11	24.06	5.384	(13.45, 34.68)	<.001
Month 60	12	18.38	5.151	(8.23, 28.54)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	15.68	5.589	(3.38, 27.98)	0.017
Month 3	3	21.91	5.589	(9.61, 34.22)	0.002
Month 6	3	27.11	5.589	(14.81, 39.42)	<.001
Month 9	2	27.48	6.896	(12.30, 42.66)	0.002
Month 12	2	33.68	6.896	(18.50, 48.86)	<.001
Month 18	2	38.38	6.896	(23.20, 53.56)	<.001
Month 24	2	36.37	6.955	(21.06, 51.67)	<.001
Month 36	2	39.52	6.955	(24.21, 54.82)	<.001
Month 48	1	42.08	9.700	(20.73, 63.43)	0.001
Month 60	2	42.62	6.955	(27.31, 57.92)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	34	4.74	3.436	(-2.04, 11.51)	0.169
Month 3	35	18.78	3.388	(12.10, 25.46)	<.001
Month 6	33	21.23	3.488	(14.35, 28.10)	<.001
Month 9	27	25.90	3.856	(18.30, 33.50)	<.001
Month 12	21	30.37	4.373	(21.74, 38.99)	<.001
Month 18	16	29.37	5.011	(19.49, 39.24)	<.001
Month 24	18	34.04	4.725	(24.73, 43.36)	<.001
Month 36	15	27.05	5.178	(16.85, 37.26)	<.001
Month 48	11	37.01	6.043	(25.09, 48.92)	<.001
Month 60	12	37.64	5.792	(26.22, 49.06)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	18.43	5.129	(7.14, 29.72)	0.004
Month 3	3	17.00	5.129	(5.71, 28.29)	0.007
Month 6	3	19.23	5.129	(7.94, 30.52)	0.003
Month 9	2	14.63	6.288	(0.79, 28.47)	0.040
Month 12	2	30.43	6.288	(16.59, 44.27)	<.001
Month 18	2	23.78	6.288	(9.94, 37.62)	0.003
Month 24	2	27.35	6.345	(13.39, 41.32)	0.001
Month 36	2	33.20	6.345	(19.24, 47.17)	<.001
Month 48	1	31.84	8.866	(12.32, 51.35)	0.004
Month 60	2	31.50	6.345	(17.54, 45.47)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	34	5.27	2.064	(1.20, 9.34)	0.011
Month 3	35	10.54	2.034	(6.53, 14.55)	<.001
Month 6	33	10.49	2.095	(6.36, 14.62)	<.001
Month 9	27	13.62	2.315	(9.06, 18.19)	<.001
Month 12	21	18.67	2.625	(13.50, 23.85)	<.001
Month 18	16	17.73	3.007	(11.80, 23.65)	<.001
Month 24	18	18.20	2.835	(12.61, 23.79)	<.001
Month 36	15	13.88	3.111	(7.75, 20.02)	<.001
Month 48	11	18.97	3.626	(11.82, 26.12)	<.001
Month 60	12	16.99	3.476	(10.13, 23.84)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	2	14.29	8.870	(-5.47, 34.06)	0.138
Month 3	3	10.45	7.028	(-5.21, 26.11)	0.168
Month 6	3	17.12	7.028	(1.46, 32.78)	0.035
Month 9	2	5.00	8.598	(-14.16, 24.16)	0.574
Month 12	2	35.00	8.598	(15.84, 54.16)	0.002
Month 18	2	20.00	8.598	(0.84, 39.16)	0.042
Month 24	2	17.06	8.683	(-2.29, 36.41)	0.078
Month 36	2	37.06	8.683	(17.71, 56.41)	0.002
Month 48	1	31.35	12.198	(4.17, 58.53)	0.028
Month 60	2	34.56	8.683	(15.21, 53.91)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	24	3.90	3.090	(-2.20, 10.00)	0.208
Month 3	27	8.01	2.916	(2.25, 13.77)	0.007
Month 6	26	7.75	2.975	(1.87, 13.62)	0.010
Month 9	22	13.32	3.228	(6.95, 19.69)	<.001
Month 12	18	17.32	3.568	(10.27, 24.36)	<.001
Month 18	13	11.68	4.205	(3.37, 19.98)	0.006
Month 24	16	13.84	3.788	(6.36, 21.32)	<.001
Month 36	13	13.63	4.199	(5.34, 21.92)	0.001
Month 48	10	17.70	4.788	(8.25, 27.15)	<.001
Month 60	11	15.88	4.575	(6.85, 24.91)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Eligibility for SCT: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	13.65	4.557	(3.62, 23.68)	0.012
Month 3	3	15.31	4.557	(5.28, 25.34)	0.006
Month 6	3	18.65	4.557	(8.62, 28.68)	0.002
Month 9	2	22.04	5.608	(9.70, 34.38)	0.002
Month 12	2	24.54	5.608	(12.20, 36.88)	0.001
Month 18	2	24.54	5.608	(12.20, 36.88)	0.001
Month 24	2	28.01	5.659	(15.56, 40.47)	<.001
Month 36	2	28.01	5.659	(15.56, 40.47)	<.001
Month 48	1	26.86	7.890	(9.49, 44.22)	0.006
Month 60	2	25.51	5.659	(13.06, 37.97)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203m
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Eligibility for SCT
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Eligibility for SCT: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	33	3.84	2.233	(-0.56, 8.24)	0.087
Month 3	35	8.21	2.168	(3.94, 12.48)	<.001
Month 6	33	7.95	2.232	(3.55, 12.35)	<.001
Month 9	27	9.63	2.468	(4.76, 14.49)	<.001
Month 12	21	13.94	2.798	(8.42, 19.45)	<.001
Month 18	15	17.15	3.312	(10.62, 23.68)	<.001
Month 24	18	14.64	3.022	(8.68, 20.60)	<.001
Month 36	15	11.63	3.315	(5.10, 18.17)	<.001
Month 48	11	14.37	3.865	(6.75, 21.99)	<.001
Month 60	12	17.00	3.704	(9.70, 24.30)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	3.80	3.573	(-3.30, 10.89)	0.290
Month 3	15	16.97	3.452	(10.12, 23.83)	<.001
Month 6	12	13.65	3.858	(5.98, 21.31)	<.001
Month 9	12	19.34	3.857	(11.68, 27.00)	<.001
Month 12	11	16.27	4.029	(8.27, 24.27)	<.001
Month 18	8	13.81	4.726	(4.43, 23.20)	0.004
Month 24	9	14.60	4.457	(5.75, 23.46)	0.001
Month 36	8	4.28	4.738	(-5.13, 13.68)	0.369
Month 48	8	15.35	4.725	(5.96, 24.73)	0.002
Month 60	7	15.15	5.053	(5.11, 25.18)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	13.87	4.135	(5.69, 22.05)	0.001
Month 3	23	14.86	4.127	(6.69, 23.02)	<.001
Month 6	24	17.03	4.032	(9.06, 25.01)	<.001
Month 9	17	16.15	4.799	(6.66, 25.65)	0.001
Month 12	12	30.21	5.715	(18.90, 41.52)	<.001
Month 18	10	31.43	6.268	(19.03, 43.83)	<.001
Month 24	11	34.84	5.961	(23.04, 46.63)	<.001
Month 36	9	27.82	6.627	(14.71, 40.93)	<.001
Month 48	4	41.60	9.879	(22.05, 61.14)	<.001
Month 60	7	26.31	7.475	(11.52, 41.10)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	0.51	5.654	(-10.72, 11.73)	0.929
Month 3	15	15.96	5.465	(5.10, 26.81)	0.004
Month 6	12	21.02	6.103	(8.91, 33.14)	<.001
Month 9	12	25.63	6.103	(13.51, 37.75)	<.001
Month 12	11	25.14	6.376	(12.48, 37.80)	<.001
Month 18	8	27.44	7.476	(12.60, 42.29)	<.001
Month 24	9	28.50	7.056	(14.49, 42.51)	<.001
Month 36	8	22.30	7.504	(7.39, 37.20)	0.004
Month 48	8	35.26	7.474	(20.41, 50.10)	<.001
Month 60	7	35.66	7.992	(19.79, 51.53)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	8.64	3.989	(0.75, 16.53)	0.032
Month 3	23	20.86	3.991	(12.97, 28.76)	<.001
Month 6	24	22.17	3.905	(14.44, 29.89)	<.001
Month 9	17	25.76	4.646	(16.57, 34.95)	<.001
Month 12	12	34.68	5.534	(23.73, 45.63)	<.001
Month 18	10	32.14	6.051	(20.17, 44.11)	<.001
Month 24	11	39.89	5.775	(28.46, 51.32)	<.001
Month 36	9	35.37	6.379	(22.75, 47.99)	<.001
Month 48	4	40.85	9.570	(21.91, 59.78)	<.001
Month 60	7	42.85	7.240	(28.53, 57.17)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	2.39	2.685	(-2.94, 7.72)	0.376
Month 3	15	10.63	2.594	(5.48, 15.78)	<.001
Month 6	12	11.14	2.900	(5.38, 16.90)	<.001
Month 9	12	15.44	2.899	(9.69, 21.20)	<.001
Month 12	11	15.35	3.028	(9.34, 21.36)	<.001
Month 18	8	12.46	3.552	(5.40, 19.51)	<.001
Month 24	9	10.20	3.349	(3.55, 16.85)	0.003
Month 36	8	7.43	3.558	(0.36, 14.49)	0.040
Month 48	8	13.73	3.551	(6.68, 20.78)	<.001
Month 60	7	15.46	3.796	(7.92, 22.99)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	8.74	2.785	(3.23, 14.24)	0.002
Month 3	23	11.28	2.783	(5.77, 16.78)	<.001
Month 6	24	11.34	2.723	(5.95, 16.73)	<.001
Month 9	17	12.16	3.239	(5.75, 18.57)	<.001
Month 12	12	23.26	3.855	(15.63, 30.89)	<.001
Month 18	10	22.92	4.221	(14.57, 31.28)	<.001
Month 24	11	26.97	4.023	(19.01, 34.93)	<.001
Month 36	9	24.54	4.461	(15.72, 33.37)	<.001
Month 48	4	30.85	6.671	(17.65, 44.05)	<.001
Month 60	7	23.68	5.043	(13.70, 33.66)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	2.31	4.218	(-6.09, 10.71)	0.586
Month 3	12	9.84	3.648	(2.57, 17.11)	0.009
Month 6	9	12.30	4.211	(3.91, 20.69)	0.005
Month 9	10	14.39	3.993	(6.43, 22.35)	<.001
Month 12	10	17.89	3.993	(9.93, 25.85)	<.001
Month 18	7	11.23	4.778	(1.71, 20.75)	0.021
Month 24	8	5.26	4.469	(-3.64, 14.16)	0.243
Month 36	7	6.27	4.786	(-3.27, 15.80)	0.194
Month 48	7	13.63	4.776	(4.12, 23.15)	0.006
Month 60	6	15.45	5.157	(5.17, 25.72)	0.004

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	5.54	4.053	(-2.50, 13.58)	0.175
Month 3	18	6.97	3.950	(-0.86, 14.80)	0.081
Month 6	20	6.92	3.743	(-0.50, 14.35)	0.067
Month 9	14	11.29	4.466	(2.44, 20.15)	0.013
Month 12	10	20.16	5.284	(9.69, 30.64)	<.001
Month 18	8	14.52	5.915	(2.79, 26.25)	0.016
Month 24	10	21.98	5.296	(11.48, 32.48)	<.001
Month 36	8	26.48	5.909	(14.77, 38.20)	<.001
Month 48	4	27.11	8.355	(10.54, 43.68)	0.002
Month 60	7	22.73	6.322	(10.20, 35.27)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Baseline bone marrow tumor burden: Low

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	13	4.49	3.284	(-2.03, 11.02)	0.175
Month 3	15	9.13	3.052	(3.06, 15.19)	0.004
Month 6	12	10.90	3.414	(4.12, 17.68)	0.002
Month 9	12	11.25	3.412	(4.47, 18.03)	0.001
Month 12	11	11.96	3.567	(4.87, 19.04)	0.001
Month 18	7	12.86	4.467	(3.98, 21.73)	0.005
Month 24	9	7.57	3.941	(-0.26, 15.39)	0.058
Month 36	8	7.65	4.186	(-0.67, 15.96)	0.071
Month 48	8	10.39	4.180	(2.08, 18.69)	0.015
Month 60	7	15.71	4.467	(6.84, 24.59)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203n
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline bone marrow tumor burden
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Baseline bone marrow tumor burden: High

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	23	4.90	2.827	(-0.69, 10.49)	0.085
Month 3	23	8.48	2.828	(2.89, 14.08)	0.003
Month 6	24	7.93	2.766	(2.45, 13.40)	0.005
Month 9	17	9.60	3.290	(3.09, 16.11)	0.004
Month 12	12	17.12	3.915	(9.37, 24.87)	<.001
Month 18	10	21.35	4.288	(12.86, 29.83)	<.001
Month 24	11	23.36	4.089	(15.27, 31.45)	<.001
Month 36	9	19.33	4.528	(10.37, 28.29)	<.001
Month 48	4	23.94	6.776	(10.53, 37.35)	<.001
Month 60	7	21.36	5.125	(11.22, 31.50)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	14.51	7.633	(-0.92, 29.94)	0.065
Month 3	7	27.08	7.109	(12.71, 41.45)	<.001
Month 6	6	24.05	7.614	(8.67, 39.44)	0.003
Month 9	5	25.32	8.346	(8.45, 42.19)	0.004
Month 12	5	24.82	8.346	(7.95, 41.69)	0.005
Month 18	5	24.82	8.346	(7.95, 41.69)	0.005
Month 24	5	17.82	8.346	(0.95, 34.69)	0.039
Month 36	5	14.82	8.346	(-2.05, 31.69)	0.083
Month 48	3	18.86	10.767	(-2.90, 40.63)	0.087
Month 60	4	20.51	9.326	(1.66, 39.36)	0.034

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	31	8.89	3.179	(2.62, 15.16)	0.006
Month 3	31	13.20	3.177	(6.93, 19.46)	<.001
Month 6	30	13.64	3.230	(7.27, 20.02)	<.001
Month 9	24	15.32	3.613	(8.20, 22.45)	<.001
Month 12	18	23.42	4.168	(15.19, 31.64)	<.001
Month 18	13	23.52	4.905	(13.84, 33.20)	<.001
Month 24	15	28.40	4.567	(19.39, 37.41)	<.001
Month 36	12	17.90	5.124	(7.79, 28.01)	<.001
Month 48	9	27.68	5.898	(16.05, 39.32)	<.001
Month 60	10	21.60	5.592	(10.57, 32.63)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
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Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	3.95	8.763	(-13.76, 21.66)	0.655
Month 3	7	16.28	8.118	(-0.13, 32.68)	0.052
Month 6	6	20.44	8.764	(2.72, 38.15)	0.025
Month 9	5	19.97	9.600	(0.57, 39.37)	0.044
Month 12	5	24.33	9.600	(4.93, 43.73)	0.015
Month 18	5	27.47	9.600	(8.07, 46.87)	0.007
Month 24	5	24.35	9.600	(4.95, 43.75)	0.015
Month 36	5	24.33	9.600	(4.93, 43.73)	0.015
Month 48	3	37.92	12.400	(12.86, 62.98)	0.004
Month 60	4	36.46	10.759	(14.71, 58.20)	0.002

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
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Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	31	5.59	3.395	(-1.11, 12.29)	0.102
Month 3	31	19.37	3.397	(12.67, 26.07)	<.001
Month 6	30	21.27	3.453	(14.46, 28.08)	<.001
Month 9	24	26.87	3.861	(19.25, 34.48)	<.001
Month 12	18	32.00	4.456	(23.21, 40.79)	<.001
Month 18	13	31.63	5.243	(21.29, 41.97)	<.001
Month 24	15	38.23	4.888	(28.59, 47.87)	<.001
Month 36	12	31.52	5.466	(20.73, 42.30)	<.001
Month 48	9	38.61	6.307	(26.17, 51.06)	<.001
Month 60	10	41.04	5.981	(29.24, 52.84)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	8.74	3.897	(0.86, 16.61)	0.031
Month 3	7	13.22	3.612	(5.92, 20.52)	<.001
Month 6	6	15.65	3.894	(7.78, 23.52)	<.001
Month 9	5	18.01	4.262	(9.40, 26.63)	<.001
Month 12	5	16.95	4.262	(8.34, 25.57)	<.001
Month 18	5	13.97	4.262	(5.36, 22.59)	0.002
Month 24	5	11.33	4.262	(2.72, 19.95)	0.011
Month 36	5	7.97	4.262	(-0.64, 16.59)	0.069
Month 48	3	12.94	5.519	(1.79, 24.10)	0.024
Month 60	4	16.79	4.764	(7.16, 26.41)	0.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	31	5.72	2.315	(1.16, 10.29)	0.014
Month 3	31	10.39	2.314	(5.82, 14.95)	<.001
Month 6	30	10.01	2.354	(5.37, 14.66)	<.001
Month 9	24	12.66	2.631	(7.47, 17.85)	<.001
Month 12	18	20.24	3.037	(14.25, 26.23)	<.001
Month 18	13	19.98	3.574	(12.93, 27.03)	<.001
Month 24	15	22.23	3.328	(15.66, 28.79)	<.001
Month 36	12	20.08	3.731	(12.71, 27.44)	<.001
Month 48	9	22.68	4.297	(14.20, 31.15)	<.001
Month 60	10	21.16	4.078	(13.11, 29.20)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	5	5.41	5.043	(-4.80, 15.62)	0.290
Month 3	6	4.11	4.600	(-5.20, 13.42)	0.377
Month 6	6	16.87	4.607	(7.54, 26.19)	<.001
Month 9	5	24.38	5.038	(14.18, 34.58)	<.001
Month 12	5	22.38	5.038	(12.18, 32.58)	<.001
Month 18	5	14.38	5.038	(4.18, 24.58)	0.007
Month 24	5	11.38	5.038	(1.18, 21.58)	0.030
Month 36	5	9.38	5.038	(-0.82, 19.58)	0.070
Month 48	3	14.43	6.529	(1.22, 27.65)	0.033
Month 60	4	18.13	5.634	(6.73, 29.53)	0.003

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	21	3.86	3.561	(-3.18, 10.90)	0.280
Month 3	24	8.95	3.330	(2.36, 15.53)	0.008
Month 6	23	6.28	3.412	(-0.47, 13.03)	0.068
Month 9	19	9.35	3.740	(1.96, 16.75)	0.014
Month 12	15	18.02	4.209	(9.70, 26.34)	<.001
Month 18	10	12.68	5.170	(2.46, 22.90)	0.015
Month 24	13	15.92	4.523	(6.98, 24.86)	<.001
Month 36	10	21.39	5.157	(11.19, 31.59)	<.001
Month 48	8	20.30	5.765	(8.90, 31.69)	<.001
Month 60	9	20.20	5.442	(9.44, 30.96)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Baseline extramedullary disease presence: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	6	7.81	3.454	(0.82, 14.79)	0.029
Month 3	7	5.73	3.193	(-0.73, 12.19)	0.080
Month 6	6	8.12	3.448	(1.15, 15.09)	0.024
Month 9	5	2.84	3.774	(-4.79, 10.48)	0.456
Month 12	5	2.84	3.774	(-4.79, 10.48)	0.456
Month 18	4	5.32	4.224	(-3.23, 13.86)	0.215
Month 24	5	3.84	3.774	(-3.79, 11.48)	0.315
Month 36	5	-1.16	3.774	(-8.79, 6.48)	0.761
Month 48	3	5.59	4.907	(-4.34, 15.52)	0.262
Month 60	4	11.09	4.219	(2.56, 19.63)	0.012

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203o
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Baseline extramedullary disease presence
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Baseline extramedullary disease presence: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	30	3.99	2.409	(-0.77, 8.74)	0.100
Month 3	31	9.39	2.369	(4.71, 14.06)	<.001
Month 6	30	8.92	2.408	(4.16, 13.67)	<.001
Month 9	24	11.99	2.693	(6.67, 17.30)	<.001
Month 12	18	17.92	3.108	(11.79, 24.06)	<.001
Month 18	13	21.59	3.658	(14.37, 28.81)	<.001
Month 24	15	20.33	3.407	(13.61, 27.06)	<.001
Month 36	12	19.95	3.820	(12.41, 27.49)	<.001
Month 48	9	19.00	4.395	(10.32, 27.67)	<.001
Month 60	10	21.68	4.171	(13.45, 29.92)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in

PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	9.10	2.962	(3.26, 14.94)	0.002
Month 3	37	15.67	2.920	(9.92, 21.43)	<.001
Month 6	35	14.82	3.000	(8.91, 20.74)	<.001
Month 9	28	17.10	3.356	(10.48, 23.71)	<.001
Month 12	22	22.70	3.785	(15.24, 30.16)	<.001
Month 18	17	22.37	4.306	(13.88, 30.86)	<.001
Month 24	19	24.56	4.074	(16.53, 32.59)	<.001
Month 36	16	14.84	4.454	(6.06, 23.62)	0.001
Month 48	11	23.15	5.355	(12.60, 33.70)	<.001
Month 60	14	21.00	4.743	(11.65, 30.35)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	3.45	3.248	(-2.95, 9.86)	0.289
Month 3	37	18.93	3.205	(12.61, 25.25)	<.001
Month 6	35	21.24	3.295	(14.75, 27.73)	<.001
Month 9	28	25.16	3.684	(17.89, 32.42)	<.001
Month 12	22	28.98	4.155	(20.79, 37.17)	<.001
Month 18	17	29.99	4.727	(20.67, 39.30)	<.001
Month 24	19	32.96	4.476	(24.14, 41.78)	<.001
Month 36	16	26.82	4.878	(17.20, 36.43)	<.001
Month 48	11	36.17	5.879	(24.59, 47.76)	<.001
Month 60	14	38.79	5.211	(28.52, 49.06)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	36	5.05	2.029	(1.05, 9.05)	0.014
Month 3	37	10.90	2.001	(6.96, 14.84)	<.001
Month 6	35	10.82	2.058	(6.76, 14.87)	<.001
Month 9	28	13.36	2.301	(8.82, 17.89)	<.001
Month 12	22	18.40	2.595	(13.29, 23.52)	<.001
Month 18	17	17.17	2.952	(11.35, 22.98)	<.001
Month 24	19	17.98	2.793	(12.48, 23.48)	<.001
Month 36	16	15.29	3.049	(9.28, 21.30)	<.001
Month 48	11	18.87	3.670	(11.63, 26.10)	<.001
Month 60	14	19.47	3.253	(13.06, 25.88)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	25	2.44	3.021	(-3.53, 8.40)	0.421
Month 3	29	8.00	2.806	(2.46, 13.54)	0.005
Month 6	28	8.65	2.858	(3.01, 14.29)	0.003
Month 9	23	12.24	3.149	(6.03, 18.45)	<.001
Month 12	19	18.02	3.464	(11.18, 24.85)	<.001
Month 18	14	11.49	4.042	(3.51, 19.47)	0.005
Month 24	17	12.23	3.663	(5.00, 19.46)	0.001
Month 36	14	16.03	4.037	(8.07, 24.00)	<.001
Month 48	10	18.46	4.775	(9.04, 27.89)	<.001
Month 60	13	18.96	4.190	(10.70, 27.23)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Down syndrome: Yes

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	1	NE	NE	(NE, NE)	NE
Month 3	1	NE	NE	(NE, NE)	NE
Month 6	1	NE	NE	(NE, NE)	NE
Month 9	1	NE	NE	(NE, NE)	NE
Month 12	1	NE	NE	(NE, NE)	NE
Month 18	1	NE	NE	(NE, NE)	NE
Month 24	1	NE	NE	(NE, NE)	NE
Month 36	1	NE	NE	(NE, NE)	NE
Month 48	1	NE	NE	(NE, NE)	NE

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.

LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203p
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Down syndrome
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Down syndrome: No

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	35	3.01	2.152	(-1.23, 7.25)	0.163
Month 3	37	8.52	2.093	(4.39, 12.64)	<.001
Month 6	35	8.48	2.152	(4.24, 12.72)	<.001
Month 9	28	10.28	2.406	(5.54, 15.02)	<.001
Month 12	22	13.36	2.713	(8.01, 18.70)	<.001
Month 18	16	17.28	3.182	(11.01, 23.55)	<.001
Month 24	19	14.97	2.921	(9.22, 20.73)	<.001
Month 36	16	12.95	3.187	(6.67, 19.23)	<.001
Month 48	11	14.30	3.837	(6.74, 21.86)	<.001
Month 60	14	18.35	3.402	(11.65, 25.06)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	10.41	4.491	(1.52, 19.31)	0.022
Month 3	19	17.77	4.244	(9.36, 26.17)	<.001
Month 6	18	13.71	4.369	(5.05, 22.36)	0.002
Month 9	15	18.09	4.791	(8.61, 27.58)	<.001
Month 12	13	24.33	5.130	(14.17, 34.49)	<.001
Month 18	10	25.40	5.850	(13.82, 36.99)	<.001
Month 24	11	27.20	5.577	(16.16, 38.25)	<.001
Month 36	9	21.07	6.188	(8.81, 33.32)	<.001
Month 48	6	22.51	7.569	(7.52, 37.50)	0.004
Month 60	10	21.80	5.855	(10.21, 33.40)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	9.36	3.947	(1.53, 17.18)	0.020
Month 3	19	13.26	4.054	(5.22, 21.30)	0.001
Month 6	18	16.83	4.155	(8.59, 25.07)	<.001
Month 9	14	16.99	4.709	(7.65, 26.33)	<.001
Month 12	10	23.43	5.579	(12.37, 34.49)	<.001
Month 18	8	21.91	6.238	(9.54, 34.28)	<.001
Month 24	9	24.25	5.889	(12.58, 35.93)	<.001
Month 36	8	11.81	6.256	(-0.60, 24.21)	0.062
Month 48	6	28.21	7.192	(13.95, 42.47)	<.001
Month 60	4	19.01	8.824	(1.52, 36.51)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square;
n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	7.74	3.947	(-0.07, 15.56)	0.052
Month 3	19	19.76	3.734	(12.36, 27.16)	<.001
Month 6	18	25.44	3.839	(17.83, 33.04)	<.001
Month 9	15	25.66	4.214	(17.31, 34.00)	<.001
Month 12	13	30.90	4.516	(21.96, 39.85)	<.001
Month 18	10	31.54	5.147	(21.35, 41.74)	<.001
Month 24	11	34.53	4.910	(24.80, 44.25)	<.001
Month 36	9	32.27	5.436	(21.51, 43.04)	<.001
Month 48	6	40.48	6.644	(27.32, 53.63)	<.001
Month 60	10	40.35	5.149	(30.15, 50.55)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	4.21	5.117	(-5.94, 14.35)	0.413
Month 3	19	18.35	5.252	(7.93, 28.76)	<.001
Month 6	18	17.88	5.387	(7.19, 28.56)	0.001
Month 9	14	25.86	6.109	(13.74, 37.97)	<.001
Month 12	10	29.04	7.251	(14.66, 43.41)	<.001
Month 18	8	27.85	8.097	(11.80, 43.90)	<.001
Month 24	9	34.61	7.636	(19.47, 49.75)	<.001
Month 36	8	25.47	8.090	(9.43, 41.51)	0.002
Month 48	6	35.24	9.339	(16.72, 53.76)	<.001
Month 60	4	33.92	11.488	(11.14, 56.69)	0.004

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	17	6.29	2.922	(0.50, 12.08)	0.033
Month 3	19	11.83	2.763	(6.36, 17.31)	<.001
Month 6	18	11.01	2.844	(5.37, 16.64)	<.001
Month 9	15	12.76	3.117	(6.59, 18.93)	<.001
Month 12	13	20.02	3.341	(13.41, 26.64)	<.001
Month 18	10	19.19	3.809	(11.65, 26.73)	<.001
Month 24	11	21.54	3.631	(14.35, 28.73)	<.001
Month 36	9	19.94	4.022	(11.97, 27.90)	<.001
Month 48	6	21.38	4.917	(11.65, 31.12)	<.001
Month 60	10	21.87	3.810	(14.32, 29.41)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	6.34	2.918	(0.56, 12.13)	0.032
Month 3	19	10.32	2.995	(4.38, 16.25)	<.001
Month 6	18	11.41	3.073	(5.32, 17.50)	<.001
Month 9	14	14.06	3.485	(7.15, 20.97)	<.001
Month 12	10	18.44	4.127	(10.26, 26.62)	<.001
Month 18	8	16.74	4.611	(7.60, 25.88)	<.001
Month 24	9	16.63	4.352	(8.00, 25.26)	<.001
Month 36	8	12.55	4.624	(3.38, 21.72)	0.008
Month 48	6	18.73	5.323	(8.17, 29.28)	<.001
Month 60	4	15.28	6.548	(2.29, 28.26)	0.022

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	12	6.00	4.450	(-2.83, 14.84)	0.180
Month 3	15	8.79	3.990	(0.87, 16.71)	0.030
Month 6	15	7.77	3.991	(-0.16, 15.69)	0.055
Month 9	12	11.01	4.449	(2.17, 19.84)	0.015
Month 12	11	22.45	4.649	(13.22, 31.68)	<.001
Month 18	8	15.05	5.455	(4.22, 25.88)	0.007
Month 24	10	19.07	4.878	(9.39, 28.76)	<.001
Month 36	8	20.67	5.449	(9.85, 31.49)	<.001
Month 48	5	24.77	6.896	(11.08, 38.47)	<.001
Month 60	9	24.29	5.141	(14.08, 34.49)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	3.35	4.101	(-4.81, 11.50)	0.417
Month 3	15	7.82	3.948	(-0.03, 15.67)	0.051
Month 6	14	9.59	4.085	(1.46, 17.71)	0.021
Month 9	12	13.93	4.413	(5.16, 22.71)	0.002
Month 12	9	14.59	5.099	(4.45, 24.73)	0.005
Month 18	7	10.80	5.785	(-0.70, 22.30)	0.065
Month 24	8	8.60	5.405	(-2.14, 19.35)	0.115
Month 36	7	12.25	5.797	(0.72, 23.78)	0.038
Month 48	6	12.57	6.256	(0.13, 25.01)	0.048
Month 60	4	9.39	7.655	(-5.83, 24.61)	0.223

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Time since enrollment to CTL019 infusion: > Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	16	5.68	3.174	(-0.60, 11.97)	0.076
Month 3	19	9.17	2.907	(3.41, 14.93)	0.002
Month 6	18	11.63	2.987	(5.72, 17.55)	<.001
Month 9	15	12.24	3.281	(5.74, 18.74)	<.001
Month 12	13	15.12	3.513	(8.16, 22.07)	<.001
Month 18	10	17.45	4.005	(9.52, 25.38)	<.001
Month 24	11	18.01	3.820	(10.45, 25.58)	<.001
Month 36	9	15.18	4.236	(6.79, 23.57)	<.001
Month 48	6	18.79	5.182	(8.53, 29.05)	<.001
Month 60	10	20.33	4.010	(12.39, 28.27)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203q
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Time since enrollment to CTL019 infusion
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Time since enrollment to CTL019 infusion: <=Median

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	20	3.72	3.038	(-2.30, 9.75)	0.223
Month 3	19	8.27	3.118	(2.08, 14.45)	0.009
Month 6	18	5.90	3.202	(-0.45, 12.25)	0.068
Month 9	14	8.13	3.631	(0.93, 15.33)	0.027
Month 12	10	13.92	4.298	(5.40, 22.44)	0.002
Month 18	7	18.04	5.140	(7.85, 28.23)	<.001
Month 24	9	14.17	4.531	(5.18, 23.16)	0.002
Month 36	8	12.61	4.808	(3.07, 22.14)	0.010
Month 48	6	12.51	5.550	(1.51, 23.52)	0.026
Month 60	4	15.20	6.842	(1.64, 28.77)	0.028

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	5.07	5.836	(-7.54, 17.67)	0.401
Month 3	4	18.82	5.836	(6.21, 31.42)	0.007
Month 6	3	13.51	6.590	(-0.73, 27.74)	0.061
Month 9	3	30.17	6.590	(15.94, 44.41)	<.001
Month 12	2	37.47	8.230	(19.69, 55.25)	<.001
Month 18	1	13.09	11.430	(-11.60, 37.79)	0.273
Month 24	3	15.17	6.590	(0.94, 29.41)	0.038
Month 36	2	-7.53	8.230	(-25.31, 10.25)	0.377
Month 48	1	-3.15	11.709	(-28.45, 22.14)	0.792
Month 60	1	-36.91	11.430	(-61.60, -12.21)	0.007

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.
P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.

Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	1.35	5.448	(-9.73, 12.42)	0.806
Month 3	8	-0.20	5.728	(-11.84, 11.44)	0.972
Month 6	6	-0.65	6.578	(-14.02, 12.72)	0.922
Month 9	7	5.30	6.089	(-7.08, 17.67)	0.391
Month 12	4	12.81	8.097	(-3.64, 29.27)	0.123
Month 18	3	3.42	9.355	(-15.59, 22.44)	0.717
Month 24	3	10.98	9.303	(-7.93, 29.88)	0.246
Month 36	1	3.31	16.298	(-29.81, 36.43)	0.840
Month 48	2	9.65	11.474	(-13.67, 32.96)	0.406
Month 60	2	12.15	11.474	(-11.17, 35.46)	0.297

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	10.65	6.109	(-1.65, 22.95)	0.088
Month 3	9	18.99	6.109	(6.69, 31.28)	0.003
Month 6	9	16.21	6.109	(3.91, 28.51)	0.011
Month 9	6	13.60	7.516	(-1.53, 28.73)	0.077
Month 12	5	24.12	8.197	(7.62, 40.62)	0.005
Month 18	4	33.31	9.101	(14.99, 51.63)	<.001
Month 24	4	34.56	9.101	(16.24, 52.88)	<.001
Month 36	4	35.81	9.101	(17.49, 54.13)	<.001
Month 48	4	42.06	9.101	(23.74, 60.38)	<.001
Month 60	3	21.59	10.491	(0.47, 42.71)	0.045

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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: EMOTIONAL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	12.86	4.805	(3.34, 22.38)	0.009
Month 3	17	18.94	4.512	(10.00, 27.89)	<.001
Month 6	18	20.96	4.385	(12.26, 29.65)	<.001
Month 9	13	21.42	5.165	(11.18, 31.66)	<.001
Month 12	12	26.18	5.368	(15.54, 36.83)	<.001
Month 18	10	28.39	5.889	(16.72, 40.07)	<.001
Month 24	10	30.66	5.892	(18.98, 42.34)	<.001
Month 36	10	18.66	5.892	(6.98, 30.34)	0.002
Month 48	5	24.41	8.362	(7.83, 40.99)	0.004
Month 60	8	32.00	6.575	(18.97, 45.04)	<.001

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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	6.99	6.062	(-6.11, 20.08)	0.270
Month 3	4	24.16	6.062	(11.07, 37.26)	0.002
Month 6	3	39.93	6.742	(25.36, 54.50)	<.001
Month 9	3	48.23	6.742	(33.66, 62.80)	<.001
Month 12	2	59.34	8.317	(41.37, 77.31)	<.001
Month 18	1	53.78	11.788	(28.32, 79.25)	<.001
Month 24	3	46.13	6.742	(31.56, 60.70)	<.001
Month 36	2	57.79	8.317	(39.82, 75.76)	<.001
Month 48	1	46.20	11.656	(21.02, 71.38)	0.002
Month 60	1	53.78	11.788	(28.32, 79.25)	<.001

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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-8.08	7.221	(-22.76, 6.59)	0.271
Month 3	8	2.25	7.626	(-13.25, 17.75)	0.770
Month 6	6	3.79	8.799	(-14.09, 21.67)	0.669
Month 9	7	18.65	8.144	(2.10, 35.20)	0.028
Month 12	4	23.48	10.779	(1.57, 45.38)	0.036
Month 18	3	18.29	12.440	(-6.99, 43.57)	0.151
Month 24	3	23.65	12.449	(-1.65, 48.95)	0.066
Month 36	1	1.07	21.727	(-43.09, 45.22)	0.961
Month 48	2	16.95	15.360	(-14.26, 48.17)	0.277
Month 60	2	20.05	15.360	(-11.16, 51.27)	0.200

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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	10.03	7.969	(-6.01, 26.07)	0.215
Month 3	9	19.42	7.969	(3.38, 35.46)	0.019
Month 6	9	16.29	7.969	(0.24, 32.33)	0.047
Month 9	6	16.97	9.755	(-2.67, 36.60)	0.089
Month 12	5	22.60	10.733	(0.99, 44.20)	0.041
Month 18	4	31.75	11.924	(7.75, 55.75)	0.011
Month 24	4	37.12	11.924	(13.12, 61.12)	0.003
Month 36	4	40.12	11.924	(16.12, 64.12)	0.002
Month 48	4	37.77	11.924	(13.77, 61.77)	0.003
Month 60	3	37.45	13.765	(9.74, 65.15)	0.009

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PHYSICAL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	6.82	4.575	(-2.25, 15.89)	0.139
Month 3	17	23.08	4.296	(14.57, 31.60)	<.001
Month 6	18	28.02	4.177	(19.74, 36.30)	<.001
Month 9	13	25.81	4.921	(16.06, 35.56)	<.001
Month 12	12	31.52	5.114	(21.38, 41.66)	<.001
Month 18	10	31.35	5.601	(20.25, 42.46)	<.001
Month 24	10	35.60	5.605	(24.49, 46.71)	<.001
Month 36	10	26.83	5.605	(15.72, 37.94)	<.001
Month 48	5	45.92	7.925	(30.21, 61.63)	<.001
Month 60	8	45.03	6.271	(32.60, 57.46)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	3.38	5.094	(-7.62, 14.39)	0.518
Month 3	4	13.16	5.094	(2.15, 24.16)	0.023
Month 6	3	10.90	5.790	(-1.61, 23.41)	0.082
Month 9	3	24.23	5.790	(11.72, 36.74)	0.001
Month 12	2	30.08	7.181	(14.57, 45.60)	0.001
Month 18	1	8.03	10.046	(-13.68, 29.73)	0.439
Month 24	3	8.67	5.790	(-3.84, 21.17)	0.158
Month 36	2	9.23	7.181	(-6.28, 24.75)	0.221
Month 48	1	10.54	10.441	(-12.02, 33.10)	0.331
Month 60	1	-8.67	10.046	(-30.38, 13.03)	0.404

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-0.83	4.032	(-9.03, 7.36)	0.837
Month 3	8	-0.90	4.224	(-9.48, 7.69)	0.833
Month 6	6	-0.22	4.851	(-10.08, 9.64)	0.964
Month 9	7	3.90	4.490	(-5.22, 13.03)	0.391
Month 12	4	10.63	5.992	(-1.54, 22.81)	0.085
Month 18	3	2.43	6.937	(-11.67, 16.52)	0.729
Month 24	3	7.38	6.867	(-6.58, 21.33)	0.290
Month 36	1	-0.56	12.006	(-24.96, 23.84)	0.963
Month 48	2	4.85	8.445	(-12.32, 22.01)	0.570
Month 60	2	7.35	8.445	(-9.82, 24.51)	0.390

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	8.82	4.794	(-0.83, 18.47)	0.072
Month 3	9	13.58	4.794	(3.93, 23.23)	0.007
Month 6	9	9.76	4.794	(0.11, 19.41)	0.048
Month 9	6	11.08	5.921	(-0.84, 23.00)	0.068
Month 12	5	17.81	6.450	(4.83, 30.80)	0.008
Month 18	4	22.37	7.183	(7.91, 36.83)	0.003
Month 24	4	25.32	7.183	(10.86, 39.78)	<.001
Month 36	4	25.72	7.183	(11.26, 40.18)	<.001
Month 48	4	26.54	7.183	(12.08, 41.00)	<.001
Month 60	3	18.36	8.331	(1.59, 35.13)	0.033

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: PSYCHOSOCIAL HEALTH SUMMARY SCORE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	15	7.21	3.093	(1.08, 13.34)	0.022
Month 3	17	13.45	2.905	(7.69, 19.21)	<.001
Month 6	18	15.98	2.824	(10.38, 21.58)	<.001
Month 9	13	15.82	3.326	(9.23, 22.42)	<.001
Month 12	12	22.25	3.458	(15.39, 29.10)	<.001
Month 18	10	23.48	3.789	(15.97, 30.99)	<.001
Month 24	10	24.99	3.791	(17.48, 32.51)	<.001
Month 36	10	18.82	3.791	(11.31, 26.34)	<.001
Month 48	5	23.53	5.362	(12.90, 34.16)	<.001
Month 60	8	27.89	4.236	(19.49, 36.29)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	3	10.98	10.858	(-12.68, 34.64)	0.332
Month 3	4	8.73	9.137	(-11.18, 28.64)	0.358
Month 6	3	1.17	10.565	(-21.85, 24.19)	0.914
Month 9	3	16.17	10.565	(-6.85, 39.19)	0.152
Month 12	2	19.20	12.956	(-9.03, 47.43)	0.164
Month 18	1	-3.58	18.666	(-44.25, 37.09)	0.851
Month 24	3	-0.50	10.565	(-23.52, 22.52)	0.963
Month 36	2	1.70	12.956	(-26.53, 29.93)	0.898
Month 48	1	11.98	19.264	(-29.99, 53.95)	0.546
Month 60	1	-13.58	18.666	(-54.25, 27.09)	0.481

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	7	-4.76	5.799	(-16.62, 7.10)	0.418
Month 3	7	-3.37	5.690	(-15.01, 8.27)	0.559
Month 6	5	1.94	6.666	(-11.69, 15.57)	0.773
Month 9	6	-3.05	6.089	(-15.50, 9.41)	0.620
Month 12	4	5.60	7.562	(-9.86, 21.07)	0.465
Month 18	3	-8.20	8.862	(-26.32, 9.93)	0.362
Month 24	3	-1.45	8.641	(-19.12, 16.23)	0.868
Month 36	1	-10.68	15.011	(-41.38, 20.02)	0.483
Month 48	2	0.67	10.543	(-20.89, 22.23)	0.950
Month 60	2	0.67	10.543	(-20.89, 22.23)	0.950

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	7	5.23	6.636	(-8.16, 18.62)	0.435
Month 3	8	17.76	6.205	(5.24, 30.29)	0.007
Month 6	8	10.26	6.205	(-2.26, 22.79)	0.106
Month 9	6	16.92	7.222	(2.35, 31.50)	0.024
Month 12	5	17.04	7.843	(1.21, 32.87)	0.036
Month 18	4	20.78	8.784	(3.06, 38.51)	0.023
Month 24	4	23.28	8.784	(5.56, 41.01)	0.011
Month 36	4	25.78	8.784	(8.06, 43.51)	0.005
Month 48	4	22.03	8.784	(4.31, 39.76)	0.016
Month 60	3	16.64	10.185	(-3.91, 37.20)	0.110

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SCHOOL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	5.75	4.678	(-3.58, 15.07)	0.223
Month 3	11	6.91	4.249	(-1.56, 15.37)	0.108
Month 6	13	13.02	3.897	(5.25, 20.78)	0.001
Month 9	9	17.65	4.678	(8.33, 26.97)	<.001
Month 12	9	26.38	4.678	(17.06, 35.70)	<.001
Month 18	7	20.12	5.304	(9.55, 30.69)	<.001
Month 24	8	21.85	4.965	(11.96, 31.75)	<.001
Month 36	8	23.10	4.965	(13.21, 33.00)	<.001
Month 48	4	26.31	7.028	(12.31, 40.32)	<.001
Month 60	7	31.34	5.308	(20.77, 41.92)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Number of previous relapses: 0

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	4	-3.44	6.096	(-16.61, 9.73)	0.582
Month 3	4	11.56	6.096	(-1.61, 24.73)	0.080
Month 6	3	16.68	6.837	(1.91, 31.45)	0.030
Month 9	3	25.01	6.837	(10.24, 39.78)	0.003
Month 12	2	32.13	8.547	(13.67, 50.60)	0.002
Month 18	1	19.63	11.965	(-6.21, 45.48)	0.125
Month 24	3	10.01	6.837	(-4.76, 24.78)	0.167
Month 36	2	32.13	8.547	(13.67, 50.60)	0.002
Month 48	1	14.63	11.965	(-11.21, 40.48)	0.243
Month 60	1	29.63	11.965	(3.79, 55.48)	0.028

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

P-values are for nominal use only and should be interpreted as descriptive rather than inferential statistics.
Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Number of previous relapses: 1

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	-0.20	3.700	(-7.72, 7.32)	0.957
Month 3	8	1.02	3.891	(-6.88, 8.93)	0.794
Month 6	6	-3.22	4.487	(-12.34, 5.90)	0.478
Month 9	7	5.34	4.153	(-3.11, 13.78)	0.208
Month 12	4	11.34	5.508	(0.15, 22.53)	0.047
Month 18	3	9.56	6.358	(-3.36, 22.48)	0.142
Month 24	3	10.48	6.344	(-2.41, 23.38)	0.108
Month 36	1	3.92	11.068	(-18.58, 26.41)	0.726
Month 48	2	2.80	7.810	(-13.07, 18.67)	0.722
Month 60	2	7.80	7.810	(-8.07, 23.67)	0.325

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Number of previous relapses: 2

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	9	6.92	4.279	(-1.70, 15.53)	0.113
Month 3	9	6.36	4.279	(-2.26, 14.98)	0.144
Month 6	9	5.81	4.279	(-2.81, 14.42)	0.182
Month 9	6	3.98	5.241	(-6.57, 14.54)	0.451
Month 12	5	12.73	5.761	(1.13, 24.33)	0.032
Month 18	3	20.75	7.430	(5.79, 35.72)	0.008
Month 24	4	18.12	6.414	(5.20, 31.04)	0.007
Month 36	4	15.62	6.414	(2.70, 28.54)	0.019
Month 48	4	15.62	6.414	(2.70, 28.54)	0.019
Month 60	3	17.01	7.457	(1.99, 32.02)	0.027

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
LS Mean, 95% CI, and P value are from a mixed-effects model for repeated measures where the change from baseline in PRO score is modeled as a function of analysis visit as a categorical covariate and baseline score as a continuous covariate with an Variance Component covariance structure.

Table 203r
Summary of Mixed-Model Repeated Measure Analysis for Change from Baseline in pedSQL subscales score by Number of previous relapses
Full analysis set - Patients >= 8 years at enrollment with BOR of CR or CRi within 3 months
Parameter: SOCIAL SUBSCALE | Number of previous relapses: >=3

Analysis visit	n	LS Mean Change from Baseline	SE	95% CI	P Value
Day 28	14	5.05	3.689	(-2.26, 12.37)	0.173
Month 3	17	11.43	3.348	(4.80, 18.07)	<.001
Month 6	18	13.23	3.255	(6.78, 19.69)	<.001
Month 9	13	11.23	3.831	(3.63, 18.82)	0.004
Month 12	12	14.53	3.986	(6.63, 22.44)	<.001
Month 18	10	20.31	4.364	(11.66, 28.96)	<.001
Month 24	10	20.16	4.367	(11.51, 28.82)	<.001
Month 36	10	13.66	4.367	(5.01, 22.32)	0.002
Month 48	5	22.00	6.175	(9.76, 34.24)	<.001
Month 60	8	22.66	4.881	(12.98, 32.33)	<.001

-Full analysis set (FAS) = All patients who received an infusion of CTL019 CI = confidence interval; LS = least square; n = number of subjects with measurements at both baseline and the post-baseline visits.

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Note: Only subjects with baseline and post-baseline assessments are included.
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Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	2 (6.1)	4 (12.1)	7 (21.2)	20 (60.6)
Blood and lymphatic system disorders					
-Total	21 (63.6)	2 (6.1)	3 (9.1)	12 (36.4)	4 (12.1)
Anaemia	13 (39.4)	3 (9.1)	3 (9.1)	7 (21.2)	0
Febrile neutropenia	12 (36.4)	0	0	12 (36.4)	0
Disseminated intravascular coagulation	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Thrombocytopenia	4 (12.1)	0	0	0	4 (12.1)
Neutropenia	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Coagulopathy	1 (3.0)	0	0	1 (3.0)	0
Eosinophilia	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (3.0)	0	0	1 (3.0)	0
Lymphopenia	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Splenomegaly	1 (3.0)	1 (3.0)	0	0	0
Cardiac disorders					
-Total	10 (30.3)	4 (12.1)	2 (6.1)	3 (9.1)	1 (3.0)
Tachycardia	9 (27.3)	4 (12.1)	3 (9.1)	1 (3.0)	1 (3.0)
Left ventricular dysfunction	2 (6.1)	0	0	2 (6.1)	0
Cardiac dysfunction	1 (3.0)	1 (3.0)	0	0	0
Cardiac failure congestive	1 (3.0)	0	1 (3.0)	0	0
Mitral valve incompetence	1 (3.0)	1 (3.0)	0	0	0
Right ventricular dysfunction	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Ear pain	1 (3.0)	1 (3.0)	0	0	0
Endocrine disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypothyroidism	1 (3.0)	0	1 (3.0)	0	0
Eye disorders					
-Total	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Eyelid oedema	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Ocular hyperaemia	2 (6.1)	2 (6.1)	0	0	0
Conjunctival haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Eye pain	1 (3.0)	1 (3.0)	0	0	0
Visual impairment	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	23 (69.7)	6 (18.2)	10 (30.3)	6 (18.2)	1 (3.0)
Vomiting	12 (36.4)	7 (21.2)	5 (15.2)	0	0
Nausea	11 (33.3)	5 (15.2)	5 (15.2)	1 (3.0)	0
Diarrhoea	8 (24.2)	3 (9.1)	4 (12.1)	1 (3.0)	0
Abdominal pain	6 (18.2)	1 (3.0)	3 (9.1)	2 (6.1)	0
Constipation	6 (18.2)	4 (12.1)	2 (6.1)	0	0
Abdominal distension	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Ascites	3 (9.1)	2 (6.1)	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	2 (6.1)	2 (6.1)	0	0	0
Mouth haemorrhage	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Abdominal compartment syndrome	1 (3.0)	0	0	0	1 (3.0)
Abdominal pain upper	1 (3.0)	0	1 (3.0)	0	0
Anal fissure	1 (3.0)	0	1 (3.0)	0	0
Anal haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Haematemesis	1 (3.0)	1 (3.0)	0	0	0
Lip oedema	1 (3.0)	1 (3.0)	0	0	0
Melaena	1 (3.0)	0	0	1 (3.0)	0
Neutropenic colitis	1 (3.0)	0	0	1 (3.0)	0
Pancreatitis	1 (3.0)	0	1 (3.0)	0	0
Stomatitis	1 (3.0)	0	0	1 (3.0)	0
Upper gastrointestinal haemorrhage	1 (3.0)	1 (3.0)	0	0	0
General disorders and administration site conditions					
-Total	15 (45.5)	7 (21.2)	5 (15.2)	1 (3.0)	2 (6.1)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	8 (24.2)	6 (18.2)	2 (6.1)	0	0
Pyrexia	8 (24.2)	3 (9.1)	3 (9.1)	1 (3.0)	1 (3.0)
Chills	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Face oedema	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Generalised oedema	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Asthenia	1 (3.0)	1 (3.0)	0	0	0
Catheter site erythema	1 (3.0)	1 (3.0)	0	0	0
Chest discomfort	1 (3.0)	0	0	1 (3.0)	0
Influenza like illness	1 (3.0)	0	1 (3.0)	0	0
Multiple organ dysfunction syndrome	1 (3.0)	0	0	0	1 (3.0)
Pain	1 (3.0)	0	0	1 (3.0)	0
Systemic inflammatory response syndrome	1 (3.0)	0	0	1 (3.0)	0
Hepatobiliary disorders					
-Total	7 (21.2)	3 (9.1)	2 (6.1)	1 (3.0)	1 (3.0)
Cholelithiasis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Hyperbilirubinaemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Cholestasis	1 (3.0)	0	0	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gallbladder enlargement	1 (3.0)	1 (3.0)	0	0	0
Hepatic function abnormal	1 (3.0)	0	0	1 (3.0)	0
Hepatomegaly	1 (3.0)	1 (3.0)	0	0	0
Ocular icterus	1 (3.0)	1 (3.0)	0	0	0
Immune system disorders					
-Total	27 (81.8)	2 (6.1)	11 (33.3)	6 (18.2)	8 (24.2)
Cytokine release syndrome	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)
Hypogammaglobulinaemia	10 (30.3)	1 (3.0)	7 (21.2)	2 (6.1)	0
Haemophagocytic lymphohistiocytosis	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Immunodeficiency	2 (6.1)	0	0	2 (6.1)	0
Infections and infestations					
-Total	14 (42.4)	3 (9.1)	4 (12.1)	6 (18.2)	1 (3.0)
Conjunctivitis	4 (12.1)	1 (3.0)	3 (9.1)	0	0
Clostridium difficile infection	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Oral infection	2 (6.1)	0	2 (6.1)	0	0
Staphylococcal infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Bk virus infection	1 (3.0)	1 (3.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Klebsiella infection	1 (3.0)	0	0	1 (3.0)	0
Localised infection	1 (3.0)	1 (3.0)	0	0	0
Nail infection	1 (3.0)	1 (3.0)	0	0	0
Oral herpes	1 (3.0)	0	0	1 (3.0)	0
Pneumonia viral	1 (3.0)	0	0	1 (3.0)	0
Soft tissue infection	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Injury, poisoning and procedural complications					
-Total	6 (18.2)	2 (6.1)	3 (9.1)	0	1 (3.0)
Transfusion reaction	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Fall	1 (3.0)	0	1 (3.0)	0	0
Infusion related reaction	1 (3.0)	0	1 (3.0)	0	0
Scratch	1 (3.0)	1 (3.0)	0	0	0
Skin injury	1 (3.0)	0	1 (3.0)	0	0
Skin wound	1 (3.0)	1 (3.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (3.0)	0	0	0	1 (3.0)
Wound	1 (3.0)	0	0	1 (3.0)	0
Investigations					
-Total	27 (81.8)	2 (6.1)	3 (9.1)	7 (21.2)	15 (45.5)
White blood cell count decreased	16 (48.5)	2 (6.1)	1 (3.0)	2 (6.1)	11 (33.3)
Neutrophil count decreased	13 (39.4)	0	2 (6.1)	1 (3.0)	10 (30.3)
Platelet count decreased	11 (33.3)	2 (6.1)	1 (3.0)	4 (12.1)	4 (12.1)
Alanine aminotransferase increased	9 (27.3)	2 (6.1)	6 (18.2)	1 (3.0)	0
Aspartate aminotransferase increased	8 (24.2)	1 (3.0)	3 (9.1)	2 (6.1)	2 (6.1)
Lymphocyte count decreased	8 (24.2)	0	0	5 (15.2)	3 (9.1)
Blood immunoglobulin m decreased	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Blood bilirubin increased	5 (15.2)	0	1 (3.0)	4 (12.1)	0
Blood immunoglobulin a decreased	4 (12.1)	3 (9.1)	1 (3.0)	0	0
International normalised ratio increased	4 (12.1)	3 (9.1)	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Blood fibrinogen decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Serum ferritin increased	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Blood immunoglobulin g decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Blood lactate dehydrogenase increased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Blood uric acid increased	2 (6.1)	2 (6.1)	0	0	0
Fibrin d dimer increased	2 (6.1)	2 (6.1)	0	0	0
Gamma-glutamyltransferase increased	2 (6.1)	0	0	2 (6.1)	0
Weight increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Blood creatine phosphokinase increased	1 (3.0)	0	0	0	1 (3.0)
Blood creatinine increased	1 (3.0)	0	0	1 (3.0)	0
C-reactive protein increased	1 (3.0)	0	0	1 (3.0)	0
Electrocardiogram qt prolonged	1 (3.0)	0	1 (3.0)	0	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (3.0)	0	0	0	1 (3.0)
Oxygen saturation decreased	1 (3.0)	1 (3.0)	0	0	0
Urine output decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	19 (57.6)	4 (12.1)	5 (15.2)	5 (15.2)	5 (15.2)
Hypophosphataemia	10 (30.3)	2 (6.1)	4 (12.1)	3 (9.1)	1 (3.0)
Decreased appetite	8 (24.2)	2 (6.1)	1 (3.0)	4 (12.1)	1 (3.0)
Hypocalcaemia	7 (21.2)	1 (3.0)	4 (12.1)	2 (6.1)	0
Hypokalaemia	7 (21.2)	2 (6.1)	1 (3.0)	2 (6.1)	2 (6.1)
Hypoalbuminaemia	4 (12.1)	0	4 (12.1)	0	0
Hyperglycaemia	3 (9.1)	0	0	3 (9.1)	0
Hypernatraemia	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Hyperphosphataemia	2 (6.1)	2 (6.1)	0	0	0
Hyperuricaemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Metabolic acidosis	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Dehydration	1 (3.0)	0	1 (3.0)	0	0
Haemosiderosis	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (3.0)	0	0	1 (3.0)	0
Hyperkalaemia	1 (3.0)	0	0	1 (3.0)	0
Hyperlactacidaemia	1 (3.0)	1 (3.0)	0	0	0
Hypermagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hypertriglyceridaemia	1 (3.0)	0	0	1 (3.0)	0
Hypervolaemia	1 (3.0)	0	1 (3.0)	0	0
Hypomagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hyponatraemia	1 (3.0)	1 (3.0)	0	0	0
Malnutrition	1 (3.0)	0	0	1 (3.0)	0
Musculoskeletal and connective tissue disorders					
-Total	16 (48.5)	6 (18.2)	8 (24.2)	1 (3.0)	1 (3.0)
Pain in extremity	8 (24.2)	4 (12.1)	4 (12.1)	0	0
Back pain	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Arthralgia	3 (9.1)	0	3 (9.1)	0	0
Myalgia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Bone pain	1 (3.0)	0	1 (3.0)	0	0
Muscular weakness	1 (3.0)	1 (3.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (3.0)	0	1 (3.0)	0	0
Rhabdomyolysis	1 (3.0)	0	0	0	1 (3.0)
Nervous system disorders					
-Total	16 (48.5)	7 (21.2)	4 (12.1)	4 (12.1)	1 (3.0)
Headache	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)	0
Encephalopathy	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Dysgeusia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Lethargy	2 (6.1)	2 (6.1)	0	0	0
Tremor	2 (6.1)	2 (6.1)	0	0	0
Cerebral haemorrhage	1 (3.0)	0	0	0	1 (3.0)
Depressed level of consciousness	1 (3.0)	0	0	1 (3.0)	0
Monoparesis	1 (3.0)	0	1 (3.0)	0	0
Neuralgia	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0
Psychiatric disorders					
-Total	14 (42.4)	8 (24.2)	6 (18.2)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	4 (12.1)	4 (12.1)	0	0	0
Anxiety	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Insomnia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Delirium	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Hallucination	2 (6.1)	0	2 (6.1)	0	0
Irritability	2 (6.1)	2 (6.1)	0	0	0
Agitation	1 (3.0)	1 (3.0)	0	0	0
Restlessness	1 (3.0)	0	1 (3.0)	0	0
Sleep disorder	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	9 (27.3)	4 (12.1)	2 (6.1)	0	3 (9.1)
Acute kidney injury	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Dysuria	2 (6.1)	2 (6.1)	0	0	0
Haematuria	2 (6.1)	2 (6.1)	0	0	0
Anuria	1 (3.0)	0	0	0	1 (3.0)
Bladder dilatation	1 (3.0)	0	1 (3.0)	0	0
Incontinence	1 (3.0)	0	1 (3.0)	0	0
Proteinuria	1 (3.0)	1 (3.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (3.0)	0	1 (3.0)	0	0
Renal tubular dysfunction	1 (3.0)	1 (3.0)	0	0	0
Renal tubular necrosis	1 (3.0)	0	0	0	1 (3.0)
Urinary retention	1 (3.0)	0	1 (3.0)	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Vaginal ulceration	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (51.5)	7 (21.2)	3 (9.1)	4 (12.1)	3 (9.1)
Cough	6 (18.2)	5 (15.2)	1 (3.0)	0	0
Hypoxia	6 (18.2)	0	2 (6.1)	2 (6.1)	2 (6.1)
Pulmonary oedema	4 (12.1)	0	1 (3.0)	3 (9.1)	0
Tachypnoea	4 (12.1)	2 (6.1)	0	2 (6.1)	0
Dyspnoea	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Epistaxis	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Pleural effusion	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Rhinorrhoea	2 (6.1)	2 (6.1)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (3.0)	0	0	0	1 (3.0)
Atelectasis	1 (3.0)	0	0	1 (3.0)	0
Lung infiltration	1 (3.0)	0	0	1 (3.0)	0
Nasal congestion	1 (3.0)	0	1 (3.0)	0	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Productive cough	1 (3.0)	1 (3.0)	0	0	0
Respiratory acidosis	1 (3.0)	0	0	1 (3.0)	0
Respiratory distress	1 (3.0)	0	1 (3.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (36.4)	7 (21.2)	3 (9.1)	2 (6.1)	0
Pruritus	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Blister	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Dermatitis atopic	2 (6.1)	2 (6.1)	0	0	0
Erythema	2 (6.1)	2 (6.1)	0	0	0
Rash maculo-papular	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Rash papular	2 (6.1)	2 (6.1)	0	0	0
Decubitus ulcer	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis	1 (3.0)	1 (3.0)	0	0	0
Dry skin	1 (3.0)	1 (3.0)	0	0	0
Eczema	1 (3.0)	1 (3.0)	0	0	0
Petechiae	1 (3.0)	0	0	1 (3.0)	0
Pruritus allergic	1 (3.0)	0	1 (3.0)	0	0
Purpura	1 (3.0)	1 (3.0)	0	0	0
Rash	1 (3.0)	0	1 (3.0)	0	0
Rash pruritic	1 (3.0)	1 (3.0)	0	0	0
Rash vesicular	1 (3.0)	1 (3.0)	0	0	0
Scab	1 (3.0)	1 (3.0)	0	0	0
Skin discolouration	1 (3.0)	1 (3.0)	0	0	0
Skin necrosis	1 (3.0)	0	0	1 (3.0)	0
Skin ulcer	1 (3.0)	1 (3.0)	0	0	0
Urticaria	1 (3.0)	0	1 (3.0)	0	0
Vascular disorders					
-Total	13 (39.4)	2 (6.1)	4 (12.1)	4 (12.1)	3 (9.1)
Hypotension	10 (30.3)	1 (3.0)	3 (9.1)	3 (9.1)	3 (9.1)
Hypertension	5 (15.2)	2 (6.1)	1 (3.0)	2 (6.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	2 (6.1)	3 (9.1)	9 (27.3)	19 (57.6)
Blood and lymphatic system disorders					
-Total	21 (63.6)	0	3 (9.1)	10 (30.3)	8 (24.2)
Febrile neutropenia	12 (36.4)	0	0	10 (30.3)	2 (6.1)
Anaemia	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Neutropenia	4 (12.1)	0	0	0	4 (12.1)
Disseminated intravascular coagulation	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Splenomegaly	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Thrombocytopenia	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Coagulopathy	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Leukopenia	2 (6.1)	0	1 (3.0)	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Cardiac disorders					
-Total	9 (27.3)	3 (9.1)	3 (9.1)	2 (6.1)	1 (3.0)
Tachycardia	6 (18.2)	2 (6.1)	3 (9.1)	1 (3.0)	0
Bradycardia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Atrioventricular block first degree	1 (3.0)	0	1 (3.0)	0	0
Cardiac arrest	1 (3.0)	0	0	0	1 (3.0)
Left ventricular dysfunction	1 (3.0)	0	0	1 (3.0)	0
Pericardial effusion	1 (3.0)	1 (3.0)	0	0	0
Sinus bradycardia	1 (3.0)	0	0	1 (3.0)	0
Sinus tachycardia	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Ear pruritus	1 (3.0)	1 (3.0)	0	0	0
Endocrine disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Conjunctival haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Eye oedema	1 (3.0)	1 (3.0)	0	0	0
Periorbital oedema	1 (3.0)	1 (3.0)	0	0	0
Retinal haemorrhage	1 (3.0)	0	1 (3.0)	0	0
Visual field defect	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	16 (48.5)	6 (18.2)	5 (15.2)	5 (15.2)	0
Diarrhoea	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Nausea	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Vomiting	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Abdominal pain	3 (9.1)	0	3 (9.1)	0	0
Pancreatitis	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Abdominal pain upper	1 (3.0)	1 (3.0)	0	0	0
Constipation	1 (3.0)	0	1 (3.0)	0	0
Dysphagia	1 (3.0)	0	0	1 (3.0)	0
Enterocolitis	1 (3.0)	0	1 (3.0)	0	0
Gastrooesophageal reflux disease	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival erythema	1 (3.0)	1 (3.0)	0	0	0
Mouth swelling	1 (3.0)	1 (3.0)	0	0	0
Odynophagia	1 (3.0)	1 (3.0)	0	0	0
Proctalgia	1 (3.0)	0	0	1 (3.0)	0
Trichoglossia	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	16 (48.5)	8 (24.2)	3 (9.1)	4 (12.1)	1 (3.0)
Pyrexia	10 (30.3)	5 (15.2)	1 (3.0)	3 (9.1)	1 (3.0)
Face oedema	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Oedema peripheral	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Fatigue	2 (6.1)	2 (6.1)	0	0	0
Generalised oedema	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Localised oedema	2 (6.1)	2 (6.1)	0	0	0
Catheter site haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Catheter site pain	1 (3.0)	1 (3.0)	0	0	0
Chills	1 (3.0)	1 (3.0)	0	0	0
Drug withdrawal syndrome	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema due to hepatic disease	1 (3.0)	0	1 (3.0)	0	0
Hepatobiliary disorders					
-Total	6 (18.2)	1 (3.0)	2 (6.1)	1 (3.0)	2 (6.1)
Hepatic function abnormal	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Hepatomegaly	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Hyperbilirubinaemia	2 (6.1)	0	2 (6.1)	0	0
Hypertransaminasaemia	1 (3.0)	0	1 (3.0)	0	0
Immune system disorders					
-Total	28 (84.8)	0	7 (21.2)	12 (36.4)	9 (27.3)
Cytokine release syndrome	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Hypogammaglobulinaemia	10 (30.3)	0	5 (15.2)	5 (15.2)	0
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hypersensitivity	1 (3.0)	1 (3.0)	0	0	0
Immunodeficiency	1 (3.0)	0	0	1 (3.0)	0
Seasonal allergy	1 (3.0)	0	1 (3.0)	0	0
Selective igg subclass deficiency	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (36.4)	2 (6.1)	4 (12.1)	5 (15.2)	1 (3.0)
Anal abscess	1 (3.0)	0	0	1 (3.0)	0
Bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Bronchopulmonary aspergillosis	1 (3.0)	0	0	1 (3.0)	0
Cholecystitis infective	1 (3.0)	0	1 (3.0)	0	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Encephalitis viral	1 (3.0)	0	0	0	1 (3.0)
Gastroenteritis norovirus	1 (3.0)	1 (3.0)	0	0	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Meningitis bacterial	1 (3.0)	0	0	1 (3.0)	0
Nail infection	1 (3.0)	1 (3.0)	0	0	0
Otitis externa	1 (3.0)	0	1 (3.0)	0	0
Paronychia	1 (3.0)	0	1 (3.0)	0	0
Pneumonia fungal	1 (3.0)	0	0	1 (3.0)	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Staphylococcal bacteraemia	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	4 (12.1)	1 (3.0)	3 (9.1)	0	0
Procedural pain	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Contusion	1 (3.0)	1 (3.0)	0	0	0
Infusion related reaction	1 (3.0)	0	1 (3.0)	0	0
Skin abrasion	1 (3.0)	1 (3.0)	0	0	0
Wound	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	21 (63.6)	0	4 (12.1)	7 (21.2)	10 (30.3)
Alanine aminotransferase increased	7 (21.2)	2 (6.1)	1 (3.0)	4 (12.1)	0
Aspartate aminotransferase increased	7 (21.2)	0	3 (9.1)	3 (9.1)	1 (3.0)
Platelet count decreased	7 (21.2)	1 (3.0)	2 (6.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	7 (21.2)	1 (3.0)	2 (6.1)	0	4 (12.1)
Blood bilirubin increased	6 (18.2)	1 (3.0)	1 (3.0)	4 (12.1)	0
Lymphocyte count decreased	6 (18.2)	1 (3.0)	0	3 (9.1)	2 (6.1)
Neutrophil count decreased	6 (18.2)	0	1 (3.0)	1 (3.0)	4 (12.1)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Blood fibrinogen decreased	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Electrocardiogram qt prolonged	4 (12.1)	1 (3.0)	1 (3.0)	1 (3.0)	1 (3.0)
Activated partial thromboplastin time prolonged	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Blood creatinine increased	3 (9.1)	1 (3.0)	0	1 (3.0)	1 (3.0)
C-reactive protein increased	3 (9.1)	1 (3.0)	0	2 (6.1)	0
International normalised ratio increased	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Blood lactate dehydrogenase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Weight increased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Amylase increased	1 (3.0)	1 (3.0)	0	0	0
Bacterial test positive	1 (3.0)	0	0	1 (3.0)	0
Blood alkaline phosphatase increased	1 (3.0)	1 (3.0)	0	0	0
Blood bicarbonate decreased	1 (3.0)	0	1 (3.0)	0	0
Blood creatine phosphokinase increased	1 (3.0)	0	0	1 (3.0)	0
Blood phosphorus increased	1 (3.0)	0	1 (3.0)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood testosterone decreased	1 (3.0)	1 (3.0)	0	0	0
Cardiac murmur	1 (3.0)	1 (3.0)	0	0	0
Coagulation test abnormal	1 (3.0)	1 (3.0)	0	0	0
Electrocardiogram t wave abnormal	1 (3.0)	0	1 (3.0)	0	0
Enterovirus test positive	1 (3.0)	0	1 (3.0)	0	0
Fibrin d dimer increased	1 (3.0)	0	0	1 (3.0)	0
Haemoglobin decreased	1 (3.0)	0	0	1 (3.0)	0
Haptoglobin decreased	1 (3.0)	1 (3.0)	0	0	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0
Lipase increased	1 (3.0)	1 (3.0)	0	0	0
Prothrombin time prolonged	1 (3.0)	0	1 (3.0)	0	0
Troponin increased	1 (3.0)	0	0	1 (3.0)	0
Urine output decreased	1 (3.0)	0	0	0	1 (3.0)
Weight decreased	1 (3.0)	0	1 (3.0)	0	0
Metabolism and nutrition disorders					
-Total	20 (60.6)	3 (9.1)	4 (12.1)	11 (33.3)	2 (6.1)
Decreased appetite	11 (33.3)	4 (12.1)	3 (9.1)	4 (12.1)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	6 (18.2)	1 (3.0)	4 (12.1)	1 (3.0)	0
Hypokalaemia	6 (18.2)	0	1 (3.0)	5 (15.2)	0
Hypoalbuminaemia	5 (15.2)	0	5 (15.2)	0	0
Hypophosphataemia	5 (15.2)	1 (3.0)	1 (3.0)	3 (9.1)	0
Hyperuricaemia	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Hyperphosphataemia	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Hypomagnesaemia	3 (9.1)	3 (9.1)	0	0	0
Tumour lysis syndrome	3 (9.1)	0	0	3 (9.1)	0
Hypercalcaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hyperglycaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hypervolaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hyponatraemia	2 (6.1)	2 (6.1)	0	0	0
Acidosis	1 (3.0)	0	0	1 (3.0)	0
Calcium deficiency	1 (3.0)	1 (3.0)	0	0	0
Hyperchloraemia	1 (3.0)	1 (3.0)	0	0	0
Hyperkalaemia	1 (3.0)	0	0	0	1 (3.0)
Hypermagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hypertriglyceridaemia	1 (3.0)	0	0	0	1 (3.0)
Metabolic acidosis	1 (3.0)	0	0	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	11 (33.3)	6 (18.2)	3 (9.1)	2 (6.1)	0
Arthralgia	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Myalgia	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Pain in extremity	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Back pain	1 (3.0)	0	1 (3.0)	0	0
Bone pain	1 (3.0)	0	1 (3.0)	0	0
Haemarthrosis	1 (3.0)	0	0	1 (3.0)	0
Muscle rigidity	1 (3.0)	1 (3.0)	0	0	0
Muscular weakness	1 (3.0)	0	0	1 (3.0)	0
Pain in jaw	1 (3.0)	1 (3.0)	0	0	0
Nervous system disorders					
-Total	19 (57.6)	6 (18.2)	10 (30.3)	3 (9.1)	0
Headache	13 (39.4)	5 (15.2)	7 (21.2)	1 (3.0)	0
Encephalopathy	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Cognitive disorder	2 (6.1)	0	2 (6.1)	0	0
Dizziness	2 (6.1)	2 (6.1)	0	0	0
Somnolence	2 (6.1)	0	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Dysarthria	1 (3.0)	0	0	1 (3.0)	0
Generalised tonic-clonic seizure	1 (3.0)	0	1 (3.0)	0	0
Hypoaesthesia	1 (3.0)	1 (3.0)	0	0	0
Seizure	1 (3.0)	0	1 (3.0)	0	0
Psychiatric disorders					
-Total	10 (30.3)	4 (12.1)	2 (6.1)	4 (12.1)	0
Anxiety	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Confusional state	3 (9.1)	3 (9.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Agitation	2 (6.1)	0	2 (6.1)	0	0
Mental status changes	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Automatism	1 (3.0)	1 (3.0)	0	0	0
Insomnia	1 (3.0)	0	1 (3.0)	0	0
Sleep disorder	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	7 (21.2)	1 (3.0)	2 (6.1)	2 (6.1)	2 (6.1)
Acute kidney injury	4 (12.1)	0	0	2 (6.1)	2 (6.1)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anuria	1 (3.0)	1 (3.0)	0	0	0
Azotaemia	1 (3.0)	0	1 (3.0)	0	0
Dysuria	1 (3.0)	1 (3.0)	0	0	0
Micturition urgency	1 (3.0)	0	1 (3.0)	0	0
Pollakiuria	1 (3.0)	0	1 (3.0)	0	0
Urinary tract disorder	1 (3.0)	0	1 (3.0)	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Perineal rash	1 (3.0)	0	1 (3.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (42.4)	2 (6.1)	1 (3.0)	4 (12.1)	7 (21.2)
Hypoxia	8 (24.2)	0	3 (9.1)	1 (3.0)	4 (12.1)
Pleural effusion	5 (15.2)	3 (9.1)	0	1 (3.0)	1 (3.0)
Cough	4 (12.1)	4 (12.1)	0	0	0
Pulmonary oedema	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Tachypnoea	3 (9.1)	1 (3.0)	0	2 (6.1)	0
Oropharyngeal pain	2 (6.1)	2 (6.1)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	2 (6.1)	0	0	0	2 (6.1)
Acute respiratory distress syndrome	1 (3.0)	0	0	0	1 (3.0)
Acute respiratory failure	1 (3.0)	0	0	1 (3.0)	0
Atelectasis	1 (3.0)	0	0	1 (3.0)	0
Bradypnoea	1 (3.0)	0	0	1 (3.0)	0
Epistaxis	1 (3.0)	0	1 (3.0)	0	0
Haemoptysis	1 (3.0)	0	1 (3.0)	0	0
Nasal congestion	1 (3.0)	1 (3.0)	0	0	0
Nasal discomfort	1 (3.0)	0	1 (3.0)	0	0
Painful respiration	1 (3.0)	1 (3.0)	0	0	0
Pharyngeal haemorrhage	1 (3.0)	0	1 (3.0)	0	0
Respiratory disorder	1 (3.0)	0	1 (3.0)	0	0
Respiratory distress	1 (3.0)	0	1 (3.0)	0	0
Wheezing	1 (3.0)	0	1 (3.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (27.3)	3 (9.1)	5 (15.2)	1 (3.0)	0
Rash	4 (12.1)	2 (6.1)	2 (6.1)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	1 (3.0)	1 (3.0)	0	0	0
Dermatitis diaper	1 (3.0)	0	1 (3.0)	0	0
Erythema	1 (3.0)	1 (3.0)	0	0	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0	0	0
Petechiae	1 (3.0)	0	1 (3.0)	0	0
Pruritus	1 (3.0)	0	1 (3.0)	0	0
Skin ulcer	1 (3.0)	0	1 (3.0)	0	0
Vancomycin infusion reaction	1 (3.0)	0	0	1 (3.0)	0
Vascular disorders					
-Total	10 (30.3)	1 (3.0)	2 (6.1)	5 (15.2)	2 (6.1)
Hypotension	7 (21.2)	0	2 (6.1)	3 (9.1)	2 (6.1)
Hypertension	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Capillary leak syndrome	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Thrombosis	1 (3.0)	0	1 (3.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	1 (7.1)	5 (35.7)	7 (50.0)
Blood and lymphatic system disorders					
-Total	8 (57.1)	1 (7.1)	2 (14.3)	4 (28.6)	1 (7.1)
Anaemia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Coagulopathy	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Neutropenia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
B-cell aplasia	1 (7.1)	0	1 (7.1)	0	0
Hypofibrinogenaemia	1 (7.1)	0	1 (7.1)	0	0
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	5 (35.7)	3 (21.4)	1 (7.1)	0	1 (7.1)
Sinus tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Cardiac dysfunction	1 (7.1)	1 (7.1)	0	0	0
Cardiac failure	1 (7.1)	0	0	0	1 (7.1)
Endocrine disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Adrenal insufficiency	2 (14.3)	0	2 (14.3)	0	0
Eye disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Periorbital swelling	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	12 (85.7)	7 (50.0)	3 (21.4)	2 (14.3)	0
Vomiting	5 (35.7)	3 (21.4)	2 (14.3)	0	0
Constipation	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Nausea	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Abdominal pain	2 (14.3)	2 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Mouth haemorrhage	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Abdominal pain upper	1 (7.1)	1 (7.1)	0	0	0
Dry mouth	1 (7.1)	0	1 (7.1)	0	0
Gingival bleeding	1 (7.1)	0	1 (7.1)	0	0
Gingivitis ulcerative	1 (7.1)	0	0	1 (7.1)	0
Ileus	1 (7.1)	0	1 (7.1)	0	0
Lip dry	1 (7.1)	0	1 (7.1)	0	0
Stomatitis	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	9 (64.3)	5 (35.7)	1 (7.1)	2 (14.3)	1 (7.1)
Pyrexia	6 (42.9)	3 (21.4)	1 (7.1)	2 (14.3)	0
Chills	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Oedema peripheral	2 (14.3)	2 (14.3)	0	0	0
Asthenia	1 (7.1)	1 (7.1)	0	0	0
Catheter site pain	1 (7.1)	0	0	1 (7.1)	0
Crying	1 (7.1)	0	1 (7.1)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	1 (7.1)	0	1 (7.1)	0	0
Face oedema	1 (7.1)	1 (7.1)	0	0	0
Facial pain	1 (7.1)	0	1 (7.1)	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Influenza like illness	1 (7.1)	1 (7.1)	0	0	0
Malaise	1 (7.1)	0	1 (7.1)	0	0
Multiple organ dysfunction syndrome	1 (7.1)	0	0	0	1 (7.1)
Sluggishness	1 (7.1)	0	1 (7.1)	0	0
Swelling face	1 (7.1)	1 (7.1)	0	0	0
Vascular device occlusion	1 (7.1)	1 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Hepatic function abnormal	2 (14.3)	0	2 (14.3)	0	0
Biliary tract disorder	1 (7.1)	1 (7.1)	0	0	0
Gallbladder enlargement	1 (7.1)	1 (7.1)	0	0	0
Hyperbilirubinaemia	1 (7.1)	0	0	1 (7.1)	0
Hypertransaminasaemia	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Cytokine release syndrome	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Hypogammaglobulinaemia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Haemophagocytic lymphohistiocytosis	1 (7.1)	0	0	1 (7.1)	0
Infections and infestations					
-Total	9 (64.3)	1 (7.1)	2 (14.3)	5 (35.7)	1 (7.1)
Candida infection	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Staphylococcal infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0
Atypical pneumonia	1 (7.1)	1 (7.1)	0	0	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Conjunctivitis	1 (7.1)	0	1 (7.1)	0	0
Encephalitis viral	1 (7.1)	0	0	1 (7.1)	0
Granulicatella infection	1 (7.1)	0	0	1 (7.1)	0
Herpes simplex	1 (7.1)	0	0	1 (7.1)	0
Human herpesvirus 6 infection	1 (7.1)	0	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (7.1)	0	1 (7.1)	0	0
Myringitis	1 (7.1)	1 (7.1)	0	0	0
Oral candidiasis	1 (7.1)	0	1 (7.1)	0	0
Oral herpes	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Sinusitis	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Stomatococcal infection	1 (7.1)	0	1 (7.1)	0	0
Systemic candida	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection viral	1 (7.1)	1 (7.1)	0	0	0
Varicella zoster virus infection	1 (7.1)	0	0	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	0	0	0	1 (7.1)
Fall	1 (7.1)	0	1 (7.1)	0	0
Transplant failure	1 (7.1)	0	0	0	1 (7.1)
Investigations					

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (64.3)	2 (14.3)	1 (7.1)	3 (21.4)	3 (21.4)
Aspartate aminotransferase increased	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Platelet count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
International normalised ratio increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Blood bilirubin increased	1 (7.1)	0	0	1 (7.1)	0
Blood glucose increased	1 (7.1)	0	0	0	1 (7.1)
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Breath sounds abnormal	1 (7.1)	0	1 (7.1)	0	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
Staphylococcus test positive	1 (7.1)	1 (7.1)	0	0	0
White blood cell count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (50.0)	1 (7.1)	0	5 (35.7)	1 (7.1)
Hypokalaemia	6 (42.9)	1 (7.1)	3 (21.4)	2 (14.3)	0
Decreased appetite	5 (35.7)	3 (21.4)	0	2 (14.3)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)	0	0
Hypervolaemia	3 (21.4)	0	0	3 (21.4)	0
Hypocalcaemia	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Hypoalbuminaemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	0	0	2 (14.3)	0
Acidosis	1 (7.1)	0	0	0	1 (7.1)
Hyperuricaemia	1 (7.1)	1 (7.1)	0	0	0
Hypoglycaemia	1 (7.1)	0	1 (7.1)	0	0
Polydipsia	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (42.9)	3 (21.4)	2 (14.3)	1 (7.1)	0
Arthralgia	3 (21.4)	1 (7.1)	2 (14.3)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Back pain	1 (7.1)	1 (7.1)	0	0	0
Muscle spasms	1 (7.1)	0	1 (7.1)	0	0
Musculoskeletal chest pain	1 (7.1)	1 (7.1)	0	0	0
Neck pain	1 (7.1)	0	1 (7.1)	0	0
Pain in extremity	1 (7.1)	1 (7.1)	0	0	0
Pain in jaw	1 (7.1)	0	0	1 (7.1)	0
Nervous system disorders					
-Total	5 (35.7)	1 (7.1)	2 (14.3)	1 (7.1)	1 (7.1)
Headache	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Somnolence	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Tremor	2 (14.3)	2 (14.3)	0	0	0
Amnesia	1 (7.1)	0	1 (7.1)	0	0
Aphasia	1 (7.1)	1 (7.1)	0	0	0
Cognitive disorder	1 (7.1)	0	0	1 (7.1)	0
Disturbance in attention	1 (7.1)	1 (7.1)	0	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Dysgeusia	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Hyperaesthesia	1 (7.1)	1 (7.1)	0	0	0
Lethargy	1 (7.1)	0	1 (7.1)	0	0
Neurological decompensation	1 (7.1)	0	0	0	1 (7.1)
Paraesthesia	1 (7.1)	1 (7.1)	0	0	0
Psychiatric disorders					
-Total	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Agitation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Delirium	2 (14.3)	0	0	2 (14.3)	0
Affect lability	1 (7.1)	0	1 (7.1)	0	0
Hallucination	1 (7.1)	1 (7.1)	0	0	0
Hallucination, visual	1 (7.1)	0	1 (7.1)	0	0
Irritability	1 (7.1)	1 (7.1)	0	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Social avoidant behaviour	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	4 (28.6)	0	2 (14.3)	1 (7.1)	1 (7.1)
Acute kidney injury	2 (14.3)	0	1 (7.1)	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pollakiuria	1 (7.1)	0	1 (7.1)	0	0
Renal failure	1 (7.1)	0	0	0	1 (7.1)
Urinary incontinence	1 (7.1)	0	1 (7.1)	0	0
Urinary retention	1 (7.1)	0	1 (7.1)	0	0
Reproductive system and breast disorders					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Female genital tract fistula	1 (7.1)	1 (7.1)	0	0	0
Heavy menstrual bleeding	1 (7.1)	1 (7.1)	0	0	0
Vaginal haemorrhage	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (71.4)	5 (35.7)	0	3 (21.4)	2 (14.3)
Pulmonary oedema	4 (28.6)	1 (7.1)	0	2 (14.3)	1 (7.1)
Hypoxia	3 (21.4)	0	0	3 (21.4)	0
Oropharyngeal pain	2 (14.3)	2 (14.3)	0	0	0
Respiratory failure	2 (14.3)	0	0	0	2 (14.3)
Atelectasis	1 (7.1)	0	1 (7.1)	0	0
Dyspnoea	1 (7.1)	0	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (7.1)	1 (7.1)	0	0	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Nasal dryness	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal plaque	1 (7.1)	0	1 (7.1)	0	0
Paranasal sinus discomfort	1 (7.1)	0	1 (7.1)	0	0
Pharyngeal erythema	1 (7.1)	0	1 (7.1)	0	0
Pharyngeal exudate	1 (7.1)	0	1 (7.1)	0	0
Pharyngeal oedema	1 (7.1)	0	1 (7.1)	0	0
Pulmonary mass	1 (7.1)	0	1 (7.1)	0	0
Respiratory distress	1 (7.1)	0	0	0	1 (7.1)
Tachypnoea	1 (7.1)	0	1 (7.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (42.9)	3 (21.4)	3 (21.4)	0	0
Hyperhidrosis	2 (14.3)	0	2 (14.3)	0	0
Pruritus	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Erythema	1 (7.1)	1 (7.1)	0	0	0
Erythema nodosum	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (7.1)	1 (7.1)	0	0	0
Rash papular	1 (7.1)	0	1 (7.1)	0	0
Skin lesion	1 (7.1)	0	1 (7.1)	0	0
Social circumstances					
-Total	1 (7.1)	0	1 (7.1)	0	0
Patient uncooperative	1 (7.1)	0	1 (7.1)	0	0
Surgical and medical procedures					
-Total	1 (7.1)	0	0	1 (7.1)	0
Thrombolysis	1 (7.1)	0	0	1 (7.1)	0
Vascular disorders					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	2 (14.3)	1 (7.1)
Hypertension	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Hypotension	4 (28.6)	0	1 (7.1)	2 (14.3)	1 (7.1)
Flushing	1 (7.1)	1 (7.1)	0	0	0
Hot flush	1 (7.1)	1 (7.1)	0	0	0
Peripheral ischaemia	1 (7.1)	0	1 (7.1)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (93.3)	5 (16.7)	6 (20.0)	7 (23.3)	10 (33.3)
Blood and lymphatic system disorders					
-Total	6 (20.0)	2 (6.7)	1 (3.3)	2 (6.7)	1 (3.3)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Anaemia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Thrombocytopenia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Eosinophilia	1 (3.3)	0	1 (3.3)	0	0
Leukocytosis	1 (3.3)	0	1 (3.3)	0	0
Lymphadenopathy	1 (3.3)	1 (3.3)	0	0	0
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.0)	2 (6.7)	0	0	1 (3.3)
Cardiac arrest	1 (3.3)	0	0	0	1 (3.3)
Tachycardia	1 (3.3)	1 (3.3)	0	0	0
Tricuspid valve incompetence	1 (3.3)	1 (3.3)	0	0	0
Eye disorders					
-Total	2 (6.7)	2 (6.7)	0	0	0
Cataract	1 (3.3)	1 (3.3)	0	0	0
Hypermetropia	1 (3.3)	1 (3.3)	0	0	0
Ocular hyperaemia	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	8 (26.7)	7 (23.3)	0	1 (3.3)	0
Vomiting	6 (20.0)	6 (20.0)	0	0	0
Diarrhoea	5 (16.7)	5 (16.7)	0	0	0
Nausea	3 (10.0)	3 (10.0)	0	0	0
Abdominal pain	1 (3.3)	1 (3.3)	0	0	0
Abdominal pain upper	1 (3.3)	1 (3.3)	0	0	0
Constipation	1 (3.3)	0	1 (3.3)	0	0
Dyspepsia	1 (3.3)	1 (3.3)	0	0	0
Pancreatitis	1 (3.3)	0	0	1 (3.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (3.3)	1 (3.3)	0	0	0
General disorders and administration site conditions					
-Total	10 (33.3)	7 (23.3)	2 (6.7)	1 (3.3)	0
Pyrexia	6 (20.0)	3 (10.0)	3 (10.0)	0	0
Fatigue	4 (13.3)	4 (13.3)	0	0	0
Pain	1 (3.3)	0	0	1 (3.3)	0
Hepatobiliary disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Liver disorder	1 (3.3)	0	1 (3.3)	0	0
Immune system disorders					
-Total	6 (20.0)	1 (3.3)	4 (13.3)	1 (3.3)	0
Hypogammaglobulinaemia	3 (10.0)	0	3 (10.0)	0	0
Allergy to immunoglobulin therapy	1 (3.3)	1 (3.3)	0	0	0
Drug hypersensitivity	1 (3.3)	0	1 (3.3)	0	0
Graft versus host disease	1 (3.3)	0	0	1 (3.3)	0
Infections and infestations					
-Total	17 (56.7)	2 (6.7)	5 (16.7)	5 (16.7)	5 (16.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Nasopharyngitis	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Otitis media	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Gastroenteritis	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Metapneumovirus infection	2 (6.7)	0	0	2 (6.7)	0
Pneumocystis jirovecii pneumonia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Pneumonia	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Rhinovirus infection	2 (6.7)	0	2 (6.7)	0	0
Viral infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Bronchopulmonary aspergillosis	1 (3.3)	0	0	0	1 (3.3)
Cellulitis	1 (3.3)	0	1 (3.3)	0	0
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Cystitis	1 (3.3)	0	1 (3.3)	0	0
Cytomegalovirus infection reactivation	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	1 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (3.3)	0	0	1 (3.3)	0
Gingivitis	1 (3.3)	1 (3.3)	0	0	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Human herpesvirus 6 infection	1 (3.3)	0	0	1 (3.3)	0
Klebsiella infection	1 (3.3)	0	0	1 (3.3)	0
Mastoiditis	1 (3.3)	0	0	1 (3.3)	0
Oral candidiasis	1 (3.3)	0	1 (3.3)	0	0
Oral herpes	1 (3.3)	0	1 (3.3)	0	0
Otitis externa	1 (3.3)	0	0	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	0	0	0	1 (3.3)
Respiratory syncytial virus infection	1 (3.3)	0	1 (3.3)	0	0
Respiratory tract infection viral	1 (3.3)	0	1 (3.3)	0	0
Rhinitis	1 (3.3)	0	1 (3.3)	0	0
Salmonellosis	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal sepsis	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal skin infection	1 (3.3)	0	1 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Infusion related reaction	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Contusion	1 (3.3)	1 (3.3)	0	0	0
Ligament sprain	1 (3.3)	1 (3.3)	0	0	0
Skin abrasion	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	14 (46.7)	4 (13.3)	2 (6.7)	5 (16.7)	3 (10.0)
Neutrophil count decreased	7 (23.3)	1 (3.3)	1 (3.3)	2 (6.7)	3 (10.0)
White blood cell count decreased	7 (23.3)	3 (10.0)	2 (6.7)	1 (3.3)	1 (3.3)
Platelet count decreased	5 (16.7)	3 (10.0)	0	1 (3.3)	1 (3.3)
Lymphocyte count decreased	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Alanine aminotransferase increased	1 (3.3)	0	0	1 (3.3)	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Blood lactate dehydrogenase increased	1 (3.3)	1 (3.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (3.3)	0	0	1 (3.3)	0
C-reactive protein increased	1 (3.3)	1 (3.3)	0	0	0
Hepatitis b virus test positive	1 (3.3)	0	1 (3.3)	0	0
Metabolism and nutrition disorders					
-Total	5 (16.7)	2 (6.7)	1 (3.3)	1 (3.3)	1 (3.3)
Decreased appetite	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Hypokalaemia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Hyperkalaemia	1 (3.3)	0	1 (3.3)	0	0
Hypophagia	1 (3.3)	0	1 (3.3)	0	0
Iron overload	1 (3.3)	0	1 (3.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (16.7)	2 (6.7)	1 (3.3)	2 (6.7)	0
Pain in extremity	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Arthralgia	1 (3.3)	1 (3.3)	0	0	0
Back pain	1 (3.3)	0	0	1 (3.3)	0
Bone pain	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal chest pain	1 (3.3)	1 (3.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.3)	0	0	1 (3.3)	0
Myelodysplastic syndrome	1 (3.3)	0	0	1 (3.3)	0
Nervous system disorders					
-Total	3 (10.0)	2 (6.7)	0	0	1 (3.3)
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Headache	1 (3.3)	1 (3.3)	0	0	0
Hydrocephalus	1 (3.3)	0	0	0	1 (3.3)
Psychiatric disorders					
-Total	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Anxiety	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Agitation	1 (3.3)	1 (3.3)	0	0	0
Delirium	1 (3.3)	0	1 (3.3)	0	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Mood altered	1 (3.3)	1 (3.3)	0	0	0
Nightmare	1 (3.3)	1 (3.3)	0	0	0
Tearfulness	1 (3.3)	1 (3.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	12 (40.0)	7 (23.3)	2 (6.7)	2 (6.7)	1 (3.3)
Cough	6 (20.0)	6 (20.0)	0	0	0
Nasal congestion	3 (10.0)	3 (10.0)	0	0	0
Rhinorrhoea	3 (10.0)	3 (10.0)	0	0	0
Epistaxis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Hypoxia	2 (6.7)	0	0	2 (6.7)	0
Rhinitis allergic	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Bronchospasm	1 (3.3)	0	1 (3.3)	0	0
Respiratory failure	1 (3.3)	0	0	0	1 (3.3)
Skin and subcutaneous tissue disorders					
-Total	7 (23.3)	4 (13.3)	3 (10.0)	0	0
Dermatitis allergic	1 (3.3)	1 (3.3)	0	0	0
Dermatitis atopic	1 (3.3)	1 (3.3)	0	0	0
Dry skin	1 (3.3)	0	1 (3.3)	0	0
Erythema	1 (3.3)	0	1 (3.3)	0	0
Miliaria	1 (3.3)	1 (3.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

Primary system organ class Preferred term	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
			All patients N=30		
Night sweats	1 (3.3)	1 (3.3)	0	0	0
Photosensitivity reaction	1 (3.3)	0	1 (3.3)	0	0
Rash	1 (3.3)	1 (3.3)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (93.5)	4 (12.9)	12 (38.7)	5 (16.1)	8 (25.8)
Blood and lymphatic system disorders					
-Total	7 (22.6)	1 (3.2)	2 (6.5)	2 (6.5)	2 (6.5)
Neutropenia	3 (9.7)	0	0	1 (3.2)	2 (6.5)
Anaemia	1 (3.2)	1 (3.2)	0	0	0
Disseminated intravascular coagulation	1 (3.2)	0	0	1 (3.2)	0
Leukopenia	1 (3.2)	0	1 (3.2)	0	0
Lymphocytosis	1 (3.2)	0	1 (3.2)	0	0
Cardiac disorders					
-Total	4 (12.9)	1 (3.2)	1 (3.2)	0	2 (6.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (6.5)	0	0	1 (3.2)	1 (3.2)
Cardiac arrest	1 (3.2)	0	0	0	1 (3.2)
Left ventricular dysfunction	1 (3.2)	0	1 (3.2)	0	0
Tachycardia	1 (3.2)	1 (3.2)	0	0	0
Endocrine disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Hypothyroidism	1 (3.2)	0	1 (3.2)	0	0
Eye disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Visual impairment	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	7 (22.6)	4 (12.9)	3 (9.7)	0	0
Constipation	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Diarrhoea	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Abdominal rigidity	1 (3.2)	0	1 (3.2)	0	0
Gastrointestinal inflammation	1 (3.2)	0	1 (3.2)	0	0
Mouth haemorrhage	1 (3.2)	1 (3.2)	0	0	0
Nausea	1 (3.2)	0	1 (3.2)	0	0
Peritoneal haematoma	1 (3.2)	1 (3.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	9 (29.0)	6 (19.4)	1 (3.2)	2 (6.5)	0
Pyrexia	6 (19.4)	3 (9.7)	1 (3.2)	2 (6.5)	0
Fatigue	2 (6.5)	2 (6.5)	0	0	0
Asthenia	1 (3.2)	1 (3.2)	0	0	0
Chills	1 (3.2)	1 (3.2)	0	0	0
Malaise	1 (3.2)	1 (3.2)	0	0	0
Oedema peripheral	1 (3.2)	1 (3.2)	0	0	0
Hepatobiliary disorders					
-Total	2 (6.5)	2 (6.5)	0	0	0
Hepatic cytolysis	1 (3.2)	1 (3.2)	0	0	0
Hypertransaminasaemia	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	6 (19.4)	0	5 (16.1)	1 (3.2)	0
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)	0	0
Engraftment syndrome	1 (3.2)	0	0	1 (3.2)	0
Graft versus host disease	1 (3.2)	0	0	1 (3.2)	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (48.4)	2 (6.5)	7 (22.6)	4 (12.9)	2 (6.5)
Sinusitis	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Upper respiratory tract infection	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Gastroenteritis	2 (6.5)	2 (6.5)	0	0	0
Nasopharyngitis	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Respiratory tract infection	2 (6.5)	0	2 (6.5)	0	0
Adenovirus infection	1 (3.2)	0	0	1 (3.2)	0
Bacteraemia	1 (3.2)	0	1 (3.2)	0	0
Bk virus infection	1 (3.2)	0	0	1 (3.2)	0
Coronavirus infection	1 (3.2)	0	0	1 (3.2)	0
Ear infection	1 (3.2)	0	1 (3.2)	0	0
Encephalitis	1 (3.2)	0	0	0	1 (3.2)
Gastroenteritis clostridial	1 (3.2)	0	1 (3.2)	0	0
Gastroenteritis viral	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal infection	1 (3.2)	1 (3.2)	0	0	0
Herpes simplex	1 (3.2)	0	1 (3.2)	0	0
Influenza	1 (3.2)	0	1 (3.2)	0	0
Metapneumovirus infection	1 (3.2)	0	0	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (3.2)	1 (3.2)	0	0	0
Otitis externa	1 (3.2)	0	1 (3.2)	0	0
Parainfluenzae virus infection	1 (3.2)	1 (3.2)	0	0	0
Paronychia	1 (3.2)	0	1 (3.2)	0	0
Pneumonia	1 (3.2)	0	1 (3.2)	0	0
Respiratory syncytial virus infection	1 (3.2)	0	0	1 (3.2)	0
Rhinitis	1 (3.2)	1 (3.2)	0	0	0
Rhinovirus infection	1 (3.2)	0	1 (3.2)	0	0
Septic shock	1 (3.2)	0	0	0	1 (3.2)
Sinusitis fungal	1 (3.2)	0	0	1 (3.2)	0
Tinea pedis	1 (3.2)	1 (3.2)	0	0	0
Viral haemorrhagic cystitis	1 (3.2)	0	0	1 (3.2)	0
Injury, poisoning and procedural complications					
-Total	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Fibula fracture	1 (3.2)	0	1 (3.2)	0	0
Infusion related reaction	1 (3.2)	1 (3.2)	0	0	0
Limb injury	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	12 (38.7)	2 (6.5)	3 (9.7)	5 (16.1)	2 (6.5)
Neutrophil count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
White blood cell count decreased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0	0	0
Blood bilirubin increased	1 (3.2)	0	0	1 (3.2)	0
Blood creatinine increased	1 (3.2)	0	1 (3.2)	0	0
Blood immunoglobulin a decreased	1 (3.2)	0	0	1 (3.2)	0
Blood immunoglobulin m decreased	1 (3.2)	0	0	1 (3.2)	0
Blood thyroid stimulating hormone increased	1 (3.2)	1 (3.2)	0	0	0
Blood urea increased	1 (3.2)	0	0	1 (3.2)	0
Blood uric acid increased	1 (3.2)	0	0	0	1 (3.2)
Bone density decreased	1 (3.2)	1 (3.2)	0	0	0
Ejection fraction decreased	1 (3.2)	0	1 (3.2)	0	0
Immunoglobulins decreased	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (3.2)	0	1 (3.2)	0	0
Oxygen saturation decreased	1 (3.2)	0	1 (3.2)	0	0
Weight decreased	1 (3.2)	0	0	1 (3.2)	0
Weight increased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	9 (29.0)	2 (6.5)	3 (9.7)	2 (6.5)	2 (6.5)
Decreased appetite	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Hyperuricaemia	3 (9.7)	3 (9.7)	0	0	0
Haemochromatosis	1 (3.2)	0	0	1 (3.2)	0
Hyperchloraemia	1 (3.2)	1 (3.2)	0	0	0
Hypervolaemia	1 (3.2)	0	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	1 (3.2)	0	0
Hypophosphataemia	1 (3.2)	0	1 (3.2)	0	0
Metabolic acidosis	1 (3.2)	0	0	0	1 (3.2)
Metabolic syndrome	1 (3.2)	0	1 (3.2)	0	0
Tumour lysis syndrome	1 (3.2)	0	0	0	1 (3.2)
Musculoskeletal and connective tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (22.6)	3 (9.7)	3 (9.7)	1 (3.2)	0
Back pain	4 (12.9)	2 (6.5)	1 (3.2)	1 (3.2)	0
Pain in extremity	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Arthralgia	1 (3.2)	1 (3.2)	0	0	0
Growth retardation	1 (3.2)	0	1 (3.2)	0	0
Musculoskeletal pain	1 (3.2)	0	1 (3.2)	0	0
Myalgia	1 (3.2)	0	1 (3.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Skin papilloma	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Cancer pain	1 (3.2)	0	1 (3.2)	0	0
Nervous system disorders					
-Total	7 (22.6)	4 (12.9)	2 (6.5)	0	1 (3.2)
Headache	6 (19.4)	4 (12.9)	2 (6.5)	0	0
Autonomic neuropathy	1 (3.2)	0	0	1 (3.2)	0
Cerebral haemorrhage	1 (3.2)	0	0	0	1 (3.2)
Memory impairment	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (3.2)	0	0	1 (3.2)	0
Psychiatric disorders					
-Total	4 (12.9)	0	4 (12.9)	0	0
Anxiety	1 (3.2)	0	1 (3.2)	0	0
Mental status changes	1 (3.2)	0	1 (3.2)	0	0
Persistent depressive disorder	1 (3.2)	0	1 (3.2)	0	0
Sleep disorder	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	4 (12.9)	1 (3.2)	0	2 (6.5)	1 (3.2)
Acute kidney injury	3 (9.7)	1 (3.2)	1 (3.2)	0	1 (3.2)
Dysuria	1 (3.2)	0	1 (3.2)	0	0
Haematuria	1 (3.2)	0	0	1 (3.2)	0
Kidney enlargement	1 (3.2)	0	1 (3.2)	0	0
Renal mass	1 (3.2)	0	1 (3.2)	0	0
Renal tubular disorder	1 (3.2)	0	0	1 (3.2)	0
Reproductive system and breast disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Dysmenorrhoea	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	9 (29.0)	3 (9.7)	3 (9.7)	1 (3.2)	2 (6.5)
Cough	5 (16.1)	2 (6.5)	3 (9.7)	0	0
Nasal congestion	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Acute respiratory distress syndrome	1 (3.2)	0	0	0	1 (3.2)
Dyspnoea	1 (3.2)	0	1 (3.2)	0	0
Epistaxis	1 (3.2)	0	1 (3.2)	0	0
Hypoxia	1 (3.2)	0	0	1 (3.2)	0
Lung disorder	1 (3.2)	1 (3.2)	0	0	0
Paranasal sinus inflammation	1 (3.2)	1 (3.2)	0	0	0
Pleural effusion	1 (3.2)	1 (3.2)	0	0	0
Respiratory distress	1 (3.2)	0	0	0	1 (3.2)
Skin and subcutaneous tissue disorders					
-Total	9 (29.0)	6 (19.4)	3 (9.7)	0	0
Dry skin	4 (12.9)	3 (9.7)	1 (3.2)	0	0
Rash	3 (9.7)	2 (6.5)	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	2 (6.5)	0	2 (6.5)	0	0
Eczema	1 (3.2)	1 (3.2)	0	0	0
Skin discolouration	1 (3.2)	1 (3.2)	0	0	0
Skin hypopigmentation	1 (3.2)	1 (3.2)	0	0	0
Skin swelling	1 (3.2)	1 (3.2)	0	0	0
Vascular disorders					
-Total	5 (16.1)	1 (3.2)	0	2 (6.5)	2 (6.5)
Hypotension	4 (12.9)	1 (3.2)	0	1 (3.2)	2 (6.5)
Hypertension	1 (3.2)	0	1 (3.2)	0	0
Venoocclusive disease	1 (3.2)	0	0	1 (3.2)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	0	6 (42.9)	3 (21.4)	3 (21.4)
Blood and lymphatic system disorders					
-Total	4 (28.6)	0	1 (7.1)	2 (14.3)	1 (7.1)
Anaemia	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Neutropenia	2 (14.3)	0	0	1 (7.1)	1 (7.1)
B-cell aplasia	1 (7.1)	0	1 (7.1)	0	0
Eye disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Cataract	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Enteritis	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal haemorrhage	1 (7.1)	0	1 (7.1)	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
Pancreatitis	1 (7.1)	1 (7.1)	0	0	0
Stomatitis	1 (7.1)	1 (7.1)	0	0	0
Trichoglossia	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Pyrexia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Non-cardiac chest pain	1 (7.1)	1 (7.1)	0	0	0
Pain	1 (7.1)	0	1 (7.1)	0	0
Immune system disorders					
-Total	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Allergy to immunoglobulin therapy	1 (7.1)	0	0	1 (7.1)	0
Immunodeficiency	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	3 (21.4)	1 (7.1)
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Parainfluenzae virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Acute sinusitis	1 (7.1)	0	1 (7.1)	0	0
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Ear, nose and throat infection	1 (7.1)	0	1 (7.1)	0	0
Gastroenteritis	1 (7.1)	0	0	1 (7.1)	0
Nail infection	1 (7.1)	1 (7.1)	0	0	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (7.1)	0	1 (7.1)	0	0
Post-traumatic neck syndrome	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Blood bilirubin increased	1 (7.1)	0	1 (7.1)	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Heart sounds abnormal	1 (7.1)	1 (7.1)	0	0	0
White blood cell count decreased	1 (7.1)	0	0	1 (7.1)	0
Metabolism and nutrition disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Malnutrition	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (21.4)	0	3 (21.4)	0	0
Arthralgia	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (7.1)	0	1 (7.1)	0	0
Bone pain	1 (7.1)	0	1 (7.1)	0	0
Neck pain	1 (7.1)	1 (7.1)	0	0	0
Nervous system disorders					
-Total	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Headache	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Extrapyramidal disorder	1 (7.1)	0	1 (7.1)	0	0
Migraine	1 (7.1)	0	1 (7.1)	0	0
Psychiatric disorders					
-Total	3 (21.4)	0	3 (21.4)	0	0
Anxiety	3 (21.4)	0	3 (21.4)	0	0
Renal and urinary disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Cystitis haemorrhagic	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Bronchial oedema	1 (7.1)	1 (7.1)	0	0	0
Pleural effusion	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract inflammation	1 (7.1)	0	1 (7.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	0
Decubitus ulcer	1 (7.1)	0	0	1 (7.1)	0
Dry skin	1 (7.1)	1 (7.1)	0	0	0
Hangnail	1 (7.1)	1 (7.1)	0	0	0
Pruritus	1 (7.1)	0	1 (7.1)	0	0
Vascular disorders					
-Total	1 (7.1)	0	0	0	1 (7.1)
Venoocclusive disease	1 (7.1)	0	0	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (60.0)	2 (10.0)	5 (25.0)	3 (15.0)	2 (10.0)
Blood and lymphatic system disorders					
-Total	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Agranulocytosis	1 (5.0)	0	0	1 (5.0)	0
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Hypercoagulation	1 (5.0)	0	1 (5.0)	0	0
Lymphadenopathy	1 (5.0)	0	1 (5.0)	0	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	1 (5.0)	0	0	1 (5.0)	0
Eyelid oedema	1 (5.0)	1 (5.0)	0	0	0
Mydriasis	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Diarrhoea	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Constipation	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Pyrexia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Multiple organ dysfunction syndrome	1 (5.0)	0	0	0	1 (5.0)
Immune system disorders					
-Total	3 (15.0)	0	2 (10.0)	0	1 (5.0)
Chronic graft versus host disease	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	0	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	8 (40.0)	1 (5.0)	4 (20.0)	1 (5.0)	2 (10.0)
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Covid-19 pneumonia	1 (5.0)	0	0	0	1 (5.0)
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Fungal infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis	1 (5.0)	1 (5.0)	0	0	0
Herpes virus infection	1 (5.0)	0	1 (5.0)	0	0
Influenza	1 (5.0)	0	0	0	1 (5.0)
Neutropenic infection	1 (5.0)	0	0	1 (5.0)	0
Ophthalmic herpes zoster	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	0	0	1 (5.0)
Rhinovirus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Streptococcal sepsis	1 (5.0)	0	1 (5.0)	0	0
Viral skin infection	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.0)	1 (5.0)	0	0	0
Abdominal injury	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0
Oxygen saturation decreased	1 (5.0)	0	0	1 (5.0)	0
Platelet count decreased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (10.0)	0	0	2 (10.0)	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (5.0)	0	0	1 (5.0)	0
Obesity	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0
Pain in extremity	2 (10.0)	0	2 (10.0)	0	0
Growth retardation	1 (5.0)	0	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.0)	0	0	1 (5.0)	0
Bone giant cell tumour benign	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Headache	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Cough	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (5.0)	0	0	0	1 (5.0)
Dyspnoea exertional	1 (5.0)	1 (5.0)	0	0	0
Pharyngeal erythema	1 (5.0)	1 (5.0)	0	0	0
Pleural effusion	1 (5.0)	0	1 (5.0)	0	0
Sleep apnoea syndrome	1 (5.0)	0	1 (5.0)	0	0
Tachypnoea	1 (5.0)	0	0	0	1 (5.0)
Skin and subcutaneous tissue disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Dry skin	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	1 (5.0)	0	0	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hypertension	1 (5.0)	0	0	1 (5.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (77.3)	1 (4.5)	5 (22.7)	8 (36.4)	3 (13.6)
Blood and lymphatic system disorders					
-Total	1 (4.5)	0	0	0	1 (4.5)
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Endocrine disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Delayed puberty	1 (4.5)	0	1 (4.5)	0	0
Hypothyroidism	1 (4.5)	0	1 (4.5)	0	0
Eye disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Dry eye	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Diarrhoea	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Irritable bowel syndrome	1 (4.5)	0	1 (4.5)	0	0
Nausea	1 (4.5)	1 (4.5)	0	0	0
Vomiting	1 (4.5)	1 (4.5)	0	0	0
General disorders and administration site conditions					
-Total	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Pyrexia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Fatigue	1 (4.5)	0	1 (4.5)	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Xerosis	1 (4.5)	1 (4.5)	0	0	0
Immune system disorders					
-Total	6 (27.3)	2 (9.1)	3 (13.6)	1 (4.5)	0
Seasonal allergy	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Hypogammaglobulinaemia	2 (9.1)	0	2 (9.1)	0	0
Drug hypersensitivity	1 (4.5)	0	0	1 (4.5)	0
Infections and infestations					

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (54.5)	1 (4.5)	1 (4.5)	8 (36.4)	2 (9.1)
Sinusitis	4 (18.2)	0	4 (18.2)	0	0
Conjunctivitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Covid-19	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Herpes zoster	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Otitis media	2 (9.1)	0	2 (9.1)	0	0
Rhinovirus infection	2 (9.1)	0	2 (9.1)	0	0
Sepsis	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Skin infection	2 (9.1)	0	2 (9.1)	0	0
Upper respiratory tract infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Bronchiolitis	1 (4.5)	0	0	1 (4.5)	0
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Clostridium difficile colitis	1 (4.5)	0	0	1 (4.5)	0
Device related sepsis	1 (4.5)	0	0	1 (4.5)	0
Ear infection	1 (4.5)	0	0	1 (4.5)	0
Folliculitis	1 (4.5)	0	1 (4.5)	0	0
Fungal infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis escherichia coli	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis viral	1 (4.5)	0	1 (4.5)	0	0
Meningitis pneumococcal	1 (4.5)	0	0	1 (4.5)	0
Nail infection	1 (4.5)	0	1 (4.5)	0	0
Oral candidiasis	1 (4.5)	0	1 (4.5)	0	0
Oral herpes	1 (4.5)	1 (4.5)	0	0	0
Pneumonia	1 (4.5)	0	0	1 (4.5)	0
Pneumonia respiratory syncytial viral	1 (4.5)	0	0	1 (4.5)	0
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Septic shock	1 (4.5)	0	0	0	1 (4.5)
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Syphilis	1 (4.5)	0	1 (4.5)	0	0
Urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Urinary tract infection pseudomonal	1 (4.5)	0	1 (4.5)	0	0
Injury, poisoning and procedural complications					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Infusion related reaction	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

		All patients N=22			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ligament sprain	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	1 (4.5)	0	1 (4.5)	0	0
Blood immunoglobulin g decreased	1 (4.5)	0	1 (4.5)	0	0
Metabolism and nutrition disorders					
-Total	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Decreased appetite	1 (4.5)	0	0	0	1 (4.5)
Hyperlipidaemia	1 (4.5)	0	1 (4.5)	0	0
Hypernatraemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Arthralgia	1 (4.5)	0	1 (4.5)	0	0
Osteonecrosis	1 (4.5)	1 (4.5)	0	0	0
Osteopenia	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					
-Total	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Dysarthria	1 (4.5)	0	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (4.5)	0	1 (4.5)	0	0
Nervous system disorder	1 (4.5)	0	0	1 (4.5)	0
Seizure	1 (4.5)	0	0	1 (4.5)	0
Psychiatric disorders					
-Total	2 (9.1)	0	2 (9.1)	0	0
Anxiety	1 (4.5)	0	1 (4.5)	0	0
Tic	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (27.3)	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)
Cough	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Rhinorrhoea	2 (9.1)	0	2 (9.1)	0	0
Dyspnoea	1 (4.5)	0	1 (4.5)	0	0
Epistaxis	1 (4.5)	1 (4.5)	0	0	0
Hypoxia	1 (4.5)	0	0	1 (4.5)	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0	0	0
Respiratory failure	1 (4.5)	0	0	0	1 (4.5)
Sleep apnoea syndrome	1 (4.5)	1 (4.5)	0	0	0
Wheezing	1 (4.5)	0	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	5 (22.7)	1 (4.5)	1 (4.5)	3 (13.6)	0
Dermatitis atopic	1 (4.5)	0	0	1 (4.5)	0
Eczema	1 (4.5)	0	0	1 (4.5)	0
Papule	1 (4.5)	1 (4.5)	0	0	0
Rash	1 (4.5)	0	1 (4.5)	0	0
Rash erythematous	1 (4.5)	1 (4.5)	0	0	0
Rash macular	1 (4.5)	0	0	1 (4.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Congenital, familial and genetic disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Cerebral cavernous malformation	1 (12.5)	1 (12.5)	0	0	0
Ear and labyrinth disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Deafness unilateral	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Diarrhoea	1 (12.5)	1 (12.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (25.0)	2 (25.0)	0	0	0
Non-cardiac chest pain	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	1 (12.5)	0	0	0
Pyrexia	1 (12.5)	1 (12.5)	0	0	0
Infections and infestations					
-Total	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Sinusitis	2 (25.0)	0	2 (25.0)	0	0
Acute sinusitis	1 (12.5)	0	1 (12.5)	0	0
Fungal skin infection	1 (12.5)	0	1 (12.5)	0	0
Influenza	1 (12.5)	0	1 (12.5)	0	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal abscess	1 (12.5)	0	0	1 (12.5)	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0	0	0
Urinary tract infection	1 (12.5)	0	1 (12.5)	0	0
Varicella zoster virus infection	1 (12.5)	0	1 (12.5)	0	0
Investigations					

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Neutrophil count decreased	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	1 (12.5)	0	0	0
Platelet count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypercholesterolaemia	1 (12.5)	0	1 (12.5)	0	0
Hypertriglyceridaemia	1 (12.5)	0	1 (12.5)	0	0
Iron overload	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Joint effusion	1 (12.5)	0	1 (12.5)	0	0
Synovitis	1 (12.5)	0	1 (12.5)	0	0
Psychiatric disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Anxiety	1 (12.5)	1 (12.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Endometriosis	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	1 (12.5)	0	0	0
Laryngeal oedema	1 (12.5)	0	0	0	1 (12.5)
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypertension	1 (12.5)	0	1 (12.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	0	4 (12.1)	7 (21.2)	22 (66.7)
Blood and lymphatic system disorders					
-Total	23 (69.7)	1 (3.0)	5 (15.2)	13 (39.4)	4 (12.1)
Anaemia	14 (42.4)	3 (9.1)	4 (12.1)	7 (21.2)	0
Febrile neutropenia	13 (39.4)	0	0	13 (39.4)	0
Thrombocytopenia	5 (15.2)	0	0	1 (3.0)	4 (12.1)
Disseminated intravascular coagulation	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Neutropenia	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Lymphadenopathy	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Lymphopenia	2 (6.1)	0	0	2 (6.1)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agranulocytosis	1 (3.0)	0	0	1 (3.0)	0
Coagulopathy	1 (3.0)	0	0	1 (3.0)	0
Eosinophilia	1 (3.0)	0	1 (3.0)	0	0
Hypercoagulation	1 (3.0)	0	1 (3.0)	0	0
Leukocytosis	1 (3.0)	0	1 (3.0)	0	0
Leukopenia	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Splenomegaly	1 (3.0)	1 (3.0)	0	0	0
Cardiac disorders					
-Total	11 (33.3)	4 (12.1)	2 (6.1)	3 (9.1)	2 (6.1)
Tachycardia	9 (27.3)	4 (12.1)	3 (9.1)	1 (3.0)	1 (3.0)
Left ventricular dysfunction	2 (6.1)	0	0	2 (6.1)	0
Cardiac arrest	1 (3.0)	0	0	0	1 (3.0)
Cardiac dysfunction	1 (3.0)	1 (3.0)	0	0	0
Cardiac failure congestive	1 (3.0)	0	1 (3.0)	0	0
Mitral valve incompetence	1 (3.0)	1 (3.0)	0	0	0
Right ventricular dysfunction	1 (3.0)	1 (3.0)	0	0	0
Tricuspid valve incompetence	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Ear pain	1 (3.0)	1 (3.0)	0	0	0
Endocrine disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Hypothyroidism	1 (3.0)	0	1 (3.0)	0	0
Eye disorders					
-Total	8 (24.2)	5 (15.2)	2 (6.1)	1 (3.0)	0
Eyelid oedema	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Ocular hyperaemia	3 (9.1)	3 (9.1)	0	0	0
Eye pain	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Cataract	1 (3.0)	1 (3.0)	0	0	0
Conjunctival haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Hypermetropia	1 (3.0)	1 (3.0)	0	0	0
Mydriasis	1 (3.0)	0	1 (3.0)	0	0
Visual impairment	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	27 (81.8)	9 (27.3)	9 (27.3)	8 (24.2)	1 (3.0)
Vomiting	16 (48.5)	11 (33.3)	5 (15.2)	0	0
Diarrhoea	14 (42.4)	8 (24.2)	4 (12.1)	2 (6.1)	0
Nausea	13 (39.4)	7 (21.2)	5 (15.2)	1 (3.0)	0
Constipation	7 (21.2)	4 (12.1)	3 (9.1)	0	0
Abdominal pain	6 (18.2)	1 (3.0)	3 (9.1)	2 (6.1)	0
Abdominal distension	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Ascites	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Abdominal pain upper	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Gastrointestinal sounds abnormal	2 (6.1)	2 (6.1)	0	0	0
Mouth haemorrhage	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Pancreatitis	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Abdominal compartment syndrome	1 (3.0)	0	0	0	1 (3.0)
Anal fissure	1 (3.0)	0	1 (3.0)	0	0
Anal haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Dyspepsia	1 (3.0)	1 (3.0)	0	0	0
Haematemesis	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip oedema	1 (3.0)	1 (3.0)	0	0	0
Melaena	1 (3.0)	0	0	1 (3.0)	0
Neutropenic colitis	1 (3.0)	0	0	1 (3.0)	0
Proctalgia	1 (3.0)	1 (3.0)	0	0	0
Stomatitis	1 (3.0)	0	0	1 (3.0)	0
Upper gastrointestinal haemorrhage	1 (3.0)	1 (3.0)	0	0	0
General disorders and administration site conditions					
-Total	20 (60.6)	10 (30.3)	5 (15.2)	2 (6.1)	3 (9.1)
Pyrexia	13 (39.4)	6 (18.2)	4 (12.1)	2 (6.1)	1 (3.0)
Fatigue	11 (33.3)	9 (27.3)	2 (6.1)	0	0
Chills	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Face oedema	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Generalised oedema	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Multiple organ dysfunction syndrome	2 (6.1)	0	0	0	2 (6.1)
Pain	2 (6.1)	0	0	2 (6.1)	0
Asthenia	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site erythema	1 (3.0)	1 (3.0)	0	0	0
Chest discomfort	1 (3.0)	0	0	1 (3.0)	0
Influenza like illness	1 (3.0)	0	1 (3.0)	0	0
Systemic inflammatory response syndrome	1 (3.0)	0	0	1 (3.0)	0
Hepatobiliary disorders					
-Total	8 (24.2)	3 (9.1)	3 (9.1)	1 (3.0)	1 (3.0)
Cholelithiasis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Hyperbilirubinaemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Cholestasis	1 (3.0)	0	0	0	1 (3.0)
Gallbladder enlargement	1 (3.0)	1 (3.0)	0	0	0
Hepatic function abnormal	1 (3.0)	0	0	1 (3.0)	0
Hepatomegaly	1 (3.0)	1 (3.0)	0	0	0
Liver disorder	1 (3.0)	0	1 (3.0)	0	0
Ocular icterus	1 (3.0)	1 (3.0)	0	0	0
Immune system disorders					
-Total	29 (87.9)	2 (6.1)	11 (33.3)	7 (21.2)	9 (27.3)
Cytokine release syndrome	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	13 (39.4)	1 (3.0)	10 (30.3)	2 (6.1)	0
Haemophagocytic lymphohistiocytosis	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Chronic graft versus host disease	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Immunodeficiency	2 (6.1)	0	0	2 (6.1)	0
Allergy to immunoglobulin therapy	1 (3.0)	1 (3.0)	0	0	0
Drug hypersensitivity	1 (3.0)	0	1 (3.0)	0	0
Graft versus host disease	1 (3.0)	0	0	1 (3.0)	0
Infections and infestations					
-Total	25 (75.8)	4 (12.1)	7 (21.2)	7 (21.2)	7 (21.2)
Upper respiratory tract infection	6 (18.2)	4 (12.1)	2 (6.1)	0	0
Conjunctivitis	5 (15.2)	1 (3.0)	4 (12.1)	0	0
Gastroenteritis	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Nasopharyngitis	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Otitis media	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Pneumonia	3 (9.1)	1 (3.0)	0	0	2 (6.1)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Candida infection	2 (6.1)	0	2 (6.1)	0	0
Clostridium difficile infection	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Metapneumovirus infection	2 (6.1)	0	0	2 (6.1)	0
Oral herpes	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Oral infection	2 (6.1)	0	2 (6.1)	0	0
Parainfluenzae virus infection	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Pneumocystis jirovecii pneumonia	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Staphylococcal bacteraemia	2 (6.1)	0	0	2 (6.1)	0
Staphylococcal infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Viral infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Bk virus infection	1 (3.0)	1 (3.0)	0	0	0
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Bronchopulmonary aspergillosis	1 (3.0)	0	0	0	1 (3.0)
Cellulitis	1 (3.0)	0	1 (3.0)	0	0
Covid-19 pneumonia	1 (3.0)	0	0	0	1 (3.0)
Cystitis	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (3.0)	0	0	1 (3.0)	0
Device related infection	1 (3.0)	0	0	1 (3.0)	0
Ear infection	1 (3.0)	0	1 (3.0)	0	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)
Enterobacter infection	1 (3.0)	0	0	1 (3.0)	0
Enterovirus infection	1 (3.0)	0	0	1 (3.0)	0
Fungal infection	1 (3.0)	0	1 (3.0)	0	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Herpes virus infection	1 (3.0)	0	1 (3.0)	0	0
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Human herpesvirus 6 infection	1 (3.0)	0	0	1 (3.0)	0
Influenza	1 (3.0)	0	0	0	1 (3.0)
Klebsiella infection	1 (3.0)	0	0	1 (3.0)	0
Localised infection	1 (3.0)	1 (3.0)	0	0	0
Mastoiditis	1 (3.0)	0	0	1 (3.0)	0
Nail infection	1 (3.0)	1 (3.0)	0	0	0
Neutropenic infection	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (3.0)	0	1 (3.0)	0	0
Oral candidiasis	1 (3.0)	0	1 (3.0)	0	0
Otitis externa	1 (3.0)	0	0	1 (3.0)	0
Otitis media acute	1 (3.0)	0	1 (3.0)	0	0
Pneumonia viral	1 (3.0)	0	0	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection viral	1 (3.0)	0	1 (3.0)	0	0
Rhinitis	1 (3.0)	0	1 (3.0)	0	0
Salmonellosis	1 (3.0)	0	1 (3.0)	0	0
Sepsis	1 (3.0)	0	0	0	1 (3.0)
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Soft tissue infection	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal sepsis	1 (3.0)	0	0	0	1 (3.0)
Staphylococcal skin infection	1 (3.0)	0	1 (3.0)	0	0
Streptococcal sepsis	1 (3.0)	0	1 (3.0)	0	0
Viral skin infection	1 (3.0)	1 (3.0)	0	0	0
Injury, poisoning and procedural complications					

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (30.3)	6 (18.2)	3 (9.1)	0	1 (3.0)
Infusion related reaction	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Transfusion reaction	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Abdominal injury	1 (3.0)	1 (3.0)	0	0	0
Contusion	1 (3.0)	1 (3.0)	0	0	0
Fall	1 (3.0)	0	1 (3.0)	0	0
Ligament sprain	1 (3.0)	1 (3.0)	0	0	0
Scratch	1 (3.0)	1 (3.0)	0	0	0
Skin abrasion	1 (3.0)	1 (3.0)	0	0	0
Skin injury	1 (3.0)	0	1 (3.0)	0	0
Skin wound	1 (3.0)	1 (3.0)	0	0	0
Vasoplegia syndrome	1 (3.0)	0	0	0	1 (3.0)
Wound	1 (3.0)	0	0	1 (3.0)	0
Investigations					
-Total	27 (81.8)	2 (6.1)	2 (6.1)	8 (24.2)	15 (45.5)
White blood cell count decreased	17 (51.5)	2 (6.1)	2 (6.1)	2 (6.1)	11 (33.3)
Neutrophil count decreased	16 (48.5)	0	1 (3.0)	3 (9.1)	12 (36.4)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	14 (42.4)	4 (12.1)	1 (3.0)	5 (15.2)	4 (12.1)
Lymphocyte count decreased	10 (30.3)	0	0	7 (21.2)	3 (9.1)
Alanine aminotransferase increased	9 (27.3)	1 (3.0)	6 (18.2)	2 (6.1)	0
Aspartate aminotransferase increased	8 (24.2)	1 (3.0)	3 (9.1)	2 (6.1)	2 (6.1)
Blood immunoglobulin m decreased	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Blood bilirubin increased	5 (15.2)	0	1 (3.0)	4 (12.1)	0
Blood immunoglobulin a decreased	5 (15.2)	4 (12.1)	1 (3.0)	0	0
International normalised ratio increased	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Activated partial thromboplastin time prolonged	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Blood fibrinogen decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Blood lactate dehydrogenase increased	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Blood uric acid increased	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Serum ferritin increased	3 (9.1)	1 (3.0)	2 (6.1)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
C-reactive protein increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Fibrin d dimer increased	2 (6.1)	2 (6.1)	0	0	0
Gamma-glutamyltransferase increased	2 (6.1)	0	0	2 (6.1)	0
Oxygen saturation decreased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Weight increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Blood creatine phosphokinase increased	1 (3.0)	0	0	0	1 (3.0)
Blood creatinine increased	1 (3.0)	0	0	1 (3.0)	0
Electrocardiogram qt prolonged	1 (3.0)	0	1 (3.0)	0	0
Hepatitis b virus test positive	1 (3.0)	0	1 (3.0)	0	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0
Lipase increased	1 (3.0)	0	0	0	1 (3.0)
Urine output decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	21 (63.6)	5 (15.2)	4 (12.1)	7 (21.2)	5 (15.2)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	11 (33.3)	4 (12.1)	2 (6.1)	4 (12.1)	1 (3.0)
Hypophosphataemia	10 (30.3)	2 (6.1)	4 (12.1)	3 (9.1)	1 (3.0)
Hypocalcaemia	7 (21.2)	1 (3.0)	4 (12.1)	2 (6.1)	0
Hypokalaemia	7 (21.2)	2 (6.1)	1 (3.0)	2 (6.1)	2 (6.1)
Hyperglycaemia	4 (12.1)	0	0	4 (12.1)	0
Hypoalbuminaemia	4 (12.1)	0	4 (12.1)	0	0
Hyperkalaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hypernatraemia	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Hyperphosphataemia	2 (6.1)	2 (6.1)	0	0	0
Hyperuricaemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Metabolic acidosis	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Dehydration	1 (3.0)	0	1 (3.0)	0	0
Haemosiderosis	1 (3.0)	0	1 (3.0)	0	0
Hypercalcaemia	1 (3.0)	0	0	1 (3.0)	0
Hyperlactacidaemia	1 (3.0)	1 (3.0)	0	0	0
Hypermagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hypertriglyceridaemia	1 (3.0)	0	0	1 (3.0)	0
Hypervolaemia	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hyponatraemia	1 (3.0)	1 (3.0)	0	0	0
Hypophagia	1 (3.0)	0	1 (3.0)	0	0
Iron overload	1 (3.0)	0	1 (3.0)	0	0
Malnutrition	1 (3.0)	0	0	1 (3.0)	0
Obesity	1 (3.0)	0	0	1 (3.0)	0
Musculoskeletal and connective tissue disorders					
-Total	19 (57.6)	7 (21.2)	8 (24.2)	3 (9.1)	1 (3.0)
Pain in extremity	12 (36.4)	5 (15.2)	6 (18.2)	1 (3.0)	0
Back pain	5 (15.2)	1 (3.0)	2 (6.1)	2 (6.1)	0
Arthralgia	4 (12.1)	1 (3.0)	3 (9.1)	0	0
Myalgia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Bone pain	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Growth retardation	1 (3.0)	0	1 (3.0)	0	0
Muscular weakness	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal chest pain	1 (3.0)	1 (3.0)	0	0	0
Myositis	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (3.0)	0	0	0	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (6.1)	0	0	2 (6.1)	0
Bone giant cell tumour benign	1 (3.0)	0	0	1 (3.0)	0
Myelodysplastic syndrome	1 (3.0)	0	0	1 (3.0)	0
Nervous system disorders					
-Total	18 (54.5)	7 (21.2)	4 (12.1)	5 (15.2)	2 (6.1)
Headache	8 (24.2)	5 (15.2)	1 (3.0)	2 (6.1)	0
Encephalopathy	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Dysgeusia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Lethargy	2 (6.1)	2 (6.1)	0	0	0
Tremor	2 (6.1)	2 (6.1)	0	0	0
Cerebral haemorrhage	1 (3.0)	0	0	0	1 (3.0)
Depressed level of consciousness	1 (3.0)	0	0	1 (3.0)	0
Dizziness	1 (3.0)	1 (3.0)	0	0	0
Hydrocephalus	1 (3.0)	0	0	0	1 (3.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Monoparesis	1 (3.0)	0	1 (3.0)	0	0
Neuralgia	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0
Psychiatric disorders					
-Total	16 (48.5)	8 (24.2)	7 (21.2)	1 (3.0)	0
Anxiety	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Confusional state	4 (12.1)	4 (12.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Insomnia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Agitation	2 (6.1)	2 (6.1)	0	0	0
Hallucination	2 (6.1)	0	2 (6.1)	0	0
Irritability	2 (6.1)	2 (6.1)	0	0	0
Mental status changes	1 (3.0)	0	0	1 (3.0)	0
Mood altered	1 (3.0)	1 (3.0)	0	0	0
Nightmare	1 (3.0)	1 (3.0)	0	0	0
Restlessness	1 (3.0)	0	1 (3.0)	0	0
Sleep disorder	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tearfulness	1 (3.0)	1 (3.0)	0	0	0
Renal and urinary disorders					
-Total	9 (27.3)	4 (12.1)	2 (6.1)	0	3 (9.1)
Acute kidney injury	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Dysuria	2 (6.1)	2 (6.1)	0	0	0
Haematuria	2 (6.1)	2 (6.1)	0	0	0
Anuria	1 (3.0)	0	0	0	1 (3.0)
Bladder dilatation	1 (3.0)	0	1 (3.0)	0	0
Incontinence	1 (3.0)	0	1 (3.0)	0	0
Proteinuria	1 (3.0)	1 (3.0)	0	0	0
Renal failure	1 (3.0)	0	1 (3.0)	0	0
Renal tubular dysfunction	1 (3.0)	1 (3.0)	0	0	0
Renal tubular necrosis	1 (3.0)	0	0	0	1 (3.0)
Urinary retention	1 (3.0)	0	1 (3.0)	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Vaginal ulceration	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	23 (69.7)	9 (27.3)	4 (12.1)	5 (15.2)	5 (15.2)
Cough	11 (33.3)	10 (30.3)	1 (3.0)	0	0
Hypoxia	8 (24.2)	0	2 (6.1)	4 (12.1)	2 (6.1)
Tachypnoea	5 (15.2)	2 (6.1)	0	2 (6.1)	1 (3.0)
Nasal congestion	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Pulmonary oedema	4 (12.1)	0	1 (3.0)	3 (9.1)	0
Dyspnoea	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Epistaxis	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Pleural effusion	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Rhinorrhoea	3 (9.1)	3 (9.1)	0	0	0
Rhinitis allergic	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Acute respiratory distress syndrome	1 (3.0)	0	0	0	1 (3.0)
Atelectasis	1 (3.0)	0	0	1 (3.0)	0
Bronchospasm	1 (3.0)	0	1 (3.0)	0	0
Dyspnoea exertional	1 (3.0)	1 (3.0)	0	0	0
Lung infiltration	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Pharyngeal erythema	1 (3.0)	1 (3.0)	0	0	0
Productive cough	1 (3.0)	1 (3.0)	0	0	0
Respiratory acidosis	1 (3.0)	0	0	1 (3.0)	0
Respiratory distress	1 (3.0)	0	1 (3.0)	0	0
Respiratory failure	1 (3.0)	0	0	0	1 (3.0)
Sleep apnoea syndrome	1 (3.0)	0	1 (3.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (51.5)	9 (27.3)	6 (18.2)	2 (6.1)	0
Dry skin	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Erythema	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Pruritus	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Rash	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Rash maculo-papular	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Blister	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Dermatitis atopic	2 (6.1)	2 (6.1)	0	0	0
Rash papular	2 (6.1)	2 (6.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decubitus ulcer	1 (3.0)	0	1 (3.0)	0	0
Dermatitis	1 (3.0)	1 (3.0)	0	0	0
Dermatitis allergic	1 (3.0)	1 (3.0)	0	0	0
Eczema	1 (3.0)	1 (3.0)	0	0	0
Miliaria	1 (3.0)	1 (3.0)	0	0	0
Night sweats	1 (3.0)	1 (3.0)	0	0	0
Petechiae	1 (3.0)	0	0	1 (3.0)	0
Photosensitivity reaction	1 (3.0)	0	1 (3.0)	0	0
Pruritus allergic	1 (3.0)	0	1 (3.0)	0	0
Purpura	1 (3.0)	1 (3.0)	0	0	0
Rash pruritic	1 (3.0)	1 (3.0)	0	0	0
Rash vesicular	1 (3.0)	1 (3.0)	0	0	0
Scab	1 (3.0)	1 (3.0)	0	0	0
Skin discolouration	1 (3.0)	1 (3.0)	0	0	0
Skin necrosis	1 (3.0)	0	0	1 (3.0)	0
Skin ulcer	1 (3.0)	1 (3.0)	0	0	0
Urticaria	1 (3.0)	0	1 (3.0)	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (42.4)	2 (6.1)	4 (12.1)	5 (15.2)	3 (9.1)
Hypotension	10 (30.3)	1 (3.0)	3 (9.1)	3 (9.1)	3 (9.1)
Hypertension	6 (18.2)	2 (6.1)	1 (3.0)	3 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	1 (3.0)	1 (3.0)	8 (24.2)	23 (69.7)
Blood and lymphatic system disorders					
-Total	23 (69.7)	0	4 (12.1)	10 (30.3)	9 (27.3)
Febrile neutropenia	12 (36.4)	0	0	10 (30.3)	2 (6.1)
Anaemia	6 (18.2)	3 (9.1)	3 (9.1)	0	0
Neutropenia	5 (15.2)	0	0	0	5 (15.2)
Disseminated intravascular coagulation	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Splenomegaly	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Thrombocytopenia	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Coagulopathy	2 (6.1)	0	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (6.1)	0	1 (3.0)	0	1 (3.0)
Lymphocytosis	1 (3.0)	0	1 (3.0)	0	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Cardiac disorders					
-Total	12 (36.4)	3 (9.1)	4 (12.1)	2 (6.1)	3 (9.1)
Tachycardia	6 (18.2)	2 (6.1)	3 (9.1)	1 (3.0)	0
Bradycardia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Cardiac arrest	2 (6.1)	0	0	0	2 (6.1)
Cardiac failure	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Left ventricular dysfunction	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Atrioventricular block first degree	1 (3.0)	0	1 (3.0)	0	0
Pericardial effusion	1 (3.0)	1 (3.0)	0	0	0
Sinus bradycardia	1 (3.0)	0	0	1 (3.0)	0
Sinus tachycardia	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Ear pruritus	1 (3.0)	1 (3.0)	0	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.1)	0	3 (9.1)	0	0
Hypothyroidism	2 (6.1)	0	2 (6.1)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Delayed puberty	1 (3.0)	0	1 (3.0)	0	0
Eye disorders					
-Total	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Conjunctival haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Dry eye	1 (3.0)	1 (3.0)	0	0	0
Eye oedema	1 (3.0)	1 (3.0)	0	0	0
Periorbital oedema	1 (3.0)	1 (3.0)	0	0	0
Retinal haemorrhage	1 (3.0)	0	1 (3.0)	0	0
Visual field defect	1 (3.0)	0	1 (3.0)	0	0
Visual impairment	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	20 (60.6)	5 (15.2)	10 (30.3)	5 (15.2)	0
Diarrhoea	9 (27.3)	6 (18.2)	3 (9.1)	0	0
Nausea	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Vomiting	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Abdominal pain	3 (9.1)	0	3 (9.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Pancreatitis	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Abdominal pain upper	1 (3.0)	1 (3.0)	0	0	0
Abdominal rigidity	1 (3.0)	0	1 (3.0)	0	0
Dysphagia	1 (3.0)	0	0	1 (3.0)	0
Enterocolitis	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal inflammation	1 (3.0)	0	1 (3.0)	0	0
Gastrooesophageal reflux disease	1 (3.0)	0	1 (3.0)	0	0
Gingival erythema	1 (3.0)	1 (3.0)	0	0	0
Irritable bowel syndrome	1 (3.0)	0	1 (3.0)	0	0
Mouth haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Mouth swelling	1 (3.0)	1 (3.0)	0	0	0
Odynophagia	1 (3.0)	1 (3.0)	0	0	0
Peritoneal haematoma	1 (3.0)	1 (3.0)	0	0	0
Proctalgia	1 (3.0)	0	0	1 (3.0)	0
Trichoglossia	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (66.7)	10 (30.3)	5 (15.2)	6 (18.2)	1 (3.0)
Pyrexia	15 (45.5)	6 (18.2)	3 (9.1)	5 (15.2)	1 (3.0)
Fatigue	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Oedema peripheral	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Face oedema	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Chills	2 (6.1)	2 (6.1)	0	0	0
Generalised oedema	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Localised oedema	2 (6.1)	2 (6.1)	0	0	0
Asthenia	1 (3.0)	1 (3.0)	0	0	0
Catheter site haemorrhage	1 (3.0)	1 (3.0)	0	0	0
Catheter site pain	1 (3.0)	1 (3.0)	0	0	0
Drug withdrawal syndrome	1 (3.0)	0	1 (3.0)	0	0
Malaise	1 (3.0)	1 (3.0)	0	0	0
Oedema due to hepatic disease	1 (3.0)	0	1 (3.0)	0	0
Pain	1 (3.0)	0	1 (3.0)	0	0
Xerosis	1 (3.0)	1 (3.0)	0	0	0
Hepatobiliary disorders					
-Total	7 (21.2)	2 (6.1)	2 (6.1)	1 (3.0)	2 (6.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Hepatomegaly	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Hyperbilirubinaemia	2 (6.1)	0	2 (6.1)	0	0
Hepatic cytolysis	1 (3.0)	1 (3.0)	0	0	0
Hypertransaminasaemia	1 (3.0)	0	1 (3.0)	0	0
Immune system disorders					
-Total	29 (87.9)	0	8 (24.2)	12 (36.4)	9 (27.3)
Cytokine release syndrome	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Hypogammaglobulinaemia	15 (45.5)	0	10 (30.3)	5 (15.2)	0
Seasonal allergy	4 (12.1)	2 (6.1)	2 (6.1)	0	0
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Drug hypersensitivity	1 (3.0)	0	0	1 (3.0)	0
Engraftment syndrome	1 (3.0)	0	0	1 (3.0)	0
Graft versus host disease	1 (3.0)	0	0	1 (3.0)	0
Hypersensitivity	1 (3.0)	1 (3.0)	0	0	0
Immunodeficiency	1 (3.0)	0	0	1 (3.0)	0
Selective igg subclass deficiency	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	22 (66.7)	2 (6.1)	3 (9.1)	12 (36.4)	5 (15.2)
Upper respiratory tract infection	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Rhinovirus infection	4 (12.1)	0	4 (12.1)	0	0
Sinusitis	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Bacteraemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Conjunctivitis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Covid-19	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Ear infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Gastroenteritis	2 (6.1)	2 (6.1)	0	0	0
Gastroenteritis viral	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Herpes zoster	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Nail infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Nasopharyngitis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Otitis externa	2 (6.1)	0	2 (6.1)	0	0
Otitis media	2 (6.1)	0	2 (6.1)	0	0
Paronychia	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	2 (6.1)	0	2 (6.1)	0	0
Rhinitis	2 (6.1)	2 (6.1)	0	0	0
Sepsis	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Septic shock	2 (6.1)	0	0	0	2 (6.1)
Skin infection	2 (6.1)	0	2 (6.1)	0	0
Staphylococcal bacteraemia	2 (6.1)	0	0	2 (6.1)	0
Adenovirus infection	1 (3.0)	0	0	1 (3.0)	0
Anal abscess	1 (3.0)	0	0	1 (3.0)	0
Bk virus infection	1 (3.0)	0	0	1 (3.0)	0
Bronchiolitis	1 (3.0)	0	0	1 (3.0)	0
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Bronchopulmonary aspergillosis	1 (3.0)	0	0	1 (3.0)	0
Cholecystitis infective	1 (3.0)	0	1 (3.0)	0	0
Clostridium difficile colitis	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Coronavirus infection	1 (3.0)	0	0	1 (3.0)	0
Device related sepsis	1 (3.0)	0	0	1 (3.0)	0
Encephalitis	1 (3.0)	0	0	0	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (3.0)	0	0	0	1 (3.0)
Folliculitis	1 (3.0)	0	1 (3.0)	0	0
Fungal infection	1 (3.0)	0	1 (3.0)	0	0
Gastroenteritis clostridial	1 (3.0)	0	1 (3.0)	0	0
Gastroenteritis escherichia coli	1 (3.0)	0	0	1 (3.0)	0
Gastroenteritis norovirus	1 (3.0)	1 (3.0)	0	0	0
Gastroenteritis salmonella	1 (3.0)	0	0	1 (3.0)	0
Gastrointestinal infection	1 (3.0)	1 (3.0)	0	0	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Herpes simplex	1 (3.0)	0	1 (3.0)	0	0
Influenza	1 (3.0)	0	1 (3.0)	0	0
Meningitis bacterial	1 (3.0)	0	0	1 (3.0)	0
Meningitis pneumococcal	1 (3.0)	0	0	1 (3.0)	0
Metapneumovirus infection	1 (3.0)	0	0	1 (3.0)	0
Molluscum contagiosum	1 (3.0)	1 (3.0)	0	0	0
Oral candidiasis	1 (3.0)	0	1 (3.0)	0	0
Oral herpes	1 (3.0)	1 (3.0)	0	0	0
Parainfluenzae virus infection	1 (3.0)	1 (3.0)	0	0	0
Pneumonia fungal	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (3.0)	0	0	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	0	0	1 (3.0)	0
Sinusitis fungal	1 (3.0)	0	0	1 (3.0)	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)	0	0
Syphilis	1 (3.0)	0	1 (3.0)	0	0
Tinea pedis	1 (3.0)	1 (3.0)	0	0	0
Urinary tract infection	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection pseudomonal	1 (3.0)	0	1 (3.0)	0	0
Viral haemorrhagic cystitis	1 (3.0)	0	0	1 (3.0)	0
Injury, poisoning and procedural complications					
-Total	9 (27.3)	3 (9.1)	5 (15.2)	1 (3.0)	0
Infusion related reaction	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Procedural pain	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Contusion	1 (3.0)	1 (3.0)	0	0	0
Fibula fracture	1 (3.0)	0	1 (3.0)	0	0
Ligament sprain	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (3.0)	0	1 (3.0)	0	0
Skin abrasion	1 (3.0)	1 (3.0)	0	0	0
Wound	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	24 (72.7)	0	5 (15.2)	8 (24.2)	11 (33.3)
Alanine aminotransferase increased	7 (21.2)	2 (6.1)	1 (3.0)	4 (12.1)	0
Aspartate aminotransferase increased	7 (21.2)	0	3 (9.1)	3 (9.1)	1 (3.0)
Platelet count decreased	7 (21.2)	1 (3.0)	2 (6.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	7 (21.2)	1 (3.0)	2 (6.1)	0	4 (12.1)
Blood bilirubin increased	6 (18.2)	1 (3.0)	1 (3.0)	4 (12.1)	0
Lymphocyte count decreased	6 (18.2)	0	1 (3.0)	3 (9.1)	2 (6.1)
Neutrophil count decreased	6 (18.2)	0	1 (3.0)	1 (3.0)	4 (12.1)
Serum ferritin increased	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Blood creatinine increased	4 (12.1)	1 (3.0)	1 (3.0)	1 (3.0)	1 (3.0)
Blood fibrinogen decreased	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Electrocardiogram qt prolonged	4 (12.1)	1 (3.0)	1 (3.0)	1 (3.0)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (9.1)	2 (6.1)	0	1 (3.0)	0
C-reactive protein increased	3 (9.1)	1 (3.0)	0	2 (6.1)	0
International normalised ratio increased	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Blood lactate dehydrogenase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Weight decreased	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Weight increased	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Amylase increased	1 (3.0)	1 (3.0)	0	0	0
Bacterial test positive	1 (3.0)	0	0	1 (3.0)	0
Blood alkaline phosphatase increased	1 (3.0)	1 (3.0)	0	0	0
Blood bicarbonate decreased	1 (3.0)	0	1 (3.0)	0	0
Blood creatine phosphokinase increased	1 (3.0)	0	0	1 (3.0)	0
Blood immunoglobulin a decreased	1 (3.0)	0	0	1 (3.0)	0
Blood immunoglobulin g decreased	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (3.0)	0	0	1 (3.0)	0
Blood phosphorus increased	1 (3.0)	0	1 (3.0)	0	0
Blood testosterone decreased	1 (3.0)	1 (3.0)	0	0	0
Blood thyroid stimulating hormone increased	1 (3.0)	1 (3.0)	0	0	0
Blood urea increased	1 (3.0)	0	0	1 (3.0)	0
Blood uric acid increased	1 (3.0)	0	0	0	1 (3.0)
Bone density decreased	1 (3.0)	1 (3.0)	0	0	0
Cardiac murmur	1 (3.0)	1 (3.0)	0	0	0
Coagulation test abnormal	1 (3.0)	1 (3.0)	0	0	0
Ejection fraction decreased	1 (3.0)	0	1 (3.0)	0	0
Electrocardiogram t wave abnormal	1 (3.0)	0	1 (3.0)	0	0
Enterovirus test positive	1 (3.0)	0	1 (3.0)	0	0
Fibrin d dimer increased	1 (3.0)	0	0	1 (3.0)	0
Haemoglobin decreased	1 (3.0)	0	0	1 (3.0)	0
Haptoglobin decreased	1 (3.0)	1 (3.0)	0	0	0
Immunoglobulins decreased	1 (3.0)	0	1 (3.0)	0	0
Lipase increased	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oxygen saturation decreased	1 (3.0)	0	1 (3.0)	0	0
Prothrombin time prolonged	1 (3.0)	0	1 (3.0)	0	0
Troponin increased	1 (3.0)	0	0	1 (3.0)	0
Urine output decreased	1 (3.0)	0	0	0	1 (3.0)
Metabolism and nutrition disorders					
-Total	23 (69.7)	3 (9.1)	5 (15.2)	10 (30.3)	5 (15.2)
Decreased appetite	14 (42.4)	4 (12.1)	5 (15.2)	4 (12.1)	1 (3.0)
Hypokalaemia	7 (21.2)	0	2 (6.1)	5 (15.2)	0
Hyperuricaemia	6 (18.2)	5 (15.2)	0	1 (3.0)	0
Hypocalcaemia	6 (18.2)	1 (3.0)	4 (12.1)	1 (3.0)	0
Hypophosphataemia	6 (18.2)	1 (3.0)	2 (6.1)	3 (9.1)	0
Hypoalbuminaemia	5 (15.2)	0	5 (15.2)	0	0
Tumour lysis syndrome	4 (12.1)	0	0	3 (9.1)	1 (3.0)
Hyperphosphataemia	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Hypervolaemia	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Hypomagnesaemia	3 (9.1)	3 (9.1)	0	0	0
Hypercalcaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hyperchloraemia	2 (6.1)	2 (6.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hyponatraemia	2 (6.1)	2 (6.1)	0	0	0
Metabolic acidosis	2 (6.1)	0	0	0	2 (6.1)
Acidosis	1 (3.0)	0	0	1 (3.0)	0
Calcium deficiency	1 (3.0)	1 (3.0)	0	0	0
Haemochromatosis	1 (3.0)	0	0	1 (3.0)	0
Hyperkalaemia	1 (3.0)	0	0	0	1 (3.0)
Hyperlipidaemia	1 (3.0)	0	1 (3.0)	0	0
Hypermagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hypernatraemia	1 (3.0)	0	0	1 (3.0)	0
Hypertriglyceridaemia	1 (3.0)	0	0	0	1 (3.0)
Metabolic syndrome	1 (3.0)	0	1 (3.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (54.5)	8 (24.2)	7 (21.2)	3 (9.1)	0
Arthralgia	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Myalgia	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Back pain	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Pain in extremity	4 (12.1)	2 (6.1)	2 (6.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	1 (3.0)	0	1 (3.0)	0	0
Growth retardation	1 (3.0)	0	1 (3.0)	0	0
Haemarthrosis	1 (3.0)	0	0	1 (3.0)	0
Muscle rigidity	1 (3.0)	1 (3.0)	0	0	0
Muscular weakness	1 (3.0)	0	0	1 (3.0)	0
Musculoskeletal pain	1 (3.0)	0	1 (3.0)	0	0
Osteonecrosis	1 (3.0)	1 (3.0)	0	0	0
Osteopenia	1 (3.0)	1 (3.0)	0	0	0
Pain in jaw	1 (3.0)	1 (3.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Skin papilloma	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Cancer pain	1 (3.0)	0	1 (3.0)	0	0
Nervous system disorders					
-Total	22 (66.7)	7 (21.2)	10 (30.3)	4 (12.1)	1 (3.0)
Headache	15 (45.5)	6 (18.2)	8 (24.2)	1 (3.0)	0
Encephalopathy	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Cognitive disorder	2 (6.1)	0	2 (6.1)	0	0
Dizziness	2 (6.1)	2 (6.1)	0	0	0
Dysarthria	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Somnolence	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Tremor	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Autonomic neuropathy	1 (3.0)	0	0	1 (3.0)	0
Cerebral haemorrhage	1 (3.0)	0	0	0	1 (3.0)
Generalised tonic-clonic seizure	1 (3.0)	0	1 (3.0)	0	0
Hypoaesthesia	1 (3.0)	1 (3.0)	0	0	0
Memory impairment	1 (3.0)	0	1 (3.0)	0	0
Nervous system disorder	1 (3.0)	0	0	1 (3.0)	0
Psychiatric disorders					
-Total	16 (48.5)	4 (12.1)	8 (24.2)	4 (12.1)	0
Anxiety	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Confusional state	3 (9.1)	3 (9.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Mental status changes	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (6.1)	0	2 (6.1)	0	0
Sleep disorder	2 (6.1)	0	2 (6.1)	0	0
Automatism	1 (3.0)	1 (3.0)	0	0	0
Insomnia	1 (3.0)	0	1 (3.0)	0	0
Persistent depressive disorder	1 (3.0)	0	1 (3.0)	0	0
Tic	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	11 (33.3)	2 (6.1)	2 (6.1)	4 (12.1)	3 (9.1)
Acute kidney injury	7 (21.2)	1 (3.0)	1 (3.0)	2 (6.1)	3 (9.1)
Dysuria	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Anuria	1 (3.0)	1 (3.0)	0	0	0
Azotaemia	1 (3.0)	0	1 (3.0)	0	0
Haematuria	1 (3.0)	0	0	1 (3.0)	0
Kidney enlargement	1 (3.0)	0	1 (3.0)	0	0
Micturition urgency	1 (3.0)	0	1 (3.0)	0	0
Pollakiuria	1 (3.0)	0	1 (3.0)	0	0
Renal mass	1 (3.0)	0	1 (3.0)	0	0
Renal tubular disorder	1 (3.0)	0	0	1 (3.0)	0
Urinary tract disorder	1 (3.0)	0	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Dysmenorrhoea	1 (3.0)	0	1 (3.0)	0	0
Perineal rash	1 (3.0)	0	1 (3.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	21 (63.6)	6 (18.2)	2 (6.1)	4 (12.1)	9 (27.3)
Cough	11 (33.3)	7 (21.2)	4 (12.1)	0	0
Hypoxia	9 (27.3)	0	2 (6.1)	3 (9.1)	4 (12.1)
Oropharyngeal pain	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Pleural effusion	5 (15.2)	3 (9.1)	0	1 (3.0)	1 (3.0)
Nasal congestion	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Pulmonary oedema	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Epistaxis	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Respiratory failure	3 (9.1)	0	0	0	3 (9.1)
Tachypnoea	3 (9.1)	1 (3.0)	0	2 (6.1)	0
Acute respiratory distress syndrome	2 (6.1)	0	0	0	2 (6.1)
Dyspnoea	2 (6.1)	0	2 (6.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	2 (6.1)	0	1 (3.0)	0	1 (3.0)
Rhinorrhoea	2 (6.1)	0	2 (6.1)	0	0
Wheezing	2 (6.1)	0	2 (6.1)	0	0
Acute respiratory failure	1 (3.0)	0	0	1 (3.0)	0
Atelectasis	1 (3.0)	0	0	1 (3.0)	0
Bradypnoea	1 (3.0)	0	0	1 (3.0)	0
Haemoptysis	1 (3.0)	0	1 (3.0)	0	0
Lung disorder	1 (3.0)	1 (3.0)	0	0	0
Nasal discomfort	1 (3.0)	0	1 (3.0)	0	0
Painful respiration	1 (3.0)	1 (3.0)	0	0	0
Paranasal sinus inflammation	1 (3.0)	1 (3.0)	0	0	0
Pharyngeal haemorrhage	1 (3.0)	0	1 (3.0)	0	0
Respiratory disorder	1 (3.0)	0	1 (3.0)	0	0
Sleep apnoea syndrome	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (42.4)	4 (12.1)	6 (18.2)	4 (12.1)	0
Rash	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Dry skin	4 (12.1)	3 (9.1)	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Ingrowing nail	2 (6.1)	0	2 (6.1)	0	0
Blister	1 (3.0)	1 (3.0)	0	0	0
Dermatitis atopic	1 (3.0)	0	0	1 (3.0)	0
Dermatitis diaper	1 (3.0)	0	1 (3.0)	0	0
Erythema	1 (3.0)	1 (3.0)	0	0	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0	0	0
Papule	1 (3.0)	1 (3.0)	0	0	0
Petechiae	1 (3.0)	0	1 (3.0)	0	0
Pruritus	1 (3.0)	0	1 (3.0)	0	0
Rash erythematous	1 (3.0)	1 (3.0)	0	0	0
Rash macular	1 (3.0)	0	0	1 (3.0)	0
Skin discolouration	1 (3.0)	1 (3.0)	0	0	0
Skin hypopigmentation	1 (3.0)	1 (3.0)	0	0	0
Skin swelling	1 (3.0)	1 (3.0)	0	0	0
Skin ulcer	1 (3.0)	0	1 (3.0)	0	0
Vancomycin infusion reaction	1 (3.0)	0	0	1 (3.0)	0
Vascular disorders					
-Total	13 (39.4)	2 (6.1)	2 (6.1)	5 (15.2)	4 (12.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

Primary system organ class Preferred term	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
			All patients N=33		
Hypotension	10 (30.3)	1 (3.0)	2 (6.1)	3 (9.1)	4 (12.1)
Hypertension	5 (15.2)	1 (3.0)	3 (9.1)	1 (3.0)	0
Capillary leak syndrome	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Thrombosis	1 (3.0)	0	1 (3.0)	0	0
Venoocclusive disease	1 (3.0)	0	0	1 (3.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	1 (7.1)	4 (28.6)	9 (64.3)
Blood and lymphatic system disorders					
-Total	9 (64.3)	0	2 (14.3)	6 (42.9)	1 (7.1)
Anaemia	5 (35.7)	1 (7.1)	2 (14.3)	2 (14.3)	0
Neutropenia	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Coagulopathy	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
B-cell aplasia	1 (7.1)	0	1 (7.1)	0	0
Hypofibrinogenaemia	1 (7.1)	0	1 (7.1)	0	0
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	5 (35.7)	3 (21.4)	1 (7.1)	0	1 (7.1)
Sinus tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Cardiac dysfunction	1 (7.1)	1 (7.1)	0	0	0
Cardiac failure	1 (7.1)	0	0	0	1 (7.1)
Congenital, familial and genetic disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Cerebral cavernous malformation	1 (7.1)	1 (7.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Deafness unilateral	1 (7.1)	0	1 (7.1)	0	0
Endocrine disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Adrenal insufficiency	2 (14.3)	0	2 (14.3)	0	0
Eye disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cataract	1 (7.1)	1 (7.1)	0	0	0
Periorbital swelling	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	13 (92.9)	7 (50.0)	4 (28.6)	2 (14.3)	0
Vomiting	5 (35.7)	3 (21.4)	2 (14.3)	0	0
Constipation	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Nausea	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Diarrhoea	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Abdominal pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Mouth haemorrhage	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Stomatitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Abdominal pain upper	1 (7.1)	1 (7.1)	0	0	0
Dry mouth	1 (7.1)	0	1 (7.1)	0	0
Enteritis	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal haemorrhage	1 (7.1)	0	1 (7.1)	0	0
Gingival bleeding	1 (7.1)	0	1 (7.1)	0	0
Gingivitis ulcerative	1 (7.1)	0	0	1 (7.1)	0
Ileus	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip dry	1 (7.1)	0	1 (7.1)	0	0
Pancreatitis	1 (7.1)	1 (7.1)	0	0	0
Trichoglossia	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	11 (78.6)	5 (35.7)	3 (21.4)	2 (14.3)	1 (7.1)
Pyrexia	7 (50.0)	2 (14.3)	3 (21.4)	2 (14.3)	0
Chills	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Non-cardiac chest pain	2 (14.3)	2 (14.3)	0	0	0
Oedema peripheral	2 (14.3)	2 (14.3)	0	0	0
Pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Asthenia	1 (7.1)	1 (7.1)	0	0	0
Catheter site pain	1 (7.1)	0	0	1 (7.1)	0
Crying	1 (7.1)	0	1 (7.1)	0	0
Drug withdrawal syndrome	1 (7.1)	0	1 (7.1)	0	0
Face oedema	1 (7.1)	1 (7.1)	0	0	0
Facial pain	1 (7.1)	0	1 (7.1)	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza like illness	1 (7.1)	1 (7.1)	0	0	0
Malaise	1 (7.1)	0	1 (7.1)	0	0
Multiple organ dysfunction syndrome	1 (7.1)	0	0	0	1 (7.1)
Sluggishness	1 (7.1)	0	1 (7.1)	0	0
Swelling face	1 (7.1)	1 (7.1)	0	0	0
Vascular device occlusion	1 (7.1)	1 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Hepatic function abnormal	2 (14.3)	0	2 (14.3)	0	0
Biliary tract disorder	1 (7.1)	1 (7.1)	0	0	0
Gallbladder enlargement	1 (7.1)	1 (7.1)	0	0	0
Hyperbilirubinaemia	1 (7.1)	0	0	1 (7.1)	0
Hypertransaminasaemia	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	13 (92.9)	0	4 (28.6)	5 (35.7)	4 (28.6)
Cytokine release syndrome	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Hypogammaglobulinaemia	5 (35.7)	1 (7.1)	4 (28.6)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	1 (7.1)	0	0	1 (7.1)	0
Haemophagocytic lymphohistiocytosis	1 (7.1)	0	0	1 (7.1)	0
Immunodeficiency	1 (7.1)	0	0	1 (7.1)	0
Infections and infestations					
-Total	13 (92.9)	2 (14.3)	3 (21.4)	6 (42.9)	2 (14.3)
Sinusitis	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Acute sinusitis	2 (14.3)	0	2 (14.3)	0	0
Candida infection	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Parainfluenzae virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Staphylococcal infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Urinary tract infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Varicella zoster virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atypical pneumonia	1 (7.1)	1 (7.1)	0	0	0
Bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Conjunctivitis	1 (7.1)	0	1 (7.1)	0	0
Ear, nose and throat infection	1 (7.1)	0	1 (7.1)	0	0
Encephalitis viral	1 (7.1)	0	0	1 (7.1)	0
Fungal skin infection	1 (7.1)	0	1 (7.1)	0	0
Gastroenteritis	1 (7.1)	0	0	1 (7.1)	0
Granulicatella infection	1 (7.1)	0	0	1 (7.1)	0
Herpes simplex	1 (7.1)	0	0	1 (7.1)	0
Human herpesvirus 6 infection	1 (7.1)	0	0	1 (7.1)	0
Influenza	1 (7.1)	0	1 (7.1)	0	0
Klebsiella bacteraemia	1 (7.1)	0	1 (7.1)	0	0
Myringitis	1 (7.1)	1 (7.1)	0	0	0
Nail infection	1 (7.1)	1 (7.1)	0	0	0
Oral candidiasis	1 (7.1)	0	1 (7.1)	0	0
Oral herpes	1 (7.1)	0	1 (7.1)	0	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (7.1)	0	0	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Staphylococcal abscess	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Stomatococcal infection	1 (7.1)	0	1 (7.1)	0	0
Systemic candida	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection viral	1 (7.1)	1 (7.1)	0	0	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Fall	1 (7.1)	0	1 (7.1)	0	0
Post-traumatic neck syndrome	1 (7.1)	0	1 (7.1)	0	0
Transplant failure	1 (7.1)	0	0	0	1 (7.1)
Investigations					
-Total	9 (64.3)	1 (7.1)	2 (14.3)	3 (21.4)	3 (21.4)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Platelet count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
International normalised ratio increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Neutrophil count decreased	2 (14.3)	1 (7.1)	0	0	1 (7.1)
Blood glucose increased	1 (7.1)	0	0	0	1 (7.1)
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Breath sounds abnormal	1 (7.1)	0	1 (7.1)	0	0
Heart sounds abnormal	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Staphylococcus test positive	1 (7.1)	1 (7.1)	0	0	0
White blood cell count decreased	1 (7.1)	0	0	0	1 (7.1)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	8 (57.1)	1 (7.1)	1 (7.1)	5 (35.7)	1 (7.1)
Hypokalaemia	6 (42.9)	1 (7.1)	3 (21.4)	2 (14.3)	0
Decreased appetite	5 (35.7)	3 (21.4)	0	2 (14.3)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)	0	0
Hypervolaemia	3 (21.4)	0	0	3 (21.4)	0
Hypocalcaemia	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Hypoalbuminaemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	0	0	2 (14.3)	0
Acidosis	1 (7.1)	0	0	0	1 (7.1)
Hypercholesterolaemia	1 (7.1)	0	1 (7.1)	0	0
Hypertriglyceridaemia	1 (7.1)	0	1 (7.1)	0	0
Hyperuricaemia	1 (7.1)	1 (7.1)	0	0	0
Hypoglycaemia	1 (7.1)	0	1 (7.1)	0	0
Iron overload	1 (7.1)	0	1 (7.1)	0	0
Malnutrition	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Polydipsia	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (50.0)	2 (14.3)	4 (28.6)	1 (7.1)	0
Arthralgia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Myalgia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Neck pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Back pain	1 (7.1)	0	1 (7.1)	0	0
Bone pain	1 (7.1)	0	1 (7.1)	0	0
Joint effusion	1 (7.1)	0	1 (7.1)	0	0
Muscle spasms	1 (7.1)	0	1 (7.1)	0	0
Musculoskeletal chest pain	1 (7.1)	1 (7.1)	0	0	0
Pain in extremity	1 (7.1)	1 (7.1)	0	0	0
Pain in jaw	1 (7.1)	0	0	1 (7.1)	0
Synovitis	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	7 (50.0)	1 (7.1)	4 (28.6)	1 (7.1)	1 (7.1)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Somnolence	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Tremor	2 (14.3)	2 (14.3)	0	0	0
Amnesia	1 (7.1)	0	1 (7.1)	0	0
Aphasia	1 (7.1)	1 (7.1)	0	0	0
Cognitive disorder	1 (7.1)	0	0	1 (7.1)	0
Disturbance in attention	1 (7.1)	1 (7.1)	0	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Dysgeusia	1 (7.1)	1 (7.1)	0	0	0
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Extrapyramidal disorder	1 (7.1)	0	1 (7.1)	0	0
Hyperaesthesia	1 (7.1)	1 (7.1)	0	0	0
Lethargy	1 (7.1)	0	1 (7.1)	0	0
Migraine	1 (7.1)	0	1 (7.1)	0	0
Neurological decompensation	1 (7.1)	0	0	0	1 (7.1)
Paraesthesia	1 (7.1)	1 (7.1)	0	0	0
Psychiatric disorders					
-Total	7 (50.0)	1 (7.1)	4 (28.6)	2 (14.3)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Agitation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Delirium	2 (14.3)	0	0	2 (14.3)	0
Affect lability	1 (7.1)	0	1 (7.1)	0	0
Hallucination	1 (7.1)	1 (7.1)	0	0	0
Hallucination, visual	1 (7.1)	0	1 (7.1)	0	0
Irritability	1 (7.1)	1 (7.1)	0	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Social avoidant behaviour	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	5 (35.7)	0	3 (21.4)	1 (7.1)	1 (7.1)
Acute kidney injury	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Cystitis haemorrhagic	1 (7.1)	0	1 (7.1)	0	0
Pollakiuria	1 (7.1)	0	1 (7.1)	0	0
Renal failure	1 (7.1)	0	0	0	1 (7.1)
Urinary incontinence	1 (7.1)	0	1 (7.1)	0	0
Urinary retention	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	0
Endometriosis	1 (7.1)	0	0	1 (7.1)	0
Female genital tract fistula	1 (7.1)	1 (7.1)	0	0	0
Heavy menstrual bleeding	1 (7.1)	1 (7.1)	0	0	0
Vaginal haemorrhage	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (78.6)	3 (21.4)	2 (14.3)	3 (21.4)	3 (21.4)
Pulmonary oedema	4 (28.6)	1 (7.1)	0	2 (14.3)	1 (7.1)
Hypoxia	3 (21.4)	0	0	3 (21.4)	0
Dyspnoea	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Oropharyngeal pain	2 (14.3)	2 (14.3)	0	0	0
Respiratory failure	2 (14.3)	0	0	0	2 (14.3)
Atelectasis	1 (7.1)	0	1 (7.1)	0	0
Bronchial oedema	1 (7.1)	1 (7.1)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (7.1)	0	0	0	1 (7.1)
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Nasal dryness	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal plaque	1 (7.1)	0	1 (7.1)	0	0
Paranasal sinus discomfort	1 (7.1)	0	1 (7.1)	0	0
Pharyngeal erythema	1 (7.1)	0	1 (7.1)	0	0
Pharyngeal exudate	1 (7.1)	0	1 (7.1)	0	0
Pharyngeal oedema	1 (7.1)	0	1 (7.1)	0	0
Pleural effusion	1 (7.1)	0	1 (7.1)	0	0
Pulmonary mass	1 (7.1)	0	1 (7.1)	0	0
Respiratory distress	1 (7.1)	0	0	0	1 (7.1)
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0
Tachypnoea	1 (7.1)	0	1 (7.1)	0	0
Upper respiratory tract inflammation	1 (7.1)	0	1 (7.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (64.3)	4 (28.6)	4 (28.6)	1 (7.1)	0
Pruritus	3 (21.4)	1 (7.1)	2 (14.3)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperhidrosis	2 (14.3)	0	2 (14.3)	0	0
Decubitus ulcer	1 (7.1)	0	0	1 (7.1)	0
Dry skin	1 (7.1)	1 (7.1)	0	0	0
Erythema	1 (7.1)	1 (7.1)	0	0	0
Erythema nodosum	1 (7.1)	1 (7.1)	0	0	0
Hangnail	1 (7.1)	1 (7.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (7.1)	1 (7.1)	0	0	0
Rash papular	1 (7.1)	0	1 (7.1)	0	0
Skin lesion	1 (7.1)	0	1 (7.1)	0	0
Social circumstances					
-Total	1 (7.1)	0	1 (7.1)	0	0
Patient uncooperative	1 (7.1)	0	1 (7.1)	0	0
Surgical and medical procedures					
-Total	1 (7.1)	0	0	1 (7.1)	0
Thrombolysis	1 (7.1)	0	0	1 (7.1)	0
Vascular disorders					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	2 (14.3)	2 (14.3)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	5 (35.7)	1 (7.1)	3 (21.4)	1 (7.1)	0
Hypotension	4 (28.6)	0	1 (7.1)	2 (14.3)	1 (7.1)
Flushing	1 (7.1)	1 (7.1)	0	0	0
Hot flush	1 (7.1)	1 (7.1)	0	0	0
Peripheral ischaemia	1 (7.1)	0	1 (7.1)	0	0
Venoocclusive disease	1 (7.1)	0	0	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (97.8)	3 (6.5)	7 (15.2)	11 (23.9)	24 (52.2)
Blood and lymphatic system disorders					
-Total	25 (54.3)	1 (2.2)	7 (15.2)	10 (21.7)	7 (15.2)
Febrile neutropenia	11 (23.9)	0	0	11 (23.9)	0
Anaemia	7 (15.2)	1 (2.2)	3 (6.5)	3 (6.5)	0
Disseminated intravascular coagulation	5 (10.9)	0	5 (10.9)	0	0
Thrombocytopenia	5 (10.9)	0	0	0	5 (10.9)
Neutropenia	4 (8.7)	0	1 (2.2)	0	3 (6.5)
Coagulopathy	2 (4.3)	0	2 (4.3)	0	0
Leukopenia	2 (4.3)	0	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Eosinophilia	1 (2.2)	0	1 (2.2)	0	0
Lymphopenia	1 (2.2)	0	0	1 (2.2)	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Cardiac disorders					
-Total	11 (23.9)	4 (8.7)	3 (6.5)	4 (8.7)	0
Tachycardia	9 (19.6)	3 (6.5)	4 (8.7)	2 (4.3)	0
Bradycardia	2 (4.3)	2 (4.3)	0	0	0
Left ventricular dysfunction	2 (4.3)	0	0	2 (4.3)	0
Atrioventricular block first degree	1 (2.2)	0	1 (2.2)	0	0
Cardiac dysfunction	1 (2.2)	1 (2.2)	0	0	0
Cardiac failure congestive	1 (2.2)	0	1 (2.2)	0	0
Mitral valve incompetence	1 (2.2)	1 (2.2)	0	0	0
Pericardial effusion	1 (2.2)	1 (2.2)	0	0	0
Right ventricular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear pain	1 (2.2)	1 (2.2)	0	0	0
Endocrine disorders					
-Total	2 (4.3)	0	2 (4.3)	0	0
Adrenal insufficiency	1 (2.2)	0	1 (2.2)	0	0
Hypothyroidism	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Ocular hyperaemia	2 (4.3)	2 (4.3)	0	0	0
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Eye oedema	1 (2.2)	1 (2.2)	0	0	0
Eye pain	1 (2.2)	1 (2.2)	0	0	0
Eyelid oedema	1 (2.2)	0	1 (2.2)	0	0
Visual impairment	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal disorders					
-Total	28 (60.9)	10 (21.7)	10 (21.7)	7 (15.2)	1 (2.2)
Nausea	12 (26.1)	7 (15.2)	4 (8.7)	1 (2.2)	0
Vomiting	12 (26.1)	9 (19.6)	3 (6.5)	0	0
Diarrhoea	7 (15.2)	4 (8.7)	2 (4.3)	1 (2.2)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	6 (13.0)	0	4 (8.7)	2 (4.3)	0
Constipation	5 (10.9)	2 (4.3)	3 (6.5)	0	0
Pancreatitis	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Abdominal pain upper	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Gastrointestinal sounds abnormal	2 (4.3)	2 (4.3)	0	0	0
Abdominal compartment syndrome	1 (2.2)	0	0	0	1 (2.2)
Abdominal distension	1 (2.2)	0	1 (2.2)	0	0
Anal fissure	1 (2.2)	0	1 (2.2)	0	0
Ascites	1 (2.2)	1 (2.2)	0	0	0
Dry mouth	1 (2.2)	0	1 (2.2)	0	0
Enterocolitis	1 (2.2)	0	1 (2.2)	0	0
Gastrooesophageal reflux disease	1 (2.2)	0	1 (2.2)	0	0
Haematemesis	1 (2.2)	1 (2.2)	0	0	0
Mouth haemorrhage	1 (2.2)	0	0	1 (2.2)	0
Mouth swelling	1 (2.2)	1 (2.2)	0	0	0
Neutropenic colitis	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (2.2)	1 (2.2)	0	0	0
Proctalgia	1 (2.2)	0	0	1 (2.2)	0
Trichoglossia	1 (2.2)	0	1 (2.2)	0	0
Upper gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	19 (41.3)	10 (21.7)	5 (10.9)	2 (4.3)	2 (4.3)
Pyrexia	11 (23.9)	6 (13.0)	2 (4.3)	1 (2.2)	2 (4.3)
Fatigue	7 (15.2)	5 (10.9)	2 (4.3)	0	0
Face oedema	4 (8.7)	3 (6.5)	0	1 (2.2)	0
Chills	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Oedema peripheral	3 (6.5)	2 (4.3)	0	1 (2.2)	0
Asthenia	1 (2.2)	1 (2.2)	0	0	0
Catheter site erythema	1 (2.2)	1 (2.2)	0	0	0
Catheter site pain	1 (2.2)	1 (2.2)	0	0	0
Chest discomfort	1 (2.2)	0	0	1 (2.2)	0
Generalised oedema	1 (2.2)	0	1 (2.2)	0	0
Localised oedema	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema due to hepatic disease	1 (2.2)	0	1 (2.2)	0	0
Pain	1 (2.2)	0	0	1 (2.2)	0
Vascular device occlusion	1 (2.2)	1 (2.2)	0	0	0
Hepatobiliary disorders					
-Total	8 (17.4)	4 (8.7)	2 (4.3)	1 (2.2)	1 (2.2)
Hepatic function abnormal	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Hepatomegaly	2 (4.3)	2 (4.3)	0	0	0
Hyperbilirubinaemia	2 (4.3)	0	2 (4.3)	0	0
Biliary tract disorder	1 (2.2)	1 (2.2)	0	0	0
Gallbladder enlargement	1 (2.2)	1 (2.2)	0	0	0
Hypertransaminasaemia	1 (2.2)	1 (2.2)	0	0	0
Ocular icterus	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	36 (78.3)	1 (2.2)	13 (28.3)	11 (23.9)	11 (23.9)
Cytokine release syndrome	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Hypogammaglobulinaemia	12 (26.1)	1 (2.2)	8 (17.4)	3 (6.5)	0
Haemophagocytic lymphohistiocytosis	3 (6.5)	1 (2.2)	0	2 (4.3)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	2 (4.3)	0	0	2 (4.3)	0
Hypersensitivity	1 (2.2)	1 (2.2)	0	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Infections and infestations					
-Total	19 (41.3)	3 (6.5)	7 (15.2)	9 (19.6)	0
Clostridium difficile infection	3 (6.5)	1 (2.2)	0	2 (4.3)	0
Conjunctivitis	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Staphylococcal infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Candida infection	2 (4.3)	0	2 (4.3)	0	0
Oral infection	2 (4.3)	0	2 (4.3)	0	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Bk virus infection	1 (2.2)	1 (2.2)	0	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Gingivitis	1 (2.2)	1 (2.2)	0	0	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Nail infection	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (2.2)	0	0	1 (2.2)	0
Otitis externa	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Pneumonia fungal	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Injury, poisoning and procedural complications					
-Total	4 (8.7)	2 (4.3)	2 (4.3)	0	0
Transfusion reaction	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Fall	1 (2.2)	0	1 (2.2)	0	0
Scratch	1 (2.2)	1 (2.2)	0	0	0
Investigations					
-Total	29 (63.0)	2 (4.3)	5 (10.9)	9 (19.6)	13 (28.3)
Alanine aminotransferase increased	13 (28.3)	4 (8.7)	6 (13.0)	3 (6.5)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	12 (26.1)	1 (2.2)	5 (10.9)	4 (8.7)	2 (4.3)
White blood cell count decreased	12 (26.1)	2 (4.3)	1 (2.2)	1 (2.2)	8 (17.4)
Platelet count decreased	11 (23.9)	2 (4.3)	2 (4.3)	4 (8.7)	3 (6.5)
Blood bilirubin increased	8 (17.4)	0	1 (2.2)	7 (15.2)	0
Neutrophil count decreased	8 (17.4)	0	0	0	8 (17.4)
Serum ferritin increased	6 (13.0)	1 (2.2)	4 (8.7)	1 (2.2)	0
Lymphocyte count decreased	5 (10.9)	0	0	2 (4.3)	3 (6.5)
Activated partial thromboplastin time prolonged	4 (8.7)	2 (4.3)	1 (2.2)	1 (2.2)	0
Blood fibrinogen decreased	4 (8.7)	1 (2.2)	2 (4.3)	0	1 (2.2)
Blood lactate dehydrogenase increased	3 (6.5)	2 (4.3)	1 (2.2)	0	0
International normalised ratio increased	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Blood creatinine increased	2 (4.3)	0	0	2 (4.3)	0
Blood immunoglobulin a decreased	2 (4.3)	1 (2.2)	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
C-reactive protein increased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Electrocardiogram qt prolonged	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Fibrin d dimer increased	2 (4.3)	2 (4.3)	0	0	0
Gamma-glutamyltransferase increased	2 (4.3)	0	0	2 (4.3)	0
Immunoglobulins decreased	2 (4.3)	0	2 (4.3)	0	0
Weight increased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Amylase increased	1 (2.2)	1 (2.2)	0	0	0
Bacterial test positive	1 (2.2)	0	0	1 (2.2)	0
Blood creatine phosphokinase increased	1 (2.2)	0	0	1 (2.2)	0
Blood immunoglobulin g decreased	1 (2.2)	1 (2.2)	0	0	0
Blood testosterone decreased	1 (2.2)	1 (2.2)	0	0	0
Blood uric acid increased	1 (2.2)	1 (2.2)	0	0	0
Coagulation test abnormal	1 (2.2)	1 (2.2)	0	0	0
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (2.2)	1 (2.2)	0	0	0
Oxygen saturation decreased	1 (2.2)	1 (2.2)	0	0	0
Prothrombin time prolonged	1 (2.2)	0	1 (2.2)	0	0
Staphylococcus test positive	1 (2.2)	1 (2.2)	0	0	0
Urine output decreased	1 (2.2)	0	0	1 (2.2)	0
Metabolism and nutrition disorders					
-Total	25 (54.3)	5 (10.9)	7 (15.2)	8 (17.4)	5 (10.9)
Decreased appetite	10 (21.7)	3 (6.5)	3 (6.5)	3 (6.5)	1 (2.2)
Hypocalcaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Hypokalaemia	9 (19.6)	1 (2.2)	3 (6.5)	4 (8.7)	1 (2.2)
Hypophosphataemia	7 (15.2)	3 (6.5)	1 (2.2)	2 (4.3)	1 (2.2)
Hyperuricaemia	4 (8.7)	3 (6.5)	1 (2.2)	0	0
Hypoalbuminaemia	4 (8.7)	0	4 (8.7)	0	0
Hyperglycaemia	3 (6.5)	0	0	3 (6.5)	0
Hypomagnesaemia	3 (6.5)	3 (6.5)	0	0	0
Tumour lysis syndrome	3 (6.5)	0	0	3 (6.5)	0
Hyperphosphataemia	2 (4.3)	2 (4.3)	0	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Hypervolaemia	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Metabolic acidosis	2 (4.3)	1 (2.2)	0	0	1 (2.2)
Dehydration	1 (2.2)	0	1 (2.2)	0	0
Hypercalcaemia	1 (2.2)	0	0	1 (2.2)	0
Hyperkalaemia	1 (2.2)	0	0	1 (2.2)	0
Hypermagnesaemia	1 (2.2)	1 (2.2)	0	0	0
Hypernatraemia	1 (2.2)	1 (2.2)	0	0	0
Malnutrition	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (32.6)	6 (13.0)	9 (19.6)	0	0
Arthralgia	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Pain in extremity	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Back pain	2 (4.3)	0	2 (4.3)	0	0
Myalgia	2 (4.3)	2 (4.3)	0	0	0
Bone pain	1 (2.2)	0	1 (2.2)	0	0
Muscle spasms	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (2.2)	1 (2.2)	0	0	0
Pain in jaw	1 (2.2)	1 (2.2)	0	0	0
Nervous system disorders					
-Total	21 (45.7)	11 (23.9)	5 (10.9)	3 (6.5)	2 (4.3)
Headache	11 (23.9)	7 (15.2)	2 (4.3)	2 (4.3)	0
Encephalopathy	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Dizziness	2 (4.3)	2 (4.3)	0	0	0
Dysgeusia	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Somnolence	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Cerebral haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Cognitive disorder	1 (2.2)	0	1 (2.2)	0	0
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Hypoaesthesia	1 (2.2)	1 (2.2)	0	0	0
Lethargy	1 (2.2)	1 (2.2)	0	0	0
Neuralgia	1 (2.2)	0	1 (2.2)	0	0
Neurological decompensation	1 (2.2)	0	0	0	1 (2.2)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	15 (32.6)	7 (15.2)	6 (13.0)	2 (4.3)	0
Delirium	5 (10.9)	2 (4.3)	1 (2.2)	2 (4.3)	0
Confusional state	4 (8.7)	4 (8.7)	0	0	0
Anxiety	3 (6.5)	0	3 (6.5)	0	0
Insomnia	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Agitation	2 (4.3)	0	2 (4.3)	0	0
Hallucination	1 (2.2)	0	1 (2.2)	0	0
Irritability	1 (2.2)	1 (2.2)	0	0	0
Mental status changes	1 (2.2)	0	1 (2.2)	0	0
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Sleep disorder	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	10 (21.7)	4 (8.7)	3 (6.5)	0	3 (6.5)
Acute kidney injury	3 (6.5)	1 (2.2)	0	0	2 (4.3)
Dysuria	2 (4.3)	2 (4.3)	0	0	0
Haematuria	2 (4.3)	2 (4.3)	0	0	0
Renal failure	2 (4.3)	0	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Incontinence	1 (2.2)	0	1 (2.2)	0	0
Proteinuria	1 (2.2)	1 (2.2)	0	0	0
Renal tubular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Urinary tract disorder	1 (2.2)	0	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (41.3)	6 (13.0)	4 (8.7)	2 (4.3)	7 (15.2)
Hypoxia	9 (19.6)	0	3 (6.5)	2 (4.3)	4 (8.7)
Pleural effusion	6 (13.0)	3 (6.5)	0	2 (4.3)	1 (2.2)
Pulmonary oedema	6 (13.0)	1 (2.2)	2 (4.3)	2 (4.3)	1 (2.2)
Cough	4 (8.7)	4 (8.7)	0	0	0
Oropharyngeal pain	3 (6.5)	3 (6.5)	0	0	0
Tachypnoea	3 (6.5)	2 (4.3)	0	1 (2.2)	0
Nasal congestion	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Respiratory distress	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Respiratory failure	2 (4.3)	0	0	0	2 (4.3)
Atelectasis	1 (2.2)	0	0	1 (2.2)	0
Bradypnoea	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (2.2)	0	0	1 (2.2)	0
Epistaxis	1 (2.2)	1 (2.2)	0	0	0
Lung infiltration	1 (2.2)	0	0	1 (2.2)	0
Painful respiration	1 (2.2)	1 (2.2)	0	0	0
Productive cough	1 (2.2)	1 (2.2)	0	0	0
Respiratory disorder	1 (2.2)	0	1 (2.2)	0	0
Wheezing	1 (2.2)	0	1 (2.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (30.4)	6 (13.0)	7 (15.2)	1 (2.2)	0
Pruritus	4 (8.7)	1 (2.2)	3 (6.5)	0	0
Rash	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Blister	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Erythema	2 (4.3)	2 (4.3)	0	0	0
Dermatitis	1 (2.2)	1 (2.2)	0	0	0
Dermatitis atopic	1 (2.2)	1 (2.2)	0	0	0
Erythema nodosum	1 (2.2)	1 (2.2)	0	0	0
Pruritus allergic	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Scab	1 (2.2)	1 (2.2)	0	0	0
Skin discolouration	1 (2.2)	1 (2.2)	0	0	0
Skin ulcer	1 (2.2)	0	1 (2.2)	0	0
Urticaria	1 (2.2)	0	1 (2.2)	0	0
Vancomycin infusion reaction	1 (2.2)	0	0	1 (2.2)	0
Vascular disorders					
-Total	16 (34.8)	2 (4.3)	6 (13.0)	6 (13.0)	2 (4.3)
Hypotension	10 (21.7)	0	5 (10.9)	3 (6.5)	2 (4.3)
Hypertension	7 (15.2)	3 (6.5)	2 (4.3)	2 (4.3)	0
Capillary leak syndrome	2 (4.3)	0	1 (2.2)	1 (2.2)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	1 (2.9)	10 (29.4)	22 (64.7)
Blood and lymphatic system disorders					
-Total	25 (73.5)	2 (5.9)	1 (2.9)	16 (47.1)	6 (17.6)
Febrile neutropenia	15 (44.1)	0	0	13 (38.2)	2 (5.9)
Anaemia	14 (41.2)	4 (11.8)	5 (14.7)	5 (14.7)	0
Neutropenia	5 (14.7)	0	1 (2.9)	1 (2.9)	3 (8.8)
Coagulopathy	3 (8.8)	1 (2.9)	0	2 (5.9)	0
Thrombocytopenia	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Disseminated intravascular coagulation	2 (5.9)	0	0	2 (5.9)	0
Splenomegaly	2 (5.9)	2 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Hypofibrinogenaemia	1 (2.9)	0	1 (2.9)	0	0
Leukopenia	1 (2.9)	0	0	1 (2.9)	0
Pancytopenia	1 (2.9)	0	0	1 (2.9)	0
Cardiac disorders					
-Total	13 (38.2)	6 (17.6)	3 (8.8)	1 (2.9)	3 (8.8)
Tachycardia	8 (23.5)	4 (11.8)	3 (8.8)	0	1 (2.9)
Sinus tachycardia	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Bradycardia	1 (2.9)	0	1 (2.9)	0	0
Cardiac arrest	1 (2.9)	0	0	0	1 (2.9)
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Cardiac failure	1 (2.9)	0	0	0	1 (2.9)
Left ventricular dysfunction	1 (2.9)	0	0	1 (2.9)	0
Sinus bradycardia	1 (2.9)	0	0	1 (2.9)	0
Ear and labyrinth disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Ear pruritus	1 (2.9)	1 (2.9)	0	0	0
Endocrine disorders					

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (8.8)	0	3 (8.8)	0	0
Adrenal insufficiency	3 (8.8)	0	3 (8.8)	0	0
Eye disorders					
-Total	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Eyelid oedema	1 (2.9)	1 (2.9)	0	0	0
Periorbital oedema	1 (2.9)	1 (2.9)	0	0	0
Periorbital swelling	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Visual field defect	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	23 (67.6)	9 (26.5)	8 (23.5)	6 (17.6)	0
Vomiting	9 (26.5)	3 (8.8)	5 (14.7)	1 (2.9)	0
Diarrhoea	8 (23.5)	4 (11.8)	4 (11.8)	0	0
Constipation	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Nausea	6 (17.6)	3 (8.8)	2 (5.9)	1 (2.9)	0
Abdominal pain	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Mouth haemorrhage	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal distension	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Ascites	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Stomatitis	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Abdominal pain upper	1 (2.9)	1 (2.9)	0	0	0
Anal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	0	1 (2.9)	0
Gingival bleeding	1 (2.9)	0	1 (2.9)	0	0
Gingival erythema	1 (2.9)	1 (2.9)	0	0	0
Gingivitis ulcerative	1 (2.9)	0	0	1 (2.9)	0
Ileus	1 (2.9)	0	1 (2.9)	0	0
Lip dry	1 (2.9)	0	1 (2.9)	0	0
Lip oedema	1 (2.9)	1 (2.9)	0	0	0
Melaena	1 (2.9)	0	0	1 (2.9)	0
Pancreatitis	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	21 (61.8)	10 (29.4)	4 (11.8)	5 (14.7)	2 (5.9)
Pyrexia	13 (38.2)	5 (14.7)	3 (8.8)	5 (14.7)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Fatigue	4 (11.8)	4 (11.8)	0	0	0
Generalised oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Chills	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Oedema peripheral	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Drug withdrawal syndrome	2 (5.9)	0	2 (5.9)	0	0
Influenza like illness	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Multiple organ dysfunction syndrome	2 (5.9)	0	0	0	2 (5.9)
Asthenia	1 (2.9)	1 (2.9)	0	0	0
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Catheter site pain	1 (2.9)	0	0	1 (2.9)	0
Crying	1 (2.9)	0	1 (2.9)	0	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0
Localised oedema	1 (2.9)	1 (2.9)	0	0	0
Malaise	1 (2.9)	0	1 (2.9)	0	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Swelling face	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	9 (26.5)	1 (2.9)	4 (11.8)	2 (5.9)	2 (5.9)
Hepatic function abnormal	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Hyperbilirubinaemia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cholelithiasis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Cholestasis	1 (2.9)	0	0	0	1 (2.9)
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Hepatomegaly	1 (2.9)	0	0	0	1 (2.9)
Hypertransaminasaemia	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	31 (91.2)	2 (5.9)	8 (23.5)	11 (32.4)	10 (29.4)
Cytokine release syndrome	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Hypogammaglobulinaemia	11 (32.4)	1 (2.9)	6 (17.6)	4 (11.8)	0
Haemophagocytic lymphohistiocytosis	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Immunodeficiency	1 (2.9)	0	0	1 (2.9)	0
Seasonal allergy	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	16 (47.1)	3 (8.8)	3 (8.8)	7 (20.6)	3 (8.8)
Conjunctivitis	2 (5.9)	0	2 (5.9)	0	0
Encephalitis viral	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Rhinovirus infection	2 (5.9)	0	2 (5.9)	0	0
Staphylococcal bacteraemia	2 (5.9)	0	0	2 (5.9)	0
Staphylococcal infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Localised infection	1 (2.9)	1 (2.9)	0	0	0
Meningitis bacterial	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Nail infection	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Urinary tract infection viral	1 (2.9)	1 (2.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	7 (20.6)	1 (2.9)	4 (11.8)	0	2 (5.9)
Infusion related reaction	2 (5.9)	0	2 (5.9)	0	0
Procedural pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Wound	2 (5.9)	0	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (2.9)	1 (2.9)	0	0	0
Fall	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0
Skin injury	1 (2.9)	0	1 (2.9)	0	0
Skin wound	1 (2.9)	1 (2.9)	0	0	0
Transplant failure	1 (2.9)	0	0	0	1 (2.9)
Vasoplegia syndrome	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	28 (82.4)	2 (5.9)	3 (8.8)	8 (23.5)	15 (44.1)
Neutrophil count decreased	12 (35.3)	0	3 (8.8)	2 (5.9)	7 (20.6)
White blood cell count decreased	12 (35.3)	1 (2.9)	2 (5.9)	1 (2.9)	8 (23.5)
Lymphocyte count decreased	10 (29.4)	2 (5.9)	0	6 (17.6)	2 (5.9)
Platelet count decreased	10 (29.4)	2 (5.9)	1 (2.9)	2 (5.9)	5 (14.7)
Aspartate aminotransferase increased	7 (20.6)	1 (2.9)	1 (2.9)	4 (11.8)	1 (2.9)
International normalised ratio increased	6 (17.6)	4 (11.8)	2 (5.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (14.7)	0	2 (5.9)	3 (8.8)	0
Blood bilirubin increased	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood fibrinogen decreased	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Electrocardiogram qt prolonged	3 (8.8)	1 (2.9)	1 (2.9)	0	1 (2.9)
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood creatinine increased	2 (5.9)	1 (2.9)	0	0	1 (2.9)
C-reactive protein increased	2 (5.9)	0	0	2 (5.9)	0
Serum ferritin increased	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Weight increased	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood alkaline phosphatase increased	1 (2.9)	1 (2.9)	0	0	0
Blood bicarbonate decreased	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (2.9)	0	0	0	1 (2.9)
Blood glucose increased	1 (2.9)	0	0	0	1 (2.9)
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Blood lactate dehydrogenase increased	1 (2.9)	0	0	1 (2.9)	0
Blood phosphorus increased	1 (2.9)	0	1 (2.9)	0	0
Blood uric acid increased	1 (2.9)	1 (2.9)	0	0	0
Breath sounds abnormal	1 (2.9)	0	1 (2.9)	0	0
Cardiac murmur	1 (2.9)	1 (2.9)	0	0	0
Electrocardiogram t wave abnormal	1 (2.9)	0	1 (2.9)	0	0
Enterovirus test positive	1 (2.9)	0	1 (2.9)	0	0
Fibrin d dimer increased	1 (2.9)	0	0	1 (2.9)	0
Haptoglobin decreased	1 (2.9)	1 (2.9)	0	0	0
Lipase increased	1 (2.9)	0	0	0	1 (2.9)
Troponin increased	1 (2.9)	0	0	1 (2.9)	0
Urine output decreased	1 (2.9)	0	0	0	1 (2.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (2.9)	0	1 (2.9)	0	0
Metabolism and nutrition disorders					
-Total	21 (61.8)	3 (8.8)	2 (5.9)	13 (38.2)	3 (8.8)
Decreased appetite	14 (41.2)	6 (17.6)	1 (2.9)	7 (20.6)	0
Hypokalaemia	10 (29.4)	2 (5.9)	2 (5.9)	5 (14.7)	1 (2.9)
Hypophosphataemia	10 (29.4)	0	4 (11.8)	6 (17.6)	0
Hypoalbuminaemia	7 (20.6)	0	6 (17.6)	1 (2.9)	0
Hypocalcaemia	7 (20.6)	0	5 (14.7)	2 (5.9)	0
Hyperglycaemia	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Hypervolaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Hyperphosphataemia	3 (8.8)	2 (5.9)	0	0	1 (2.9)
Hyperuricaemia	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Hypomagnesaemia	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Hyponatraemia	3 (8.8)	3 (8.8)	0	0	0
Acidosis	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Hypercalcaemia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Calcium deficiency	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemosiderosis	1 (2.9)	0	1 (2.9)	0	0
Hyperchloraemia	1 (2.9)	1 (2.9)	0	0	0
Hyperkalaemia	1 (2.9)	0	0	0	1 (2.9)
Hyperlactacidaemia	1 (2.9)	1 (2.9)	0	0	0
Hypermagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hypernatraemia	1 (2.9)	0	0	0	1 (2.9)
Hypoglycaemia	1 (2.9)	0	1 (2.9)	0	0
Metabolic acidosis	1 (2.9)	0	0	0	1 (2.9)
Polydipsia	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	18 (52.9)	9 (26.5)	4 (11.8)	4 (11.8)	1 (2.9)
Myalgia	7 (20.6)	4 (11.8)	3 (8.8)	0	0
Back pain	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Pain in extremity	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Arthralgia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Bone pain	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (2.9)	0	0	1 (2.9)	0
Muscle rigidity	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal chest pain	1 (2.9)	1 (2.9)	0	0	0
Myositis	1 (2.9)	0	1 (2.9)	0	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Pain in jaw	1 (2.9)	0	0	1 (2.9)	0
Rhabdomyolysis	1 (2.9)	0	0	0	1 (2.9)
Nervous system disorders					
-Total	19 (55.9)	3 (8.8)	11 (32.4)	5 (14.7)	0
Headache	12 (35.3)	5 (14.7)	7 (20.6)	0	0
Tremor	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Encephalopathy	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Somnolence	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cognitive disorder	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Lethargy	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Dysgeusia	1 (2.9)	1 (2.9)	0	0	0
Generalised tonic-clonic seizure	1 (2.9)	0	1 (2.9)	0	0
Hyperaesthesia	1 (2.9)	1 (2.9)	0	0	0
Monoparesis	1 (2.9)	0	1 (2.9)	0	0
Paraesthesia	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	13 (38.2)	5 (14.7)	4 (11.8)	4 (11.8)	0
Agitation	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Anxiety	3 (8.8)	1 (2.9)	0	2 (5.9)	0
Confusional state	3 (8.8)	3 (8.8)	0	0	0
Delirium	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Irritability	2 (5.9)	2 (5.9)	0	0	0
Mental status changes	2 (5.9)	1 (2.9)	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Automatism	1 (2.9)	1 (2.9)	0	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Insomnia	1 (2.9)	0	1 (2.9)	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	10 (29.4)	1 (2.9)	3 (8.8)	3 (8.8)	3 (8.8)
Acute kidney injury	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)
Anuria	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Pollakiuria	2 (5.9)	0	2 (5.9)	0	0
Urinary retention	2 (5.9)	0	2 (5.9)	0	0
Azotaemia	1 (2.9)	0	1 (2.9)	0	0
Bladder dilatation	1 (2.9)	0	1 (2.9)	0	0
Dysuria	1 (2.9)	1 (2.9)	0	0	0
Micturition urgency	1 (2.9)	0	1 (2.9)	0	0
Renal tubular necrosis	1 (2.9)	0	0	0	1 (2.9)
Urinary incontinence	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Female genital tract fistula	1 (2.9)	1 (2.9)	0	0	0
Heavy menstrual bleeding	1 (2.9)	1 (2.9)	0	0	0
Perineal rash	1 (2.9)	0	1 (2.9)	0	0
Vaginal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Vaginal ulceration	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (64.7)	8 (23.5)	0	9 (26.5)	5 (14.7)
Hypoxia	8 (23.5)	0	2 (5.9)	4 (11.8)	2 (5.9)
Cough	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Pulmonary oedema	6 (17.6)	1 (2.9)	1 (2.9)	4 (11.8)	0
Tachypnoea	5 (14.7)	1 (2.9)	1 (2.9)	3 (8.8)	0
Epistaxis	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Acute respiratory distress syndrome	2 (5.9)	0	0	0	2 (5.9)
Atelectasis	2 (5.9)	0	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	2 (5.9)	0	0	0
Respiratory failure	2 (5.9)	0	0	0	2 (5.9)
Rhinorrhoea	2 (5.9)	2 (5.9)	0	0	0
Acute respiratory failure	1 (2.9)	0	0	1 (2.9)	0
Haemoptysis	1 (2.9)	0	1 (2.9)	0	0
Nasal congestion	1 (2.9)	1 (2.9)	0	0	0
Nasal discomfort	1 (2.9)	0	1 (2.9)	0	0
Nasal dryness	1 (2.9)	1 (2.9)	0	0	0
Oropharyngeal plaque	1 (2.9)	0	1 (2.9)	0	0
Paranasal sinus discomfort	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal erythema	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal exudate	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal oedema	1 (2.9)	0	1 (2.9)	0	0
Pleural effusion	1 (2.9)	1 (2.9)	0	0	0
Pulmonary mass	1 (2.9)	0	1 (2.9)	0	0
Respiratory acidosis	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (38.2)	7 (20.6)	4 (11.8)	2 (5.9)	0
Hyperhidrosis	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Rash papular	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Erythema	2 (5.9)	2 (5.9)	0	0	0
Petechiae	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Pruritus	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rash	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rash maculo-papular	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Blister	1 (2.9)	1 (2.9)	0	0	0
Decubitus ulcer	1 (2.9)	0	1 (2.9)	0	0
Dermatitis atopic	1 (2.9)	1 (2.9)	0	0	0
Dermatitis diaper	1 (2.9)	0	1 (2.9)	0	0
Dry skin	1 (2.9)	1 (2.9)	0	0	0
Eczema	1 (2.9)	1 (2.9)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Purpura	1 (2.9)	1 (2.9)	0	0	0
Rash pruritic	1 (2.9)	1 (2.9)	0	0	0
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin lesion	1 (2.9)	0	1 (2.9)	0	0
Skin necrosis	1 (2.9)	0	0	1 (2.9)	0
Skin ulcer	1 (2.9)	1 (2.9)	0	0	0
Social circumstances					
-Total	1 (2.9)	0	1 (2.9)	0	0
Patient uncooperative	1 (2.9)	0	1 (2.9)	0	0
Surgical and medical procedures					
-Total	1 (2.9)	0	0	1 (2.9)	0
Thrombolysis	1 (2.9)	0	0	1 (2.9)	0
Vascular disorders					
-Total	12 (35.3)	2 (5.9)	1 (2.9)	5 (14.7)	4 (11.8)
Hypotension	11 (32.4)	1 (2.9)	1 (2.9)	5 (14.7)	4 (11.8)
Hypertension	6 (17.6)	1 (2.9)	3 (8.8)	2 (5.9)	0
Flushing	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hot flush	1 (2.9)	1 (2.9)	0	0	0
Peripheral ischaemia	1 (2.9)	0	1 (2.9)	0	0
Thrombosis	1 (2.9)	0	1 (2.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (93.0)	6 (14.0)	12 (27.9)	10 (23.3)	12 (27.9)
Blood and lymphatic system disorders					
-Total	10 (23.3)	2 (4.7)	3 (7.0)	3 (7.0)	2 (4.7)
Febrile neutropenia	3 (7.0)	0	0	3 (7.0)	0
Anaemia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Thrombocytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Disseminated intravascular coagulation	1 (2.3)	0	0	1 (2.3)	0
Eosinophilia	1 (2.3)	0	1 (2.3)	0	0
Leukocytosis	1 (2.3)	0	1 (2.3)	0	0
Leukopenia	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (2.3)	1 (2.3)	0	0	0
Lymphocytosis	1 (2.3)	0	1 (2.3)	0	0
Lymphopenia	1 (2.3)	0	0	1 (2.3)	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Cardiac disorders					
-Total	5 (11.6)	3 (7.0)	1 (2.3)	0	1 (2.3)
Tachycardia	2 (4.7)	2 (4.7)	0	0	0
Cardiac arrest	1 (2.3)	0	0	0	1 (2.3)
Cardiac failure	1 (2.3)	0	0	1 (2.3)	0
Left ventricular dysfunction	1 (2.3)	0	1 (2.3)	0	0
Tricuspid valve incompetence	1 (2.3)	1 (2.3)	0	0	0
Eye disorders					
-Total	3 (7.0)	3 (7.0)	0	0	0
Cataract	2 (4.7)	2 (4.7)	0	0	0
Hypermetropia	1 (2.3)	1 (2.3)	0	0	0
Visual impairment	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	13 (30.2)	8 (18.6)	4 (9.3)	1 (2.3)	0
Diarrhoea	5 (11.6)	4 (9.3)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (7.0)	3 (7.0)	0	0	0
Constipation	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Nausea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Abdominal pain	1 (2.3)	1 (2.3)	0	0	0
Enteritis	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal inflammation	1 (2.3)	0	1 (2.3)	0	0
Mouth haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Pancreatitis	1 (2.3)	0	0	1 (2.3)	0
Peritoneal haematoma	1 (2.3)	1 (2.3)	0	0	0
Trichoglossia	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					
-Total	13 (30.2)	7 (16.3)	4 (9.3)	2 (4.7)	0
Pyrexia	10 (23.3)	4 (9.3)	4 (9.3)	2 (4.7)	0
Fatigue	3 (7.0)	3 (7.0)	0	0	0
Asthenia	1 (2.3)	1 (2.3)	0	0	0
Malaise	1 (2.3)	1 (2.3)	0	0	0
Hepatobiliary disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Hepatic cytolysis	1 (2.3)	1 (2.3)	0	0	0
Liver disorder	1 (2.3)	0	1 (2.3)	0	0
Immune system disorders					
-Total	10 (23.3)	1 (2.3)	6 (14.0)	3 (7.0)	0
Hypogammaglobulinaemia	5 (11.6)	0	5 (11.6)	0	0
Graft versus host disease	2 (4.7)	0	0	2 (4.7)	0
Allergy to immunoglobulin therapy	1 (2.3)	1 (2.3)	0	0	0
Drug hypersensitivity	1 (2.3)	0	1 (2.3)	0	0
Engraftment syndrome	1 (2.3)	0	0	1 (2.3)	0
Immunodeficiency	1 (2.3)	0	0	1 (2.3)	0
Infections and infestations					
-Total	23 (53.5)	5 (11.6)	6 (14.0)	7 (16.3)	5 (11.6)
Upper respiratory tract infection	6 (14.0)	3 (7.0)	2 (4.7)	1 (2.3)	0
Nasopharyngitis	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Metapneumovirus infection	3 (7.0)	0	0	3 (7.0)	0
Pneumonia	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (4.7)	2 (4.7)	0	0	0
Otitis media	2 (4.7)	0	2 (4.7)	0	0
Parainfluenzae virus infection	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Pneumocystis jirovecii pneumonia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Respiratory syncytial virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Respiratory tract infection	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Rhinovirus infection	2 (4.7)	0	2 (4.7)	0	0
Viral infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Adenovirus infection	1 (2.3)	0	0	1 (2.3)	0
Bacteraemia	1 (2.3)	0	1 (2.3)	0	0
Bk virus infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis	1 (2.3)	0	1 (2.3)	0	0
Conjunctivitis	1 (2.3)	0	1 (2.3)	0	0
Coronavirus infection	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection reactivation	1 (2.3)	0	0	1 (2.3)	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.3)	0	0	0	1 (2.3)
Gastroenteritis clostridial	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal infection	1 (2.3)	1 (2.3)	0	0	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Herpes simplex	1 (2.3)	0	1 (2.3)	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Human herpesvirus 6 infection	1 (2.3)	0	0	1 (2.3)	0
Influenza	1 (2.3)	0	1 (2.3)	0	0
Molluscum contagiosum	1 (2.3)	1 (2.3)	0	0	0
Nail infection	1 (2.3)	1 (2.3)	0	0	0
Oral herpes	1 (2.3)	0	1 (2.3)	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	0	1 (2.3)	0	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Salmonellosis	1 (2.3)	0	1 (2.3)	0	0
Sinusitis	1 (2.3)	0	1 (2.3)	0	0
Sinusitis fungal	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (2.3)	0	0	0	1 (2.3)
Tinea pedis	1 (2.3)	1 (2.3)	0	0	0
Viral haemorrhagic cystitis	1 (2.3)	0	0	1 (2.3)	0
Injury, poisoning and procedural complications					
-Total	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Contusion	1 (2.3)	1 (2.3)	0	0	0
Fibula fracture	1 (2.3)	0	1 (2.3)	0	0
Infusion related reaction	1 (2.3)	1 (2.3)	0	0	0
Ligament sprain	1 (2.3)	1 (2.3)	0	0	0
Skin abrasion	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	18 (41.9)	4 (9.3)	4 (9.3)	8 (18.6)	2 (4.7)
White blood cell count decreased	5 (11.6)	2 (4.7)	2 (4.7)	0	1 (2.3)
Neutrophil count decreased	4 (9.3)	0	0	2 (4.7)	2 (4.7)
Platelet count decreased	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Alanine aminotransferase increased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Blood bilirubin increased	2 (4.7)	0	1 (2.3)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Lymphocyte count decreased	2 (4.7)	0	0	2 (4.7)	0
Blood creatinine increased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin m decreased	1 (2.3)	0	0	1 (2.3)	0
Blood lactate dehydrogenase increased	1 (2.3)	1 (2.3)	0	0	0
Blood urea increased	1 (2.3)	0	0	1 (2.3)	0
Blood uric acid increased	1 (2.3)	0	0	1 (2.3)	0
Bone density decreased	1 (2.3)	1 (2.3)	0	0	0
C-reactive protein increased	1 (2.3)	1 (2.3)	0	0	0
Ejection fraction decreased	1 (2.3)	0	1 (2.3)	0	0
Heart sounds abnormal	1 (2.3)	1 (2.3)	0	0	0
Hepatitis b virus test positive	1 (2.3)	0	1 (2.3)	0	0
Immunoglobulins decreased	1 (2.3)	0	1 (2.3)	0	0
Oxygen saturation decreased	1 (2.3)	0	1 (2.3)	0	0
Weight decreased	1 (2.3)	0	0	1 (2.3)	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (18.6)	2 (4.7)	3 (7.0)	2 (4.7)	1 (2.3)
Decreased appetite	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Haemochromatosis	1 (2.3)	0	0	1 (2.3)	0
Hyperkalaemia	1 (2.3)	0	1 (2.3)	0	0
Hyperuricaemia	1 (2.3)	1 (2.3)	0	0	0
Hypervolaemia	1 (2.3)	0	0	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	0	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	1 (2.3)	0	0
Iron overload	1 (2.3)	0	1 (2.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (20.9)	4 (9.3)	3 (7.0)	2 (4.7)	0
Back pain	4 (9.3)	2 (4.7)	0	2 (4.7)	0
Arthralgia	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Pain in extremity	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Bone pain	1 (2.3)	1 (2.3)	0	0	0
Growth retardation	1 (2.3)	0	1 (2.3)	0	0
Musculoskeletal chest pain	1 (2.3)	1 (2.3)	0	0	0
Myalgia	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (2.3)	1 (2.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Skin papilloma	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Cancer pain	1 (2.3)	0	1 (2.3)	0	0
Nervous system disorders					
-Total	6 (14.0)	3 (7.0)	1 (2.3)	0	2 (4.7)
Headache	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Autonomic neuropathy	1 (2.3)	0	0	1 (2.3)	0
Cerebral haemorrhage	1 (2.3)	0	0	0	1 (2.3)
Dizziness	1 (2.3)	1 (2.3)	0	0	0
Hydrocephalus	1 (2.3)	0	0	0	1 (2.3)
Memory impairment	1 (2.3)	0	1 (2.3)	0	0
Seizure	1 (2.3)	0	0	1 (2.3)	0
Psychiatric disorders					
-Total	6 (14.0)	1 (2.3)	5 (11.6)	0	0
Anxiety	4 (9.3)	1 (2.3)	3 (7.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (2.3)	1 (2.3)	0	0	0
Delirium	1 (2.3)	0	1 (2.3)	0	0
Mood altered	1 (2.3)	1 (2.3)	0	0	0
Nightmare	1 (2.3)	1 (2.3)	0	0	0
Persistent depressive disorder	1 (2.3)	0	1 (2.3)	0	0
Sleep disorder	1 (2.3)	0	1 (2.3)	0	0
Tearfulness	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Acute kidney injury	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Cystitis haemorrhagic	1 (2.3)	0	1 (2.3)	0	0
Dysuria	1 (2.3)	0	1 (2.3)	0	0
Haematuria	1 (2.3)	0	0	1 (2.3)	0
Kidney enlargement	1 (2.3)	0	1 (2.3)	0	0
Renal mass	1 (2.3)	0	1 (2.3)	0	0
Renal tubular disorder	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (27.9)	5 (11.6)	3 (7.0)	2 (4.7)	2 (4.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Nasal congestion	3 (7.0)	3 (7.0)	0	0	0
Hypoxia	2 (4.7)	0	0	2 (4.7)	0
Pleural effusion	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Bronchospasm	1 (2.3)	0	1 (2.3)	0	0
Epistaxis	1 (2.3)	0	1 (2.3)	0	0
Lung disorder	1 (2.3)	1 (2.3)	0	0	0
Oropharyngeal pain	1 (2.3)	0	1 (2.3)	0	0
Paranasal sinus inflammation	1 (2.3)	1 (2.3)	0	0	0
Respiratory distress	1 (2.3)	0	0	0	1 (2.3)
Respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Rhinitis allergic	1 (2.3)	1 (2.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (23.3)	6 (14.0)	4 (9.3)	0	0
Rash	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Dry skin	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Dermatitis allergic	1 (2.3)	1 (2.3)	0	0	0
Erythema	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	1 (2.3)	0	1 (2.3)	0	0
Miliaria	1 (2.3)	1 (2.3)	0	0	0
Night sweats	1 (2.3)	1 (2.3)	0	0	0
Photosensitivity reaction	1 (2.3)	0	1 (2.3)	0	0
Skin discolouration	1 (2.3)	1 (2.3)	0	0	0
Skin swelling	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	4 (9.3)	1 (2.3)	0	2 (4.7)	1 (2.3)
Hypotension	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Venoocclusive disease	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Hypertension	1 (2.3)	0	1 (2.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (90.6)	3 (9.4)	12 (37.5)	5 (15.6)	9 (28.1)
Blood and lymphatic system disorders					
-Total	7 (21.9)	1 (3.1)	1 (3.1)	3 (9.4)	2 (6.3)
Anaemia	4 (12.5)	3 (9.4)	0	1 (3.1)	0
Neutropenia	4 (12.5)	0	0	2 (6.3)	2 (6.3)
B-cell aplasia	1 (3.1)	0	1 (3.1)	0	0
Cardiac disorders					
-Total	2 (6.3)	0	0	0	2 (6.3)
Cardiac arrest	1 (3.1)	0	0	0	1 (3.1)
Cardiac failure	1 (3.1)	0	0	0	1 (3.1)
Endocrine disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	1 (3.1)	0	0
Hypothyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Ocular hyperaemia	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Nausea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Vomiting	3 (9.4)	3 (9.4)	0	0	0
Diarrhoea	2 (6.3)	2 (6.3)	0	0	0
Abdominal pain	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain upper	1 (3.1)	1 (3.1)	0	0	0
Abdominal rigidity	1 (3.1)	0	1 (3.1)	0	0
Constipation	1 (3.1)	0	1 (3.1)	0	0
Dyspepsia	1 (3.1)	1 (3.1)	0	0	0
Pancreatitis	1 (3.1)	1 (3.1)	0	0	0
Proctalgia	1 (3.1)	1 (3.1)	0	0	0
Stomatitis	1 (3.1)	1 (3.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	11 (34.4)	8 (25.0)	2 (6.3)	1 (3.1)	0
Pyrexia	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Fatigue	3 (9.4)	3 (9.4)	0	0	0
Pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Chills	1 (3.1)	1 (3.1)	0	0	0
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	1 (3.1)	0	0	0
Hepatobiliary disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Hypertransaminasaemia	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Hypogammaglobulinaemia	5 (15.6)	0	5 (15.6)	0	0
Allergy to immunoglobulin therapy	1 (3.1)	0	0	1 (3.1)	0
Infections and infestations					
-Total	16 (50.0)	0	8 (25.0)	5 (15.6)	3 (9.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Rhinovirus infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Parainfluenzae virus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Sinusitis	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Bronchopulmonary aspergillosis	1 (3.1)	0	0	0	1 (3.1)
Cystitis	1 (3.1)	0	1 (3.1)	0	0
Ear infection	1 (3.1)	0	1 (3.1)	0	0
Ear, nose and throat infection	1 (3.1)	0	1 (3.1)	0	0
Enterobacter infection	1 (3.1)	0	0	1 (3.1)	0
Klebsiella infection	1 (3.1)	0	0	1 (3.1)	0
Mastoiditis	1 (3.1)	0	0	1 (3.1)	0
Oral candidiasis	1 (3.1)	0	1 (3.1)	0	0
Otitis externa	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (3.1)	0	0	1 (3.1)	0
Pharyngitis streptococcal	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection viral	1 (3.1)	0	1 (3.1)	0	0
Rhinitis	1 (3.1)	0	1 (3.1)	0	0
Septic shock	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal skin infection	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Injury, poisoning and procedural complications					
-Total	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Infusion related reaction	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Limb injury	1 (3.1)	0	1 (3.1)	0	0
Post-traumatic neck syndrome	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	12 (37.5)	3 (9.4)	3 (9.4)	3 (9.4)	3 (9.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	6 (18.8)	2 (6.3)	1 (3.1)	1 (3.1)	2 (6.3)
White blood cell count decreased	5 (15.6)	2 (6.3)	0	3 (9.4)	0
Lymphocyte count decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Platelet count decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Blood thyroid stimulating hormone increased	1 (3.1)	1 (3.1)	0	0	0
Blood uric acid increased	1 (3.1)	0	0	0	1 (3.1)
Weight increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	7 (21.9)	2 (6.3)	1 (3.1)	2 (6.3)	2 (6.3)
Hyperuricaemia	2 (6.3)	2 (6.3)	0	0	0
Hypokalaemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Decreased appetite	1 (3.1)	1 (3.1)	0	0	0
Hyperchloraemia	1 (3.1)	1 (3.1)	0	0	0
Hypophagia	1 (3.1)	0	1 (3.1)	0	0
Malnutrition	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (3.1)	0	0	0	1 (3.1)
Metabolic syndrome	1 (3.1)	0	1 (3.1)	0	0
Tumour lysis syndrome	1 (3.1)	0	0	0	1 (3.1)
Musculoskeletal and connective tissue disorders					
-Total	6 (18.8)	1 (3.1)	4 (12.5)	1 (3.1)	0
Back pain	2 (6.3)	0	2 (6.3)	0	0
Pain in extremity	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Bone pain	1 (3.1)	0	1 (3.1)	0	0
Musculoskeletal pain	1 (3.1)	0	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.1)	0	0	1 (3.1)	0
Myelodysplastic syndrome	1 (3.1)	0	0	1 (3.1)	0
Nervous system disorders					
-Total	8 (25.0)	4 (12.5)	4 (12.5)	0	0
Headache	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Extrapyramidal disorder	1 (3.1)	0	1 (3.1)	0	0
Migraine	1 (3.1)	0	1 (3.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Anxiety	2 (6.3)	0	2 (6.3)	0	0
Mental status changes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Renal and urinary disorders					
-Total	1 (3.1)	0	0	0	1 (3.1)
Acute kidney injury	1 (3.1)	0	0	0	1 (3.1)
Reproductive system and breast disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Dysmenorrhoea	1 (3.1)	0	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (37.5)	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)
Cough	6 (18.8)	4 (12.5)	2 (6.3)	0	0
Nasal congestion	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rhinorrhoea	3 (9.4)	3 (9.4)	0	0	0
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute respiratory distress syndrome	1 (3.1)	0	0	0	1 (3.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchial oedema	1 (3.1)	1 (3.1)	0	0	0
Dyspnoea	1 (3.1)	0	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0	1 (3.1)	0
Oropharyngeal pain	1 (3.1)	1 (3.1)	0	0	0
Rhinitis allergic	1 (3.1)	0	1 (3.1)	0	0
Upper respiratory tract inflammation	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (31.3)	6 (18.8)	3 (9.4)	1 (3.1)	0
Dry skin	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Decubitus ulcer	1 (3.1)	0	0	1 (3.1)	0
Dermatitis atopic	1 (3.1)	1 (3.1)	0	0	0
Eczema	1 (3.1)	1 (3.1)	0	0	0
Hangnail	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Pruritus	1 (3.1)	0	1 (3.1)	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Skin hypopigmentation	1 (3.1)	1 (3.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	2 (6.3)	0	0	0	2 (6.3)
Hypotension	2 (6.3)	0	0	0	2 (6.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (65.5)	2 (6.9)	7 (24.1)	6 (20.7)	4 (13.8)
Blood and lymphatic system disorders					
-Total	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Agranulocytosis	1 (3.4)	0	0	1 (3.4)	0
Anaemia	1 (3.4)	0	1 (3.4)	0	0
Hypercoagulation	1 (3.4)	0	1 (3.4)	0	0
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Congenital, familial and genetic disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral cavernous malformation	1 (3.4)	1 (3.4)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Deafness unilateral	1 (3.4)	0	1 (3.4)	0	0
Endocrine disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Delayed puberty	1 (3.4)	0	1 (3.4)	0	0
Hypothyroidism	1 (3.4)	0	1 (3.4)	0	0
Eye disorders					
-Total	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Dry eye	1 (3.4)	1 (3.4)	0	0	0
Eye pain	1 (3.4)	0	0	1 (3.4)	0
Eyelid oedema	1 (3.4)	1 (3.4)	0	0	0
Mydriasis	1 (3.4)	0	1 (3.4)	0	0
Gastrointestinal disorders					
-Total	4 (13.8)	1 (3.4)	2 (6.9)	1 (3.4)	0
Diarrhoea	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (3.4)	0	1 (3.4)	0	0
Nausea	1 (3.4)	1 (3.4)	0	0	0
Vomiting	1 (3.4)	1 (3.4)	0	0	0
General disorders and administration site conditions					
-Total	7 (24.1)	2 (6.9)	3 (10.3)	1 (3.4)	1 (3.4)
Pyrexia	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Fatigue	1 (3.4)	0	1 (3.4)	0	0
Multiple organ dysfunction syndrome	1 (3.4)	0	0	0	1 (3.4)
Non-cardiac chest pain	1 (3.4)	1 (3.4)	0	0	0
Pain	1 (3.4)	0	1 (3.4)	0	0
Xerosis	1 (3.4)	1 (3.4)	0	0	0
Immune system disorders					
-Total	4 (13.8)	2 (6.9)	1 (3.4)	0	1 (3.4)
Chronic graft versus host disease	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Seasonal allergy	2 (6.9)	2 (6.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (3.4)	0	0	0	1 (3.4)
Infections and infestations					
-Total	13 (44.8)	2 (6.9)	2 (6.9)	7 (24.1)	2 (6.9)
Conjunctivitis	4 (13.8)	2 (6.9)	2 (6.9)	0	0
Covid-19	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Influenza	2 (6.9)	0	1 (3.4)	0	1 (3.4)
Oral herpes	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Pneumonia	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Rhinovirus infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Sepsis	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Skin infection	2 (6.9)	0	2 (6.9)	0	0
Upper respiratory tract infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Acute sinusitis	1 (3.4)	0	1 (3.4)	0	0
Candida infection	1 (3.4)	0	1 (3.4)	0	0
Clostridium difficile colitis	1 (3.4)	0	0	1 (3.4)	0
Covid-19 pneumonia	1 (3.4)	0	0	0	1 (3.4)

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (3.4)	0	0	1 (3.4)	0
Enterovirus infection	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis escherichia coli	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis salmonella	1 (3.4)	0	0	1 (3.4)	0
Herpes virus infection	1 (3.4)	0	1 (3.4)	0	0
Herpes zoster	1 (3.4)	0	1 (3.4)	0	0
Ophthalmic herpes zoster	1 (3.4)	0	1 (3.4)	0	0
Otitis media	1 (3.4)	0	1 (3.4)	0	0
Otitis media acute	1 (3.4)	0	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	0	0	1 (3.4)	0
Rhinitis	1 (3.4)	1 (3.4)	0	0	0
Staphylococcal abscess	1 (3.4)	0	0	1 (3.4)	0
Staphylococcal bacteraemia	1 (3.4)	0	0	1 (3.4)	0
Streptococcal sepsis	1 (3.4)	0	1 (3.4)	0	0
Syphilis	1 (3.4)	0	1 (3.4)	0	0
Viral skin infection	1 (3.4)	1 (3.4)	0	0	0
Injury, poisoning and procedural complications					

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.4)	0	0	1 (3.4)	0
Infusion related reaction	1 (3.4)	0	0	1 (3.4)	0
Investigations					
-Total	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Blood bilirubin increased	1 (3.4)	1 (3.4)	0	0	0
Blood immunoglobulin g decreased	1 (3.4)	0	1 (3.4)	0	0
Neutrophil count decreased	1 (3.4)	1 (3.4)	0	0	0
Oxygen saturation decreased	1 (3.4)	0	0	1 (3.4)	0
Platelet count decreased	1 (3.4)	1 (3.4)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Decreased appetite	1 (3.4)	0	0	0	1 (3.4)
Hyperglycaemia	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (13.8)	2 (6.9)	2 (6.9)	0	0
Arthralgia	1 (3.4)	0	1 (3.4)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (3.4)	1 (3.4)	0	0	0
Osteopenia	1 (3.4)	1 (3.4)	0	0	0
Pain in extremity	1 (3.4)	0	1 (3.4)	0	0
Nervous system disorders					
-Total	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Dysarthria	1 (3.4)	0	1 (3.4)	0	0
Headache	1 (3.4)	0	0	1 (3.4)	0
Psychiatric disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Anxiety	1 (3.4)	0	1 (3.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (17.2)	2 (6.9)	1 (3.4)	0	2 (6.9)
Cough	4 (13.8)	3 (10.3)	1 (3.4)	0	0
Dyspnoea	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Rhinorrhoea	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Laryngeal oedema	1 (3.4)	0	0	0	1 (3.4)
Oropharyngeal pain	1 (3.4)	1 (3.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	1 (3.4)	0	1 (3.4)	0	0
Sleep apnoea syndrome	1 (3.4)	1 (3.4)	0	0	0
Tachypnoea	1 (3.4)	0	0	0	1 (3.4)
Skin and subcutaneous tissue disorders					
-Total	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Dermatitis atopic	1 (3.4)	0	0	1 (3.4)	0
Eczema	1 (3.4)	0	0	1 (3.4)	0
Papule	1 (3.4)	1 (3.4)	0	0	0
Vascular disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Hypertension	1 (3.4)	0	0	1 (3.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (61.9)	1 (4.8)	3 (14.3)	6 (28.6)	3 (14.3)
Blood and lymphatic system disorders					
-Total	2 (9.5)	0	1 (4.8)	0	1 (4.8)
Lymphadenopathy	1 (4.8)	0	1 (4.8)	0	0
Neutropenia	1 (4.8)	0	0	0	1 (4.8)
Gastrointestinal disorders					
-Total	3 (14.3)	3 (14.3)	0	0	0
Diarrhoea	2 (9.5)	2 (9.5)	0	0	0
Constipation	1 (4.8)	1 (4.8)	0	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (9.5)	2 (9.5)	0	0	0
Pyrexia	2 (9.5)	2 (9.5)	0	0	0
Pain	1 (4.8)	1 (4.8)	0	0	0
Immune system disorders					
-Total	5 (23.8)	0	4 (19.0)	1 (4.8)	0
Hypogammaglobulinaemia	3 (14.3)	0	3 (14.3)	0	0
Drug hypersensitivity	1 (4.8)	0	0	1 (4.8)	0
Seasonal allergy	1 (4.8)	0	1 (4.8)	0	0
Infections and infestations					
-Total	10 (47.6)	0	5 (23.8)	3 (14.3)	2 (9.5)
Sinusitis	4 (19.0)	0	4 (19.0)	0	0
Upper respiratory tract infection	3 (14.3)	1 (4.8)	2 (9.5)	0	0
Bronchitis	2 (9.5)	0	2 (9.5)	0	0
Fungal infection	2 (9.5)	0	2 (9.5)	0	0
Rhinovirus infection	2 (9.5)	0	2 (9.5)	0	0
Urinary tract infection	2 (9.5)	0	2 (9.5)	0	0
Bronchiolitis	1 (4.8)	0	0	1 (4.8)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (4.8)	0	0	1 (4.8)	0
Folliculitis	1 (4.8)	0	1 (4.8)	0	0
Fungal skin infection	1 (4.8)	0	1 (4.8)	0	0
Gastroenteritis	1 (4.8)	1 (4.8)	0	0	0
Gastroenteritis viral	1 (4.8)	0	1 (4.8)	0	0
Herpes zoster	1 (4.8)	0	0	1 (4.8)	0
Meningitis pneumococcal	1 (4.8)	0	0	1 (4.8)	0
Nail infection	1 (4.8)	0	1 (4.8)	0	0
Neutropenic infection	1 (4.8)	0	0	1 (4.8)	0
Oral candidiasis	1 (4.8)	0	1 (4.8)	0	0
Otitis media	1 (4.8)	0	1 (4.8)	0	0
Pneumonia respiratory syncytial viral	1 (4.8)	0	0	1 (4.8)	0
Sepsis	1 (4.8)	0	0	0	1 (4.8)
Septic shock	1 (4.8)	0	0	0	1 (4.8)
Skin infection	1 (4.8)	0	1 (4.8)	0	0
Urinary tract infection pseudomonal	1 (4.8)	0	1 (4.8)	0	0
Varicella zoster virus infection	1 (4.8)	0	1 (4.8)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (9.5)	2 (9.5)	0	0	0
Abdominal injury	1 (4.8)	1 (4.8)	0	0	0
Ligament sprain	1 (4.8)	1 (4.8)	0	0	0
Investigations					
-Total	3 (14.3)	2 (9.5)	0	0	1 (4.8)
Neutrophil count decreased	2 (9.5)	1 (4.8)	0	0	1 (4.8)
Platelet count decreased	1 (4.8)	1 (4.8)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (19.0)	0	2 (9.5)	2 (9.5)	0
Hypercholesterolaemia	1 (4.8)	0	1 (4.8)	0	0
Hyperlipidaemia	1 (4.8)	0	1 (4.8)	0	0
Hypernatraemia	1 (4.8)	0	0	1 (4.8)	0
Hypertriglyceridaemia	1 (4.8)	0	1 (4.8)	0	0
Iron overload	1 (4.8)	0	1 (4.8)	0	0
Obesity	1 (4.8)	0	0	1 (4.8)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (14.3)	0	3 (14.3)	0	0
Growth retardation	1 (4.8)	0	1 (4.8)	0	0
Joint effusion	1 (4.8)	0	1 (4.8)	0	0
Pain in extremity	1 (4.8)	0	1 (4.8)	0	0
Synovitis	1 (4.8)	0	1 (4.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.8)	0	0	1 (4.8)	0
Bone giant cell tumour benign	1 (4.8)	0	0	1 (4.8)	0
Nervous system disorders					
-Total	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Headache	1 (4.8)	0	1 (4.8)	0	0
Nervous system disorder	1 (4.8)	0	0	1 (4.8)	0
Seizure	1 (4.8)	0	0	1 (4.8)	0
Psychiatric disorders					
-Total	2 (9.5)	1 (4.8)	1 (4.8)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (4.8)	1 (4.8)	0	0	0
Tic	1 (4.8)	0	1 (4.8)	0	0
Reproductive system and breast disorders					
-Total	1 (4.8)	0	0	1 (4.8)	0
Endometriosis	1 (4.8)	0	0	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (23.8)	2 (9.5)	1 (4.8)	1 (4.8)	1 (4.8)
Dyspnoea	1 (4.8)	0	1 (4.8)	0	0
Dyspnoea exertional	1 (4.8)	1 (4.8)	0	0	0
Epistaxis	1 (4.8)	1 (4.8)	0	0	0
Hypoxia	1 (4.8)	0	0	1 (4.8)	0
Pharyngeal erythema	1 (4.8)	1 (4.8)	0	0	0
Respiratory failure	1 (4.8)	0	0	0	1 (4.8)
Rhinorrhoea	1 (4.8)	0	1 (4.8)	0	0
Sleep apnoea syndrome	1 (4.8)	0	1 (4.8)	0	0
Wheezing	1 (4.8)	0	1 (4.8)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	4 (19.0)	2 (9.5)	1 (4.8)	1 (4.8)	0
Rash	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Dry skin	1 (4.8)	1 (4.8)	0	0	0
Rash erythematous	1 (4.8)	1 (4.8)	0	0	0
Rash macular	1 (4.8)	0	0	1 (4.8)	0
Rash maculo-papular	1 (4.8)	1 (4.8)	0	0	0
Vascular disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Hypertension	1 (4.8)	0	1 (4.8)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (100)	1 (2.2)	4 (8.7)	11 (23.9)	30 (65.2)
Blood and lymphatic system disorders					
-Total	27 (58.7)	0	9 (19.6)	11 (23.9)	7 (15.2)
Febrile neutropenia	12 (26.1)	0	0	12 (26.1)	0
Anaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Disseminated intravascular coagulation	6 (13.0)	0	5 (10.9)	1 (2.2)	0
Thrombocytopenia	6 (13.0)	0	0	1 (2.2)	5 (10.9)
Neutropenia	4 (8.7)	0	1 (2.2)	0	3 (6.5)
Coagulopathy	2 (4.3)	0	2 (4.3)	0	0
Leukopenia	2 (4.3)	0	1 (2.2)	0	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (4.3)	0	0	2 (4.3)	0
Splenomegaly	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Agranulocytosis	1 (2.2)	0	0	1 (2.2)	0
Eosinophilia	1 (2.2)	0	1 (2.2)	0	0
Hypercoagulation	1 (2.2)	0	1 (2.2)	0	0
Leukocytosis	1 (2.2)	0	1 (2.2)	0	0
Lymphadenopathy	1 (2.2)	1 (2.2)	0	0	0
Lymphocytosis	1 (2.2)	0	1 (2.2)	0	0
Pancytopenia	1 (2.2)	0	0	1 (2.2)	0
Cardiac disorders					
-Total	13 (28.3)	4 (8.7)	4 (8.7)	4 (8.7)	1 (2.2)
Tachycardia	9 (19.6)	3 (6.5)	4 (8.7)	2 (4.3)	0
Left ventricular dysfunction	3 (6.5)	0	1 (2.2)	2 (4.3)	0
Bradycardia	2 (4.3)	2 (4.3)	0	0	0
Atrioventricular block first degree	1 (2.2)	0	1 (2.2)	0	0
Cardiac arrest	1 (2.2)	0	0	0	1 (2.2)
Cardiac dysfunction	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (2.2)	0	0	1 (2.2)	0
Cardiac failure congestive	1 (2.2)	0	1 (2.2)	0	0
Mitral valve incompetence	1 (2.2)	1 (2.2)	0	0	0
Pericardial effusion	1 (2.2)	1 (2.2)	0	0	0
Right ventricular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Tricuspid valve incompetence	1 (2.2)	1 (2.2)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.2)	1 (2.2)	0	0	0
Cerebral cavernous malformation	1 (2.2)	1 (2.2)	0	0	0
Ear and labyrinth disorders					
-Total	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Deafness unilateral	1 (2.2)	0	1 (2.2)	0	0
Ear pain	1 (2.2)	1 (2.2)	0	0	0
Endocrine disorders					
-Total	3 (6.5)	0	3 (6.5)	0	0
Hypothyroidism	2 (4.3)	0	2 (4.3)	0	0
Adrenal insufficiency	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delayed puberty	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	10 (21.7)	7 (15.2)	2 (4.3)	1 (2.2)	0
Cataract	2 (4.3)	2 (4.3)	0	0	0
Eye pain	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Eyelid oedema	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Ocular hyperaemia	2 (4.3)	2 (4.3)	0	0	0
Visual impairment	2 (4.3)	2 (4.3)	0	0	0
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Dry eye	1 (2.2)	1 (2.2)	0	0	0
Eye oedema	1 (2.2)	1 (2.2)	0	0	0
Hypermetropia	1 (2.2)	1 (2.2)	0	0	0
Mydriasis	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	35 (76.1)	11 (23.9)	14 (30.4)	9 (19.6)	1 (2.2)
Vomiting	15 (32.6)	12 (26.1)	3 (6.5)	0	0
Diarrhoea	14 (30.4)	8 (17.4)	4 (8.7)	2 (4.3)	0
Nausea	14 (30.4)	8 (17.4)	5 (10.9)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Abdominal pain	6 (13.0)	0	4 (8.7)	2 (4.3)	0
Pancreatitis	4 (8.7)	0	2 (4.3)	2 (4.3)	0
Abdominal pain upper	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Gastrointestinal sounds abnormal	2 (4.3)	2 (4.3)	0	0	0
Mouth haemorrhage	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Trichoglossia	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Abdominal compartment syndrome	1 (2.2)	0	0	0	1 (2.2)
Abdominal distension	1 (2.2)	0	1 (2.2)	0	0
Anal fissure	1 (2.2)	0	1 (2.2)	0	0
Ascites	1 (2.2)	1 (2.2)	0	0	0
Dry mouth	1 (2.2)	0	1 (2.2)	0	0
Enteritis	1 (2.2)	0	1 (2.2)	0	0
Enterocolitis	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal inflammation	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrooesophageal reflux disease	1 (2.2)	0	1 (2.2)	0	0
Haematemesis	1 (2.2)	1 (2.2)	0	0	0
Irritable bowel syndrome	1 (2.2)	0	1 (2.2)	0	0
Mouth swelling	1 (2.2)	1 (2.2)	0	0	0
Neutropenic colitis	1 (2.2)	0	0	1 (2.2)	0
Odynophagia	1 (2.2)	1 (2.2)	0	0	0
Peritoneal haematoma	1 (2.2)	1 (2.2)	0	0	0
Proctalgia	1 (2.2)	0	0	1 (2.2)	0
Upper gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	28 (60.9)	11 (23.9)	9 (19.6)	5 (10.9)	3 (6.5)
Pyrexia	19 (41.3)	6 (13.0)	7 (15.2)	4 (8.7)	2 (4.3)
Fatigue	11 (23.9)	8 (17.4)	3 (6.5)	0	0
Face oedema	4 (8.7)	3 (6.5)	0	1 (2.2)	0
Chills	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Oedema peripheral	3 (6.5)	2 (4.3)	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Asthenia	2 (4.3)	2 (4.3)	0	0	0
Pain	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Catheter site erythema	1 (2.2)	1 (2.2)	0	0	0
Catheter site pain	1 (2.2)	1 (2.2)	0	0	0
Chest discomfort	1 (2.2)	0	0	1 (2.2)	0
Generalised oedema	1 (2.2)	0	1 (2.2)	0	0
Localised oedema	1 (2.2)	1 (2.2)	0	0	0
Malaise	1 (2.2)	1 (2.2)	0	0	0
Multiple organ dysfunction syndrome	1 (2.2)	0	0	0	1 (2.2)
Non-cardiac chest pain	1 (2.2)	1 (2.2)	0	0	0
Oedema due to hepatic disease	1 (2.2)	0	1 (2.2)	0	0
Vascular device occlusion	1 (2.2)	1 (2.2)	0	0	0
Xerosis	1 (2.2)	1 (2.2)	0	0	0
Hepatobiliary disorders					
-Total	10 (21.7)	5 (10.9)	3 (6.5)	1 (2.2)	1 (2.2)
Hepatic function abnormal	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Hepatomegaly	2 (4.3)	2 (4.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	2 (4.3)	0	2 (4.3)	0	0
Biliary tract disorder	1 (2.2)	1 (2.2)	0	0	0
Gallbladder enlargement	1 (2.2)	1 (2.2)	0	0	0
Hepatic cytolysis	1 (2.2)	1 (2.2)	0	0	0
Hypertransaminasaemia	1 (2.2)	1 (2.2)	0	0	0
Liver disorder	1 (2.2)	0	1 (2.2)	0	0
Ocular icterus	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	39 (84.8)	1 (2.2)	13 (28.3)	13 (28.3)	12 (26.1)
Cytokine release syndrome	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Hypogammaglobulinaemia	17 (37.0)	1 (2.2)	13 (28.3)	3 (6.5)	0
Haemophagocytic lymphohistiocytosis	4 (8.7)	1 (2.2)	0	2 (4.3)	1 (2.2)
Immunodeficiency	3 (6.5)	0	0	3 (6.5)	0
Chronic graft versus host disease	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Graft versus host disease	2 (4.3)	0	0	2 (4.3)	0
Seasonal allergy	2 (4.3)	2 (4.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	1 (2.2)	1 (2.2)	0	0	0
Drug hypersensitivity	1 (2.2)	0	1 (2.2)	0	0
Engraftment syndrome	1 (2.2)	0	0	1 (2.2)	0
Hypersensitivity	1 (2.2)	1 (2.2)	0	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Infections and infestations					
-Total	36 (78.3)	7 (15.2)	8 (17.4)	15 (32.6)	6 (13.0)
Upper respiratory tract infection	8 (17.4)	4 (8.7)	2 (4.3)	2 (4.3)	0
Conjunctivitis	6 (13.0)	2 (4.3)	4 (8.7)	0	0
Pneumonia	6 (13.0)	1 (2.2)	1 (2.2)	2 (4.3)	2 (4.3)
Nasopharyngitis	5 (10.9)	3 (6.5)	2 (4.3)	0	0
Rhinovirus infection	4 (8.7)	0	3 (6.5)	1 (2.2)	0
Candida infection	3 (6.5)	0	3 (6.5)	0	0
Clostridium difficile infection	3 (6.5)	1 (2.2)	0	2 (4.3)	0
Influenza	3 (6.5)	0	2 (4.3)	0	1 (2.2)
Metapneumovirus infection	3 (6.5)	0	0	3 (6.5)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Otitis media	3 (6.5)	0	3 (6.5)	0	0
Parainfluenzae virus infection	3 (6.5)	1 (2.2)	0	1 (2.2)	1 (2.2)
Staphylococcal bacteraemia	3 (6.5)	0	0	3 (6.5)	0
Staphylococcal infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Bk virus infection	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Covid-19	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Ear infection	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Gastroenteritis	2 (4.3)	2 (4.3)	0	0	0
Gingivitis	2 (4.3)	2 (4.3)	0	0	0
Herpes zoster	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Nail infection	2 (4.3)	2 (4.3)	0	0	0
Oral infection	2 (4.3)	0	2 (4.3)	0	0
Otitis externa	2 (4.3)	0	2 (4.3)	0	0
Paronychia	2 (4.3)	0	2 (4.3)	0	0
Pneumocystis jirovecii pneumonia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Respiratory syncytial virus infection	2 (4.3)	0	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Rhinitis	2 (4.3)	2 (4.3)	0	0	0
Sepsis	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Sinusitis	2 (4.3)	0	2 (4.3)	0	0
Skin infection	2 (4.3)	0	2 (4.3)	0	0
Viral infection	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Adenovirus infection	1 (2.2)	0	0	1 (2.2)	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Cellulitis	1 (2.2)	0	1 (2.2)	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Coronavirus infection	1 (2.2)	0	0	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	0	0	1 (2.2)
Cytomegalovirus infection reactivation	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.2)	0	0	1 (2.2)	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis clostridial	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis viral	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal infection	1 (2.2)	1 (2.2)	0	0	0
Herpes simplex	1 (2.2)	0	1 (2.2)	0	0
Herpes virus infection	1 (2.2)	0	1 (2.2)	0	0
Human herpesvirus 6 infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Molluscum contagiosum	1 (2.2)	1 (2.2)	0	0	0
Ophthalmic herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Pneumonia fungal	1 (2.2)	0	0	1 (2.2)	0
Salmonellosis	1 (2.2)	0	1 (2.2)	0	0
Sinusitis fungal	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Streptococcal sepsis	1 (2.2)	0	1 (2.2)	0	0
Syphilis	1 (2.2)	0	1 (2.2)	0	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Viral haemorrhagic cystitis	1 (2.2)	0	0	1 (2.2)	0
Viral skin infection	1 (2.2)	1 (2.2)	0	0	0
Injury, poisoning and procedural complications					
-Total	9 (19.6)	5 (10.9)	3 (6.5)	1 (2.2)	0
Infusion related reaction	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Transfusion reaction	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Contusion	1 (2.2)	1 (2.2)	0	0	0
Fall	1 (2.2)	0	1 (2.2)	0	0
Fibula fracture	1 (2.2)	0	1 (2.2)	0	0
Ligament sprain	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scratch	1 (2.2)	1 (2.2)	0	0	0
Skin abrasion	1 (2.2)	1 (2.2)	0	0	0
Investigations					
-Total	32 (69.6)	1 (2.2)	7 (15.2)	11 (23.9)	13 (28.3)
Alanine aminotransferase increased	13 (28.3)	3 (6.5)	6 (13.0)	4 (8.7)	0
Aspartate aminotransferase increased	12 (26.1)	1 (2.2)	5 (10.9)	4 (8.7)	2 (4.3)
Neutrophil count decreased	12 (26.1)	1 (2.2)	0	2 (4.3)	9 (19.6)
Platelet count decreased	12 (26.1)	2 (4.3)	2 (4.3)	5 (10.9)	3 (6.5)
White blood cell count decreased	12 (26.1)	1 (2.2)	2 (4.3)	1 (2.2)	8 (17.4)
Blood bilirubin increased	9 (19.6)	0	2 (4.3)	7 (15.2)	0
Lymphocyte count decreased	7 (15.2)	0	0	4 (8.7)	3 (6.5)
Serum ferritin increased	6 (13.0)	1 (2.2)	4 (8.7)	1 (2.2)	0
Activated partial thromboplastin time prolonged	4 (8.7)	2 (4.3)	1 (2.2)	1 (2.2)	0
Blood fibrinogen decreased	4 (8.7)	1 (2.2)	2 (4.3)	0	1 (2.2)
Blood immunoglobulin a decreased	4 (8.7)	2 (4.3)	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	4 (8.7)	3 (6.5)	1 (2.2)	0	0
Blood creatinine increased	3 (6.5)	0	1 (2.2)	2 (4.3)	0
Blood immunoglobulin m decreased	3 (6.5)	1 (2.2)	0	2 (4.3)	0
C-reactive protein increased	3 (6.5)	2 (4.3)	0	1 (2.2)	0
International normalised ratio increased	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Oxygen saturation decreased	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin g decreased	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Blood uric acid increased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Electrocardiogram qt prolonged	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Fibrin d dimer increased	2 (4.3)	2 (4.3)	0	0	0
Gamma-glutamyltransferase increased	2 (4.3)	0	0	2 (4.3)	0
Immunoglobulins decreased	2 (4.3)	0	2 (4.3)	0	0
Weight increased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Amylase increased	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial test positive	1 (2.2)	0	0	1 (2.2)	0
Blood creatine phosphokinase increased	1 (2.2)	0	0	1 (2.2)	0
Blood testosterone decreased	1 (2.2)	1 (2.2)	0	0	0
Blood urea increased	1 (2.2)	0	0	1 (2.2)	0
Bone density decreased	1 (2.2)	1 (2.2)	0	0	0
Coagulation test abnormal	1 (2.2)	1 (2.2)	0	0	0
Ejection fraction decreased	1 (2.2)	0	1 (2.2)	0	0
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Heart sounds abnormal	1 (2.2)	1 (2.2)	0	0	0
Hepatitis b virus test positive	1 (2.2)	0	1 (2.2)	0	0
Lipase increased	1 (2.2)	1 (2.2)	0	0	0
Prothrombin time prolonged	1 (2.2)	0	1 (2.2)	0	0
Staphylococcus test positive	1 (2.2)	1 (2.2)	0	0	0
Urine output decreased	1 (2.2)	0	0	1 (2.2)	0
Weight decreased	1 (2.2)	0	0	1 (2.2)	0
Metabolism and nutrition disorders					
-Total	28 (60.9)	5 (10.9)	8 (17.4)	9 (19.6)	6 (13.0)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	15 (32.6)	4 (8.7)	6 (13.0)	3 (6.5)	2 (4.3)
Hypocalcaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Hypokalaemia	9 (19.6)	1 (2.2)	3 (6.5)	4 (8.7)	1 (2.2)
Hypophosphataemia	8 (17.4)	3 (6.5)	2 (4.3)	2 (4.3)	1 (2.2)
Hyperuricaemia	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Hyperglycaemia	4 (8.7)	0	0	4 (8.7)	0
Hypoalbuminaemia	4 (8.7)	0	4 (8.7)	0	0
Hypervolaemia	3 (6.5)	0	1 (2.2)	2 (4.3)	0
Hypomagnesaemia	3 (6.5)	3 (6.5)	0	0	0
Tumour lysis syndrome	3 (6.5)	0	0	3 (6.5)	0
Hyperkalaemia	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Hyperphosphataemia	2 (4.3)	2 (4.3)	0	0	0
Hypertriglyceridaemia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Metabolic acidosis	2 (4.3)	1 (2.2)	0	0	1 (2.2)
Dehydration	1 (2.2)	0	1 (2.2)	0	0
Haemochromatosis	1 (2.2)	0	0	1 (2.2)	0
Hypercalcaemia	1 (2.2)	0	0	1 (2.2)	0
Hypermagnesaemia	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (2.2)	1 (2.2)	0	0	0
Iron overload	1 (2.2)	0	1 (2.2)	0	0
Malnutrition	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	23 (50.0)	10 (21.7)	11 (23.9)	2 (4.3)	0
Pain in extremity	10 (21.7)	4 (8.7)	6 (13.0)	0	0
Arthralgia	9 (19.6)	4 (8.7)	5 (10.9)	0	0
Back pain	5 (10.9)	1 (2.2)	2 (4.3)	2 (4.3)	0
Myalgia	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Bone pain	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Growth retardation	1 (2.2)	0	1 (2.2)	0	0
Muscle spasms	1 (2.2)	0	1 (2.2)	0	0
Muscular weakness	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal chest pain	1 (2.2)	1 (2.2)	0	0	0
Neck pain	1 (2.2)	1 (2.2)	0	0	0
Osteonecrosis	1 (2.2)	1 (2.2)	0	0	0
Osteopenia	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	1 (2.2)	1 (2.2)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Skin papilloma	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Cancer pain	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorders					
-Total	24 (52.2)	11 (23.9)	5 (10.9)	4 (8.7)	4 (8.7)
Headache	12 (26.1)	7 (15.2)	2 (4.3)	3 (6.5)	0
Encephalopathy	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Dizziness	3 (6.5)	3 (6.5)	0	0	0
Cerebral haemorrhage	2 (4.3)	0	0	0	2 (4.3)
Dysarthria	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Dysgeusia	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Somnolence	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Autonomic neuropathy	1 (2.2)	0	0	1 (2.2)	0
Cognitive disorder	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Hydrocephalus	1 (2.2)	0	0	0	1 (2.2)
Hypoaesthesia	1 (2.2)	1 (2.2)	0	0	0
Lethargy	1 (2.2)	1 (2.2)	0	0	0
Memory impairment	1 (2.2)	0	1 (2.2)	0	0
Neuralgia	1 (2.2)	0	1 (2.2)	0	0
Neurological decompensation	1 (2.2)	0	0	0	1 (2.2)
Seizure	1 (2.2)	0	0	1 (2.2)	0
Psychiatric disorders					
-Total	21 (45.7)	7 (15.2)	12 (26.1)	2 (4.3)	0
Anxiety	8 (17.4)	1 (2.2)	7 (15.2)	0	0
Delirium	6 (13.0)	2 (4.3)	2 (4.3)	2 (4.3)	0
Confusional state	4 (8.7)	4 (8.7)	0	0	0
Agitation	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Insomnia	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Sleep disorder	2 (4.3)	0	2 (4.3)	0	0
Hallucination	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (2.2)	1 (2.2)	0	0	0
Mental status changes	1 (2.2)	0	1 (2.2)	0	0
Mood altered	1 (2.2)	1 (2.2)	0	0	0
Nightmare	1 (2.2)	1 (2.2)	0	0	0
Persistent depressive disorder	1 (2.2)	0	1 (2.2)	0	0
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Tearfulness	1 (2.2)	1 (2.2)	0	0	0
Renal and urinary disorders					
-Total	14 (30.4)	5 (10.9)	4 (8.7)	2 (4.3)	3 (6.5)
Acute kidney injury	5 (10.9)	2 (4.3)	1 (2.2)	0	2 (4.3)
Dysuria	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Haematuria	3 (6.5)	2 (4.3)	0	1 (2.2)	0
Renal failure	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Cystitis haemorrhagic	1 (2.2)	0	1 (2.2)	0	0
Incontinence	1 (2.2)	0	1 (2.2)	0	0
Kidney enlargement	1 (2.2)	0	1 (2.2)	0	0
Proteinuria	1 (2.2)	1 (2.2)	0	0	0
Renal mass	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular disorder	1 (2.2)	0	0	1 (2.2)	0
Renal tubular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Urinary tract disorder	1 (2.2)	0	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (60.9)	9 (19.6)	6 (13.0)	3 (6.5)	10 (21.7)
Cough	13 (28.3)	11 (23.9)	2 (4.3)	0	0
Hypoxia	11 (23.9)	0	3 (6.5)	4 (8.7)	4 (8.7)
Pleural effusion	8 (17.4)	3 (6.5)	2 (4.3)	2 (4.3)	1 (2.2)
Pulmonary oedema	6 (13.0)	1 (2.2)	2 (4.3)	2 (4.3)	1 (2.2)
Nasal congestion	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Oropharyngeal pain	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Tachypnoea	4 (8.7)	2 (4.3)	0	1 (2.2)	1 (2.2)
Dyspnoea	3 (6.5)	1 (2.2)	0	1 (2.2)	1 (2.2)
Respiratory distress	3 (6.5)	0	1 (2.2)	0	2 (4.3)
Respiratory failure	3 (6.5)	0	0	0	3 (6.5)
Epistaxis	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Rhinorrhoea	2 (4.3)	1 (2.2)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	1 (2.2)	0	0	1 (2.2)	0
Bradypnoea	1 (2.2)	0	0	1 (2.2)	0
Bronchospasm	1 (2.2)	0	1 (2.2)	0	0
Laryngeal oedema	1 (2.2)	0	0	0	1 (2.2)
Lung disorder	1 (2.2)	1 (2.2)	0	0	0
Lung infiltration	1 (2.2)	0	0	1 (2.2)	0
Painful respiration	1 (2.2)	1 (2.2)	0	0	0
Paranasal sinus inflammation	1 (2.2)	1 (2.2)	0	0	0
Productive cough	1 (2.2)	1 (2.2)	0	0	0
Respiratory disorder	1 (2.2)	0	1 (2.2)	0	0
Rhinitis allergic	1 (2.2)	1 (2.2)	0	0	0
Sleep apnoea syndrome	1 (2.2)	1 (2.2)	0	0	0
Wheezing	1 (2.2)	0	1 (2.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (43.5)	8 (17.4)	9 (19.6)	3 (6.5)	0
Pruritus	4 (8.7)	1 (2.2)	3 (6.5)	0	0
Rash	4 (8.7)	2 (4.3)	2 (4.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Blister	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Dermatitis atopic	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Dry skin	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Skin discolouration	2 (4.3)	2 (4.3)	0	0	0
Dermatitis	1 (2.2)	1 (2.2)	0	0	0
Dermatitis allergic	1 (2.2)	1 (2.2)	0	0	0
Eczema	1 (2.2)	0	0	1 (2.2)	0
Erythema nodosum	1 (2.2)	1 (2.2)	0	0	0
Ingrowing nail	1 (2.2)	0	1 (2.2)	0	0
Miliaria	1 (2.2)	1 (2.2)	0	0	0
Night sweats	1 (2.2)	1 (2.2)	0	0	0
Papule	1 (2.2)	1 (2.2)	0	0	0
Photosensitivity reaction	1 (2.2)	0	1 (2.2)	0	0
Pruritus allergic	1 (2.2)	0	1 (2.2)	0	0
Scab	1 (2.2)	1 (2.2)	0	0	0
Skin swelling	1 (2.2)	1 (2.2)	0	0	0
Skin ulcer	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urticaria	1 (2.2)	0	1 (2.2)	0	0
Vancomycin infusion reaction	1 (2.2)	0	0	1 (2.2)	0
Vascular disorders					
-Total	20 (43.5)	3 (6.5)	6 (13.0)	8 (17.4)	3 (6.5)
Hypotension	12 (26.1)	1 (2.2)	5 (10.9)	4 (8.7)	2 (4.3)
Hypertension	9 (19.6)	3 (6.5)	3 (6.5)	3 (6.5)	0
Capillary leak syndrome	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Venoocclusive disease	2 (4.3)	0	0	1 (2.2)	1 (2.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	2 (5.9)	8 (23.5)	24 (70.6)
Blood and lymphatic system disorders					
-Total	28 (82.4)	1 (2.9)	2 (5.9)	18 (52.9)	7 (20.6)
Anaemia	16 (47.1)	5 (14.7)	5 (14.7)	6 (17.6)	0
Febrile neutropenia	15 (44.1)	0	0	13 (38.2)	2 (5.9)
Neutropenia	7 (20.6)	0	1 (2.9)	2 (5.9)	4 (11.8)
Coagulopathy	3 (8.8)	1 (2.9)	0	2 (5.9)	0
Thrombocytopenia	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Disseminated intravascular coagulation	2 (5.9)	0	0	2 (5.9)	0
Splenomegaly	2 (5.9)	2 (5.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Hypofibrinogenaemia	1 (2.9)	0	1 (2.9)	0	0
Leukopenia	1 (2.9)	0	0	1 (2.9)	0
Lymphadenopathy	1 (2.9)	0	1 (2.9)	0	0
Pancytopenia	1 (2.9)	0	0	1 (2.9)	0
Cardiac disorders					
-Total	15 (44.1)	6 (17.6)	3 (8.8)	1 (2.9)	5 (14.7)
Tachycardia	8 (23.5)	4 (11.8)	3 (8.8)	0	1 (2.9)
Sinus tachycardia	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Cardiac arrest	2 (5.9)	0	0	0	2 (5.9)
Cardiac failure	2 (5.9)	0	0	0	2 (5.9)
Bradycardia	1 (2.9)	0	1 (2.9)	0	0
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Left ventricular dysfunction	1 (2.9)	0	0	1 (2.9)	0
Sinus bradycardia	1 (2.9)	0	0	1 (2.9)	0
Ear and labyrinth disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Ear pruritus	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	4 (11.8)	0	4 (11.8)	0	0
Adrenal insufficiency	3 (8.8)	0	3 (8.8)	0	0
Hypothyroidism	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Eyelid oedema	1 (2.9)	1 (2.9)	0	0	0
Ocular hyperaemia	1 (2.9)	1 (2.9)	0	0	0
Periorbital oedema	1 (2.9)	1 (2.9)	0	0	0
Periorbital swelling	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Visual field defect	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	25 (73.5)	10 (29.4)	9 (26.5)	6 (17.6)	0
Diarrhoea	12 (35.3)	8 (23.5)	4 (11.8)	0	0
Vomiting	11 (32.4)	5 (14.7)	5 (14.7)	1 (2.9)	0
Nausea	8 (23.5)	4 (11.8)	3 (8.8)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	7 (20.6)	4 (11.8)	3 (8.8)	0	0
Abdominal pain	5 (14.7)	2 (5.9)	3 (8.8)	0	0
Mouth haemorrhage	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Stomatitis	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Abdominal distension	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Abdominal pain upper	2 (5.9)	2 (5.9)	0	0	0
Ascites	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Pancreatitis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Abdominal rigidity	1 (2.9)	0	1 (2.9)	0	0
Anal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Dyspepsia	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	0	1 (2.9)	0
Gingival bleeding	1 (2.9)	0	1 (2.9)	0	0
Gingival erythema	1 (2.9)	1 (2.9)	0	0	0
Gingivitis ulcerative	1 (2.9)	0	0	1 (2.9)	0
Ileus	1 (2.9)	0	1 (2.9)	0	0
Lip dry	1 (2.9)	0	1 (2.9)	0	0
Lip oedema	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Melaena	1 (2.9)	0	0	1 (2.9)	0
Proctalgia	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	25 (73.5)	14 (41.2)	4 (11.8)	5 (14.7)	2 (5.9)
Pyrexia	16 (47.1)	8 (23.5)	3 (8.8)	5 (14.7)	0
Fatigue	6 (17.6)	6 (17.6)	0	0	0
Chills	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Face oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Generalised oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Oedema peripheral	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Pain	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Drug withdrawal syndrome	2 (5.9)	0	2 (5.9)	0	0
Influenza like illness	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Multiple organ dysfunction syndrome	2 (5.9)	0	0	0	2 (5.9)
Asthenia	1 (2.9)	1 (2.9)	0	0	0
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Catheter site pain	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Crying	1 (2.9)	0	1 (2.9)	0	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0
Localised oedema	1 (2.9)	1 (2.9)	0	0	0
Malaise	1 (2.9)	0	1 (2.9)	0	0
Non-cardiac chest pain	1 (2.9)	1 (2.9)	0	0	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Swelling face	1 (2.9)	1 (2.9)	0	0	0
Systemic inflammatory response syndrome	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	9 (26.5)	1 (2.9)	4 (11.8)	2 (5.9)	2 (5.9)
Hepatic function abnormal	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Hyperbilirubinaemia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cholelithiasis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Cholestasis	1 (2.9)	0	0	0	1 (2.9)
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Hepatomegaly	1 (2.9)	0	0	0	1 (2.9)
Hypertransaminasaemia	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	32 (94.1)	1 (2.9)	10 (29.4)	11 (32.4)	10 (29.4)
Cytokine release syndrome	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Hypogammaglobulinaemia	16 (47.1)	1 (2.9)	11 (32.4)	4 (11.8)	0
Haemophagocytic lymphohistiocytosis	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Seasonal allergy	2 (5.9)	0	2 (5.9)	0	0
Allergy to immunoglobulin therapy	1 (2.9)	0	0	1 (2.9)	0
Drug hypersensitivity	1 (2.9)	0	0	1 (2.9)	0
Immunodeficiency	1 (2.9)	0	0	1 (2.9)	0
Infections and infestations					
-Total	24 (70.6)	1 (2.9)	5 (14.7)	10 (29.4)	8 (23.5)
Rhinovirus infection	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Sinusitis	5 (14.7)	0	3 (8.8)	2 (5.9)	0
Upper respiratory tract infection	5 (14.7)	1 (2.9)	3 (8.8)	1 (2.9)	0
Gastroenteritis	4 (11.8)	2 (5.9)	0	2 (5.9)	0
Oral candidiasis	3 (8.8)	0	3 (8.8)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Bacteraemia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Bronchitis	2 (5.9)	0	2 (5.9)	0	0
Bronchopulmonary aspergillosis	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Conjunctivitis	2 (5.9)	0	2 (5.9)	0	0
Encephalitis viral	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Fungal infection	2 (5.9)	0	2 (5.9)	0	0
Nail infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Nasopharyngitis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Otitis media	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Septic shock	2 (5.9)	0	0	0	2 (5.9)
Staphylococcal bacteraemia	2 (5.9)	0	0	2 (5.9)	0
Staphylococcal infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Bronchiolitis	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	1 (2.9)	0	0	0	1 (2.9)
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Cystitis	1 (2.9)	0	1 (2.9)	0	0
Device related sepsis	1 (2.9)	0	0	1 (2.9)	0
Ear infection	1 (2.9)	0	1 (2.9)	0	0
Ear, nose and throat infection	1 (2.9)	0	1 (2.9)	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis viral	1 (2.9)	0	1 (2.9)	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Localised infection	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Meningitis bacterial	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Pharyngitis streptococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia respiratory syncytial viral	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection viral	1 (2.9)	0	1 (2.9)	0	0
Rhinitis	1 (2.9)	0	1 (2.9)	0	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal skin infection	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Urinary tract infection pseudomonal	1 (2.9)	0	1 (2.9)	0	0
Urinary tract infection viral	1 (2.9)	1 (2.9)	0	0	0
Varicella zoster virus infection	1 (2.9)	0	1 (2.9)	0	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	12 (35.3)	4 (11.8)	6 (17.6)	0	2 (5.9)
Infusion related reaction	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Procedural pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Wound	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Abdominal injury	1 (2.9)	1 (2.9)	0	0	0
Contusion	1 (2.9)	1 (2.9)	0	0	0
Fall	1 (2.9)	0	1 (2.9)	0	0
Ligament sprain	1 (2.9)	1 (2.9)	0	0	0
Limb injury	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post-traumatic neck syndrome	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0
Skin injury	1 (2.9)	0	1 (2.9)	0	0
Skin wound	1 (2.9)	1 (2.9)	0	0	0
Transplant failure	1 (2.9)	0	0	0	1 (2.9)
Vasoplegia syndrome	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	28 (82.4)	2 (5.9)	2 (5.9)	8 (23.5)	16 (47.1)
White blood cell count decreased	13 (38.2)	2 (5.9)	2 (5.9)	1 (2.9)	8 (23.5)
Neutrophil count decreased	12 (35.3)	0	2 (5.9)	2 (5.9)	8 (23.5)
Platelet count decreased	12 (35.3)	4 (11.8)	1 (2.9)	2 (5.9)	5 (14.7)
Lymphocyte count decreased	10 (29.4)	1 (2.9)	1 (2.9)	6 (17.6)	2 (5.9)
Aspartate aminotransferase increased	7 (20.6)	1 (2.9)	1 (2.9)	4 (11.8)	1 (2.9)
International normalised ratio increased	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Alanine aminotransferase increased	5 (14.7)	0	2 (5.9)	3 (8.8)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood fibrinogen decreased	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Electrocardiogram qt prolonged	3 (8.8)	1 (2.9)	1 (2.9)	0	1 (2.9)
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood creatinine increased	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Blood immunoglobulin g decreased	2 (5.9)	0	2 (5.9)	0	0
Blood uric acid increased	2 (5.9)	1 (2.9)	0	0	1 (2.9)
C-reactive protein increased	2 (5.9)	0	0	2 (5.9)	0
Serum ferritin increased	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Weight increased	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Blood alkaline phosphatase increased	1 (2.9)	1 (2.9)	0	0	0
Blood bicarbonate decreased	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (2.9)	0	0	0	1 (2.9)
Blood glucose increased	1 (2.9)	0	0	0	1 (2.9)
Blood lactate dehydrogenase increased	1 (2.9)	0	0	1 (2.9)	0
Blood phosphorus increased	1 (2.9)	0	1 (2.9)	0	0
Blood thyroid stimulating hormone increased	1 (2.9)	1 (2.9)	0	0	0
Breath sounds abnormal	1 (2.9)	0	1 (2.9)	0	0
Cardiac murmur	1 (2.9)	1 (2.9)	0	0	0
Electrocardiogram t wave abnormal	1 (2.9)	0	1 (2.9)	0	0
Enterovirus test positive	1 (2.9)	0	1 (2.9)	0	0
Fibrin d dimer increased	1 (2.9)	0	0	1 (2.9)	0
Haptoglobin decreased	1 (2.9)	1 (2.9)	0	0	0
Lipase increased	1 (2.9)	0	0	0	1 (2.9)
Troponin increased	1 (2.9)	0	0	1 (2.9)	0
Urine output decreased	1 (2.9)	0	0	0	1 (2.9)
Weight decreased	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	24 (70.6)	4 (11.8)	2 (5.9)	13 (38.2)	5 (14.7)
Decreased appetite	15 (44.1)	7 (20.6)	1 (2.9)	7 (20.6)	0
Hypokalaemia	11 (32.4)	2 (5.9)	3 (8.8)	5 (14.7)	1 (2.9)
Hypophosphataemia	10 (29.4)	0	4 (11.8)	6 (17.6)	0
Hypoalbuminaemia	7 (20.6)	0	6 (17.6)	1 (2.9)	0
Hypocalcaemia	7 (20.6)	0	5 (14.7)	2 (5.9)	0
Hyperglycaemia	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Hyperuricaemia	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Hypervolaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Hyperphosphataemia	3 (8.8)	2 (5.9)	0	0	1 (2.9)
Hypomagnesaemia	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Hyponatraemia	3 (8.8)	3 (8.8)	0	0	0
Acidosis	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Hypercalcaemia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hyperchloraemia	2 (5.9)	2 (5.9)	0	0	0
Hypernatraemia	2 (5.9)	0	0	1 (2.9)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	2 (5.9)	0	0	0	2 (5.9)
Tumour lysis syndrome	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Calcium deficiency	1 (2.9)	1 (2.9)	0	0	0
Haemosiderosis	1 (2.9)	0	1 (2.9)	0	0
Hypercholesterolaemia	1 (2.9)	0	1 (2.9)	0	0
Hyperkalaemia	1 (2.9)	0	0	0	1 (2.9)
Hyperlactacidaemia	1 (2.9)	1 (2.9)	0	0	0
Hyperlipidaemia	1 (2.9)	0	1 (2.9)	0	0
Hypermagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hypertriglyceridaemia	1 (2.9)	0	1 (2.9)	0	0
Hypoglycaemia	1 (2.9)	0	1 (2.9)	0	0
Hypophagia	1 (2.9)	0	1 (2.9)	0	0
Iron overload	1 (2.9)	0	1 (2.9)	0	0
Malnutrition	1 (2.9)	0	0	1 (2.9)	0
Metabolic syndrome	1 (2.9)	0	1 (2.9)	0	0
Obesity	1 (2.9)	0	0	1 (2.9)	0
Polydipsia	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	21 (61.8)	7 (20.6)	8 (23.5)	5 (14.7)	1 (2.9)
Myalgia	7 (20.6)	4 (11.8)	3 (8.8)	0	0
Pain in extremity	7 (20.6)	4 (11.8)	2 (5.9)	1 (2.9)	0
Back pain	5 (14.7)	1 (2.9)	3 (8.8)	1 (2.9)	0
Arthralgia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Bone pain	2 (5.9)	0	2 (5.9)	0	0
Growth retardation	1 (2.9)	0	1 (2.9)	0	0
Haemarthrosis	1 (2.9)	0	0	1 (2.9)	0
Joint effusion	1 (2.9)	0	1 (2.9)	0	0
Muscle rigidity	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal chest pain	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal pain	1 (2.9)	0	1 (2.9)	0	0
Myositis	1 (2.9)	0	1 (2.9)	0	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Pain in jaw	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (2.9)	0	0	0	1 (2.9)
Synovitis	1 (2.9)	0	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (5.9)	0	0	2 (5.9)	0
Bone giant cell tumour benign	1 (2.9)	0	0	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Nervous system disorders					
-Total	23 (67.6)	4 (11.8)	13 (38.2)	6 (17.6)	0
Headache	15 (44.1)	6 (17.6)	9 (26.5)	0	0
Tremor	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Encephalopathy	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Seizure	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Somnolence	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cognitive disorder	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Lethargy	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0
Aphasia	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Dysgeusia	1 (2.9)	1 (2.9)	0	0	0
Extrapyramidal disorder	1 (2.9)	0	1 (2.9)	0	0
Generalised tonic-clonic seizure	1 (2.9)	0	1 (2.9)	0	0
Hyperaesthesia	1 (2.9)	1 (2.9)	0	0	0
Migraine	1 (2.9)	0	1 (2.9)	0	0
Monoparesis	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorder	1 (2.9)	0	0	1 (2.9)	0
Paraesthesia	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	18 (52.9)	6 (17.6)	7 (20.6)	5 (14.7)	0
Anxiety	6 (17.6)	2 (5.9)	2 (5.9)	2 (5.9)	0
Mental status changes	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Agitation	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Confusional state	3 (8.8)	3 (8.8)	0	0	0
Delirium	2 (5.9)	0	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Irritability	2 (5.9)	2 (5.9)	0	0	0
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Automatism	1 (2.9)	1 (2.9)	0	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Insomnia	1 (2.9)	0	1 (2.9)	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Tic	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	11 (32.4)	1 (2.9)	3 (8.8)	3 (8.8)	4 (11.8)
Acute kidney injury	7 (20.6)	0	1 (2.9)	3 (8.8)	3 (8.8)
Anuria	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Pollakiuria	2 (5.9)	0	2 (5.9)	0	0
Urinary retention	2 (5.9)	0	2 (5.9)	0	0
Azotaemia	1 (2.9)	0	1 (2.9)	0	0
Bladder dilatation	1 (2.9)	0	1 (2.9)	0	0
Dysuria	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Micturition urgency	1 (2.9)	0	1 (2.9)	0	0
Renal tubular necrosis	1 (2.9)	0	0	0	1 (2.9)
Urinary incontinence	1 (2.9)	0	1 (2.9)	0	0
Reproductive system and breast disorders					
-Total	6 (17.6)	2 (5.9)	2 (5.9)	2 (5.9)	0
Dysmenorrhoea	1 (2.9)	0	1 (2.9)	0	0
Endometriosis	1 (2.9)	0	0	1 (2.9)	0
Female genital tract fistula	1 (2.9)	1 (2.9)	0	0	0
Heavy menstrual bleeding	1 (2.9)	1 (2.9)	0	0	0
Perineal rash	1 (2.9)	0	1 (2.9)	0	0
Vaginal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Vaginal ulceration	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (79.4)	9 (26.5)	2 (5.9)	9 (26.5)	7 (20.6)
Cough	10 (29.4)	7 (20.6)	3 (8.8)	0	0
Hypoxia	9 (26.5)	0	1 (2.9)	6 (17.6)	2 (5.9)
Pulmonary oedema	6 (17.6)	1 (2.9)	1 (2.9)	4 (11.8)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	5 (14.7)	3 (8.8)	1 (2.9)	1 (2.9)	0
Tachypnoea	5 (14.7)	1 (2.9)	1 (2.9)	3 (8.8)	0
Dyspnoea	4 (11.8)	0	2 (5.9)	1 (2.9)	1 (2.9)
Nasal congestion	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Rhinorrhoea	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Acute respiratory distress syndrome	3 (8.8)	0	0	0	3 (8.8)
Oropharyngeal pain	3 (8.8)	3 (8.8)	0	0	0
Respiratory failure	3 (8.8)	0	0	0	3 (8.8)
Atelectasis	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Pharyngeal erythema	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Acute respiratory failure	1 (2.9)	0	0	1 (2.9)	0
Bronchial oedema	1 (2.9)	1 (2.9)	0	0	0
Dyspnoea exertional	1 (2.9)	1 (2.9)	0	0	0
Haemoptysis	1 (2.9)	0	1 (2.9)	0	0
Nasal discomfort	1 (2.9)	0	1 (2.9)	0	0
Nasal dryness	1 (2.9)	1 (2.9)	0	0	0
Oropharyngeal plaque	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paranasal sinus discomfort	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal exudate	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal oedema	1 (2.9)	0	1 (2.9)	0	0
Pleural effusion	1 (2.9)	1 (2.9)	0	0	0
Pulmonary mass	1 (2.9)	0	1 (2.9)	0	0
Respiratory acidosis	1 (2.9)	0	0	1 (2.9)	0
Respiratory distress	1 (2.9)	0	1 (2.9)	0	0
Rhinitis allergic	1 (2.9)	0	1 (2.9)	0	0
Sleep apnoea syndrome	1 (2.9)	0	1 (2.9)	0	0
Upper respiratory tract inflammation	1 (2.9)	0	1 (2.9)	0	0
Wheezing	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (58.8)	9 (26.5)	7 (20.6)	4 (11.8)	0
Dry skin	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Rash	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Hyperhidrosis	3 (8.8)	1 (2.9)	2 (5.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Rash maculo-papular	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Rash papular	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Decubitus ulcer	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Eczema	2 (5.9)	2 (5.9)	0	0	0
Erythema	2 (5.9)	2 (5.9)	0	0	0
Petechiae	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Blister	1 (2.9)	1 (2.9)	0	0	0
Dermatitis atopic	1 (2.9)	1 (2.9)	0	0	0
Dermatitis diaper	1 (2.9)	0	1 (2.9)	0	0
Hangnail	1 (2.9)	1 (2.9)	0	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.9)	1 (2.9)	0	0	0
Purpura	1 (2.9)	1 (2.9)	0	0	0
Rash erythematous	1 (2.9)	1 (2.9)	0	0	0
Rash macular	1 (2.9)	0	0	1 (2.9)	0
Rash pruritic	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin hypopigmentation	1 (2.9)	1 (2.9)	0	0	0
Skin lesion	1 (2.9)	0	1 (2.9)	0	0
Skin necrosis	1 (2.9)	0	0	1 (2.9)	0
Skin ulcer	1 (2.9)	1 (2.9)	0	0	0
Social circumstances					
-Total	1 (2.9)	0	1 (2.9)	0	0
Patient uncooperative	1 (2.9)	0	1 (2.9)	0	0
Surgical and medical procedures					
-Total	1 (2.9)	0	0	1 (2.9)	0
Thrombolysis	1 (2.9)	0	0	1 (2.9)	0
Vascular disorders					
-Total	14 (41.2)	2 (5.9)	2 (5.9)	4 (11.8)	6 (17.6)
Hypotension	12 (35.3)	1 (2.9)	1 (2.9)	4 (11.8)	6 (17.6)
Hypertension	7 (20.6)	1 (2.9)	4 (11.8)	2 (5.9)	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Hot flush	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peripheral ischaemia	1 (2.9)	0	1 (2.9)	0	0
Thrombosis	1 (2.9)	0	1 (2.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	4 (6.8)	7 (11.9)	19 (32.2)	29 (49.2)
Blood and lymphatic system disorders					
-Total	34 (57.6)	2 (3.4)	7 (11.9)	18 (30.5)	7 (11.9)
Febrile neutropenia	18 (30.5)	0	0	17 (28.8)	1 (1.7)
Anaemia	16 (27.1)	4 (6.8)	7 (11.9)	5 (8.5)	0
Neutropenia	6 (10.2)	0	2 (3.4)	1 (1.7)	3 (5.1)
Coagulopathy	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Thrombocytopenia	5 (8.5)	0	0	1 (1.7)	4 (6.8)
Disseminated intravascular coagulation	4 (6.8)	0	3 (5.1)	1 (1.7)	0
Splenomegaly	3 (5.1)	2 (3.4)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pancytopenia	2 (3.4)	0	0	2 (3.4)	0
B-cell aplasia	1 (1.7)	0	1 (1.7)	0	0
Eosinophilia	1 (1.7)	0	1 (1.7)	0	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					
-Total	19 (32.2)	7 (11.9)	6 (10.2)	4 (6.8)	2 (3.4)
Tachycardia	15 (25.4)	6 (10.2)	6 (10.2)	2 (3.4)	1 (1.7)
Bradycardia	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Sinus tachycardia	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Left ventricular dysfunction	2 (3.4)	0	0	2 (3.4)	0
Atrioventricular block first degree	1 (1.7)	0	1 (1.7)	0	0
Cardiac failure	1 (1.7)	0	0	0	1 (1.7)
Cardiac failure congestive	1 (1.7)	0	1 (1.7)	0	0
Mitral valve incompetence	1 (1.7)	1 (1.7)	0	0	0
Pericardial effusion	1 (1.7)	1 (1.7)	0	0	0
Right ventricular dysfunction	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	2 (3.4)	2 (3.4)	0	0	0
Ear pain	1 (1.7)	1 (1.7)	0	0	0
Ear pruritus	1 (1.7)	1 (1.7)	0	0	0
Endocrine disorders					
-Total	3 (5.1)	0	3 (5.1)	0	0
Adrenal insufficiency	2 (3.4)	0	2 (3.4)	0	0
Hypothyroidism	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					
-Total	9 (15.3)	6 (10.2)	3 (5.1)	0	0
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Eyelid oedema	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Ocular hyperaemia	2 (3.4)	2 (3.4)	0	0	0
Eye oedema	1 (1.7)	1 (1.7)	0	0	0
Eye pain	1 (1.7)	1 (1.7)	0	0	0
Periorbital oedema	1 (1.7)	1 (1.7)	0	0	0
Periorbital swelling	1 (1.7)	0	1 (1.7)	0	0
Retinal haemorrhage	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual field defect	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	38 (64.4)	15 (25.4)	11 (18.6)	11 (18.6)	1 (1.7)
Vomiting	18 (30.5)	11 (18.6)	7 (11.9)	0	0
Nausea	14 (23.7)	7 (11.9)	6 (10.2)	1 (1.7)	0
Diarrhoea	12 (20.3)	7 (11.9)	4 (6.8)	1 (1.7)	0
Abdominal pain	10 (16.9)	2 (3.4)	6 (10.2)	2 (3.4)	0
Constipation	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Abdominal pain upper	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Ascites	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Mouth haemorrhage	3 (5.1)	1 (1.7)	1 (1.7)	1 (1.7)	0
Abdominal distension	2 (3.4)	0	2 (3.4)	0	0
Gastrointestinal sounds abnormal	2 (3.4)	2 (3.4)	0	0	0
Stomatitis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Abdominal compartment syndrome	1 (1.7)	0	0	0	1 (1.7)
Anal fissure	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Dry mouth	1 (1.7)	0	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0
Gastrooesophageal reflux disease	1 (1.7)	0	1 (1.7)	0	0
Gingival bleeding	1 (1.7)	0	1 (1.7)	0	0
Gingival erythema	1 (1.7)	1 (1.7)	0	0	0
Gingivitis ulcerative	1 (1.7)	0	0	1 (1.7)	0
Haematemesis	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	1 (1.7)	0	0
Lip dry	1 (1.7)	0	1 (1.7)	0	0
Melaena	1 (1.7)	0	0	1 (1.7)	0
Mouth swelling	1 (1.7)	1 (1.7)	0	0	0
Neutropenic colitis	1 (1.7)	0	0	1 (1.7)	0
Odynophagia	1 (1.7)	1 (1.7)	0	0	0
Pancreatitis	1 (1.7)	0	0	1 (1.7)	0
Proctalgia	1 (1.7)	0	0	1 (1.7)	0
Trichoglossia	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	32 (54.2)	18 (30.5)	7 (11.9)	4 (6.8)	3 (5.1)
Pyrexia	20 (33.9)	11 (18.6)	4 (6.8)	3 (5.1)	2 (3.4)
Fatigue	9 (15.3)	7 (11.9)	2 (3.4)	0	0
Face oedema	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Chills	5 (8.5)	3 (5.1)	2 (3.4)	0	0
Oedema peripheral	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Generalised oedema	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Asthenia	2 (3.4)	2 (3.4)	0	0	0
Catheter site pain	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Influenza like illness	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Localised oedema	2 (3.4)	2 (3.4)	0	0	0
Catheter site erythema	1 (1.7)	1 (1.7)	0	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Chest discomfort	1 (1.7)	0	0	1 (1.7)	0
Crying	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	1 (1.7)	0	1 (1.7)	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Malaise	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Oedema due to hepatic disease	1 (1.7)	0	1 (1.7)	0	0
Pain	1 (1.7)	0	0	1 (1.7)	0
Sluggishness	1 (1.7)	0	1 (1.7)	0	0
Swelling face	1 (1.7)	1 (1.7)	0	0	0
Systemic inflammatory response syndrome	1 (1.7)	0	0	1 (1.7)	0
Vascular device occlusion	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	10 (16.9)	4 (6.8)	5 (8.5)	0	1 (1.7)
Hyperbilirubinaemia	3 (5.1)	0	3 (5.1)	0	0
Cholelithiasis	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Gallbladder enlargement	2 (3.4)	2 (3.4)	0	0	0
Hepatomegaly	2 (3.4)	2 (3.4)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Biliary tract disorder	1 (1.7)	1 (1.7)	0	0	0
Cholestasis	1 (1.7)	0	0	0	1 (1.7)
Hepatic function abnormal	1 (1.7)	0	1 (1.7)	0	0
Ocular icterus	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	48 (81.4)	2 (3.4)	15 (25.4)	19 (32.2)	12 (20.3)
Cytokine release syndrome	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Hypogammaglobulinaemia	18 (30.5)	1 (1.7)	10 (16.9)	7 (11.9)	0
Haemophagocytic lymphohistiocytosis	5 (8.5)	1 (1.7)	1 (1.7)	2 (3.4)	1 (1.7)
Immunodeficiency	3 (5.1)	0	0	3 (5.1)	0
Hypersensitivity	1 (1.7)	1 (1.7)	0	0	0
Seasonal allergy	1 (1.7)	0	1 (1.7)	0	0
Selective igg subclass deficiency	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	24 (40.7)	4 (6.8)	8 (13.6)	10 (16.9)	2 (3.4)
Staphylococcal infection	5 (8.5)	0	3 (5.1)	2 (3.4)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	4 (6.8)	1 (1.7)	0	3 (5.1)	0
Conjunctivitis	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Candida infection	3 (5.1)	0	2 (3.4)	0	1 (1.7)
Nail infection	2 (3.4)	2 (3.4)	0	0	0
Oral infection	2 (3.4)	0	2 (3.4)	0	0
Anal abscess	1 (1.7)	0	0	1 (1.7)	0
Atypical pneumonia	1 (1.7)	1 (1.7)	0	0	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	1 (1.7)	0	0
Encephalitis	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis norovirus	1 (1.7)	1 (1.7)	0	0	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Granulicatella infection	1 (1.7)	0	0	1 (1.7)	0
Herpes simplex	1 (1.7)	0	0	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Localised infection	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myringitis	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	0	1 (1.7)	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	1 (1.7)	0	0
Sinusitis	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Stomatococcal infection	1 (1.7)	0	1 (1.7)	0	0
Systemic candida	1 (1.7)	0	0	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Injury, poisoning and procedural complications					
-Total	11 (18.6)	3 (5.1)	6 (10.2)	0	2 (3.4)
Fall	2 (3.4)	0	2 (3.4)	0	0
Infusion related reaction	2 (3.4)	0	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Transfusion reaction	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Wound	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Contusion	1 (1.7)	1 (1.7)	0	0	0
Scratch	1 (1.7)	1 (1.7)	0	0	0
Skin abrasion	1 (1.7)	1 (1.7)	0	0	0
Skin injury	1 (1.7)	0	1 (1.7)	0	0
Skin wound	1 (1.7)	1 (1.7)	0	0	0
Transplant failure	1 (1.7)	0	0	0	1 (1.7)
Vasoplegia syndrome	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	41 (69.5)	4 (6.8)	7 (11.9)	13 (22.0)	17 (28.8)
Platelet count decreased	15 (25.4)	3 (5.1)	3 (5.1)	4 (6.8)	5 (8.5)
White blood cell count decreased	15 (25.4)	3 (5.1)	3 (5.1)	2 (3.4)	7 (11.9)
Alanine aminotransferase increased	13 (22.0)	4 (6.8)	6 (10.2)	3 (5.1)	0
Aspartate aminotransferase increased	13 (22.0)	1 (1.7)	5 (8.5)	6 (10.2)	1 (1.7)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	13 (22.0)	0	3 (5.1)	1 (1.7)	9 (15.3)
Lymphocyte count decreased	12 (20.3)	2 (3.4)	0	6 (10.2)	4 (6.8)
Blood bilirubin increased	8 (13.6)	1 (1.7)	1 (1.7)	6 (10.2)	0
International normalised ratio increased	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Blood immunoglobulin m decreased	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Activated partial thromboplastin time prolonged	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Blood immunoglobulin a decreased	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Electrocardiogram qt prolonged	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Weight increased	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0
Blood creatinine increased	3 (5.1)	1 (1.7)	0	1 (1.7)	1 (1.7)
Blood fibrinogen decreased	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Blood lactate dehydrogenase increased	3 (5.1)	2 (3.4)	1 (1.7)	0	0
C-reactive protein increased	3 (5.1)	1 (1.7)	0	2 (3.4)	0
Serum ferritin increased	3 (5.1)	0	2 (3.4)	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Blood uric acid increased	2 (3.4)	2 (3.4)	0	0	0
Immunoglobulins decreased	2 (3.4)	0	2 (3.4)	0	0
Lipase increased	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Urine output decreased	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Amylase increased	1 (1.7)	1 (1.7)	0	0	0
Bacterial test positive	1 (1.7)	0	0	1 (1.7)	0
Blood alkaline phosphatase increased	1 (1.7)	1 (1.7)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood creatine phosphokinase increased	1 (1.7)	0	0	0	1 (1.7)
Blood glucose increased	1 (1.7)	0	0	0	1 (1.7)
Blood testosterone decreased	1 (1.7)	1 (1.7)	0	0	0
Breath sounds abnormal	1 (1.7)	0	1 (1.7)	0	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Coagulation test abnormal	1 (1.7)	1 (1.7)	0	0	0
Enterovirus test positive	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Gamma-glutamyltransferase increased	1 (1.7)	0	0	1 (1.7)	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Oxygen saturation decreased	1 (1.7)	1 (1.7)	0	0	0
Prothrombin time prolonged	1 (1.7)	0	1 (1.7)	0	0
Staphylococcus test positive	1 (1.7)	1 (1.7)	0	0	0
Weight decreased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	32 (54.2)	6 (10.2)	7 (11.9)	14 (23.7)	5 (8.5)
Decreased appetite	18 (30.5)	9 (15.3)	3 (5.1)	5 (8.5)	1 (1.7)
Hypokalaemia	14 (23.7)	2 (3.4)	4 (6.8)	6 (10.2)	2 (3.4)
Hypophosphataemia	12 (20.3)	3 (5.1)	3 (5.1)	6 (10.2)	0
Hypocalcaemia	11 (18.6)	2 (3.4)	6 (10.2)	3 (5.1)	0
Hypoalbuminaemia	6 (10.2)	0	6 (10.2)	0	0
Hyperglycaemia	5 (8.5)	0	2 (3.4)	3 (5.1)	0
Hyperphosphataemia	4 (6.8)	4 (6.8)	0	0	0
Hyperuricaemia	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	4 (6.8)	0	2 (3.4)	2 (3.4)	0
Hypomagnesaemia	3 (5.1)	3 (5.1)	0	0	0
Hypermagnesaemia	2 (3.4)	2 (3.4)	0	0	0
Hypernatraemia	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Hypertriglyceridaemia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Hyponatraemia	2 (3.4)	2 (3.4)	0	0	0
Metabolic acidosis	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Acidosis	1 (1.7)	0	0	1 (1.7)	0
Dehydration	1 (1.7)	0	1 (1.7)	0	0
Haemosiderosis	1 (1.7)	0	1 (1.7)	0	0
Hypercalcaemia	1 (1.7)	0	0	1 (1.7)	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hyperkalaemia	1 (1.7)	0	0	1 (1.7)	0
Hyperlactacidaemia	1 (1.7)	1 (1.7)	0	0	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Polydipsia	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	26 (44.1)	13 (22.0)	10 (16.9)	2 (3.4)	1 (1.7)
Pain in extremity	10 (16.9)	6 (10.2)	4 (6.8)	0	0
Arthralgia	8 (13.6)	4 (6.8)	4 (6.8)	0	0
Myalgia	7 (11.9)	4 (6.8)	3 (5.1)	0	0
Back pain	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Pain in jaw	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Bone pain	1 (1.7)	0	1 (1.7)	0	0
Muscle rigidity	1 (1.7)	1 (1.7)	0	0	0
Muscle spasms	1 (1.7)	0	1 (1.7)	0	0
Muscular weakness	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Myositis	1 (1.7)	0	1 (1.7)	0	0
Neck pain	1 (1.7)	0	1 (1.7)	0	0
Rhabdomyolysis	1 (1.7)	0	0	0	1 (1.7)
Nervous system disorders					
-Total	31 (52.5)	12 (20.3)	10 (16.9)	7 (11.9)	2 (3.4)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	20 (33.9)	11 (18.6)	7 (11.9)	2 (3.4)	0
Encephalopathy	8 (13.6)	1 (1.7)	3 (5.1)	4 (6.8)	0
Somnolence	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Tremor	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Dizziness	3 (5.1)	3 (5.1)	0	0	0
Dysgeusia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Lethargy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Aphasia	1 (1.7)	1 (1.7)	0	0	0
Cerebral haemorrhage	1 (1.7)	0	0	0	1 (1.7)
Depressed level of consciousness	1 (1.7)	0	0	1 (1.7)	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	0	0	1 (1.7)	0
Generalised tonic-clonic seizure	1 (1.7)	0	1 (1.7)	0	0
Hypoaesthesia	1 (1.7)	1 (1.7)	0	0	0
Monoparesis	1 (1.7)	0	1 (1.7)	0	0
Neurological decompensation	1 (1.7)	0	0	0	1 (1.7)
Seizure	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	23 (39.0)	10 (16.9)	8 (13.6)	5 (8.5)	0
Delirium	7 (11.9)	2 (3.4)	2 (3.4)	3 (5.1)	0
Confusional state	5 (8.5)	5 (8.5)	0	0	0
Agitation	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Anxiety	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Insomnia	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Hallucination	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Irritability	3 (5.1)	3 (5.1)	0	0	0
Mental status changes	3 (5.1)	1 (1.7)	1 (1.7)	1 (1.7)	0
Sleep disorder	2 (3.4)	0	2 (3.4)	0	0
Affect lability	1 (1.7)	0	1 (1.7)	0	0
Automatism	1 (1.7)	1 (1.7)	0	0	0
Restlessness	1 (1.7)	0	1 (1.7)	0	0
Social avoidant behaviour	1 (1.7)	0	1 (1.7)	0	0
Renal and urinary disorders					
-Total	16 (27.1)	4 (6.8)	5 (8.5)	3 (5.1)	4 (6.8)
Acute kidney injury	7 (11.9)	1 (1.7)	1 (1.7)	3 (5.1)	2 (3.4)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	3 (5.1)	3 (5.1)	0	0	0
Anuria	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Pollakiuria	2 (3.4)	0	2 (3.4)	0	0
Renal failure	2 (3.4)	0	1 (1.7)	0	1 (1.7)
Azotaemia	1 (1.7)	0	1 (1.7)	0	0
Bladder dilatation	1 (1.7)	0	1 (1.7)	0	0
Haematuria	1 (1.7)	1 (1.7)	0	0	0
Incontinence	1 (1.7)	0	1 (1.7)	0	0
Micturition urgency	1 (1.7)	0	1 (1.7)	0	0
Renal tubular dysfunction	1 (1.7)	1 (1.7)	0	0	0
Renal tubular necrosis	1 (1.7)	0	0	0	1 (1.7)
Urinary incontinence	1 (1.7)	0	1 (1.7)	0	0
Urinary retention	1 (1.7)	0	1 (1.7)	0	0
Urinary tract disorder	1 (1.7)	0	1 (1.7)	0	0
Reproductive system and breast disorders					
-Total	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Heavy menstrual bleeding	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Perineal rash	1 (1.7)	0	1 (1.7)	0	0
Vaginal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Vaginal ulceration	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (47.5)	10 (16.9)	4 (6.8)	8 (13.6)	6 (10.2)
Hypoxia	12 (20.3)	0	5 (8.5)	5 (8.5)	2 (3.4)
Pulmonary oedema	10 (16.9)	2 (3.4)	3 (5.1)	4 (6.8)	1 (1.7)
Cough	8 (13.6)	7 (11.9)	1 (1.7)	0	0
Tachypnoea	7 (11.9)	2 (3.4)	1 (1.7)	4 (6.8)	0
Pleural effusion	5 (8.5)	3 (5.1)	0	2 (3.4)	0
Oropharyngeal pain	4 (6.8)	4 (6.8)	0	0	0
Atelectasis	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Dyspnoea	3 (5.1)	0	0	2 (3.4)	1 (1.7)
Epistaxis	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Respiratory distress	3 (5.1)	0	2 (3.4)	0	1 (1.7)
Respiratory failure	3 (5.1)	0	0	0	3 (5.1)
Nasal congestion	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (3.4)	2 (3.4)	0	0	0
Acute respiratory distress syndrome	1 (1.7)	0	0	0	1 (1.7)
Acute respiratory failure	1 (1.7)	0	0	1 (1.7)	0
Bradypnoea	1 (1.7)	0	0	1 (1.7)	0
Lung infiltration	1 (1.7)	0	0	1 (1.7)	0
Nasal discomfort	1 (1.7)	0	1 (1.7)	0	0
Oropharyngeal plaque	1 (1.7)	0	1 (1.7)	0	0
Painful respiration	1 (1.7)	1 (1.7)	0	0	0
Paranasal sinus discomfort	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal erythema	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal exudate	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal oedema	1 (1.7)	0	1 (1.7)	0	0
Productive cough	1 (1.7)	1 (1.7)	0	0	0
Pulmonary mass	1 (1.7)	0	1 (1.7)	0	0
Respiratory acidosis	1 (1.7)	0	0	1 (1.7)	0
Respiratory disorder	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	23 (39.0)	11 (18.6)	10 (16.9)	2 (3.4)	0
Pruritus	5 (8.5)	1 (1.7)	4 (6.8)	0	0
Rash	5 (8.5)	2 (3.4)	3 (5.1)	0	0
Erythema	4 (6.8)	4 (6.8)	0	0	0
Blister	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Hyperhidrosis	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Rash papular	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Dermatitis atopic	2 (3.4)	2 (3.4)	0	0	0
Petechiae	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Decubitus ulcer	1 (1.7)	0	1 (1.7)	0	0
Dermatitis	1 (1.7)	1 (1.7)	0	0	0
Dermatitis diaper	1 (1.7)	0	1 (1.7)	0	0
Dry skin	1 (1.7)	1 (1.7)	0	0	0
Eczema	1 (1.7)	1 (1.7)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.7)	1 (1.7)	0	0	0
Pruritus allergic	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (1.7)	0	1 (1.7)	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Scab	1 (1.7)	1 (1.7)	0	0	0
Skin discolouration	1 (1.7)	1 (1.7)	0	0	0
Skin lesion	1 (1.7)	0	1 (1.7)	0	0
Skin necrosis	1 (1.7)	0	0	1 (1.7)	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Urticaria	1 (1.7)	0	1 (1.7)	0	0
Vancomycin infusion reaction	1 (1.7)	0	0	1 (1.7)	0
Social circumstances					
-Total	1 (1.7)	0	1 (1.7)	0	0
Patient uncooperative	1 (1.7)	0	1 (1.7)	0	0
Vascular disorders					
-Total	21 (35.6)	3 (5.1)	6 (10.2)	8 (13.6)	4 (6.8)
Hypotension	19 (32.2)	1 (1.7)	6 (10.2)	8 (13.6)	4 (6.8)
Hypertension	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0
Capillary leak syndrome	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flushing	1 (1.7)	1 (1.7)	0	0	0
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Peripheral ischaemia	1 (1.7)	0	1 (1.7)	0	0
Thrombosis	1 (1.7)	0	1 (1.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	2 (20.0)	7 (70.0)
Blood and lymphatic system disorders					
-Total	8 (80.0)	0	1 (10.0)	2 (20.0)	5 (50.0)
Disseminated intravascular coagulation	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Neutropenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Thrombocytopenia	2 (20.0)	0	0	0	2 (20.0)
Hypofibrinogenaemia	1 (10.0)	0	1 (10.0)	0	0
Leukopenia	1 (10.0)	0	0	0	1 (10.0)
Splenomegaly	1 (10.0)	1 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (30.0)	2 (20.0)	0	0	1 (10.0)
Cardiac dysfunction	2 (20.0)	2 (20.0)	0	0	0
Cardiac arrest	1 (10.0)	0	0	0	1 (10.0)
Tachycardia	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	3 (30.0)	3 (30.0)	0	0
Constipation	2 (20.0)	2 (20.0)	0	0	0
Nausea	2 (20.0)	2 (20.0)	0	0	0
Pancreatitis	2 (20.0)	0	2 (20.0)	0	0
Diarrhoea	1 (10.0)	0	1 (10.0)	0	0
Enterocolitis	1 (10.0)	0	1 (10.0)	0	0
General disorders and administration site conditions					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Pyrexia	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Fatigue	1 (10.0)	1 (10.0)	0	0	0
Hepatobiliary disorders					

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (50.0)	0	1 (10.0)	2 (20.0)	2 (20.0)
Hepatic function abnormal	4 (40.0)	0	1 (10.0)	2 (20.0)	1 (10.0)
Hepatomegaly	1 (10.0)	0	0	0	1 (10.0)
Immune system disorders					
-Total	9 (90.0)	0	4 (40.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Infections and infestations					
-Total	7 (70.0)	2 (20.0)	1 (10.0)	3 (30.0)	1 (10.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bk virus infection	1 (10.0)	1 (10.0)	0	0	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Urinary tract infection viral	1 (10.0)	1 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	7 (70.0)	0	1 (10.0)	2 (20.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	0	0	4 (40.0)
Blood fibrinogen decreased	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Serum ferritin increased	3 (30.0)	0	3 (30.0)	0	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)	0	0
Blood bilirubin increased	1 (10.0)	0	0	1 (10.0)	0
Blood creatine phosphokinase increased	1 (10.0)	0	0	1 (10.0)	0
Fibrin d dimer increased	1 (10.0)	1 (10.0)	0	0	0
Gamma-glutamyltransferase increased	1 (10.0)	0	0	1 (10.0)	0
Haptoglobin decreased	1 (10.0)	1 (10.0)	0	0	0
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	4 (40.0)	1 (10.0)	0	2 (20.0)	1 (10.0)
Tumour lysis syndrome	2 (20.0)	0	0	2 (20.0)	0
Hypercalcaemia	1 (10.0)	0	0	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	0	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	0	0	1 (10.0)
Hyperuricaemia	1 (10.0)	1 (10.0)	0	0	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)	0	0
Metabolic acidosis	1 (10.0)	0	0	0	1 (10.0)
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Arthralgia	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	0	1 (10.0)	0
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Headache	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	3 (30.0)	1 (10.0)	0	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Haematuria	1 (10.0)	1 (10.0)	0	0	0
Proteinuria	1 (10.0)	1 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (70.0)	3 (30.0)	0	0	4 (40.0)
Hypoxia	4 (40.0)	0	0	0	4 (40.0)
Cough	1 (10.0)	1 (10.0)	0	0	0
Haemoptysis	1 (10.0)	0	1 (10.0)	0	0
Nasal congestion	1 (10.0)	1 (10.0)	0	0	0
Nasal dryness	1 (10.0)	1 (10.0)	0	0	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0	0	0
Pleural effusion	1 (10.0)	1 (10.0)	0	0	0
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Erythema nodosum	1 (10.0)	1 (10.0)	0	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Skin ulcer	1 (10.0)	0	1 (10.0)	0	0
Vascular disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hypertension	1 (10.0)	0	1 (10.0)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	0	0	10 (90.9)
Blood and lymphatic system disorders					
-Total	8 (72.7)	1 (9.1)	0	6 (54.5)	1 (9.1)
Febrile neutropenia	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Anaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0
Thrombocytopenia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Left ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus bradycardia	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (9.1)	1 (9.1)	0	0	0
Endocrine disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Adrenal insufficiency	2 (18.2)	0	2 (18.2)	0	0
Gastrointestinal disorders					
-Total	7 (63.6)	1 (9.1)	4 (36.4)	2 (18.2)	0
Constipation	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Vomiting	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Diarrhoea	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Nausea	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Abdominal distension	1 (9.1)	1 (9.1)	0	0	0
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Lip oedema	1 (9.1)	1 (9.1)	0	0	0
Mouth haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Pancreatitis	1 (9.1)	0	1 (9.1)	0	0
General disorders and administration site conditions					
-Total	5 (45.5)	1 (9.1)	1 (9.1)	2 (18.2)	1 (9.1)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (18.2)	0	0	2 (18.2)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Drug withdrawal syndrome	1 (9.1)	0	1 (9.1)	0	0
Fatigue	1 (9.1)	1 (9.1)	0	0	0
Generalised oedema	1 (9.1)	1 (9.1)	0	0	0
Multiple organ dysfunction syndrome	1 (9.1)	0	0	0	1 (9.1)
Oedema peripheral	1 (9.1)	1 (9.1)	0	0	0
Hepatobiliary disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hyperbilirubinaemia	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Immune system disorders					
-Total	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Cytokine release syndrome	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Hypogammaglobulinaemia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Infections and infestations					
-Total	4 (36.4)	0	1 (9.1)	3 (27.3)	0
Adenovirus infection	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	9 (81.8)	0	0	2 (18.2)	7 (63.6)
Neutrophil count decreased	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Platelet count decreased	5 (45.5)	1 (9.1)	0	1 (9.1)	3 (27.3)
White blood cell count decreased	5 (45.5)	0	0	0	5 (45.5)
Alanine aminotransferase increased	4 (36.4)	0	1 (9.1)	3 (27.3)	0
Aspartate aminotransferase increased	4 (36.4)	0	0	2 (18.2)	2 (18.2)
Blood bilirubin increased	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Lymphocyte count decreased	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Activated partial thromboplastin time prolonged	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Serum ferritin increased	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Blood creatinine increased	1 (9.1)	0	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)
Blood immunoglobulin a decreased	1 (9.1)	1 (9.1)	0	0	0
Blood immunoglobulin m decreased	1 (9.1)	1 (9.1)	0	0	0
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Blood phosphorus increased	1 (9.1)	0	1 (9.1)	0	0
C-reactive protein increased	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	0	1 (9.1)
Electrocardiogram t wave abnormal	1 (9.1)	0	1 (9.1)	0	0
Fibrin d dimer increased	1 (9.1)	0	0	1 (9.1)	0
Troponin increased	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	10 (90.9)	1 (9.1)	2 (18.2)	5 (45.5)	2 (18.2)
Decreased appetite	6 (54.5)	0	1 (9.1)	5 (45.5)	0
Hypocalcaemia	5 (45.5)	0	3 (27.3)	2 (18.2)	0
Hypokalaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0
Hypophosphataemia	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Hypoalbuminaemia	4 (36.4)	0	3 (27.3)	1 (9.1)	0
Hyperglycaemia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Hypomagnesaemia	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hyperuricaemia	2 (18.2)	2 (18.2)	0	0	0
Hypervolaemia	2 (18.2)	0	0	2 (18.2)	0
Acidosis	1 (9.1)	0	0	0	1 (9.1)
Calcium deficiency	1 (9.1)	1 (9.1)	0	0	0
Hypercalcaemia	1 (9.1)	0	1 (9.1)	0	0
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hyponatraemia	1 (9.1)	1 (9.1)	0	0	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Myalgia	2 (18.2)	2 (18.2)	0	0	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Bone pain	1 (9.1)	0	1 (9.1)	0	0
Haemarthrosis	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	7 (63.6)	2 (18.2)	4 (36.4)	1 (9.1)	0
Cognitive disorder	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Headache	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Amnesia	1 (9.1)	0	1 (9.1)	0	0
Dysgeusia	1 (9.1)	1 (9.1)	0	0	0
Hyperaesthesia	1 (9.1)	1 (9.1)	0	0	0
Lethargy	1 (9.1)	1 (9.1)	0	0	0
Neuralgia	1 (9.1)	0	1 (9.1)	0	0
Paraesthesia	1 (9.1)	1 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	1 (9.1)	1 (9.1)	0	0	0
Psychiatric disorders					
-Total	5 (45.5)	2 (18.2)	2 (18.2)	1 (9.1)	0
Anxiety	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Confusional state	2 (18.2)	2 (18.2)	0	0	0
Agitation	1 (9.1)	1 (9.1)	0	0	0
Hallucination, visual	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Reproductive system and breast disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Female genital tract fistula	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (54.5)	1 (9.1)	0	3 (27.3)	2 (18.2)
Pulmonary oedema	2 (18.2)	0	0	2 (18.2)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0	0	0
Epistaxis	1 (9.1)	0	0	1 (9.1)	0
Hypoxia	1 (9.1)	0	0	1 (9.1)	0
Pleural effusion	1 (9.1)	0	0	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0	0	0
Wheezing	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Purpura	1 (9.1)	1 (9.1)	0	0	0
Rash maculo-papular	1 (9.1)	0	0	1 (9.1)	0
Surgical and medical procedures					
-Total	1 (9.1)	0	0	1 (9.1)	0
Thrombolysis	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	1 (9.1)	0	3 (27.3)	2 (18.2)

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	4 (36.4)	1 (9.1)	0	3 (27.3)	0
Hypotension	2 (18.2)	0	0	0	2 (18.2)
Capillary leak syndrome	1 (9.1)	0	0	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=55		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (94.5)	8 (14.5)	20 (36.4)	11 (20.0)	13 (23.6)
Blood and lymphatic system disorders					
-Total	11 (20.0)	2 (3.6)	4 (7.3)	4 (7.3)	1 (1.8)
Anaemia	5 (9.1)	4 (7.3)	0	1 (1.8)	0
Febrile neutropenia	2 (3.6)	0	0	2 (3.6)	0
Neutropenia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
B-cell aplasia	1 (1.8)	0	1 (1.8)	0	0
Disseminated intravascular coagulation	1 (1.8)	0	0	1 (1.8)	0
Eosinophilia	1 (1.8)	0	1 (1.8)	0	0
Leukocytosis	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.8)	0	1 (1.8)	0	0
Lymphocytosis	1 (1.8)	0	1 (1.8)	0	0
Thrombocytopenia	1 (1.8)	0	0	1 (1.8)	0
Cardiac disorders					
-Total	5 (9.1)	3 (5.5)	1 (1.8)	0	1 (1.8)
Tachycardia	2 (3.6)	2 (3.6)	0	0	0
Cardiac arrest	1 (1.8)	0	0	0	1 (1.8)
Cardiac failure	1 (1.8)	0	0	1 (1.8)	0
Left ventricular dysfunction	1 (1.8)	0	1 (1.8)	0	0
Tricuspid valve incompetence	1 (1.8)	1 (1.8)	0	0	0
Endocrine disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Hypothyroidism	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	4 (7.3)	4 (7.3)	0	0	0
Cataract	2 (3.6)	2 (3.6)	0	0	0
Hypermetropia	1 (1.8)	1 (1.8)	0	0	0
Ocular hyperaemia	1 (1.8)	1 (1.8)	0	0	0
Visual impairment	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	12 (21.8)	8 (14.5)	4 (7.3)	0	0
Diarrhoea	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Nausea	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Vomiting	3 (5.5)	3 (5.5)	0	0	0
Abdominal pain	1 (1.8)	1 (1.8)	0	0	0
Abdominal pain upper	1 (1.8)	1 (1.8)	0	0	0
Abdominal rigidity	1 (1.8)	0	1 (1.8)	0	0
Constipation	1 (1.8)	0	1 (1.8)	0	0
Dyspepsia	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal haemorrhage	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal inflammation	1 (1.8)	0	1 (1.8)	0	0
Mouth haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Pancreatitis	1 (1.8)	1 (1.8)	0	0	0
Peritoneal haematoma	1 (1.8)	1 (1.8)	0	0	0
Proctalgia	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	18 (32.7)	12 (21.8)	5 (9.1)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	10 (18.2)	5 (9.1)	4 (7.3)	1 (1.8)	0
Fatigue	6 (10.9)	6 (10.9)	0	0	0
Asthenia	1 (1.8)	1 (1.8)	0	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Malaise	1 (1.8)	1 (1.8)	0	0	0
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Pain	1 (1.8)	0	1 (1.8)	0	0
Hepatobiliary disorders					
-Total	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Hepatic cytolysis	1 (1.8)	1 (1.8)	0	0	0
Hypertransaminasaemia	1 (1.8)	1 (1.8)	0	0	0
Liver disorder	1 (1.8)	0	1 (1.8)	0	0
Immune system disorders					
-Total	10 (18.2)	1 (1.8)	7 (12.7)	2 (3.6)	0
Hypogammaglobulinaemia	6 (10.9)	0	6 (10.9)	0	0
Graft versus host disease	2 (3.6)	0	0	2 (3.6)	0
Allergy to immunoglobulin therapy	1 (1.8)	1 (1.8)	0	0	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=55		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Engraftment syndrome	1 (1.8)	0	0	1 (1.8)	0
Infections and infestations					
-Total	31 (56.4)	3 (5.5)	14 (25.5)	7 (12.7)	7 (12.7)
Upper respiratory tract infection	6 (10.9)	2 (3.6)	3 (5.5)	1 (1.8)	0
Gastroenteritis	5 (9.1)	3 (5.5)	0	2 (3.6)	0
Nasopharyngitis	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Rhinovirus infection	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Metapneumovirus infection	3 (5.5)	0	0	3 (5.5)	0
Parainfluenzae virus infection	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Pneumonia	3 (5.5)	1 (1.8)	1 (1.8)	0	1 (1.8)
Sinusitis	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Pneumocystis jirovecii pneumonia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Respiratory syncytial virus infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Respiratory tract infection	2 (3.6)	0	2 (3.6)	0	0
Rhinitis	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Adenovirus infection	1 (1.8)	0	0	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Bk virus infection	1 (1.8)	0	0	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Coronavirus infection	1 (1.8)	0	0	1 (1.8)	0
Cystitis	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Ear infection	1 (1.8)	0	1 (1.8)	0	0
Ear, nose and throat infection	1 (1.8)	0	1 (1.8)	0	0
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Gastroenteritis clostridial	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal infection	1 (1.8)	1 (1.8)	0	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Herpes simplex	1 (1.8)	0	1 (1.8)	0	0
Influenza	1 (1.8)	0	1 (1.8)	0	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral candidiasis	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=55			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Paronychia	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection viral	1 (1.8)	0	1 (1.8)	0	0
Salmonellosis	1 (1.8)	0	1 (1.8)	0	0
Septic shock	1 (1.8)	0	0	0	1 (1.8)
Sinusitis fungal	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Staphylococcal skin infection	1 (1.8)	0	1 (1.8)	0	0
Tinea pedis	1 (1.8)	1 (1.8)	0	0	0
Viral haemorrhagic cystitis	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	0	1 (1.8)	0	0
Injury, poisoning and procedural complications					
-Total	8 (14.5)	4 (7.3)	4 (7.3)	0	0
Infusion related reaction	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Contusion	1 (1.8)	1 (1.8)	0	0	0
Fibula fracture	1 (1.8)	0	1 (1.8)	0	0
Ligament sprain	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (1.8)	0	1 (1.8)	0	0
Post-traumatic neck syndrome	1 (1.8)	0	1 (1.8)	0	0
Skin abrasion	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	24 (43.6)	5 (9.1)	6 (10.9)	9 (16.4)	4 (7.3)
Neutrophil count decreased	8 (14.5)	1 (1.8)	1 (1.8)	3 (5.5)	3 (5.5)
White blood cell count decreased	8 (14.5)	3 (5.5)	2 (3.6)	2 (3.6)	1 (1.8)
Lymphocyte count decreased	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Platelet count decreased	4 (7.3)	2 (3.6)	0	1 (1.8)	1 (1.8)
Alanine aminotransferase increased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Blood bilirubin increased	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Blood immunoglobulin a decreased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Blood creatinine increased	1 (1.8)	0	1 (1.8)	0	0
Blood immunoglobulin m decreased	1 (1.8)	0	0	1 (1.8)	0
Blood lactate dehydrogenase increased	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood thyroid stimulating hormone increased	1 (1.8)	1 (1.8)	0	0	0
Blood urea increased	1 (1.8)	0	0	1 (1.8)	0
Blood uric acid increased	1 (1.8)	0	0	0	1 (1.8)
Bone density decreased	1 (1.8)	1 (1.8)	0	0	0
C-reactive protein increased	1 (1.8)	1 (1.8)	0	0	0
Ejection fraction decreased	1 (1.8)	0	1 (1.8)	0	0
Heart sounds abnormal	1 (1.8)	1 (1.8)	0	0	0
Hepatitis b virus test positive	1 (1.8)	0	1 (1.8)	0	0
Immunoglobulins decreased	1 (1.8)	0	1 (1.8)	0	0
Oxygen saturation decreased	1 (1.8)	0	1 (1.8)	0	0
Weight decreased	1 (1.8)	0	0	1 (1.8)	0
Weight increased	1 (1.8)	0	0	1 (1.8)	0
Metabolism and nutrition disorders					
-Total	11 (20.0)	3 (5.5)	4 (7.3)	2 (3.6)	2 (3.6)
Decreased appetite	5 (9.1)	1 (1.8)	3 (5.5)	1 (1.8)	0
Hyperuricaemia	3 (5.5)	3 (5.5)	0	0	0
Hypokalaemia	2 (3.6)	0	1 (1.8)	0	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemochromatosis	1 (1.8)	0	0	1 (1.8)	0
Hyperchloraemia	1 (1.8)	1 (1.8)	0	0	0
Hyperkalaemia	1 (1.8)	0	1 (1.8)	0	0
Hypervolaemia	1 (1.8)	0	0	1 (1.8)	0
Hypophosphataemia	1 (1.8)	0	1 (1.8)	0	0
Iron overload	1 (1.8)	0	1 (1.8)	0	0
Metabolic syndrome	1 (1.8)	0	1 (1.8)	0	0
Tumour lysis syndrome	1 (1.8)	0	0	0	1 (1.8)
Musculoskeletal and connective tissue disorders					
-Total	11 (20.0)	5 (9.1)	5 (9.1)	1 (1.8)	0
Back pain	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Pain in extremity	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Arthralgia	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Bone pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Musculoskeletal pain	1 (1.8)	0	1 (1.8)	0	0
Myalgia	1 (1.8)	0	1 (1.8)	0	0
Neck pain	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=55		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (7.3)	1 (1.8)	2 (3.6)	1 (1.8)	0
Skin papilloma	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Cancer pain	1 (1.8)	0	1 (1.8)	0	0
Myelodysplastic syndrome	1 (1.8)	0	0	1 (1.8)	0
Nervous system disorders					
-Total	13 (23.6)	7 (12.7)	4 (7.3)	0	2 (3.6)
Headache	9 (16.4)	6 (10.9)	3 (5.5)	0	0
Autonomic neuropathy	1 (1.8)	0	0	1 (1.8)	0
Cerebral haemorrhage	1 (1.8)	0	0	0	1 (1.8)
Dizziness	1 (1.8)	1 (1.8)	0	0	0
Hydrocephalus	1 (1.8)	0	0	0	1 (1.8)
Memory impairment	1 (1.8)	0	1 (1.8)	0	0
Migraine	1 (1.8)	0	1 (1.8)	0	0
Seizure	1 (1.8)	0	0	1 (1.8)	0
Psychiatric disorders					
-Total	5 (9.1)	1 (1.8)	4 (7.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Agitation	1 (1.8)	1 (1.8)	0	0	0
Mental status changes	1 (1.8)	0	1 (1.8)	0	0
Mood altered	1 (1.8)	1 (1.8)	0	0	0
Nightmare	1 (1.8)	1 (1.8)	0	0	0
Persistent depressive disorder	1 (1.8)	0	1 (1.8)	0	0
Sleep disorder	1 (1.8)	0	1 (1.8)	0	0
Tearfulness	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Acute kidney injury	3 (5.5)	1 (1.8)	1 (1.8)	0	1 (1.8)
Dysuria	1 (1.8)	0	1 (1.8)	0	0
Haematuria	1 (1.8)	0	0	1 (1.8)	0
Kidney enlargement	1 (1.8)	0	1 (1.8)	0	0
Renal mass	1 (1.8)	0	1 (1.8)	0	0
Renal tubular disorder	1 (1.8)	0	0	1 (1.8)	0
Reproductive system and breast disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysmenorrhoea	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (30.9)	9 (16.4)	3 (5.5)	2 (3.6)	3 (5.5)
Cough	11 (20.0)	8 (14.5)	3 (5.5)	0	0
Nasal congestion	6 (10.9)	5 (9.1)	1 (1.8)	0	0
Epistaxis	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hypoxia	2 (3.6)	0	0	2 (3.6)	0
Oropharyngeal pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Rhinorrhoea	2 (3.6)	2 (3.6)	0	0	0
Acute respiratory distress syndrome	1 (1.8)	0	0	0	1 (1.8)
Dyspnoea	1 (1.8)	0	1 (1.8)	0	0
Lung disorder	1 (1.8)	1 (1.8)	0	0	0
Paranasal sinus inflammation	1 (1.8)	1 (1.8)	0	0	0
Pleural effusion	1 (1.8)	1 (1.8)	0	0	0
Respiratory distress	1 (1.8)	0	0	0	1 (1.8)
Respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Rhinitis allergic	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	15 (27.3)	10 (18.2)	5 (9.1)	0	0
Dry skin	5 (9.1)	3 (5.5)	2 (3.6)	0	0
Rash	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Ingrowing nail	2 (3.6)	0	2 (3.6)	0	0
Dermatitis allergic	1 (1.8)	1 (1.8)	0	0	0
Dermatitis atopic	1 (1.8)	1 (1.8)	0	0	0
Eczema	1 (1.8)	1 (1.8)	0	0	0
Hangnail	1 (1.8)	1 (1.8)	0	0	0
Miliaria	1 (1.8)	1 (1.8)	0	0	0
Night sweats	1 (1.8)	1 (1.8)	0	0	0
Photosensitivity reaction	1 (1.8)	0	1 (1.8)	0	0
Skin discolouration	1 (1.8)	1 (1.8)	0	0	0
Skin hypopigmentation	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Hypotension	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Hypertension	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	1 (1.8)	0	0	1 (1.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	2 (22.2)	0	5 (55.6)
Blood and lymphatic system disorders					
-Total	4 (44.4)	0	0	1 (11.1)	3 (33.3)
Neutropenia	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Lymphopenia	1 (11.1)	0	0	1 (11.1)	0
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Cardiac failure	1 (11.1)	0	0	0	1 (11.1)
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (44.4)	3 (33.3)	1 (11.1)	0	0
Constipation	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	1 (11.1)	0	0	0
Enteritis	1 (11.1)	0	1 (11.1)	0	0
Nausea	1 (11.1)	1 (11.1)	0	0	0
Stomatitis	1 (11.1)	1 (11.1)	0	0	0
Trichoglossia	1 (11.1)	1 (11.1)	0	0	0
Vomiting	1 (11.1)	1 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	1 (11.1)	1 (11.1)	0	0	0
Pyrexia	1 (11.1)	1 (11.1)	0	0	0
Immune system disorders					
-Total	2 (22.2)	0	2 (22.2)	0	0
Hypogammaglobulinaemia	2 (22.2)	0	2 (22.2)	0	0
Infections and infestations					
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Cytomegalovirus infection reactivation	1 (11.1)	0	0	1 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (11.1)	0	0	1 (11.1)	0
Nasopharyngitis	1 (11.1)	1 (11.1)	0	0	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Viral infection	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
White blood cell count decreased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (22.2)	1 (11.1)	0	0	1 (11.1)
Decreased appetite	1 (11.1)	1 (11.1)	0	0	0
Metabolic acidosis	1 (11.1)	0	0	0	1 (11.1)
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Arthralgia	1 (11.1)	1 (11.1)	0	0	0
Back pain	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal chest pain	1 (11.1)	1 (11.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Anxiety	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	1 (11.1)	0	0
Renal and urinary disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Cystitis haemorrhagic	1 (11.1)	0	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (22.2)	0	2 (22.2)	0	0
Pleural effusion	1 (11.1)	0	1 (11.1)	0	0
Upper respiratory tract inflammation	1 (11.1)	0	1 (11.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (22.2)	2 (22.2)	0	0	0
Dry skin	1 (11.1)	1 (11.1)	0	0	0
Skin swelling	1 (11.1)	1 (11.1)	0	0	0
Vascular disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (11.1)	0	0	0	1 (11.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	1 (9.1)	2 (18.2)	4 (36.4)	3 (27.3)
Blood and lymphatic system disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Lymphadenopathy	1 (9.1)	1 (9.1)	0	0	0
Cardiac disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Cardiac arrest	1 (9.1)	0	0	0	1 (9.1)
Gastrointestinal disorders					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Diarrhoea	2 (18.2)	2 (18.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (18.2)	2 (18.2)	0	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Constipation	1 (9.1)	0	1 (9.1)	0	0
Nausea	1 (9.1)	0	1 (9.1)	0	0
Pancreatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	5 (45.5)	2 (18.2)	1 (9.1)	2 (18.2)	0
Pyrexia	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0	0	0
Pain	1 (9.1)	0	0	1 (9.1)	0
Immune system disorders					
-Total	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Hypogammaglobulinaemia	2 (18.2)	0	2 (18.2)	0	0
Allergy to immunoglobulin therapy	1 (9.1)	0	0	1 (9.1)	0
Immunodeficiency	1 (9.1)	0	0	1 (9.1)	0
Infections and infestations					
-Total	6 (54.5)	1 (9.1)	0	4 (36.4)	1 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Ear infection	1 (9.1)	0	1 (9.1)	0	0
Enterobacter infection	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Mastoiditis	1 (9.1)	0	0	1 (9.1)	0
Nail infection	1 (9.1)	1 (9.1)	0	0	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Parainfluenzae virus infection	1 (9.1)	0	1 (9.1)	0	0
Pharyngitis streptococcal	1 (9.1)	0	0	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Injury, poisoning and procedural complications					
-Total	1 (9.1)	1 (9.1)	0	0	0
Infusion related reaction	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Blood immunoglobulin g decreased	1 (9.1)	0	1 (9.1)	0	0
Blood uric acid increased	1 (9.1)	0	0	1 (9.1)	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0	0	0
Platelet count decreased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypophagia	1 (9.1)	0	1 (9.1)	0	0
Malnutrition	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Back pain	1 (9.1)	0	1 (9.1)	0	0
Growth retardation	1 (9.1)	0	1 (9.1)	0	0
Pain in extremity	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Extrapyramidal disorder	1 (9.1)	0	1 (9.1)	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	4 (36.4)	0	3 (27.3)	1 (9.1)	0
Anxiety	3 (27.3)	0	3 (27.3)	0	0
Mental status changes	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (45.5)	2 (18.2)	2 (18.2)	1 (9.1)	0
Bronchial oedema	1 (9.1)	1 (9.1)	0	0	0
Bronchospasm	1 (9.1)	0	1 (9.1)	0	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Hypoxia	1 (9.1)	0	0	1 (9.1)	0
Rhinitis allergic	1 (9.1)	0	1 (9.1)	0	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Decubitus ulcer	1 (9.1)	0	0	1 (9.1)	0
Erythema	1 (9.1)	0	1 (9.1)	0	0
Pruritus	1 (9.1)	0	1 (9.1)	0	0
Vascular disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Venoocclusive disease	1 (9.1)	0	0	0	1 (9.1)

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (61.5)	2 (5.1)	7 (17.9)	9 (23.1)	6 (15.4)
Blood and lymphatic system disorders					
-Total	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Agranulocytosis	1 (2.6)	0	0	1 (2.6)	0
Anaemia	1 (2.6)	0	1 (2.6)	0	0
Lymphadenopathy	1 (2.6)	0	1 (2.6)	0	0
Neutropenia	1 (2.6)	0	0	0	1 (2.6)
Thrombocytopenia	1 (2.6)	0	1 (2.6)	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral cavernous malformation	1 (2.6)	1 (2.6)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Deafness unilateral	1 (2.6)	0	1 (2.6)	0	0
Eye disorders					
-Total	1 (2.6)	0	0	1 (2.6)	0
Eye pain	1 (2.6)	0	0	1 (2.6)	0
Eyelid oedema	1 (2.6)	1 (2.6)	0	0	0
Gastrointestinal disorders					
-Total	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Diarrhoea	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Irritable bowel syndrome	1 (2.6)	0	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	7 (17.9)	4 (10.3)	2 (5.1)	1 (2.6)	0
Pyrexia	4 (10.3)	2 (5.1)	1 (2.6)	1 (2.6)	0
Pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Non-cardiac chest pain	1 (2.6)	1 (2.6)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Xerosis	1 (2.6)	1 (2.6)	0	0	0
Immune system disorders					
-Total	6 (15.4)	0	5 (12.8)	1 (2.6)	0
Hypogammaglobulinaemia	3 (7.7)	0	3 (7.7)	0	0
Chronic graft versus host disease	1 (2.6)	0	1 (2.6)	0	0
Drug hypersensitivity	1 (2.6)	0	0	1 (2.6)	0
Seasonal allergy	1 (2.6)	0	1 (2.6)	0	0
Infections and infestations					
-Total	18 (46.2)	2 (5.1)	4 (10.3)	9 (23.1)	3 (7.7)
Sinusitis	5 (12.8)	0	5 (12.8)	0	0
Conjunctivitis	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Rhinovirus infection	3 (7.7)	0	3 (7.7)	0	0
Sepsis	3 (7.7)	0	0	1 (2.6)	2 (5.1)
Upper respiratory tract infection	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Bronchitis	2 (5.1)	0	2 (5.1)	0	0
Fungal infection	2 (5.1)	0	2 (5.1)	0	0
Herpes zoster	2 (5.1)	0	1 (2.6)	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Skin infection	2 (5.1)	0	2 (5.1)	0	0
Urinary tract infection	2 (5.1)	0	2 (5.1)	0	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Bronchiolitis	1 (2.6)	0	0	1 (2.6)	0
Candida infection	1 (2.6)	0	1 (2.6)	0	0
Clostridium difficile colitis	1 (2.6)	0	0	1 (2.6)	0
Covid-19	1 (2.6)	0	0	1 (2.6)	0
Device related sepsis	1 (2.6)	0	0	1 (2.6)	0
Ear infection	1 (2.6)	0	0	1 (2.6)	0
Folliculitis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	1 (2.6)	0	0	0
Gastroenteritis escherichia coli	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis salmonella	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis viral	1 (2.6)	0	1 (2.6)	0	0
Herpes virus infection	1 (2.6)	0	1 (2.6)	0	0
Influenza	1 (2.6)	0	1 (2.6)	0	0
Meningitis pneumococcal	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	1 (2.6)	0	1 (2.6)	0	0
Neutropenic infection	1 (2.6)	0	0	1 (2.6)	0
Ophthalmic herpes zoster	1 (2.6)	0	1 (2.6)	0	0
Oral candidiasis	1 (2.6)	0	1 (2.6)	0	0
Otitis media	1 (2.6)	0	1 (2.6)	0	0
Otitis media acute	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	0	1 (2.6)	0
Pneumonia respiratory syncytial viral	1 (2.6)	0	0	1 (2.6)	0
Rhinitis	1 (2.6)	1 (2.6)	0	0	0
Septic shock	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal abscess	1 (2.6)	0	0	1 (2.6)	0
Staphylococcal bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Streptococcal sepsis	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection pseudomonal	1 (2.6)	0	1 (2.6)	0	0
Viral skin infection	1 (2.6)	1 (2.6)	0	0	0
Injury, poisoning and procedural complications					

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Infusion related reaction	1 (2.6)	0	0	1 (2.6)	0
Ligament sprain	1 (2.6)	1 (2.6)	0	0	0
Investigations					
-Total	4 (10.3)	2 (5.1)	1 (2.6)	0	1 (2.6)
Neutrophil count decreased	2 (5.1)	1 (2.6)	0	0	1 (2.6)
Platelet count decreased	2 (5.1)	2 (5.1)	0	0	0
Blood bilirubin increased	1 (2.6)	1 (2.6)	0	0	0
Blood immunoglobulin g decreased	1 (2.6)	0	1 (2.6)	0	0
Metabolism and nutrition disorders					
-Total	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Decreased appetite	1 (2.6)	0	0	0	1 (2.6)
Hyperlipidaemia	1 (2.6)	0	1 (2.6)	0	0
Hypernatraemia	1 (2.6)	0	0	1 (2.6)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (10.3)	1 (2.6)	3 (7.7)	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (5.1)	0	2 (5.1)	0	0
Growth retardation	1 (2.6)	0	1 (2.6)	0	0
Osteonecrosis	1 (2.6)	1 (2.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.6)	0	0	1 (2.6)	0
Bone giant cell tumour benign	1 (2.6)	0	0	1 (2.6)	0
Nervous system disorders					
-Total	4 (10.3)	0	2 (5.1)	2 (5.1)	0
Headache	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Dysarthria	1 (2.6)	0	1 (2.6)	0	0
Nervous system disorder	1 (2.6)	0	0	1 (2.6)	0
Seizure	1 (2.6)	0	0	1 (2.6)	0
Psychiatric disorders					
-Total	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Anxiety	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Tic	1 (2.6)	0	1 (2.6)	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	7 (17.9)	4 (10.3)	0	1 (2.6)	2 (5.1)
Cough	2 (5.1)	2 (5.1)	0	0	0
Dyspnoea	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Rhinorrhoea	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Dyspnoea exertional	1 (2.6)	1 (2.6)	0	0	0
Epistaxis	1 (2.6)	1 (2.6)	0	0	0
Hypoxia	1 (2.6)	0	0	1 (2.6)	0
Laryngeal oedema	1 (2.6)	0	0	0	1 (2.6)
Oropharyngeal pain	1 (2.6)	1 (2.6)	0	0	0
Pharyngeal erythema	1 (2.6)	1 (2.6)	0	0	0
Respiratory failure	1 (2.6)	0	0	0	1 (2.6)
Sleep apnoea syndrome	1 (2.6)	1 (2.6)	0	0	0
Wheezing	1 (2.6)	0	1 (2.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (15.4)	2 (5.1)	1 (2.6)	3 (7.7)	0
Dermatitis atopic	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	1 (2.6)	1 (2.6)	0	0	0
Eczema	1 (2.6)	0	0	1 (2.6)	0
Papule	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	0	1 (2.6)	0	0
Rash erythematous	1 (2.6)	1 (2.6)	0	0	0
Rash macular	1 (2.6)	0	0	1 (2.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Mydriasis	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Diarrhoea	1 (16.7)	1 (16.7)	0	0	0
Infections and infestations					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Fungal skin infection	1 (16.7)	0	1 (16.7)	0	0
Otitis media	1 (16.7)	0	1 (16.7)	0	0

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	0	1 (16.7)	0
Varicella zoster virus infection	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypercholesterolaemia	1 (16.7)	0	1 (16.7)	0	0
Hypertriglyceridaemia	1 (16.7)	0	1 (16.7)	0	0
Iron overload	1 (16.7)	0	1 (16.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Joint effusion	1 (16.7)	0	1 (16.7)	0	0
Synovitis	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Endometriosis	1 (16.7)	0	0	1 (16.7)	0

Timing: >1 year post-CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypertension	1 (16.7)	0	1 (16.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	1 (20.0)	2 (40.0)	1 (20.0)	1 (20.0)
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hypercoagulation	1 (20.0)	0	1 (20.0)	0	0
Endocrine disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Delayed puberty	1 (20.0)	0	1 (20.0)	0	0
Hypothyroidism	1 (20.0)	0	1 (20.0)	0	0
Eye disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry eye	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Diarrhoea	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Constipation	1 (20.0)	1 (20.0)	0	0	0
Nausea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Fatigue	1 (20.0)	0	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	0	1 (20.0)
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Immune system disorders					
-Total	3 (60.0)	2 (40.0)	0	0	1 (20.0)
Seasonal allergy	2 (40.0)	2 (40.0)	0	0	0
Chronic graft versus host disease	1 (20.0)	0	0	1 (20.0)	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (20.0)	0	0	0	1 (20.0)
Infections and infestations					
-Total	3 (60.0)	0	2 (40.0)	0	1 (20.0)
Conjunctivitis	1 (20.0)	1 (20.0)	0	0	0
Covid-19	1 (20.0)	1 (20.0)	0	0	0
Covid-19 pneumonia	1 (20.0)	0	0	0	1 (20.0)
Enterovirus infection	1 (20.0)	0	0	1 (20.0)	0
Influenza	1 (20.0)	0	0	0	1 (20.0)
Parainfluenzae virus infection	1 (20.0)	0	0	1 (20.0)	0
Pneumonia	1 (20.0)	0	0	0	1 (20.0)
Rhinovirus infection	1 (20.0)	0	0	1 (20.0)	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0
Syphilis	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	1 (20.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal injury	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0	0	0
Oxygen saturation decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	2 (40.0)	0	0	2 (40.0)	0
Hyperglycaemia	1 (20.0)	0	0	1 (20.0)	0
Obesity	1 (20.0)	0	0	1 (20.0)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Arthralgia	1 (20.0)	0	1 (20.0)	0	0
Osteopenia	1 (20.0)	1 (20.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (60.0)	0	2 (40.0)	0	1 (20.0)
Cough	2 (40.0)	1 (20.0)	1 (20.0)	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (20.0)	0	0	0	1 (20.0)
Pleural effusion	1 (20.0)	0	1 (20.0)	0	0
Rhinorrhoea	1 (20.0)	0	1 (20.0)	0	0
Sleep apnoea syndrome	1 (20.0)	0	1 (20.0)	0	0
Tachypnoea	1 (20.0)	0	0	0	1 (20.0)
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	1 (20.0)	0	0	0
Rash maculo-papular	1 (20.0)	1 (20.0)	0	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hypertension	1 (20.0)	0	0	1 (20.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	1 (1.7)	5 (8.5)	17 (28.8)	36 (61.0)
Blood and lymphatic system disorders					
-Total	38 (64.4)	1 (1.7)	9 (15.3)	20 (33.9)	8 (13.6)
Anaemia	19 (32.2)	6 (10.2)	8 (13.6)	5 (8.5)	0
Febrile neutropenia	19 (32.2)	0	0	18 (30.5)	1 (1.7)
Neutropenia	8 (13.6)	0	2 (3.4)	2 (3.4)	4 (6.8)
Thrombocytopenia	6 (10.2)	0	0	2 (3.4)	4 (6.8)
Coagulopathy	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Disseminated intravascular coagulation	5 (8.5)	0	3 (5.1)	2 (3.4)	0
Splenomegaly	3 (5.1)	2 (3.4)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pancytopenia	2 (3.4)	0	0	2 (3.4)	0
Agranulocytosis	1 (1.7)	0	0	1 (1.7)	0
B-cell aplasia	1 (1.7)	0	1 (1.7)	0	0
Eosinophilia	1 (1.7)	0	1 (1.7)	0	0
Leukocytosis	1 (1.7)	0	1 (1.7)	0	0
Lymphadenopathy	1 (1.7)	0	1 (1.7)	0	0
Lymphocytosis	1 (1.7)	0	1 (1.7)	0	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					
-Total	21 (35.6)	7 (11.9)	7 (11.9)	4 (6.8)	3 (5.1)
Tachycardia	15 (25.4)	6 (10.2)	6 (10.2)	2 (3.4)	1 (1.7)
Bradycardia	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Left ventricular dysfunction	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Sinus tachycardia	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Cardiac failure	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Atrioventricular block first degree	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (1.7)	0	0	0	1 (1.7)
Cardiac failure congestive	1 (1.7)	0	1 (1.7)	0	0
Mitral valve incompetence	1 (1.7)	1 (1.7)	0	0	0
Pericardial effusion	1 (1.7)	1 (1.7)	0	0	0
Right ventricular dysfunction	1 (1.7)	1 (1.7)	0	0	0
Tricuspid valve incompetence	1 (1.7)	1 (1.7)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Cerebral cavernous malformation	1 (1.7)	1 (1.7)	0	0	0
Ear and labyrinth disorders					
-Total	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Deafness unilateral	1 (1.7)	0	1 (1.7)	0	0
Ear pain	1 (1.7)	1 (1.7)	0	0	0
Ear pruritus	1 (1.7)	1 (1.7)	0	0	0
Endocrine disorders					
-Total	4 (6.8)	0	4 (6.8)	0	0
Adrenal insufficiency	2 (3.4)	0	2 (3.4)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypothyroidism	2 (3.4)	0	2 (3.4)	0	0
Eye disorders					
-Total	13 (22.0)	9 (15.3)	3 (5.1)	1 (1.7)	0
Eyelid oedema	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Ocular hyperaemia	3 (5.1)	3 (5.1)	0	0	0
Cataract	2 (3.4)	2 (3.4)	0	0	0
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Eye pain	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Visual impairment	2 (3.4)	2 (3.4)	0	0	0
Eye oedema	1 (1.7)	1 (1.7)	0	0	0
Hypermetropia	1 (1.7)	1 (1.7)	0	0	0
Periorbital oedema	1 (1.7)	1 (1.7)	0	0	0
Periorbital swelling	1 (1.7)	0	1 (1.7)	0	0
Retinal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Visual field defect	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	43 (72.9)	16 (27.1)	14 (23.7)	12 (20.3)	1 (1.7)
Vomiting	19 (32.2)	12 (20.3)	7 (11.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	18 (30.5)	11 (18.6)	5 (8.5)	2 (3.4)	0
Nausea	15 (25.4)	7 (11.9)	7 (11.9)	1 (1.7)	0
Abdominal pain	10 (16.9)	2 (3.4)	6 (10.2)	2 (3.4)	0
Constipation	7 (11.9)	3 (5.1)	4 (6.8)	0	0
Abdominal pain upper	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Mouth haemorrhage	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0
Ascites	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Abdominal distension	2 (3.4)	0	2 (3.4)	0	0
Gastrointestinal sounds abnormal	2 (3.4)	2 (3.4)	0	0	0
Pancreatitis	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Proctalgia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Stomatitis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Abdominal compartment syndrome	1 (1.7)	0	0	0	1 (1.7)
Abdominal rigidity	1 (1.7)	0	1 (1.7)	0	0
Anal fissure	1 (1.7)	0	1 (1.7)	0	0
Anal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Dry mouth	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (1.7)	1 (1.7)	0	0	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0
Gastrointestinal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal inflammation	1 (1.7)	0	1 (1.7)	0	0
Gastrooesophageal reflux disease	1 (1.7)	0	1 (1.7)	0	0
Gingival bleeding	1 (1.7)	0	1 (1.7)	0	0
Gingival erythema	1 (1.7)	1 (1.7)	0	0	0
Gingivitis ulcerative	1 (1.7)	0	0	1 (1.7)	0
Haematemesis	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	1 (1.7)	0	0
Irritable bowel syndrome	1 (1.7)	0	1 (1.7)	0	0
Lip dry	1 (1.7)	0	1 (1.7)	0	0
Melaena	1 (1.7)	0	0	1 (1.7)	0
Mouth swelling	1 (1.7)	1 (1.7)	0	0	0
Neutropenic colitis	1 (1.7)	0	0	1 (1.7)	0
Odynophagia	1 (1.7)	1 (1.7)	0	0	0
Peritoneal haematoma	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Trichoglossia	1 (1.7)	0	1 (1.7)	0	0
Upper gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	40 (67.8)	21 (35.6)	10 (16.9)	6 (10.2)	3 (5.1)
Pyrexia	26 (44.1)	12 (20.3)	7 (11.9)	5 (8.5)	2 (3.4)
Fatigue	14 (23.7)	12 (20.3)	2 (3.4)	0	0
Face oedema	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Chills	6 (10.2)	4 (6.8)	2 (3.4)	0	0
Oedema peripheral	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Generalised oedema	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Pain	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Asthenia	3 (5.1)	3 (5.1)	0	0	0
Catheter site pain	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Influenza like illness	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Localised oedema	2 (3.4)	2 (3.4)	0	0	0
Malaise	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Catheter site erythema	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Chest discomfort	1 (1.7)	0	0	1 (1.7)	0
Crying	1 (1.7)	0	1 (1.7)	0	0
Drug withdrawal syndrome	1 (1.7)	0	1 (1.7)	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Oedema due to hepatic disease	1 (1.7)	0	1 (1.7)	0	0
Sluggishness	1 (1.7)	0	1 (1.7)	0	0
Swelling face	1 (1.7)	1 (1.7)	0	0	0
Systemic inflammatory response syndrome	1 (1.7)	0	0	1 (1.7)	0
Vascular device occlusion	1 (1.7)	1 (1.7)	0	0	0
Xerosis	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	12 (20.3)	5 (8.5)	6 (10.2)	0	1 (1.7)
Hyperbilirubinaemia	3 (5.1)	0	3 (5.1)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholelithiasis	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Gallbladder enlargement	2 (3.4)	2 (3.4)	0	0	0
Hepatomegaly	2 (3.4)	2 (3.4)	0	0	0
Hypertransaminasaemia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Biliary tract disorder	1 (1.7)	1 (1.7)	0	0	0
Cholestasis	1 (1.7)	0	0	0	1 (1.7)
Hepatic cytolysis	1 (1.7)	1 (1.7)	0	0	0
Hepatic function abnormal	1 (1.7)	0	1 (1.7)	0	0
Liver disorder	1 (1.7)	0	1 (1.7)	0	0
Ocular icterus	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	51 (86.4)	1 (1.7)	18 (30.5)	20 (33.9)	12 (20.3)
Cytokine release syndrome	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Hypogammaglobulinaemia	24 (40.7)	1 (1.7)	16 (27.1)	7 (11.9)	0
Haemophagocytic lymphohistiocytosis	5 (8.5)	1 (1.7)	1 (1.7)	2 (3.4)	1 (1.7)
Immunodeficiency	3 (5.1)	0	0	3 (5.1)	0
Drug hypersensitivity	2 (3.4)	0	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	2 (3.4)	0	0	2 (3.4)	0
Seasonal allergy	2 (3.4)	0	2 (3.4)	0	0
Allergy to immunoglobulin therapy	1 (1.7)	1 (1.7)	0	0	0
Chronic graft versus host disease	1 (1.7)	0	1 (1.7)	0	0
Engraftment syndrome	1 (1.7)	0	0	1 (1.7)	0
Hypersensitivity	1 (1.7)	1 (1.7)	0	0	0
Selective igg subclass deficiency	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	44 (74.6)	5 (8.5)	10 (16.9)	18 (30.5)	11 (18.6)
Upper respiratory tract infection	9 (15.3)	4 (6.8)	4 (6.8)	1 (1.7)	0
Conjunctivitis	7 (11.9)	2 (3.4)	5 (8.5)	0	0
Rhinovirus infection	7 (11.9)	0	6 (10.2)	1 (1.7)	0
Gastroenteritis	6 (10.2)	4 (6.8)	0	2 (3.4)	0
Sinusitis	6 (10.2)	0	4 (6.8)	2 (3.4)	0
Staphylococcal infection	5 (8.5)	0	3 (5.1)	2 (3.4)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	4 (6.8)	0	3 (5.1)	0	1 (1.7)
Clostridium difficile infection	4 (6.8)	1 (1.7)	0	3 (5.1)	0
Nasopharyngitis	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Pneumonia	4 (6.8)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Metapneumovirus infection	3 (5.1)	0	0	3 (5.1)	0
Nail infection	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Oral candidiasis	3 (5.1)	0	3 (5.1)	0	0
Oral herpes	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Parainfluenzae virus infection	3 (5.1)	1 (1.7)	0	1 (1.7)	1 (1.7)
Rhinitis	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Sepsis	3 (5.1)	0	0	1 (1.7)	2 (3.4)
Acute sinusitis	2 (3.4)	0	2 (3.4)	0	0
Bronchitis	2 (3.4)	0	2 (3.4)	0	0
Bronchopulmonary aspergillosis	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Ear infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Encephalitis	2 (3.4)	0	0	0	2 (3.4)
Fungal infection	2 (3.4)	0	2 (3.4)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Gingivitis	2 (3.4)	2 (3.4)	0	0	0
Herpes simplex	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Herpes zoster	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Influenza	2 (3.4)	0	2 (3.4)	0	0
Oral infection	2 (3.4)	0	2 (3.4)	0	0
Otitis media	2 (3.4)	0	2 (3.4)	0	0
Paronychia	2 (3.4)	0	2 (3.4)	0	0
Pneumocystis jirovecii pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Respiratory syncytial virus infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Respiratory tract infection	2 (3.4)	0	2 (3.4)	0	0
Septic shock	2 (3.4)	0	0	0	2 (3.4)
Skin infection	2 (3.4)	0	2 (3.4)	0	0
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Urinary tract infection	2 (3.4)	0	2 (3.4)	0	0
Adenovirus infection	1 (1.7)	0	0	1 (1.7)	0
Anal abscess	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atypical pneumonia	1 (1.7)	1 (1.7)	0	0	0
Bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Bk virus infection	1 (1.7)	0	0	1 (1.7)	0
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	1 (1.7)	0	0
Cholecystitis infective	1 (1.7)	0	1 (1.7)	0	0
Clostridium difficile colitis	1 (1.7)	0	0	1 (1.7)	0
Coronavirus infection	1 (1.7)	0	0	1 (1.7)	0
Covid-19	1 (1.7)	0	0	1 (1.7)	0
Cystitis	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0
Ear, nose and throat infection	1 (1.7)	0	1 (1.7)	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis clostridial	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis escherichia coli	1 (1.7)	0	0	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis salmonella	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal infection	1 (1.7)	1 (1.7)	0	0	0
Granulicatella infection	1 (1.7)	0	0	1 (1.7)	0
Herpes virus infection	1 (1.7)	0	1 (1.7)	0	0
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Localised infection	1 (1.7)	1 (1.7)	0	0	0
Meningitis pneumococcal	1 (1.7)	0	0	1 (1.7)	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Myringitis	1 (1.7)	1 (1.7)	0	0	0
Neutropenic infection	1 (1.7)	0	0	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	1 (1.7)	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia respiratory syncytial viral	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.7)	0	1 (1.7)	0	0
Sinusitis fungal	1 (1.7)	0	0	1 (1.7)	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal sepsis	1 (1.7)	0	0	0	1 (1.7)
Staphylococcal skin infection	1 (1.7)	0	1 (1.7)	0	0
Stomatococcal infection	1 (1.7)	0	1 (1.7)	0	0
Streptococcal sepsis	1 (1.7)	0	1 (1.7)	0	0
Systemic candida	1 (1.7)	0	0	1 (1.7)	0
Tinea pedis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection pseudomonal	1 (1.7)	0	1 (1.7)	0	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	0	0	1 (1.7)	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Viral skin infection	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	19 (32.2)	7 (11.9)	9 (15.3)	1 (1.7)	2 (3.4)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Contusion	2 (3.4)	2 (3.4)	0	0	0
Fall	2 (3.4)	0	2 (3.4)	0	0
Ligament sprain	2 (3.4)	2 (3.4)	0	0	0
Procedural pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Skin abrasion	2 (3.4)	2 (3.4)	0	0	0
Transfusion reaction	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Wound	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Fibula fracture	1 (1.7)	0	1 (1.7)	0	0
Limb injury	1 (1.7)	0	1 (1.7)	0	0
Post-traumatic neck syndrome	1 (1.7)	0	1 (1.7)	0	0
Scratch	1 (1.7)	1 (1.7)	0	0	0
Skin injury	1 (1.7)	0	1 (1.7)	0	0
Skin wound	1 (1.7)	1 (1.7)	0	0	0
Transplant failure	1 (1.7)	0	0	0	1 (1.7)
Vasoplegia syndrome	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	44 (74.6)	3 (5.1)	8 (13.6)	15 (25.4)	18 (30.5)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	18 (30.5)	5 (8.5)	3 (5.1)	5 (8.5)	5 (8.5)
Neutrophil count decreased	17 (28.8)	1 (1.7)	2 (3.4)	3 (5.1)	11 (18.6)
White blood cell count decreased	16 (27.1)	3 (5.1)	4 (6.8)	2 (3.4)	7 (11.9)
Lymphocyte count decreased	14 (23.7)	1 (1.7)	1 (1.7)	8 (13.6)	4 (6.8)
Alanine aminotransferase increased	13 (22.0)	3 (5.1)	6 (10.2)	4 (6.8)	0
Aspartate aminotransferase increased	13 (22.0)	1 (1.7)	5 (8.5)	6 (10.2)	1 (1.7)
Blood bilirubin increased	9 (15.3)	1 (1.7)	2 (3.4)	6 (10.2)	0
International normalised ratio increased	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Blood immunoglobulin a decreased	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Blood immunoglobulin m decreased	6 (10.2)	3 (5.1)	1 (1.7)	2 (3.4)	0
Activated partial thromboplastin time prolonged	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Blood creatinine increased	4 (6.8)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Blood lactate dehydrogenase increased	4 (6.8)	3 (5.1)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	4 (6.8)	2 (3.4)	0	2 (3.4)	0
Electrocardiogram qt prolonged	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Weight increased	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Blood fibrinogen decreased	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Blood immunoglobulin g decreased	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Blood uric acid increased	3 (5.1)	2 (3.4)	0	0	1 (1.7)
Serum ferritin increased	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Immunoglobulins decreased	2 (3.4)	0	2 (3.4)	0	0
Lipase increased	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Oxygen saturation decreased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Urine output decreased	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Weight decreased	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Amylase increased	1 (1.7)	1 (1.7)	0	0	0
Bacterial test positive	1 (1.7)	0	0	1 (1.7)	0
Blood alkaline phosphatase increased	1 (1.7)	1 (1.7)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (1.7)	0	0	0	1 (1.7)
Blood glucose increased	1 (1.7)	0	0	0	1 (1.7)
Blood testosterone decreased	1 (1.7)	1 (1.7)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.7)	1 (1.7)	0	0	0
Blood urea increased	1 (1.7)	0	0	1 (1.7)	0
Bone density decreased	1 (1.7)	1 (1.7)	0	0	0
Breath sounds abnormal	1 (1.7)	0	1 (1.7)	0	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Coagulation test abnormal	1 (1.7)	1 (1.7)	0	0	0
Ejection fraction decreased	1 (1.7)	0	1 (1.7)	0	0
Enterovirus test positive	1 (1.7)	0	1 (1.7)	0	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Gamma-glutamyltransferase increased	1 (1.7)	0	0	1 (1.7)	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Heart sounds abnormal	1 (1.7)	1 (1.7)	0	0	0
Hepatitis b virus test positive	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	1 (1.7)	0	1 (1.7)	0	0
Staphylococcus test positive	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	36 (61.0)	7 (11.9)	8 (13.6)	14 (23.7)	7 (11.9)
Decreased appetite	23 (39.0)	10 (16.9)	6 (10.2)	5 (8.5)	2 (3.4)
Hypokalaemia	15 (25.4)	2 (3.4)	5 (8.5)	6 (10.2)	2 (3.4)
Hypophosphataemia	13 (22.0)	3 (5.1)	4 (6.8)	6 (10.2)	0
Hypocalcaemia	11 (18.6)	2 (3.4)	6 (10.2)	3 (5.1)	0
Hyperuricaemia	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Hypoalbuminaemia	6 (10.2)	0	6 (10.2)	0	0
Hyperglycaemia	5 (8.5)	0	2 (3.4)	3 (5.1)	0
Hypervolaemia	5 (8.5)	0	2 (3.4)	3 (5.1)	0
Hyperphosphataemia	4 (6.8)	4 (6.8)	0	0	0
Hypernatraemia	3 (5.1)	1 (1.7)	0	1 (1.7)	1 (1.7)
Hypomagnesaemia	3 (5.1)	3 (5.1)	0	0	0
Hyperchloraemia	2 (3.4)	2 (3.4)	0	0	0
Hyperkalaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	2 (3.4)	2 (3.4)	0	0	0
Hypertriglyceridaemia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Hyponatraemia	2 (3.4)	2 (3.4)	0	0	0
Metabolic acidosis	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Tumour lysis syndrome	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Acidosis	1 (1.7)	0	0	1 (1.7)	0
Dehydration	1 (1.7)	0	1 (1.7)	0	0
Haemochromatosis	1 (1.7)	0	0	1 (1.7)	0
Haemosiderosis	1 (1.7)	0	1 (1.7)	0	0
Hypercalcaemia	1 (1.7)	0	0	1 (1.7)	0
Hyperlactacidaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperlipidaemia	1 (1.7)	0	1 (1.7)	0	0
Iron overload	1 (1.7)	0	1 (1.7)	0	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic syndrome	1 (1.7)	0	1 (1.7)	0	0
Polydipsia	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	34 (57.6)	16 (27.1)	14 (23.7)	3 (5.1)	1 (1.7)
Pain in extremity	15 (25.4)	8 (13.6)	7 (11.9)	0	0
Arthralgia	8 (13.6)	4 (6.8)	4 (6.8)	0	0
Myalgia	8 (13.6)	4 (6.8)	4 (6.8)	0	0
Back pain	7 (11.9)	2 (3.4)	3 (5.1)	2 (3.4)	0
Bone pain	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Neck pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Pain in jaw	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Growth retardation	1 (1.7)	0	1 (1.7)	0	0
Muscle rigidity	1 (1.7)	1 (1.7)	0	0	0
Muscle spasms	1 (1.7)	0	1 (1.7)	0	0
Muscular weakness	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal pain	1 (1.7)	0	1 (1.7)	0	0
Myositis	1 (1.7)	0	1 (1.7)	0	0
Osteonecrosis	1 (1.7)	1 (1.7)	0	0	0
Rhabdomyolysis	1 (1.7)	0	0	0	1 (1.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Skin papilloma	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Bone giant cell tumour benign	1 (1.7)	0	0	1 (1.7)	0
Cancer pain	1 (1.7)	0	1 (1.7)	0	0
Myelodysplastic syndrome	1 (1.7)	0	0	1 (1.7)	0
Nervous system disorders					
-Total	38 (64.4)	13 (22.0)	12 (20.3)	9 (15.3)	4 (6.8)
Headache	24 (40.7)	12 (20.3)	9 (15.3)	3 (5.1)	0
Encephalopathy	8 (13.6)	1 (1.7)	3 (5.1)	4 (6.8)	0
Somnolence	5 (8.5)	1 (1.7)	2 (3.4)	2 (3.4)	0
Tremor	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Dizziness	4 (6.8)	4 (6.8)	0	0	0
Seizure	3 (5.1)	0	0	3 (5.1)	0
Cerebral haemorrhage	2 (3.4)	0	0	0	2 (3.4)
Dysarthria	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Dysgeusia	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Aphasia	1 (1.7)	1 (1.7)	0	0	0
Autonomic neuropathy	1 (1.7)	0	0	1 (1.7)	0
Depressed level of consciousness	1 (1.7)	0	0	1 (1.7)	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Generalised tonic-clonic seizure	1 (1.7)	0	1 (1.7)	0	0
Hydrocephalus	1 (1.7)	0	0	0	1 (1.7)
Hypoaesthesia	1 (1.7)	1 (1.7)	0	0	0
Memory impairment	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Monoparesis	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorder	1 (1.7)	0	0	1 (1.7)	0
Neurological decompensation	1 (1.7)	0	0	0	1 (1.7)
Psychiatric disorders					
-Total	30 (50.8)	11 (18.6)	14 (23.7)	5 (8.5)	0
Anxiety	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0
Delirium	7 (11.9)	2 (3.4)	2 (3.4)	3 (5.1)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	5 (8.5)	2 (3.4)	3 (5.1)	0	0
Confusional state	5 (8.5)	5 (8.5)	0	0	0
Insomnia	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Mental status changes	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Hallucination	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Irritability	3 (5.1)	3 (5.1)	0	0	0
Sleep disorder	3 (5.1)	0	3 (5.1)	0	0
Affect lability	1 (1.7)	0	1 (1.7)	0	0
Automatism	1 (1.7)	1 (1.7)	0	0	0
Mood altered	1 (1.7)	1 (1.7)	0	0	0
Nightmare	1 (1.7)	1 (1.7)	0	0	0
Persistent depressive disorder	1 (1.7)	0	1 (1.7)	0	0
Restlessness	1 (1.7)	0	1 (1.7)	0	0
Social avoidant behaviour	1 (1.7)	0	1 (1.7)	0	0
Tearfulness	1 (1.7)	1 (1.7)	0	0	0
Tic	1 (1.7)	0	1 (1.7)	0	0
Renal and urinary disorders					
-Total	20 (33.9)	5 (8.5)	5 (8.5)	5 (8.5)	5 (8.5)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	10 (16.9)	2 (3.4)	2 (3.4)	3 (5.1)	3 (5.1)
Dysuria	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Anuria	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Haematuria	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Pollakiuria	2 (3.4)	0	2 (3.4)	0	0
Renal failure	2 (3.4)	0	1 (1.7)	0	1 (1.7)
Azotaemia	1 (1.7)	0	1 (1.7)	0	0
Bladder dilatation	1 (1.7)	0	1 (1.7)	0	0
Incontinence	1 (1.7)	0	1 (1.7)	0	0
Kidney enlargement	1 (1.7)	0	1 (1.7)	0	0
Micturition urgency	1 (1.7)	0	1 (1.7)	0	0
Renal mass	1 (1.7)	0	1 (1.7)	0	0
Renal tubular disorder	1 (1.7)	0	0	1 (1.7)	0
Renal tubular dysfunction	1 (1.7)	1 (1.7)	0	0	0
Renal tubular necrosis	1 (1.7)	0	0	0	1 (1.7)
Urinary incontinence	1 (1.7)	0	1 (1.7)	0	0
Urinary retention	1 (1.7)	0	1 (1.7)	0	0
Urinary tract disorder	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Dysmenorrhoea	1 (1.7)	0	1 (1.7)	0	0
Heavy menstrual bleeding	1 (1.7)	1 (1.7)	0	0	0
Perineal rash	1 (1.7)	0	1 (1.7)	0	0
Vaginal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Vaginal ulceration	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	39 (66.1)	15 (25.4)	5 (8.5)	9 (15.3)	10 (16.9)
Cough	19 (32.2)	15 (25.4)	4 (6.8)	0	0
Hypoxia	14 (23.7)	0	4 (6.8)	8 (13.6)	2 (3.4)
Pulmonary oedema	10 (16.9)	2 (3.4)	3 (5.1)	4 (6.8)	1 (1.7)
Nasal congestion	8 (13.6)	6 (10.2)	2 (3.4)	0	0
Oropharyngeal pain	7 (11.9)	6 (10.2)	1 (1.7)	0	0
Tachypnoea	7 (11.9)	2 (3.4)	1 (1.7)	4 (6.8)	0
Dyspnoea	6 (10.2)	1 (1.7)	2 (3.4)	2 (3.4)	1 (1.7)
Epistaxis	6 (10.2)	4 (6.8)	2 (3.4)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	5 (8.5)	3 (5.1)	0	2 (3.4)	0
Respiratory failure	5 (8.5)	0	0	0	5 (8.5)
Respiratory distress	4 (6.8)	0	2 (3.4)	0	2 (3.4)
Rhinorrhoea	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Atelectasis	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Acute respiratory distress syndrome	2 (3.4)	0	0	0	2 (3.4)
Pharyngeal erythema	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Acute respiratory failure	1 (1.7)	0	0	1 (1.7)	0
Bradypnoea	1 (1.7)	0	0	1 (1.7)	0
Dyspnoea exertional	1 (1.7)	1 (1.7)	0	0	0
Laryngeal oedema	1 (1.7)	0	0	0	1 (1.7)
Lung disorder	1 (1.7)	1 (1.7)	0	0	0
Lung infiltration	1 (1.7)	0	0	1 (1.7)	0
Nasal discomfort	1 (1.7)	0	1 (1.7)	0	0
Oropharyngeal plaque	1 (1.7)	0	1 (1.7)	0	0
Painful respiration	1 (1.7)	1 (1.7)	0	0	0
Paranasal sinus discomfort	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paranasal sinus inflammation	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal exudate	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal oedema	1 (1.7)	0	1 (1.7)	0	0
Productive cough	1 (1.7)	1 (1.7)	0	0	0
Pulmonary mass	1 (1.7)	0	1 (1.7)	0	0
Respiratory acidosis	1 (1.7)	0	0	1 (1.7)	0
Respiratory disorder	1 (1.7)	0	1 (1.7)	0	0
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Sleep apnoea syndrome	1 (1.7)	1 (1.7)	0	0	0
Wheezing	1 (1.7)	0	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	32 (54.2)	14 (23.7)	13 (22.0)	5 (8.5)	0
Dry skin	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Rash	7 (11.9)	3 (5.1)	4 (6.8)	0	0
Pruritus	5 (8.5)	1 (1.7)	4 (6.8)	0	0
Erythema	4 (6.8)	4 (6.8)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Dermatitis atopic	3 (5.1)	2 (3.4)	0	1 (1.7)	0
Eczema	3 (5.1)	2 (3.4)	0	1 (1.7)	0
Hyperhidrosis	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Rash papular	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Ingrowing nail	2 (3.4)	0	2 (3.4)	0	0
Petechiae	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Skin discolouration	2 (3.4)	2 (3.4)	0	0	0
Decubitus ulcer	1 (1.7)	0	1 (1.7)	0	0
Dermatitis	1 (1.7)	1 (1.7)	0	0	0
Dermatitis allergic	1 (1.7)	1 (1.7)	0	0	0
Dermatitis diaper	1 (1.7)	0	1 (1.7)	0	0
Hangnail	1 (1.7)	1 (1.7)	0	0	0
Miliaria	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	1 (1.7)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.7)	1 (1.7)	0	0	0
Papule	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photosensitivity reaction	1 (1.7)	0	1 (1.7)	0	0
Pruritus allergic	1 (1.7)	0	1 (1.7)	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	0	0	1 (1.7)	0
Rash maculo-papular	1 (1.7)	0	1 (1.7)	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Scab	1 (1.7)	1 (1.7)	0	0	0
Skin hypopigmentation	1 (1.7)	1 (1.7)	0	0	0
Skin lesion	1 (1.7)	0	1 (1.7)	0	0
Skin necrosis	1 (1.7)	0	0	1 (1.7)	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Urticaria	1 (1.7)	0	1 (1.7)	0	0
Vancomycin infusion reaction	1 (1.7)	0	0	1 (1.7)	0
Social circumstances					
-Total	1 (1.7)	0	1 (1.7)	0	0
Patient uncooperative	1 (1.7)	0	1 (1.7)	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	23 (39.0)	4 (6.8)	6 (10.2)	8 (13.6)	5 (8.5)
Hypotension	21 (35.6)	2 (3.4)	6 (10.2)	8 (13.6)	5 (8.5)
Hypertension	9 (15.3)	3 (5.1)	5 (8.5)	1 (1.7)	0
Capillary leak syndrome	1 (1.7)	0	1 (1.7)	0	0
Flushing	1 (1.7)	1 (1.7)	0	0	0
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Peripheral ischaemia	1 (1.7)	0	1 (1.7)	0	0
Thrombosis	1 (1.7)	0	1 (1.7)	0	0
Venoocclusive disease	1 (1.7)	0	0	1 (1.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	2 (20.0)	7 (70.0)
Blood and lymphatic system disorders					
-Total	8 (80.0)	0	1 (10.0)	2 (20.0)	5 (50.0)
Disseminated intravascular coagulation	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Neutropenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Thrombocytopenia	2 (20.0)	0	0	0	2 (20.0)
Hypofibrinogenaemia	1 (10.0)	0	1 (10.0)	0	0
Leukopenia	1 (10.0)	0	0	0	1 (10.0)
Lymphopenia	1 (10.0)	0	0	1 (10.0)	0

Timing: Any time post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	1 (10.0)	1 (10.0)	0	0	0
Cardiac disorders					
-Total	4 (40.0)	2 (20.0)	0	0	2 (20.0)
Cardiac dysfunction	2 (20.0)	2 (20.0)	0	0	0
Cardiac arrest	1 (10.0)	0	0	0	1 (10.0)
Cardiac failure	1 (10.0)	0	0	0	1 (10.0)
Tachycardia	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Mydriasis	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	7 (70.0)	3 (30.0)	4 (40.0)	0	0
Constipation	3 (30.0)	3 (30.0)	0	0	0
Diarrhoea	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Nausea	3 (30.0)	3 (30.0)	0	0	0
Pancreatitis	2 (20.0)	0	2 (20.0)	0	0
Enteritis	1 (10.0)	0	1 (10.0)	0	0
Enterocolitis	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (10.0)	1 (10.0)	0	0	0
Trichoglossia	1 (10.0)	1 (10.0)	0	0	0
Vomiting	1 (10.0)	1 (10.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Pyrexia	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Fatigue	1 (10.0)	1 (10.0)	0	0	0
Hepatobiliary disorders					
-Total	5 (50.0)	0	1 (10.0)	2 (20.0)	2 (20.0)
Hepatic function abnormal	4 (40.0)	0	1 (10.0)	2 (20.0)	1 (10.0)
Hepatomegaly	1 (10.0)	0	0	0	1 (10.0)
Immune system disorders					
-Total	9 (90.0)	0	4 (40.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Hypogammaglobulinaemia	5 (50.0)	0	5 (50.0)	0	0
Infections and infestations					
-Total	8 (80.0)	2 (20.0)	1 (10.0)	4 (40.0)	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bk virus infection	1 (10.0)	1 (10.0)	0	0	0
Cytomegalovirus infection reactivation	1 (10.0)	0	0	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Fungal skin infection	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	0	1 (10.0)	0
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Nasopharyngitis	1 (10.0)	1 (10.0)	0	0	0
Oral herpes	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)	0	0
Otitis media	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	1 (10.0)	0
Sinusitis	1 (10.0)	0	1 (10.0)	0	0
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Upper respiratory tract infection	1 (10.0)	0	0	1 (10.0)	0
Urinary tract infection viral	1 (10.0)	1 (10.0)	0	0	0
Varicella zoster virus infection	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	7 (70.0)	0	1 (10.0)	2 (20.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	0	0	4 (40.0)
Blood fibrinogen decreased	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Serum ferritin increased	3 (30.0)	0	3 (30.0)	0	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)	0	0
Blood bilirubin increased	1 (10.0)	0	0	1 (10.0)	0
Blood creatine phosphokinase increased	1 (10.0)	0	0	1 (10.0)	0
Fibrin d dimer increased	1 (10.0)	1 (10.0)	0	0	0
Gamma-glutamyltransferase increased	1 (10.0)	0	0	1 (10.0)	0
Haptoglobin decreased	1 (10.0)	1 (10.0)	0	0	0
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	6 (60.0)	2 (20.0)	1 (10.0)	1 (10.0)	2 (20.0)
Metabolic acidosis	2 (20.0)	0	0	0	2 (20.0)
Tumour lysis syndrome	2 (20.0)	0	0	2 (20.0)	0
Decreased appetite	1 (10.0)	1 (10.0)	0	0	0
Hypercalcaemia	1 (10.0)	0	0	1 (10.0)	0
Hypercholesterolaemia	1 (10.0)	0	1 (10.0)	0	0
Hyperkalaemia	1 (10.0)	0	0	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	0	0	1 (10.0)
Hypertriglyceridaemia	1 (10.0)	0	1 (10.0)	0	0
Hyperuricaemia	1 (10.0)	1 (10.0)	0	0	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)	0	0
Iron overload	1 (10.0)	0	1 (10.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (40.0)	0	2 (20.0)	2 (20.0)	0
Arthralgia	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Back pain	1 (10.0)	0	0	1 (10.0)	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint effusion	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	0	1 (10.0)	0
Musculoskeletal chest pain	1 (10.0)	1 (10.0)	0	0	0
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Synovitis	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Headache	1 (10.0)	0	1 (10.0)	0	0
Seizure	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Anxiety	1 (10.0)	0	1 (10.0)	0	0
Delirium	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	4 (40.0)	1 (10.0)	1 (10.0)	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Cystitis haemorrhagic	1 (10.0)	0	1 (10.0)	0	0
Haematuria	1 (10.0)	1 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proteinuria	1 (10.0)	1 (10.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Endometriosis	1 (10.0)	0	0	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (80.0)	2 (20.0)	2 (20.0)	0	4 (40.0)
Hypoxia	4 (40.0)	0	0	0	4 (40.0)
Pleural effusion	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Cough	1 (10.0)	1 (10.0)	0	0	0
Haemoptysis	1 (10.0)	0	1 (10.0)	0	0
Nasal congestion	1 (10.0)	1 (10.0)	0	0	0
Nasal dryness	1 (10.0)	1 (10.0)	0	0	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0	0	0
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Upper respiratory tract inflammation	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Dry skin	1 (10.0)	1 (10.0)	0	0	0
Erythema nodosum	1 (10.0)	1 (10.0)	0	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Skin swelling	1 (10.0)	1 (10.0)	0	0	0
Skin ulcer	1 (10.0)	0	1 (10.0)	0	0
Vascular disorders					
-Total	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Hypertension	2 (20.0)	0	2 (20.0)	0	0
Hypotension	1 (10.0)	0	0	0	1 (10.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	0	0	11 (100)
Blood and lymphatic system disorders					
-Total	9 (81.8)	0	1 (9.1)	7 (63.6)	1 (9.1)
Anaemia	6 (54.5)	1 (9.1)	1 (9.1)	4 (36.4)	0
Febrile neutropenia	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Hypercoagulation	1 (9.1)	0	1 (9.1)	0	0
Lymphadenopathy	1 (9.1)	1 (9.1)	0	0	0
Thrombocytopenia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	3 (27.3)	1 (9.1)	0	1 (9.1)	1 (9.1)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (9.1)	0	0	0	1 (9.1)
Left ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus bradycardia	1 (9.1)	0	0	1 (9.1)	0
Tachycardia	1 (9.1)	1 (9.1)	0	0	0
Endocrine disorders					
-Total	3 (27.3)	0	3 (27.3)	0	0
Adrenal insufficiency	2 (18.2)	0	2 (18.2)	0	0
Delayed puberty	1 (9.1)	0	1 (9.1)	0	0
Hypothyroidism	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Dry eye	1 (9.1)	1 (9.1)	0	0	0
Gastrointestinal disorders					
-Total	10 (90.9)	2 (18.2)	5 (45.5)	3 (27.3)	0
Vomiting	6 (54.5)	4 (36.4)	1 (9.1)	1 (9.1)	0
Diarrhoea	5 (45.5)	3 (27.3)	2 (18.2)	0	0
Constipation	4 (36.4)	1 (9.1)	3 (27.3)	0	0
Nausea	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Abdominal distension	1 (9.1)	1 (9.1)	0	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Lip oedema	1 (9.1)	1 (9.1)	0	0	0
Mouth haemorrhage	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	10 (90.9)	3 (27.3)	2 (18.2)	3 (27.3)	2 (18.2)
Pyrexia	6 (54.5)	1 (9.1)	2 (18.2)	3 (27.3)	0
Fatigue	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Multiple organ dysfunction syndrome	2 (18.2)	0	0	0	2 (18.2)
Chills	1 (9.1)	1 (9.1)	0	0	0
Drug withdrawal syndrome	1 (9.1)	0	1 (9.1)	0	0
Generalised oedema	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0	0	0
Oedema peripheral	1 (9.1)	1 (9.1)	0	0	0
Pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hyperbilirubinaemia	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Immune system disorders					
-Total	11 (100)	1 (9.1)	1 (9.1)	2 (18.2)	7 (63.6)
Cytokine release syndrome	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Hypogammaglobulinaemia	4 (36.4)	1 (9.1)	3 (27.3)	0	0
Seasonal allergy	2 (18.2)	2 (18.2)	0	0	0
Allergy to immunoglobulin therapy	1 (9.1)	0	0	1 (9.1)	0
Chronic graft versus host disease	1 (9.1)	0	0	1 (9.1)	0
Haemophagocytic lymphohistiocytosis	1 (9.1)	0	0	0	1 (9.1)
Immunodeficiency	1 (9.1)	0	0	1 (9.1)	0
Infections and infestations					
-Total	8 (72.7)	1 (9.1)	2 (18.2)	3 (27.3)	2 (18.2)
Upper respiratory tract infection	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Parainfluenzae virus infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Rhinovirus infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Staphylococcal bacteraemia	2 (18.2)	0	0	2 (18.2)	0
Adenovirus infection	1 (9.1)	0	0	1 (9.1)	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Covid-19	1 (9.1)	1 (9.1)	0	0	0
Covid-19 pneumonia	1 (9.1)	0	0	0	1 (9.1)
Ear infection	1 (9.1)	0	1 (9.1)	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Enterobacter infection	1 (9.1)	0	0	1 (9.1)	0
Enterovirus infection	1 (9.1)	0	0	1 (9.1)	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Influenza	1 (9.1)	0	0	0	1 (9.1)
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Mastoiditis	1 (9.1)	0	0	1 (9.1)	0
Nail infection	1 (9.1)	1 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Skin infection	1 (9.1)	0	1 (9.1)	0	0
Syphilis	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Injury, poisoning and procedural complications					
-Total	2 (18.2)	2 (18.2)	0	0	0
Abdominal injury	1 (9.1)	1 (9.1)	0	0	0
Infusion related reaction	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	9 (81.8)	0	0	2 (18.2)	7 (63.6)
Neutrophil count decreased	5 (45.5)	0	0	1 (9.1)	4 (36.4)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (45.5)	1 (9.1)	0	1 (9.1)	3 (27.3)
White blood cell count decreased	5 (45.5)	0	0	0	5 (45.5)
Alanine aminotransferase increased	4 (36.4)	0	1 (9.1)	3 (27.3)	0
Aspartate aminotransferase increased	4 (36.4)	0	0	2 (18.2)	2 (18.2)
Blood bilirubin increased	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Lymphocyte count decreased	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Activated partial thromboplastin time prolonged	2 (18.2)	0	1 (9.1)	1 (9.1)	0
International normalised ratio increased	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Serum ferritin increased	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Blood creatinine increased	1 (9.1)	0	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)
Blood immunoglobulin a decreased	1 (9.1)	1 (9.1)	0	0	0
Blood immunoglobulin g decreased	1 (9.1)	0	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (9.1)	1 (9.1)	0	0	0
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Blood phosphorus increased	1 (9.1)	0	1 (9.1)	0	0
Blood uric acid increased	1 (9.1)	0	0	1 (9.1)	0
C-reactive protein increased	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	0	1 (9.1)
Electrocardiogram t wave abnormal	1 (9.1)	0	1 (9.1)	0	0
Fibrin d dimer increased	1 (9.1)	0	0	1 (9.1)	0
Oxygen saturation decreased	1 (9.1)	0	0	1 (9.1)	0
Troponin increased	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	10 (90.9)	0	1 (9.1)	7 (63.6)	2 (18.2)
Decreased appetite	6 (54.5)	0	1 (9.1)	5 (45.5)	0
Hypocalcaemia	5 (45.5)	0	3 (27.3)	2 (18.2)	0
Hypokalaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Hyperglycaemia	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Hypoalbuminaemia	4 (36.4)	0	3 (27.3)	1 (9.1)	0
Hypomagnesaemia	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hyperuricaemia	2 (18.2)	2 (18.2)	0	0	0
Hypervolaemia	2 (18.2)	0	0	2 (18.2)	0
Acidosis	1 (9.1)	0	0	0	1 (9.1)
Calcium deficiency	1 (9.1)	1 (9.1)	0	0	0
Hypercalcaemia	1 (9.1)	0	1 (9.1)	0	0
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hyponatraemia	1 (9.1)	1 (9.1)	0	0	0
Hypophagia	1 (9.1)	0	1 (9.1)	0	0
Malnutrition	1 (9.1)	0	0	1 (9.1)	0
Obesity	1 (9.1)	0	0	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (54.5)	1 (9.1)	3 (27.3)	2 (18.2)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Back pain	2 (18.2)	0	2 (18.2)	0	0
Myalgia	2 (18.2)	2 (18.2)	0	0	0
Bone pain	1 (9.1)	0	1 (9.1)	0	0
Growth retardation	1 (9.1)	0	1 (9.1)	0	0
Haemarthrosis	1 (9.1)	0	0	1 (9.1)	0
Osteopenia	1 (9.1)	1 (9.1)	0	0	0
Pain in extremity	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	7 (63.6)	2 (18.2)	4 (36.4)	1 (9.1)	0
Cognitive disorder	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Headache	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Amnesia	1 (9.1)	0	1 (9.1)	0	0
Dysgeusia	1 (9.1)	1 (9.1)	0	0	0
Extrapyramidal disorder	1 (9.1)	0	1 (9.1)	0	0
Hyperaesthesia	1 (9.1)	1 (9.1)	0	0	0
Lethargy	1 (9.1)	1 (9.1)	0	0	0
Neuralgia	1 (9.1)	0	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	1 (9.1)	1 (9.1)	0	0	0
Tremor	1 (9.1)	1 (9.1)	0	0	0
Psychiatric disorders					
-Total	8 (72.7)	2 (18.2)	4 (36.4)	2 (18.2)	0
Anxiety	5 (45.5)	0	4 (36.4)	1 (9.1)	0
Confusional state	2 (18.2)	2 (18.2)	0	0	0
Agitation	1 (9.1)	1 (9.1)	0	0	0
Hallucination, visual	1 (9.1)	0	1 (9.1)	0	0
Mental status changes	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Reproductive system and breast disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Female genital tract fistula	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (72.7)	1 (9.1)	1 (9.1)	3 (27.3)	3 (27.3)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hypoxia	2 (18.2)	0	0	2 (18.2)	0
Pleural effusion	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Pulmonary oedema	2 (18.2)	0	0	2 (18.2)	0
Rhinorrhoea	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Tachypnoea	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Acute respiratory distress syndrome	1 (9.1)	0	0	0	1 (9.1)
Bronchial oedema	1 (9.1)	1 (9.1)	0	0	0
Bronchospasm	1 (9.1)	0	1 (9.1)	0	0
Dyspnoea	1 (9.1)	0	0	0	1 (9.1)
Epistaxis	1 (9.1)	0	0	1 (9.1)	0
Rhinitis allergic	1 (9.1)	0	1 (9.1)	0	0
Sleep apnoea syndrome	1 (9.1)	0	1 (9.1)	0	0
Wheezing	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (45.5)	1 (9.1)	2 (18.2)	2 (18.2)	0
Rash maculo-papular	2 (18.2)	1 (9.1)	0	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Decubitus ulcer	1 (9.1)	0	0	1 (9.1)	0
Erythema	1 (9.1)	0	1 (9.1)	0	0
Pruritus	1 (9.1)	0	1 (9.1)	0	0
Purpura	1 (9.1)	1 (9.1)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Surgical and medical procedures					
-Total	1 (9.1)	0	0	1 (9.1)	0
Thrombolysis	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	8 (72.7)	1 (9.1)	0	4 (36.4)	3 (27.3)
Hypertension	5 (45.5)	1 (9.1)	0	4 (36.4)	0
Hypotension	2 (18.2)	0	0	0	2 (18.2)
Capillary leak syndrome	1 (9.1)	0	0	1 (9.1)	0
Venoocclusive disease	1 (9.1)	0	0	0	1 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	3 (20.0)	1 (6.7)	11 (73.3)
Blood and lymphatic system disorders					
-Total	10 (66.7)	0	1 (6.7)	7 (46.7)	2 (13.3)
Febrile neutropenia	8 (53.3)	0	0	6 (40.0)	2 (13.3)
Anaemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Coagulopathy	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	0	1 (6.7)	0	0
Thrombocytopenia	1 (6.7)	0	0	1 (6.7)	0
Cardiac disorders					
-Total	5 (33.3)	1 (6.7)	3 (20.0)	1 (6.7)	0
Tachycardia	3 (20.0)	0	3 (20.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (13.3)	2 (13.3)	0	0	0
Left ventricular dysfunction	1 (6.7)	0	0	1 (6.7)	0
Sinus bradycardia	1 (6.7)	0	0	1 (6.7)	0
Endocrine disorders					
-Total	3 (20.0)	0	3 (20.0)	0	0
Adrenal insufficiency	3 (20.0)	0	3 (20.0)	0	0
Gastrointestinal disorders					
-Total	9 (60.0)	3 (20.0)	3 (20.0)	2 (13.3)	1 (6.7)
Constipation	4 (26.7)	1 (6.7)	3 (20.0)	0	0
Diarrhoea	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Vomiting	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Abdominal compartment syndrome	1 (6.7)	0	0	0	1 (6.7)
Abdominal pain	1 (6.7)	1 (6.7)	0	0	0
Dry mouth	1 (6.7)	0	1 (6.7)	0	0
Mouth haemorrhage	1 (6.7)	0	0	1 (6.7)	0
Nausea	1 (6.7)	0	1 (6.7)	0	0
Pancreatitis	1 (6.7)	0	1 (6.7)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	6 (40.0)	1 (6.7)	2 (13.3)	2 (13.3)	1 (6.7)
Oedema peripheral	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Pyrexia	3 (20.0)	1 (6.7)	0	2 (13.3)	0
Chills	2 (13.3)	2 (13.3)	0	0	0
Generalised oedema	2 (13.3)	0	2 (13.3)	0	0
Drug withdrawal syndrome	1 (6.7)	0	1 (6.7)	0	0
Face oedema	1 (6.7)	1 (6.7)	0	0	0
Fatigue	1 (6.7)	1 (6.7)	0	0	0
Multiple organ dysfunction syndrome	1 (6.7)	0	0	0	1 (6.7)
Hepatobiliary disorders					
-Total	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Biliary tract disorder	1 (6.7)	1 (6.7)	0	0	0
Gallbladder enlargement	1 (6.7)	1 (6.7)	0	0	0
Hyperbilirubinaemia	1 (6.7)	0	0	1 (6.7)	0
Hypertransaminasaemia	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (100)	0	6 (40.0)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Hypogammaglobulinaemia	4 (26.7)	1 (6.7)	2 (13.3)	1 (6.7)	0
Haemophagocytic lymphohistiocytosis	1 (6.7)	0	0	1 (6.7)	0
Seasonal allergy	1 (6.7)	0	1 (6.7)	0	0
Selective igg subclass deficiency	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	5 (33.3)	1 (6.7)	1 (6.7)	3 (20.0)	0
Staphylococcal bacteraemia	2 (13.3)	0	0	2 (13.3)	0
Adenovirus infection	1 (6.7)	0	0	1 (6.7)	0
Atypical pneumonia	1 (6.7)	1 (6.7)	0	0	0
Candida infection	1 (6.7)	0	1 (6.7)	0	0
Conjunctivitis	1 (6.7)	1 (6.7)	0	0	0
Encephalitis viral	1 (6.7)	0	0	1 (6.7)	0
Gastroenteritis norovirus	1 (6.7)	1 (6.7)	0	0	0
Klebsiella bacteraemia	1 (6.7)	0	1 (6.7)	0	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (6.7)	0	1 (6.7)	0	0
Injury, poisoning and procedural complications					
-Total	2 (13.3)	0	2 (13.3)	0	0
Infusion related reaction	1 (6.7)	0	1 (6.7)	0	0
Transfusion reaction	1 (6.7)	0	1 (6.7)	0	0
Investigations					
-Total	10 (66.7)	0	1 (6.7)	3 (20.0)	6 (40.0)
Aspartate aminotransferase increased	7 (46.7)	0	1 (6.7)	4 (26.7)	2 (13.3)
Alanine aminotransferase increased	5 (33.3)	0	2 (13.3)	3 (20.0)	0
Blood bilirubin increased	4 (26.7)	0	0	4 (26.7)	0
Blood creatinine increased	3 (20.0)	1 (6.7)	0	2 (13.3)	0
Platelet count decreased	3 (20.0)	0	0	0	3 (20.0)
White blood cell count decreased	3 (20.0)	0	0	0	3 (20.0)
Activated partial thromboplastin time prolonged	2 (13.3)	0	1 (6.7)	1 (6.7)	0
International normalised ratio increased	2 (13.3)	0	2 (13.3)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

		All patients N=15			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (13.3)	0	0	0	2 (13.3)
Blood alkaline phosphatase increased	1 (6.7)	1 (6.7)	0	0	0
Blood lactate dehydrogenase increased	1 (6.7)	0	0	1 (6.7)	0
Blood phosphorus increased	1 (6.7)	0	1 (6.7)	0	0
Blood uric acid increased	1 (6.7)	1 (6.7)	0	0	0
C-reactive protein increased	1 (6.7)	0	0	1 (6.7)	0
Electrocardiogram qt prolonged	1 (6.7)	0	0	0	1 (6.7)
Electrocardiogram t wave abnormal	1 (6.7)	0	1 (6.7)	0	0
Fibrin d dimer increased	1 (6.7)	0	0	1 (6.7)	0
Serum ferritin increased	1 (6.7)	0	0	1 (6.7)	0
Staphylococcus test positive	1 (6.7)	1 (6.7)	0	0	0
Troponin increased	1 (6.7)	0	0	1 (6.7)	0
Urine output decreased	1 (6.7)	0	0	1 (6.7)	0
Weight decreased	1 (6.7)	0	1 (6.7)	0	0
Weight increased	1 (6.7)	0	1 (6.7)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	12 (80.0)	0	3 (20.0)	6 (40.0)	3 (20.0)
Hypocalcaemia	8 (53.3)	0	5 (33.3)	3 (20.0)	0
Decreased appetite	7 (46.7)	0	2 (13.3)	5 (33.3)	0
Hypokalaemia	6 (40.0)	1 (6.7)	2 (13.3)	2 (13.3)	1 (6.7)
Hyperglycaemia	5 (33.3)	0	3 (20.0)	2 (13.3)	0
Hypoalbuminaemia	5 (33.3)	0	4 (26.7)	1 (6.7)	0
Hypophosphataemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Hyperuricaemia	3 (20.0)	2 (13.3)	0	1 (6.7)	0
Hypervolaemia	3 (20.0)	0	0	3 (20.0)	0
Hypomagnesaemia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Acidosis	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypercalcaemia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Tumour lysis syndrome	2 (13.3)	0	0	2 (13.3)	0
Calcium deficiency	1 (6.7)	1 (6.7)	0	0	0
Hyperkalaemia	1 (6.7)	0	0	1 (6.7)	0
Hypermagnesaemia	1 (6.7)	1 (6.7)	0	0	0
Hyperphosphataemia	1 (6.7)	1 (6.7)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

		All patients N=15			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoglycaemia	1 (6.7)	0	1 (6.7)	0	0
Hyponatraemia	1 (6.7)	1 (6.7)	0	0	0
Malnutrition	1 (6.7)	0	0	1 (6.7)	0
Metabolic acidosis	1 (6.7)	0	0	0	1 (6.7)
Musculoskeletal and connective tissue disorders					
-Total	5 (33.3)	3 (20.0)	1 (6.7)	1 (6.7)	0
Arthralgia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Myalgia	2 (13.3)	2 (13.3)	0	0	0
Back pain	1 (6.7)	1 (6.7)	0	0	0
Haemarthrosis	1 (6.7)	0	0	1 (6.7)	0
Muscle spasms	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	8 (53.3)	0	5 (33.3)	1 (6.7)	2 (13.3)
Headache	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Cognitive disorder	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Somnolence	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Amnesia	1 (6.7)	0	1 (6.7)	0	0
Cerebral haemorrhage	1 (6.7)	0	0	0	1 (6.7)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0
Hyperaesthesia	1 (6.7)	1 (6.7)	0	0	0
Neurological decompensation	1 (6.7)	0	0	0	1 (6.7)
Paraesthesia	1 (6.7)	1 (6.7)	0	0	0
Tremor	1 (6.7)	1 (6.7)	0	0	0
Psychiatric disorders					
-Total	5 (33.3)	1 (6.7)	2 (13.3)	2 (13.3)	0
Anxiety	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Agitation	1 (6.7)	0	1 (6.7)	0	0
Delirium	1 (6.7)	0	0	1 (6.7)	0
Hallucination, visual	1 (6.7)	0	1 (6.7)	0	0
Insomnia	1 (6.7)	1 (6.7)	0	0	0
Mental status changes	1 (6.7)	0	1 (6.7)	0	0
Renal and urinary disorders					
-Total	4 (26.7)	0	1 (6.7)	1 (6.7)	2 (13.3)
Acute kidney injury	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Renal failure	1 (6.7)	0	0	0	1 (6.7)
Urinary retention	1 (6.7)	0	1 (6.7)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Female genital tract fistula	1 (6.7)	1 (6.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (53.3)	0	1 (6.7)	3 (20.0)	4 (26.7)
Pulmonary oedema	4 (26.7)	0	1 (6.7)	2 (13.3)	1 (6.7)
Hypoxia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Pleural effusion	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Acute respiratory distress syndrome	1 (6.7)	0	0	0	1 (6.7)
Acute respiratory failure	1 (6.7)	0	0	1 (6.7)	0
Nasal congestion	1 (6.7)	0	1 (6.7)	0	0
Respiratory distress	1 (6.7)	0	0	0	1 (6.7)
Respiratory failure	1 (6.7)	0	0	0	1 (6.7)
Tachypnoea	1 (6.7)	0	0	1 (6.7)	0
Wheezing	1 (6.7)	0	1 (6.7)	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Blister	1 (6.7)	0	1 (6.7)	0	0
Hyperhidrosis	1 (6.7)	1 (6.7)	0	0	0
Pruritus	1 (6.7)	0	1 (6.7)	0	0
Scab	1 (6.7)	1 (6.7)	0	0	0
Surgical and medical procedures					
-Total	1 (6.7)	0	0	1 (6.7)	0
Thrombolysis	1 (6.7)	0	0	1 (6.7)	0
Vascular disorders					
-Total	9 (60.0)	1 (6.7)	1 (6.7)	5 (33.3)	2 (13.3)
Hypotension	6 (40.0)	0	1 (6.7)	3 (20.0)	2 (13.3)
Hypertension	4 (26.7)	2 (13.3)	0	2 (13.3)	0
Capillary leak syndrome	1 (6.7)	0	0	1 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (98.5)	4 (6.2)	5 (7.7)	20 (30.8)	35 (53.8)
Blood and lymphatic system disorders					
-Total	40 (61.5)	3 (4.6)	7 (10.8)	19 (29.2)	11 (16.9)
Febrile neutropenia	18 (27.7)	0	0	18 (27.7)	0
Anaemia	17 (26.2)	5 (7.7)	7 (10.8)	5 (7.7)	0
Neutropenia	9 (13.8)	0	2 (3.1)	1 (1.5)	6 (9.2)
Thrombocytopenia	7 (10.8)	0	0	1 (1.5)	6 (9.2)
Disseminated intravascular coagulation	6 (9.2)	0	4 (6.2)	2 (3.1)	0
Splenomegaly	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Coagulopathy	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (4.6)	0	1 (1.5)	1 (1.5)	1 (1.5)
Pancytopenia	2 (3.1)	0	0	2 (3.1)	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Eosinophilia	1 (1.5)	0	1 (1.5)	0	0
Hypofibrinogenaemia	1 (1.5)	0	1 (1.5)	0	0
Lymphopenia	1 (1.5)	0	0	1 (1.5)	0
Cardiac disorders					
-Total	19 (29.2)	9 (13.8)	3 (4.6)	4 (6.2)	3 (4.6)
Tachycardia	14 (21.5)	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)
Bradycardia	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Cardiac dysfunction	2 (3.1)	2 (3.1)	0	0	0
Left ventricular dysfunction	2 (3.1)	0	0	2 (3.1)	0
Atrioventricular block first degree	1 (1.5)	0	1 (1.5)	0	0
Cardiac arrest	1 (1.5)	0	0	0	1 (1.5)
Cardiac failure	1 (1.5)	0	0	0	1 (1.5)
Cardiac failure congestive	1 (1.5)	0	1 (1.5)	0	0
Mitral valve incompetence	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (1.5)	1 (1.5)	0	0	0
Right ventricular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Sinus tachycardia	1 (1.5)	0	1 (1.5)	0	0
Ear and labyrinth disorders					
-Total	2 (3.1)	2 (3.1)	0	0	0
Ear pain	1 (1.5)	1 (1.5)	0	0	0
Ear pruritus	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					
-Total	2 (3.1)	0	2 (3.1)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Hypothyroidism	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	9 (13.8)	6 (9.2)	3 (4.6)	0	0
Conjunctival haemorrhage	2 (3.1)	2 (3.1)	0	0	0
Eyelid oedema	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Ocular hyperaemia	2 (3.1)	2 (3.1)	0	0	0
Eye oedema	1 (1.5)	1 (1.5)	0	0	0
Eye pain	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	1 (1.5)	1 (1.5)	0	0	0
Periorbital swelling	1 (1.5)	0	1 (1.5)	0	0
Retinal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Visual impairment	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	42 (64.6)	16 (24.6)	15 (23.1)	11 (16.9)	0
Vomiting	19 (29.2)	11 (16.9)	8 (12.3)	0	0
Nausea	17 (26.2)	10 (15.4)	5 (7.7)	2 (3.1)	0
Diarrhoea	13 (20.0)	7 (10.8)	5 (7.7)	1 (1.5)	0
Abdominal pain	10 (15.4)	2 (3.1)	6 (9.2)	2 (3.1)	0
Constipation	7 (10.8)	5 (7.7)	2 (3.1)	0	0
Abdominal distension	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Abdominal pain upper	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Ascites	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Mouth haemorrhage	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Pancreatitis	3 (4.6)	0	2 (3.1)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	2 (3.1)	2 (3.1)	0	0	0
Stomatitis	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Anal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Enterocolitis	1 (1.5)	0	1 (1.5)	0	0
Gastrooesophageal reflux disease	1 (1.5)	0	1 (1.5)	0	0
Gingival bleeding	1 (1.5)	0	1 (1.5)	0	0
Gingival erythema	1 (1.5)	1 (1.5)	0	0	0
Gingivitis ulcerative	1 (1.5)	0	0	1 (1.5)	0
Haematemesis	1 (1.5)	1 (1.5)	0	0	0
Ileus	1 (1.5)	0	1 (1.5)	0	0
Lip dry	1 (1.5)	0	1 (1.5)	0	0
Lip oedema	1 (1.5)	1 (1.5)	0	0	0
Melaena	1 (1.5)	0	0	1 (1.5)	0
Mouth swelling	1 (1.5)	1 (1.5)	0	0	0
Neutropenic colitis	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (1.5)	1 (1.5)	0	0	0
Proctalgia	1 (1.5)	0	0	1 (1.5)	0
Trichoglossia	1 (1.5)	0	1 (1.5)	0	0
Upper gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	34 (52.3)	19 (29.2)	7 (10.8)	5 (7.7)	3 (4.6)
Pyrexia	21 (32.3)	10 (15.4)	5 (7.7)	4 (6.2)	2 (3.1)
Fatigue	10 (15.4)	8 (12.3)	2 (3.1)	0	0
Face oedema	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Chills	4 (6.2)	2 (3.1)	2 (3.1)	0	0
Generalised oedema	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Oedema peripheral	3 (4.6)	2 (3.1)	0	1 (1.5)	0
Asthenia	2 (3.1)	2 (3.1)	0	0	0
Catheter site pain	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Influenza like illness	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Localised oedema	2 (3.1)	2 (3.1)	0	0	0
Catheter site erythema	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Chest discomfort	1 (1.5)	0	0	1 (1.5)	0
Crying	1 (1.5)	0	1 (1.5)	0	0
Drug withdrawal syndrome	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Malaise	1 (1.5)	0	1 (1.5)	0	0
Multiple organ dysfunction syndrome	1 (1.5)	0	0	0	1 (1.5)
Oedema due to hepatic disease	1 (1.5)	0	1 (1.5)	0	0
Pain	1 (1.5)	0	0	1 (1.5)	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Swelling face	1 (1.5)	1 (1.5)	0	0	0
Systemic inflammatory response syndrome	1 (1.5)	0	0	1 (1.5)	0
Vascular device occlusion	1 (1.5)	1 (1.5)	0	0	0
Hepatobiliary disorders					
-Total	15 (23.1)	4 (6.2)	6 (9.2)	2 (3.1)	3 (4.6)
Hepatic function abnormal	5 (7.7)	0	2 (3.1)	2 (3.1)	1 (1.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	4 (6.2)	1 (1.5)	3 (4.6)	0	0
Hepatomegaly	3 (4.6)	2 (3.1)	0	0	1 (1.5)
Cholelithiasis	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Cholestasis	1 (1.5)	0	0	0	1 (1.5)
Gallbladder enlargement	1 (1.5)	1 (1.5)	0	0	0
Hypertransaminasaemia	1 (1.5)	0	1 (1.5)	0	0
Ocular icterus	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	52 (80.0)	3 (4.6)	15 (23.1)	21 (32.3)	13 (20.0)
Cytokine release syndrome	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Hypogammaglobulinaemia	19 (29.2)	1 (1.5)	12 (18.5)	6 (9.2)	0
Haemophagocytic lymphohistiocytosis	4 (6.2)	1 (1.5)	1 (1.5)	1 (1.5)	1 (1.5)
Immunodeficiency	3 (4.6)	0	0	3 (4.6)	0
Hypersensitivity	1 (1.5)	1 (1.5)	0	0	0
Infections and infestations					
-Total	30 (46.2)	5 (7.7)	9 (13.8)	13 (20.0)	3 (4.6)
Clostridium difficile infection	4 (6.2)	1 (1.5)	0	3 (4.6)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	4 (6.2)	0	4 (6.2)	0	0
Staphylococcal infection	4 (6.2)	0	2 (3.1)	2 (3.1)	0
Candida infection	2 (3.1)	0	1 (1.5)	0	1 (1.5)
Nail infection	2 (3.1)	2 (3.1)	0	0	0
Oral herpes	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Oral infection	2 (3.1)	0	2 (3.1)	0	0
Anal abscess	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bk virus infection	1 (1.5)	1 (1.5)	0	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Encephalitis viral	1 (1.5)	0	0	0	1 (1.5)
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes simplex	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0
Oral candidiasis	1 (1.5)	0	1 (1.5)	0	0
Otitis externa	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	0	1 (1.5)	0	0
Pneumonia	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Urinary tract infection viral	1 (1.5)	1 (1.5)	0	0	0
Varicella zoster virus infection	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	9 (13.8)	3 (4.6)	4 (6.2)	0	2 (3.1)
Fall	2 (3.1)	0	2 (3.1)	0	0
Procedural pain	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Wound	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Contusion	1 (1.5)	1 (1.5)	0	0	0
Infusion related reaction	1 (1.5)	0	1 (1.5)	0	0
Scratch	1 (1.5)	1 (1.5)	0	0	0
Skin abrasion	1 (1.5)	1 (1.5)	0	0	0
Skin injury	1 (1.5)	0	1 (1.5)	0	0
Skin wound	1 (1.5)	1 (1.5)	0	0	0
Transfusion reaction	1 (1.5)	1 (1.5)	0	0	0
Transplant failure	1 (1.5)	0	0	0	1 (1.5)
Vasoplegia syndrome	1 (1.5)	0	0	0	1 (1.5)
Investigations					
-Total	47 (72.3)	4 (6.2)	7 (10.8)	14 (21.5)	22 (33.8)
White blood cell count decreased	21 (32.3)	3 (4.6)	3 (4.6)	2 (3.1)	13 (20.0)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	18 (27.7)	0	3 (4.6)	2 (3.1)	13 (20.0)
Platelet count decreased	18 (27.7)	4 (6.2)	3 (4.6)	6 (9.2)	5 (7.7)
Lymphocyte count decreased	15 (23.1)	2 (3.1)	0	8 (12.3)	5 (7.7)
Alanine aminotransferase increased	13 (20.0)	4 (6.2)	6 (9.2)	3 (4.6)	0
Aspartate aminotransferase increased	12 (18.5)	2 (3.1)	5 (7.7)	4 (6.2)	1 (1.5)
Blood bilirubin increased	8 (12.3)	1 (1.5)	2 (3.1)	5 (7.7)	0
Blood fibrinogen decreased	7 (10.8)	2 (3.1)	3 (4.6)	1 (1.5)	1 (1.5)
International normalised ratio increased	7 (10.8)	6 (9.2)	1 (1.5)	0	0
Serum ferritin increased	7 (10.8)	1 (1.5)	5 (7.7)	1 (1.5)	0
Blood immunoglobulin m decreased	6 (9.2)	4 (6.2)	1 (1.5)	1 (1.5)	0
Blood immunoglobulin a decreased	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Activated partial thromboplastin time prolonged	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Electrocardiogram qt prolonged	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	3 (4.6)	2 (3.1)	1 (1.5)	0	0
C-reactive protein increased	3 (4.6)	1 (1.5)	0	2 (3.1)	0
Weight increased	3 (4.6)	2 (3.1)	0	1 (1.5)	0
Blood creatine phosphokinase increased	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Blood immunoglobulin g decreased	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Fibrin d dimer increased	2 (3.1)	2 (3.1)	0	0	0
Gamma-glutamyltransferase increased	2 (3.1)	0	0	2 (3.1)	0
Immunoglobulins decreased	2 (3.1)	0	2 (3.1)	0	0
Lipase increased	2 (3.1)	1 (1.5)	0	0	1 (1.5)
Amylase increased	1 (1.5)	1 (1.5)	0	0	0
Bacterial test positive	1 (1.5)	0	0	1 (1.5)	0
Blood bicarbonate decreased	1 (1.5)	0	1 (1.5)	0	0
Blood creatinine increased	1 (1.5)	0	0	0	1 (1.5)
Blood glucose increased	1 (1.5)	0	0	0	1 (1.5)
Blood testosterone decreased	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Breath sounds abnormal	1 (1.5)	0	1 (1.5)	0	0
Cardiac murmur	1 (1.5)	1 (1.5)	0	0	0
Coagulation test abnormal	1 (1.5)	1 (1.5)	0	0	0
Enterovirus test positive	1 (1.5)	0	1 (1.5)	0	0
Haemoglobin decreased	1 (1.5)	0	0	1 (1.5)	0
Haptoglobin decreased	1 (1.5)	1 (1.5)	0	0	0
Oxygen saturation decreased	1 (1.5)	1 (1.5)	0	0	0
Prothrombin time prolonged	1 (1.5)	0	1 (1.5)	0	0
Urine output decreased	1 (1.5)	0	0	0	1 (1.5)
Metabolism and nutrition disorders					
-Total	34 (52.3)	8 (12.3)	6 (9.2)	15 (23.1)	5 (7.7)
Decreased appetite	17 (26.2)	9 (13.8)	2 (3.1)	5 (7.7)	1 (1.5)
Hypokalaemia	13 (20.0)	2 (3.1)	3 (4.6)	7 (10.8)	1 (1.5)
Hypophosphataemia	13 (20.0)	3 (4.6)	4 (6.2)	5 (7.7)	1 (1.5)
Hypocalcaemia	8 (12.3)	2 (3.1)	4 (6.2)	2 (3.1)	0
Hypoalbuminaemia	6 (9.2)	0	6 (9.2)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	4 (6.2)	3 (4.6)	0	0	1 (1.5)
Hyperuricaemia	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Hyperglycaemia	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Hypervolaemia	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Hypomagnesaemia	3 (4.6)	3 (4.6)	0	0	0
Hypernatraemia	2 (3.1)	1 (1.5)	0	0	1 (1.5)
Hypertriglyceridaemia	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Hyponatraemia	2 (3.1)	2 (3.1)	0	0	0
Metabolic acidosis	2 (3.1)	1 (1.5)	0	0	1 (1.5)
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0
Dehydration	1 (1.5)	0	1 (1.5)	0	0
Haemosiderosis	1 (1.5)	0	1 (1.5)	0	0
Hypercalcaemia	1 (1.5)	0	0	1 (1.5)	0
Hyperchloraemia	1 (1.5)	1 (1.5)	0	0	0
Hyperkalaemia	1 (1.5)	0	0	0	1 (1.5)
Hyperlactacidaemia	1 (1.5)	1 (1.5)	0	0	0
Hypermagnesaemia	1 (1.5)	1 (1.5)	0	0	0
Polydipsia	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	28 (43.1)	12 (18.5)	12 (18.5)	3 (4.6)	1 (1.5)
Pain in extremity	11 (16.9)	6 (9.2)	5 (7.7)	0	0
Arthralgia	8 (12.3)	4 (6.2)	4 (6.2)	0	0
Myalgia	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Back pain	5 (7.7)	1 (1.5)	3 (4.6)	1 (1.5)	0
Bone pain	2 (3.1)	0	2 (3.1)	0	0
Muscular weakness	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Pain in jaw	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Muscle rigidity	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal chest pain	1 (1.5)	1 (1.5)	0	0	0
Myositis	1 (1.5)	0	1 (1.5)	0	0
Neck pain	1 (1.5)	0	1 (1.5)	0	0
Rhabdomyolysis	1 (1.5)	0	0	0	1 (1.5)
Nervous system disorders					
-Total	32 (49.2)	14 (21.5)	11 (16.9)	7 (10.8)	0
Headache	19 (29.2)	10 (15.4)	7 (10.8)	2 (3.1)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	7 (10.8)	1 (1.5)	3 (4.6)	3 (4.6)	0
Tremor	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Dizziness	3 (4.6)	3 (4.6)	0	0	0
Dysgeusia	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Lethargy	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Somnolence	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Seizure	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Hypoaesthesia	1 (1.5)	1 (1.5)	0	0	0
Monoparesis	1 (1.5)	0	1 (1.5)	0	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Psychiatric disorders					
-Total	23 (35.4)	11 (16.9)	8 (12.3)	4 (6.2)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	7 (10.8)	7 (10.8)	0	0	0
Delirium	6 (9.2)	2 (3.1)	2 (3.1)	2 (3.1)	0
Agitation	4 (6.2)	2 (3.1)	2 (3.1)	0	0
Anxiety	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Hallucination	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Insomnia	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Irritability	3 (4.6)	3 (4.6)	0	0	0
Mental status changes	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Sleep disorder	2 (3.1)	0	2 (3.1)	0	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Automatism	1 (1.5)	1 (1.5)	0	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Renal and urinary disorders					
-Total	16 (24.6)	5 (7.7)	5 (7.7)	2 (3.1)	4 (6.2)
Acute kidney injury	7 (10.8)	1 (1.5)	1 (1.5)	2 (3.1)	3 (4.6)
Dysuria	3 (4.6)	3 (4.6)	0	0	0
Anuria	2 (3.1)	1 (1.5)	0	0	1 (1.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	2 (3.1)	2 (3.1)	0	0	0
Pollakiuria	2 (3.1)	0	2 (3.1)	0	0
Azotaemia	1 (1.5)	0	1 (1.5)	0	0
Bladder dilatation	1 (1.5)	0	1 (1.5)	0	0
Incontinence	1 (1.5)	0	1 (1.5)	0	0
Micturition urgency	1 (1.5)	0	1 (1.5)	0	0
Proteinuria	1 (1.5)	1 (1.5)	0	0	0
Renal failure	1 (1.5)	0	1 (1.5)	0	0
Renal tubular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Renal tubular necrosis	1 (1.5)	0	0	0	1 (1.5)
Urinary incontinence	1 (1.5)	0	1 (1.5)	0	0
Urinary retention	1 (1.5)	0	1 (1.5)	0	0
Urinary tract disorder	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					
-Total	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Heavy menstrual bleeding	1 (1.5)	1 (1.5)	0	0	0
Perineal rash	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Vaginal ulceration	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	33 (50.8)	14 (21.5)	3 (4.6)	8 (12.3)	8 (12.3)
Hypoxia	14 (21.5)	0	5 (7.7)	4 (6.2)	5 (7.7)
Cough	10 (15.4)	9 (13.8)	1 (1.5)	0	0
Pulmonary oedema	8 (12.3)	2 (3.1)	2 (3.1)	4 (6.2)	0
Tachypnoea	7 (10.8)	3 (4.6)	1 (1.5)	3 (4.6)	0
Oropharyngeal pain	5 (7.7)	5 (7.7)	0	0	0
Pleural effusion	5 (7.7)	4 (6.2)	0	1 (1.5)	0
Epistaxis	4 (6.2)	2 (3.1)	1 (1.5)	1 (1.5)	0
Atelectasis	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Dyspnoea	3 (4.6)	0	0	2 (3.1)	1 (1.5)
Respiratory failure	3 (4.6)	0	0	0	3 (4.6)
Nasal congestion	2 (3.1)	2 (3.1)	0	0	0
Respiratory distress	2 (3.1)	0	2 (3.1)	0	0
Rhinorrhoea	2 (3.1)	2 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (1.5)	0	0	0	1 (1.5)
Bradypnoea	1 (1.5)	0	0	1 (1.5)	0
Haemoptysis	1 (1.5)	0	1 (1.5)	0	0
Lung infiltration	1 (1.5)	0	0	1 (1.5)	0
Nasal discomfort	1 (1.5)	0	1 (1.5)	0	0
Nasal dryness	1 (1.5)	1 (1.5)	0	0	0
Oropharyngeal plaque	1 (1.5)	0	1 (1.5)	0	0
Painful respiration	1 (1.5)	1 (1.5)	0	0	0
Paranasal sinus discomfort	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal erythema	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal exudate	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal oedema	1 (1.5)	0	1 (1.5)	0	0
Productive cough	1 (1.5)	1 (1.5)	0	0	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory acidosis	1 (1.5)	0	0	1 (1.5)	0
Respiratory disorder	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	24 (36.9)	12 (18.5)	9 (13.8)	3 (4.6)	0
Pruritus	5 (7.7)	2 (3.1)	3 (4.6)	0	0
Rash	5 (7.7)	2 (3.1)	3 (4.6)	0	0
Erythema	4 (6.2)	4 (6.2)	0	0	0
Rash papular	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Blister	2 (3.1)	2 (3.1)	0	0	0
Dermatitis atopic	2 (3.1)	2 (3.1)	0	0	0
Hyperhidrosis	2 (3.1)	0	2 (3.1)	0	0
Petechiae	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Rash maculo-papular	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Skin ulcer	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Decubitus ulcer	1 (1.5)	0	1 (1.5)	0	0
Dermatitis	1 (1.5)	1 (1.5)	0	0	0
Dermatitis diaper	1 (1.5)	0	1 (1.5)	0	0
Dry skin	1 (1.5)	1 (1.5)	0	0	0
Eczema	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema nodosum	1 (1.5)	1 (1.5)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.5)	1 (1.5)	0	0	0
Pruritus allergic	1 (1.5)	0	1 (1.5)	0	0
Purpura	1 (1.5)	1 (1.5)	0	0	0
Rash pruritic	1 (1.5)	1 (1.5)	0	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Skin discolouration	1 (1.5)	1 (1.5)	0	0	0
Skin lesion	1 (1.5)	0	1 (1.5)	0	0
Skin necrosis	1 (1.5)	0	0	1 (1.5)	0
Urticaria	1 (1.5)	0	1 (1.5)	0	0
Vancomycin infusion reaction	1 (1.5)	0	0	1 (1.5)	0
Social circumstances					
-Total	1 (1.5)	0	1 (1.5)	0	0
Patient uncooperative	1 (1.5)	0	1 (1.5)	0	0
Vascular disorders					
-Total	19 (29.2)	3 (4.6)	6 (9.2)	6 (9.2)	4 (6.2)
Hypotension	15 (23.1)	1 (1.5)	5 (7.7)	5 (7.7)	4 (6.2)

Timing: within 8 weeks post infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	9 (13.8)	2 (3.1)	5 (7.7)	2 (3.1)	0
Capillary leak syndrome	1 (1.5)	0	1 (1.5)	0	0
Flushing	1 (1.5)	1 (1.5)	0	0	0
Hot flush	1 (1.5)	1 (1.5)	0	0	0
Peripheral ischaemia	1 (1.5)	0	1 (1.5)	0	0
Thrombosis	1 (1.5)	0	1 (1.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	1 (7.1)	4 (28.6)	3 (21.4)	4 (28.6)
Blood and lymphatic system disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Anaemia	2 (14.3)	0	0	2 (14.3)	0
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Leukocytosis	1 (7.1)	0	1 (7.1)	0	0
Cardiac disorders					
-Total	2 (14.3)	1 (7.1)	0	0	1 (7.1)
Cardiac arrest	1 (7.1)	0	0	0	1 (7.1)
Cardiac failure	1 (7.1)	0	0	1 (7.1)	0
Tachycardia	1 (7.1)	1 (7.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Visual impairment	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Diarrhoea	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal haemorrhage	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal inflammation	1 (7.1)	0	1 (7.1)	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
Vomiting	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	7 (50.0)	4 (28.6)	2 (14.3)	1 (7.1)	0
Pyrexia	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Fatigue	2 (14.3)	2 (14.3)	0	0	0
Malaise	1 (7.1)	1 (7.1)	0	0	0
Non-cardiac chest pain	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=14			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Allergy to immunoglobulin therapy	1 (7.1)	0	0	1 (7.1)	0
Infections and infestations					
-Total	7 (50.0)	0	1 (7.1)	4 (28.6)	2 (14.3)
Upper respiratory tract infection	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Bacteraemia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Respiratory syncytial virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0
Bk virus infection	1 (7.1)	0	0	1 (7.1)	0
Gastroenteritis	1 (7.1)	1 (7.1)	0	0	0
Gastroenteritis clostridial	1 (7.1)	0	1 (7.1)	0	0
Herpes simplex	1 (7.1)	0	1 (7.1)	0	0
Metapneumovirus infection	1 (7.1)	0	0	1 (7.1)	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Parainfluenzae virus infection	1 (7.1)	0	1 (7.1)	0	0
Pharyngitis streptococcal	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	1 (7.1)	0	0	1 (7.1)	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Septic shock	1 (7.1)	0	0	0	1 (7.1)
Sinusitis fungal	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	1 (7.1)	0	0	0
Skin abrasion	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	1 (7.1)	2 (14.3)
Neutrophil count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
White blood cell count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Blood uric acid increased	1 (7.1)	0	0	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ejection fraction decreased	1 (7.1)	0	1 (7.1)	0	0
Heart sounds abnormal	1 (7.1)	1 (7.1)	0	0	0
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	1 (7.1)	2 (14.3)
Decreased appetite	2 (14.3)	0	2 (14.3)	0	0
Hyperuricaemia	2 (14.3)	2 (14.3)	0	0	0
Hypokalaemia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Hyperchloraemia	1 (7.1)	1 (7.1)	0	0	0
Hyperkalaemia	1 (7.1)	0	1 (7.1)	0	0
Malnutrition	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	0	1 (7.1)
Musculoskeletal and connective tissue disorders					
-Total	5 (35.7)	1 (7.1)	3 (21.4)	1 (7.1)	0
Back pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Pain in extremity	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Arthralgia	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Growth retardation	1 (7.1)	0	1 (7.1)	0	0
Myalgia	1 (7.1)	0	1 (7.1)	0	0
Neck pain	1 (7.1)	1 (7.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (7.1)	0	1 (7.1)	0	0
Cancer pain	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Headache	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Extrapyramidal disorder	1 (7.1)	0	1 (7.1)	0	0
Psychiatric disorders					
-Total	4 (28.6)	0	4 (28.6)	0	0
Anxiety	3 (21.4)	0	3 (21.4)	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Acute kidney injury	2 (14.3)	0	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	1 (7.1)	0	1 (7.1)	0	0
Haematuria	1 (7.1)	0	0	1 (7.1)	0
Kidney enlargement	1 (7.1)	0	1 (7.1)	0	0
Renal mass	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (35.7)	3 (21.4)	1 (7.1)	0	1 (7.1)
Nasal congestion	2 (14.3)	2 (14.3)	0	0	0
Rhinitis allergic	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Acute respiratory distress syndrome	1 (7.1)	0	0	0	1 (7.1)
Bronchial oedema	1 (7.1)	1 (7.1)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	0
Dry skin	2 (14.3)	2 (14.3)	0	0	0
Decubitus ulcer	1 (7.1)	0	0	1 (7.1)	0
Pruritus	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin hypopigmentation	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Hypotension	2 (14.3)	0	0	1 (7.1)	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (93.4)	8 (13.1)	20 (32.8)	12 (19.7)	17 (27.9)
Blood and lymphatic system disorders					
-Total	15 (24.6)	3 (4.9)	4 (6.6)	4 (6.6)	4 (6.6)
Neutropenia	5 (8.2)	0	0	2 (3.3)	3 (4.9)
Anaemia	4 (6.6)	4 (6.6)	0	0	0
Febrile neutropenia	2 (3.3)	0	0	2 (3.3)	0
Thrombocytopenia	2 (3.3)	0	0	1 (1.6)	1 (1.6)
B-cell aplasia	1 (1.6)	0	1 (1.6)	0	0
Disseminated intravascular coagulation	1 (1.6)	0	0	1 (1.6)	0
Eosinophilia	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.6)	0	1 (1.6)	0	0
Lymphadenopathy	1 (1.6)	1 (1.6)	0	0	0
Lymphocytosis	1 (1.6)	0	1 (1.6)	0	0
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Cardiac disorders					
-Total	5 (8.2)	2 (3.3)	1 (1.6)	0	2 (3.3)
Cardiac arrest	1 (1.6)	0	0	0	1 (1.6)
Cardiac failure	1 (1.6)	0	0	0	1 (1.6)
Left ventricular dysfunction	1 (1.6)	0	1 (1.6)	0	0
Tachycardia	1 (1.6)	1 (1.6)	0	0	0
Tricuspid valve incompetence	1 (1.6)	1 (1.6)	0	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Hypothyroidism	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					
-Total	3 (4.9)	3 (4.9)	0	0	0
Cataract	2 (3.3)	2 (3.3)	0	0	0
Hypermetropia	1 (1.6)	1 (1.6)	0	0	0
Ocular hyperaemia	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	15 (24.6)	11 (18.0)	3 (4.9)	1 (1.6)	0
Vomiting	5 (8.2)	5 (8.2)	0	0	0
Diarrhoea	4 (6.6)	4 (6.6)	0	0	0
Nausea	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Constipation	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Pancreatitis	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Abdominal pain	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain upper	1 (1.6)	1 (1.6)	0	0	0
Abdominal rigidity	1 (1.6)	0	1 (1.6)	0	0
Dyspepsia	1 (1.6)	1 (1.6)	0	0	0
Enteritis	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Peritoneal haematoma	1 (1.6)	1 (1.6)	0	0	0
Proctalgia	1 (1.6)	1 (1.6)	0	0	0
Stomatitis	1 (1.6)	1 (1.6)	0	0	0
Trichoglossia	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (27.9)	11 (18.0)	4 (6.6)	2 (3.3)	0
Pyrexia	11 (18.0)	6 (9.8)	4 (6.6)	1 (1.6)	0
Fatigue	4 (6.6)	4 (6.6)	0	0	0
Pain	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Chills	1 (1.6)	1 (1.6)	0	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Hepatobiliary disorders					
-Total	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Hepatic cytolysis	1 (1.6)	1 (1.6)	0	0	0
Hypertransaminasaemia	1 (1.6)	1 (1.6)	0	0	0
Liver disorder	1 (1.6)	0	1 (1.6)	0	0
Immune system disorders					
-Total	13 (21.3)	1 (1.6)	9 (14.8)	3 (4.9)	0
Hypogammaglobulinaemia	8 (13.1)	0	8 (13.1)	0	0
Graft versus host disease	2 (3.3)	0	0	2 (3.3)	0
Allergy to immunoglobulin therapy	1 (1.6)	1 (1.6)	0	0	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Engraftment syndrome	1 (1.6)	0	0	1 (1.6)	0
Immunodeficiency	1 (1.6)	0	0	1 (1.6)	0
Infections and infestations					
-Total	32 (52.5)	5 (8.2)	13 (21.3)	8 (13.1)	6 (9.8)
Nasopharyngitis	7 (11.5)	4 (6.6)	3 (4.9)	0	0
Upper respiratory tract infection	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Gastroenteritis	4 (6.6)	2 (3.3)	0	2 (3.3)	0
Rhinovirus infection	4 (6.6)	0	3 (4.9)	1 (1.6)	0
Parainfluenzae virus infection	3 (4.9)	1 (1.6)	0	1 (1.6)	1 (1.6)
Pneumonia	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Respiratory tract infection	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Sinusitis	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Ear infection	2 (3.3)	0	2 (3.3)	0	0
Metapneumovirus infection	2 (3.3)	0	0	2 (3.3)	0
Otitis externa	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Otitis media	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Rhinitis	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Viral infection	2 (3.3)	0	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis	1 (1.6)	0	1 (1.6)	0	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Coronavirus infection	1 (1.6)	0	0	1 (1.6)	0
Cystitis	1 (1.6)	0	1 (1.6)	0	0
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Ear, nose and throat infection	1 (1.6)	0	1 (1.6)	0	0
Encephalitis	1 (1.6)	0	0	0	1 (1.6)
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal infection	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Influenza	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Nail infection	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	0	1 (1.6)	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	0	1 (1.6)	0	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	0	0	1 (1.6)
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection viral	1 (1.6)	0	1 (1.6)	0	0
Salmonellosis	1 (1.6)	0	1 (1.6)	0	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal skin infection	1 (1.6)	0	1 (1.6)	0	0
Tinea pedis	1 (1.6)	1 (1.6)	0	0	0
Viral haemorrhagic cystitis	1 (1.6)	0	0	1 (1.6)	0
Injury, poisoning and procedural complications					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (13.1)	4 (6.6)	4 (6.6)	0	0
Infusion related reaction	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Contusion	1 (1.6)	1 (1.6)	0	0	0
Fibula fracture	1 (1.6)	0	1 (1.6)	0	0
Ligament sprain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	0	1 (1.6)	0	0
Post-traumatic neck syndrome	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	24 (39.3)	6 (9.8)	5 (8.2)	10 (16.4)	3 (4.9)
Neutrophil count decreased	8 (13.1)	2 (3.3)	1 (1.6)	2 (3.3)	3 (4.9)
White blood cell count decreased	8 (13.1)	4 (6.6)	2 (3.3)	2 (3.3)	0
Lymphocyte count decreased	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Platelet count decreased	4 (6.6)	3 (4.9)	0	1 (1.6)	0
Alanine aminotransferase increased	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Blood bilirubin increased	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Blood immunoglobulin a decreased	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Blood creatinine increased	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.6)	0	0	1 (1.6)	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.6)	1 (1.6)	0	0	0
Blood urea increased	1 (1.6)	0	0	1 (1.6)	0
Blood uric acid increased	1 (1.6)	0	0	1 (1.6)	0
Bone density decreased	1 (1.6)	1 (1.6)	0	0	0
C-reactive protein increased	1 (1.6)	1 (1.6)	0	0	0
Hepatitis b virus test positive	1 (1.6)	0	1 (1.6)	0	0
Immunoglobulins decreased	1 (1.6)	0	1 (1.6)	0	0
Oxygen saturation decreased	1 (1.6)	0	1 (1.6)	0	0
Weight decreased	1 (1.6)	0	0	1 (1.6)	0
Weight increased	1 (1.6)	0	0	1 (1.6)	0
Metabolism and nutrition disorders					
-Total	10 (16.4)	3 (4.9)	3 (4.9)	3 (4.9)	1 (1.6)
Decreased appetite	4 (6.6)	2 (3.3)	1 (1.6)	1 (1.6)	0
Haemochromatosis	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (1.6)	1 (1.6)	0	0	0
Hypervolaemia	1 (1.6)	0	0	1 (1.6)	0
Hypokalaemia	1 (1.6)	0	0	1 (1.6)	0
Hypophagia	1 (1.6)	0	1 (1.6)	0	0
Hypophosphataemia	1 (1.6)	0	1 (1.6)	0	0
Iron overload	1 (1.6)	0	1 (1.6)	0	0
Metabolic acidosis	1 (1.6)	0	0	0	1 (1.6)
Metabolic syndrome	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (16.4)	4 (6.6)	4 (6.6)	2 (3.3)	0
Back pain	4 (6.6)	2 (3.3)	1 (1.6)	1 (1.6)	0
Pain in extremity	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Arthralgia	2 (3.3)	2 (3.3)	0	0	0
Bone pain	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal pain	1 (1.6)	0	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Skin papilloma	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Nervous system disorders					
-Total	12 (19.7)	6 (9.8)	4 (6.6)	0	2 (3.3)
Headache	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Autonomic neuropathy	1 (1.6)	0	0	1 (1.6)	0
Cerebral haemorrhage	1 (1.6)	0	0	0	1 (1.6)
Dizziness	1 (1.6)	1 (1.6)	0	0	0
Hydrocephalus	1 (1.6)	0	0	0	1 (1.6)
Memory impairment	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Seizure	1 (1.6)	0	0	1 (1.6)	0
Psychiatric disorders					
-Total	6 (9.8)	1 (1.6)	4 (6.6)	1 (1.6)	0
Anxiety	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Agitation	1 (1.6)	1 (1.6)	0	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Mental status changes	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mood altered	1 (1.6)	1 (1.6)	0	0	0
Nightmare	1 (1.6)	1 (1.6)	0	0	0
Persistent depressive disorder	1 (1.6)	0	1 (1.6)	0	0
Sleep disorder	1 (1.6)	0	1 (1.6)	0	0
Tearfulness	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acute kidney injury	1 (1.6)	1 (1.6)	0	0	0
Cystitis haemorrhagic	1 (1.6)	0	1 (1.6)	0	0
Renal tubular disorder	1 (1.6)	0	0	1 (1.6)	0
Reproductive system and breast disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Dysmenorrhoea	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (31.1)	8 (13.1)	6 (9.8)	3 (4.9)	2 (3.3)
Cough	10 (16.4)	7 (11.5)	3 (4.9)	0	0
Nasal congestion	4 (6.6)	3 (4.9)	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Hypoxia	3 (4.9)	0	0	3 (4.9)	0
Rhinorrhoea	3 (4.9)	3 (4.9)	0	0	0
Pleural effusion	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Bronchospasm	1 (1.6)	0	1 (1.6)	0	0
Dyspnoea	1 (1.6)	0	1 (1.6)	0	0
Lung disorder	1 (1.6)	1 (1.6)	0	0	0
Oropharyngeal pain	1 (1.6)	0	1 (1.6)	0	0
Paranasal sinus inflammation	1 (1.6)	1 (1.6)	0	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract inflammation	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (26.2)	10 (16.4)	6 (9.8)	0	0
Dry skin	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Rash	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Ingrowing nail	2 (3.3)	0	2 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis allergic	1 (1.6)	1 (1.6)	0	0	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Erythema	1 (1.6)	0	1 (1.6)	0	0
Hangnail	1 (1.6)	1 (1.6)	0	0	0
Miliaria	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	1 (1.6)	0	0	0
Photosensitivity reaction	1 (1.6)	0	1 (1.6)	0	0
Skin discolouration	1 (1.6)	1 (1.6)	0	0	0
Skin swelling	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	4 (6.6)	1 (1.6)	0	1 (1.6)	2 (3.3)
Hypotension	2 (3.3)	1 (1.6)	0	0	1 (1.6)
Venoocclusive disease	2 (3.3)	0	0	1 (1.6)	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	0	3 (42.9)	1 (14.3)	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Delayed puberty	1 (14.3)	0	1 (14.3)	0	0
Hypothyroidism	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dry eye	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (14.3)	1 (14.3)	0	0	0
Vomiting	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Fatigue	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Seasonal allergy	2 (28.6)	2 (28.6)	0	0	0
Infections and infestations					
-Total	3 (42.9)	0	3 (42.9)	0	0
Covid-19	1 (14.3)	1 (14.3)	0	0	0
Otitis media acute	1 (14.3)	0	1 (14.3)	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Syphilis	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (14.3)	1 (14.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal injury	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Obesity	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Arthralgia	1 (14.3)	0	1 (14.3)	0	0
Osteopenia	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Cough	1 (14.3)	0	1 (14.3)	0	0
Rhinorrhoea	1 (14.3)	0	1 (14.3)	0	0
Sleep apnoea syndrome	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Rash	1 (14.3)	1 (14.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (65.1)	3 (7.0)	7 (16.3)	11 (25.6)	7 (16.3)
Blood and lymphatic system disorders					
-Total	4 (9.3)	0	2 (4.7)	1 (2.3)	1 (2.3)
Agranulocytosis	1 (2.3)	0	0	1 (2.3)	0
Anaemia	1 (2.3)	0	1 (2.3)	0	0
Hypercoagulation	1 (2.3)	0	1 (2.3)	0	0
Lymphadenopathy	1 (2.3)	0	1 (2.3)	0	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Thrombocytopenia	1 (2.3)	0	1 (2.3)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	1 (2.3)	0	0	0
Cerebral cavernous malformation	1 (2.3)	1 (2.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Deafness unilateral	1 (2.3)	0	1 (2.3)	0	0
Eye disorders					
-Total	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Eye pain	1 (2.3)	0	0	1 (2.3)	0
Eyelid oedema	1 (2.3)	1 (2.3)	0	0	0
Mydriasis	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	5 (11.6)	3 (7.0)	1 (2.3)	1 (2.3)	0
Diarrhoea	4 (9.3)	3 (7.0)	0	1 (2.3)	0
Irritable bowel syndrome	1 (2.3)	0	1 (2.3)	0	0
General disorders and administration site conditions					
-Total	8 (18.6)	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)
Pyrexia	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Multiple organ dysfunction syndrome	1 (2.3)	0	0	0	1 (2.3)
Non-cardiac chest pain	1 (2.3)	1 (2.3)	0	0	0
Xerosis	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	7 (16.3)	0	5 (11.6)	1 (2.3)	1 (2.3)
Hypogammaglobulinaemia	3 (7.0)	0	3 (7.0)	0	0
Chronic graft versus host disease	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Drug hypersensitivity	1 (2.3)	0	0	1 (2.3)	0
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	0	0	1 (2.3)
Seasonal allergy	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	20 (46.5)	2 (4.7)	4 (9.3)	10 (23.3)	4 (9.3)
Sinusitis	6 (14.0)	0	6 (14.0)	0	0
Conjunctivitis	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Rhinovirus infection	4 (9.3)	0	3 (7.0)	1 (2.3)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Sepsis	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Bronchitis	2 (4.7)	0	2 (4.7)	0	0
Fungal infection	2 (4.7)	0	2 (4.7)	0	0
Herpes zoster	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Influenza	2 (4.7)	0	1 (2.3)	0	1 (2.3)
Oral herpes	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Otitis media	2 (4.7)	0	2 (4.7)	0	0
Pneumonia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Skin infection	2 (4.7)	0	2 (4.7)	0	0
Urinary tract infection	2 (4.7)	0	2 (4.7)	0	0
Acute sinusitis	1 (2.3)	0	1 (2.3)	0	0
Bronchiolitis	1 (2.3)	0	0	1 (2.3)	0
Candida infection	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	0	0	1 (2.3)	0
Covid-19	1 (2.3)	0	0	1 (2.3)	0
Covid-19 pneumonia	1 (2.3)	0	0	0	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	0	1 (2.3)	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Folliculitis	1 (2.3)	0	1 (2.3)	0	0
Fungal skin infection	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis	1 (2.3)	1 (2.3)	0	0	0
Gastroenteritis escherichia coli	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis salmonella	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	0	1 (2.3)	0	0
Herpes virus infection	1 (2.3)	0	1 (2.3)	0	0
Meningitis pneumococcal	1 (2.3)	0	0	1 (2.3)	0
Nail infection	1 (2.3)	0	1 (2.3)	0	0
Neutropenic infection	1 (2.3)	0	0	1 (2.3)	0
Ophthalmic herpes zoster	1 (2.3)	0	1 (2.3)	0	0
Oral candidiasis	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Pneumonia respiratory syncytial viral	1 (2.3)	0	0	1 (2.3)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Septic shock	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal abscess	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Streptococcal sepsis	1 (2.3)	0	1 (2.3)	0	0
Urinary tract infection pseudomonal	1 (2.3)	0	1 (2.3)	0	0
Varicella zoster virus infection	1 (2.3)	0	1 (2.3)	0	0
Viral skin infection	1 (2.3)	1 (2.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Infusion related reaction	1 (2.3)	0	0	1 (2.3)	0
Ligament sprain	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	6 (14.0)	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)
Neutrophil count decreased	3 (7.0)	2 (4.7)	0	0	1 (2.3)
Platelet count decreased	2 (4.7)	2 (4.7)	0	0	0
Blood bilirubin increased	1 (2.3)	1 (2.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Oxygen saturation decreased	1 (2.3)	0	0	1 (2.3)	0
Metabolism and nutrition disorders					
-Total	5 (11.6)	0	2 (4.7)	2 (4.7)	1 (2.3)
Decreased appetite	1 (2.3)	0	0	0	1 (2.3)
Hypercholesterolaemia	1 (2.3)	0	1 (2.3)	0	0
Hyperglycaemia	1 (2.3)	0	0	1 (2.3)	0
Hyperlipidaemia	1 (2.3)	0	1 (2.3)	0	0
Hypernatraemia	1 (2.3)	0	0	1 (2.3)	0
Hypertriglyceridaemia	1 (2.3)	0	1 (2.3)	0	0
Iron overload	1 (2.3)	0	1 (2.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (11.6)	1 (2.3)	4 (9.3)	0	0
Pain in extremity	2 (4.7)	0	2 (4.7)	0	0
Growth retardation	1 (2.3)	0	1 (2.3)	0	0
Joint effusion	1 (2.3)	0	1 (2.3)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (2.3)	1 (2.3)	0	0	0
Synovitis	1 (2.3)	0	1 (2.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.3)	0	0	1 (2.3)	0
Bone giant cell tumour benign	1 (2.3)	0	0	1 (2.3)	0
Nervous system disorders					
-Total	4 (9.3)	0	2 (4.7)	2 (4.7)	0
Headache	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Dysarthria	1 (2.3)	0	1 (2.3)	0	0
Nervous system disorder	1 (2.3)	0	0	1 (2.3)	0
Seizure	1 (2.3)	0	0	1 (2.3)	0
Psychiatric disorders					
-Total	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Anxiety	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Tic	1 (2.3)	0	1 (2.3)	0	0
Reproductive system and breast disorders					

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	0	0	1 (2.3)	0
Endometriosis	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (18.6)	4 (9.3)	0	1 (2.3)	3 (7.0)
Cough	3 (7.0)	3 (7.0)	0	0	0
Dyspnoea	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)
Rhinorrhoea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Dyspnoea exertional	1 (2.3)	1 (2.3)	0	0	0
Epistaxis	1 (2.3)	1 (2.3)	0	0	0
Hypoxia	1 (2.3)	0	0	1 (2.3)	0
Laryngeal oedema	1 (2.3)	0	0	0	1 (2.3)
Oropharyngeal pain	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal erythema	1 (2.3)	1 (2.3)	0	0	0
Pleural effusion	1 (2.3)	0	1 (2.3)	0	0
Respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Sleep apnoea syndrome	1 (2.3)	1 (2.3)	0	0	0
Tachypnoea	1 (2.3)	0	0	0	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (14.0)	2 (4.7)	1 (2.3)	3 (7.0)	0
Dermatitis atopic	1 (2.3)	0	0	1 (2.3)	0
Dry skin	1 (2.3)	1 (2.3)	0	0	0
Eczema	1 (2.3)	0	0	1 (2.3)	0
Papule	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	0	1 (2.3)	0	0
Rash erythematous	1 (2.3)	1 (2.3)	0	0	0
Rash macular	1 (2.3)	0	0	1 (2.3)	0
Vascular disorders					
-Total	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hypertension	2 (4.7)	0	1 (2.3)	1 (2.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	2 (13.3)	0	13 (86.7)
Blood and lymphatic system disorders					
-Total	11 (73.3)	0	1 (6.7)	8 (53.3)	2 (13.3)
Febrile neutropenia	8 (53.3)	0	0	6 (40.0)	2 (13.3)
Anaemia	5 (33.3)	0	1 (6.7)	4 (26.7)	0
Coagulopathy	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	0	1 (6.7)	0	0
Leukocytosis	1 (6.7)	0	1 (6.7)	0	0
Thrombocytopenia	1 (6.7)	0	0	1 (6.7)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (40.0)	1 (6.7)	3 (20.0)	1 (6.7)	1 (6.7)
Tachycardia	3 (20.0)	0	3 (20.0)	0	0
Sinus tachycardia	2 (13.3)	2 (13.3)	0	0	0
Cardiac arrest	1 (6.7)	0	0	0	1 (6.7)
Cardiac failure	1 (6.7)	0	0	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	0	0	1 (6.7)	0
Sinus bradycardia	1 (6.7)	0	0	1 (6.7)	0
Endocrine disorders					
-Total	4 (26.7)	0	4 (26.7)	0	0
Adrenal insufficiency	3 (20.0)	0	3 (20.0)	0	0
Delayed puberty	1 (6.7)	0	1 (6.7)	0	0
Hypothyroidism	1 (6.7)	0	1 (6.7)	0	0
Eye disorders					
-Total	2 (13.3)	2 (13.3)	0	0	0
Dry eye	1 (6.7)	1 (6.7)	0	0	0
Visual impairment	1 (6.7)	1 (6.7)	0	0	0
Gastrointestinal disorders					
-Total	12 (80.0)	4 (26.7)	5 (33.3)	2 (13.3)	1 (6.7)
Diarrhoea	6 (40.0)	3 (20.0)	3 (20.0)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	4 (26.7)	1 (6.7)	3 (20.0)	0	0
Vomiting	4 (26.7)	3 (20.0)	0	1 (6.7)	0
Nausea	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Abdominal compartment syndrome	1 (6.7)	0	0	0	1 (6.7)
Abdominal pain	1 (6.7)	0	1 (6.7)	0	0
Dry mouth	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal haemorrhage	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal inflammation	1 (6.7)	0	1 (6.7)	0	0
Mouth haemorrhage	1 (6.7)	0	0	1 (6.7)	0
Pancreatitis	1 (6.7)	0	1 (6.7)	0	0
General disorders and administration site conditions					
-Total	11 (73.3)	3 (20.0)	4 (26.7)	3 (20.0)	1 (6.7)
Pyrexia	6 (40.0)	1 (6.7)	2 (13.3)	3 (20.0)	0
Fatigue	4 (26.7)	3 (20.0)	1 (6.7)	0	0
Oedema peripheral	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Chills	2 (13.3)	2 (13.3)	0	0	0
Generalised oedema	2 (13.3)	0	2 (13.3)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	1 (6.7)	0	1 (6.7)	0	0
Face oedema	1 (6.7)	1 (6.7)	0	0	0
Malaise	1 (6.7)	1 (6.7)	0	0	0
Multiple organ dysfunction syndrome	1 (6.7)	0	0	0	1 (6.7)
Non-cardiac chest pain	1 (6.7)	1 (6.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Biliary tract disorder	1 (6.7)	1 (6.7)	0	0	0
Gallbladder enlargement	1 (6.7)	1 (6.7)	0	0	0
Hyperbilirubinaemia	1 (6.7)	0	0	1 (6.7)	0
Hypertransaminasaemia	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					
-Total	15 (100)	0	6 (40.0)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Hypogammaglobulinaemia	6 (40.0)	1 (6.7)	4 (26.7)	1 (6.7)	0
Seasonal allergy	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Allergy to immunoglobulin therapy	1 (6.7)	0	0	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (6.7)	0	0	1 (6.7)	0
Selective igg subclass deficiency	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	11 (73.3)	0	5 (33.3)	4 (26.7)	2 (13.3)
Upper respiratory tract infection	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Adenovirus infection	2 (13.3)	0	0	2 (13.3)	0
Bacteraemia	2 (13.3)	0	1 (6.7)	0	1 (6.7)
Respiratory syncytial virus infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Staphylococcal bacteraemia	2 (13.3)	0	0	2 (13.3)	0
Atypical pneumonia	1 (6.7)	1 (6.7)	0	0	0
Bk virus infection	1 (6.7)	0	0	1 (6.7)	0
Candida infection	1 (6.7)	0	1 (6.7)	0	0
Conjunctivitis	1 (6.7)	1 (6.7)	0	0	0
Covid-19	1 (6.7)	1 (6.7)	0	0	0
Encephalitis viral	1 (6.7)	0	0	1 (6.7)	0
Gastroenteritis	1 (6.7)	1 (6.7)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (6.7)	0	1 (6.7)	0	0
Gastroenteritis norovirus	1 (6.7)	1 (6.7)	0	0	0
Herpes simplex	1 (6.7)	0	1 (6.7)	0	0
Klebsiella bacteraemia	1 (6.7)	0	1 (6.7)	0	0
Metapneumovirus infection	1 (6.7)	0	0	1 (6.7)	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Otitis media acute	1 (6.7)	0	1 (6.7)	0	0
Parainfluenzae virus infection	1 (6.7)	0	1 (6.7)	0	0
Pharyngitis streptococcal	1 (6.7)	0	0	1 (6.7)	0
Pneumocystis jirovecii pneumonia	1 (6.7)	0	0	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Septic shock	1 (6.7)	0	0	0	1 (6.7)
Sinusitis fungal	1 (6.7)	0	0	1 (6.7)	0
Skin infection	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal infection	1 (6.7)	0	1 (6.7)	0	0
Syphilis	1 (6.7)	0	1 (6.7)	0	0
Urinary tract infection	1 (6.7)	0	0	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Injury, poisoning and procedural complications					
-Total	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Abdominal injury	1 (6.7)	1 (6.7)	0	0	0
Infusion related reaction	1 (6.7)	0	1 (6.7)	0	0
Skin abrasion	1 (6.7)	1 (6.7)	0	0	0
Transfusion reaction	1 (6.7)	0	1 (6.7)	0	0
Investigations					
-Total	11 (73.3)	0	1 (6.7)	3 (20.0)	7 (46.7)
Aspartate aminotransferase increased	7 (46.7)	0	1 (6.7)	4 (26.7)	2 (13.3)
Alanine aminotransferase increased	5 (33.3)	0	2 (13.3)	3 (20.0)	0
Blood bilirubin increased	4 (26.7)	0	0	4 (26.7)	0
Blood creatinine increased	3 (20.0)	1 (6.7)	0	2 (13.3)	0
Neutrophil count decreased	3 (20.0)	0	0	0	3 (20.0)
Platelet count decreased	3 (20.0)	0	0	0	3 (20.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (20.0)	0	0	0	3 (20.0)
Activated partial thromboplastin time prolonged	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Blood uric acid increased	2 (13.3)	1 (6.7)	0	0	1 (6.7)
International normalised ratio increased	2 (13.3)	0	2 (13.3)	0	0
Blood alkaline phosphatase increased	1 (6.7)	1 (6.7)	0	0	0
Blood immunoglobulin g decreased	1 (6.7)	0	1 (6.7)	0	0
Blood lactate dehydrogenase increased	1 (6.7)	0	0	1 (6.7)	0
Blood phosphorus increased	1 (6.7)	0	1 (6.7)	0	0
C-reactive protein increased	1 (6.7)	0	0	1 (6.7)	0
Ejection fraction decreased	1 (6.7)	0	1 (6.7)	0	0
Electrocardiogram qt prolonged	1 (6.7)	0	0	0	1 (6.7)
Electrocardiogram t wave abnormal	1 (6.7)	0	1 (6.7)	0	0
Fibrin d dimer increased	1 (6.7)	0	0	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heart sounds abnormal	1 (6.7)	1 (6.7)	0	0	0
Serum ferritin increased	1 (6.7)	0	0	1 (6.7)	0
Staphylococcus test positive	1 (6.7)	1 (6.7)	0	0	0
Troponin increased	1 (6.7)	0	0	1 (6.7)	0
Urine output decreased	1 (6.7)	0	0	1 (6.7)	0
Weight decreased	1 (6.7)	0	1 (6.7)	0	0
Weight increased	1 (6.7)	0	1 (6.7)	0	0
Metabolism and nutrition disorders					
-Total	13 (86.7)	0	3 (20.0)	6 (40.0)	4 (26.7)
Decreased appetite	9 (60.0)	0	4 (26.7)	5 (33.3)	0
Hypocalcaemia	8 (53.3)	0	5 (33.3)	3 (20.0)	0
Hypokalaemia	7 (46.7)	1 (6.7)	3 (20.0)	2 (13.3)	1 (6.7)
Hyperglycaemia	5 (33.3)	0	3 (20.0)	2 (13.3)	0
Hypoalbuminaemia	5 (33.3)	0	4 (26.7)	1 (6.7)	0
Hyperuricaemia	4 (26.7)	3 (20.0)	0	1 (6.7)	0
Hypophosphataemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Hypervolaemia	3 (20.0)	0	0	3 (20.0)	0
Hypomagnesaemia	3 (20.0)	2 (13.3)	1 (6.7)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Acidosis	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypercalcaemia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Hyperkalaemia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Malnutrition	2 (13.3)	0	0	2 (13.3)	0
Calcium deficiency	1 (6.7)	1 (6.7)	0	0	0
Hyperchloraemia	1 (6.7)	1 (6.7)	0	0	0
Hypermagnesaemia	1 (6.7)	1 (6.7)	0	0	0
Hyperphosphataemia	1 (6.7)	1 (6.7)	0	0	0
Hypoglycaemia	1 (6.7)	0	1 (6.7)	0	0
Hyponatraemia	1 (6.7)	1 (6.7)	0	0	0
Metabolic acidosis	1 (6.7)	0	0	0	1 (6.7)
Obesity	1 (6.7)	0	0	1 (6.7)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (60.0)	3 (20.0)	4 (26.7)	2 (13.3)	0
Arthralgia	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Myalgia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Back pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Growth retardation	1 (6.7)	0	1 (6.7)	0	0
Haemarthrosis	1 (6.7)	0	0	1 (6.7)	0
Muscle spasms	1 (6.7)	0	1 (6.7)	0	0
Neck pain	1 (6.7)	1 (6.7)	0	0	0
Osteopenia	1 (6.7)	1 (6.7)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (6.7)	0	1 (6.7)	0	0
Cancer pain	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	8 (53.3)	0	5 (33.3)	1 (6.7)	2 (13.3)
Headache	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Cognitive disorder	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Somnolence	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Amnesia	1 (6.7)	0	1 (6.7)	0	0
Cerebral haemorrhage	1 (6.7)	0	0	0	1 (6.7)
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extrapyramidal disorder	1 (6.7)	0	1 (6.7)	0	0
Hyperaesthesia	1 (6.7)	1 (6.7)	0	0	0
Neurological decompensation	1 (6.7)	0	0	0	1 (6.7)
Paraesthesia	1 (6.7)	1 (6.7)	0	0	0
Tremor	1 (6.7)	1 (6.7)	0	0	0
Psychiatric disorders					
-Total	8 (53.3)	1 (6.7)	5 (33.3)	2 (13.3)	0
Anxiety	5 (33.3)	0	4 (26.7)	1 (6.7)	0
Mental status changes	2 (13.3)	0	2 (13.3)	0	0
Agitation	1 (6.7)	0	1 (6.7)	0	0
Delirium	1 (6.7)	0	0	1 (6.7)	0
Hallucination, visual	1 (6.7)	0	1 (6.7)	0	0
Insomnia	1 (6.7)	1 (6.7)	0	0	0
Renal and urinary disorders					
-Total	6 (40.0)	0	1 (6.7)	2 (13.3)	3 (20.0)
Acute kidney injury	4 (26.7)	0	1 (6.7)	1 (6.7)	2 (13.3)
Dysuria	1 (6.7)	0	1 (6.7)	0	0
Haematuria	1 (6.7)	0	0	1 (6.7)	0
Kidney enlargement	1 (6.7)	0	1 (6.7)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (6.7)	0	0	0	1 (6.7)
Renal mass	1 (6.7)	0	1 (6.7)	0	0
Urinary retention	1 (6.7)	0	1 (6.7)	0	0
Reproductive system and breast disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Female genital tract fistula	1 (6.7)	1 (6.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (73.3)	1 (6.7)	2 (13.3)	3 (20.0)	5 (33.3)
Pulmonary oedema	4 (26.7)	0	1 (6.7)	2 (13.3)	1 (6.7)
Hypoxia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Nasal congestion	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Acute respiratory distress syndrome	2 (13.3)	0	0	0	2 (13.3)
Cough	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pleural effusion	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Rhinitis allergic	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Acute respiratory failure	1 (6.7)	0	0	1 (6.7)	0
Bronchial oedema	1 (6.7)	1 (6.7)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (6.7)	1 (6.7)	0	0	0
Respiratory distress	1 (6.7)	0	0	0	1 (6.7)
Respiratory failure	1 (6.7)	0	0	0	1 (6.7)
Rhinorrhoea	1 (6.7)	0	1 (6.7)	0	0
Sleep apnoea syndrome	1 (6.7)	0	1 (6.7)	0	0
Tachypnoea	1 (6.7)	0	0	1 (6.7)	0
Wheezing	1 (6.7)	0	1 (6.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (46.7)	3 (20.0)	3 (20.0)	1 (6.7)	0
Dry skin	2 (13.3)	2 (13.3)	0	0	0
Pruritus	2 (13.3)	0	2 (13.3)	0	0
Blister	1 (6.7)	0	1 (6.7)	0	0
Decubitus ulcer	1 (6.7)	0	0	1 (6.7)	0
Hyperhidrosis	1 (6.7)	1 (6.7)	0	0	0
Rash	1 (6.7)	1 (6.7)	0	0	0
Rash maculo-papular	1 (6.7)	1 (6.7)	0	0	0
Scab	1 (6.7)	1 (6.7)	0	0	0
Skin hypopigmentation	1 (6.7)	1 (6.7)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Surgical and medical procedures					
-Total	1 (6.7)	0	0	1 (6.7)	0
Thrombolysis	1 (6.7)	0	0	1 (6.7)	0
Vascular disorders					
-Total	10 (66.7)	1 (6.7)	1 (6.7)	5 (33.3)	3 (20.0)
Hypotension	7 (46.7)	0	1 (6.7)	3 (20.0)	3 (20.0)
Hypertension	4 (26.7)	2 (13.3)	0	2 (13.3)	0
Capillary leak syndrome	1 (6.7)	0	0	1 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (100)	1 (1.5)	4 (6.2)	19 (29.2)	41 (63.1)
Blood and lymphatic system disorders					
-Total	44 (67.7)	1 (1.5)	10 (15.4)	21 (32.3)	12 (18.5)
Anaemia	20 (30.8)	7 (10.8)	8 (12.3)	5 (7.7)	0
Febrile neutropenia	19 (29.2)	0	0	19 (29.2)	0
Neutropenia	11 (16.9)	0	2 (3.1)	2 (3.1)	7 (10.8)
Thrombocytopenia	8 (12.3)	0	0	2 (3.1)	6 (9.2)
Disseminated intravascular coagulation	7 (10.8)	0	4 (6.2)	3 (4.6)	0
Splenomegaly	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Coagulopathy	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (4.6)	0	1 (1.5)	1 (1.5)	1 (1.5)
Lymphadenopathy	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Lymphopenia	2 (3.1)	0	0	2 (3.1)	0
Pancytopenia	2 (3.1)	0	0	2 (3.1)	0
Agranulocytosis	1 (1.5)	0	0	1 (1.5)	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Eosinophilia	1 (1.5)	0	1 (1.5)	0	0
Hypercoagulation	1 (1.5)	0	1 (1.5)	0	0
Hypofibrinogenaemia	1 (1.5)	0	1 (1.5)	0	0
Lymphocytosis	1 (1.5)	0	1 (1.5)	0	0
Cardiac disorders					
-Total	22 (33.8)	9 (13.8)	4 (6.2)	4 (6.2)	5 (7.7)
Tachycardia	14 (21.5)	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)
Bradycardia	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Left ventricular dysfunction	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Cardiac arrest	2 (3.1)	0	0	0	2 (3.1)
Cardiac dysfunction	2 (3.1)	2 (3.1)	0	0	0
Cardiac failure	2 (3.1)	0	0	0	2 (3.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.5)	0	1 (1.5)	0	0
Cardiac failure congestive	1 (1.5)	0	1 (1.5)	0	0
Mitral valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Pericardial effusion	1 (1.5)	1 (1.5)	0	0	0
Right ventricular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Sinus tachycardia	1 (1.5)	0	1 (1.5)	0	0
Tricuspid valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Cerebral cavernous malformation	1 (1.5)	1 (1.5)	0	0	0
Ear and labyrinth disorders					
-Total	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Deafness unilateral	1 (1.5)	0	1 (1.5)	0	0
Ear pain	1 (1.5)	1 (1.5)	0	0	0
Ear pruritus	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.6)	0	3 (4.6)	0	0
Hypothyroidism	2 (3.1)	0	2 (3.1)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	13 (20.0)	8 (12.3)	4 (6.2)	1 (1.5)	0
Eyelid oedema	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Ocular hyperaemia	3 (4.6)	3 (4.6)	0	0	0
Cataract	2 (3.1)	2 (3.1)	0	0	0
Conjunctival haemorrhage	2 (3.1)	2 (3.1)	0	0	0
Eye pain	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Eye oedema	1 (1.5)	1 (1.5)	0	0	0
Hypermetropia	1 (1.5)	1 (1.5)	0	0	0
Mydriasis	1 (1.5)	0	1 (1.5)	0	0
Periorbital oedema	1 (1.5)	1 (1.5)	0	0	0
Periorbital swelling	1 (1.5)	0	1 (1.5)	0	0
Retinal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Visual impairment	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	48 (73.8)	17 (26.2)	18 (27.7)	13 (20.0)	0
Vomiting	22 (33.8)	14 (21.5)	8 (12.3)	0	0
Diarrhoea	20 (30.8)	13 (20.0)	5 (7.7)	2 (3.1)	0
Nausea	19 (29.2)	11 (16.9)	6 (9.2)	2 (3.1)	0
Abdominal pain	10 (15.4)	2 (3.1)	6 (9.2)	2 (3.1)	0
Constipation	10 (15.4)	6 (9.2)	4 (6.2)	0	0
Pancreatitis	5 (7.7)	1 (1.5)	2 (3.1)	2 (3.1)	0
Abdominal pain upper	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Mouth haemorrhage	4 (6.2)	2 (3.1)	1 (1.5)	1 (1.5)	0
Abdominal distension	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Ascites	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Stomatitis	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Gastrointestinal sounds abnormal	2 (3.1)	2 (3.1)	0	0	0
Proctalgia	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Trichoglossia	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Abdominal rigidity	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Anal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Dyspepsia	1 (1.5)	1 (1.5)	0	0	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Enteritis	1 (1.5)	0	1 (1.5)	0	0
Enterocolitis	1 (1.5)	0	1 (1.5)	0	0
Gastrooesophageal reflux disease	1 (1.5)	0	1 (1.5)	0	0
Gingival bleeding	1 (1.5)	0	1 (1.5)	0	0
Gingival erythema	1 (1.5)	1 (1.5)	0	0	0
Gingivitis ulcerative	1 (1.5)	0	0	1 (1.5)	0
Haematemesis	1 (1.5)	1 (1.5)	0	0	0
Ileus	1 (1.5)	0	1 (1.5)	0	0
Irritable bowel syndrome	1 (1.5)	0	1 (1.5)	0	0
Lip dry	1 (1.5)	0	1 (1.5)	0	0
Lip oedema	1 (1.5)	1 (1.5)	0	0	0
Melaena	1 (1.5)	0	0	1 (1.5)	0
Mouth swelling	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic colitis	1 (1.5)	0	0	1 (1.5)	0
Odynophagia	1 (1.5)	1 (1.5)	0	0	0
Peritoneal haematoma	1 (1.5)	1 (1.5)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	42 (64.6)	22 (33.8)	9 (13.8)	7 (10.8)	4 (6.2)
Pyrexia	29 (44.6)	13 (20.0)	8 (12.3)	6 (9.2)	2 (3.1)
Fatigue	13 (20.0)	11 (16.9)	2 (3.1)	0	0
Face oedema	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Chills	5 (7.7)	3 (4.6)	2 (3.1)	0	0
Pain	5 (7.7)	1 (1.5)	2 (3.1)	2 (3.1)	0
Oedema peripheral	4 (6.2)	3 (4.6)	0	1 (1.5)	0
Asthenia	3 (4.6)	3 (4.6)	0	0	0
Generalised oedema	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Catheter site pain	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Influenza like illness	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Localised oedema	2 (3.1)	2 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	2 (3.1)	0	0	0	2 (3.1)
Catheter site erythema	1 (1.5)	1 (1.5)	0	0	0
Catheter site haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Chest discomfort	1 (1.5)	0	0	1 (1.5)	0
Crying	1 (1.5)	0	1 (1.5)	0	0
Drug withdrawal syndrome	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Malaise	1 (1.5)	0	1 (1.5)	0	0
Non-cardiac chest pain	1 (1.5)	1 (1.5)	0	0	0
Oedema due to hepatic disease	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Swelling face	1 (1.5)	1 (1.5)	0	0	0
Systemic inflammatory response syndrome	1 (1.5)	0	0	1 (1.5)	0
Vascular device occlusion	1 (1.5)	1 (1.5)	0	0	0
Xerosis	1 (1.5)	1 (1.5)	0	0	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (26.2)	5 (7.7)	7 (10.8)	2 (3.1)	3 (4.6)
Hepatic function abnormal	5 (7.7)	0	2 (3.1)	2 (3.1)	1 (1.5)
Hyperbilirubinaemia	4 (6.2)	1 (1.5)	3 (4.6)	0	0
Hepatomegaly	3 (4.6)	2 (3.1)	0	0	1 (1.5)
Cholelithiasis	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Cholestasis	1 (1.5)	0	0	0	1 (1.5)
Gallbladder enlargement	1 (1.5)	1 (1.5)	0	0	0
Hepatic cytolysis	1 (1.5)	1 (1.5)	0	0	0
Hypertransaminasaemia	1 (1.5)	0	1 (1.5)	0	0
Liver disorder	1 (1.5)	0	1 (1.5)	0	0
Ocular icterus	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	56 (86.2)	2 (3.1)	17 (26.2)	23 (35.4)	14 (21.5)
Cytokine release syndrome	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Hypogammaglobulinaemia	27 (41.5)	1 (1.5)	20 (30.8)	6 (9.2)	0
Haemophagocytic lymphohistiocytosis	5 (7.7)	1 (1.5)	1 (1.5)	1 (1.5)	2 (3.1)
Immunodeficiency	4 (6.2)	0	0	4 (6.2)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Drug hypersensitivity	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Graft versus host disease	2 (3.1)	0	0	2 (3.1)	0
Allergy to immunoglobulin therapy	1 (1.5)	1 (1.5)	0	0	0
Engraftment syndrome	1 (1.5)	0	0	1 (1.5)	0
Hypersensitivity	1 (1.5)	1 (1.5)	0	0	0
Seasonal allergy	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	49 (75.4)	8 (12.3)	8 (12.3)	21 (32.3)	12 (18.5)
Upper respiratory tract infection	9 (13.8)	5 (7.7)	2 (3.1)	2 (3.1)	0
Rhinovirus infection	8 (12.3)	0	6 (9.2)	2 (3.1)	0
Conjunctivitis	7 (10.8)	1 (1.5)	6 (9.2)	0	0
Nasopharyngitis	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Sinusitis	7 (10.8)	0	5 (7.7)	2 (3.1)	0
Pneumonia	6 (9.2)	1 (1.5)	1 (1.5)	2 (3.1)	2 (3.1)
Gastroenteritis	5 (7.7)	3 (4.6)	0	2 (3.1)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	4 (6.2)	1 (1.5)	0	3 (4.6)	0
Nail infection	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Oral herpes	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Otitis media	4 (6.2)	0	3 (4.6)	1 (1.5)	0
Parainfluenzae virus infection	4 (6.2)	1 (1.5)	0	2 (3.1)	1 (1.5)
Staphylococcal infection	4 (6.2)	0	2 (3.1)	2 (3.1)	0
Candida infection	3 (4.6)	0	2 (3.1)	0	1 (1.5)
Ear infection	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Herpes zoster	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Influenza	3 (4.6)	0	2 (3.1)	0	1 (1.5)
Oral candidiasis	3 (4.6)	0	3 (4.6)	0	0
Otitis externa	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Respiratory tract infection	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Rhinitis	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Sepsis	3 (4.6)	0	0	1 (1.5)	2 (3.1)
Staphylococcal bacteraemia	3 (4.6)	0	0	3 (4.6)	0
Acute sinusitis	2 (3.1)	0	2 (3.1)	0	0
Bronchitis	2 (3.1)	0	2 (3.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Encephalitis	2 (3.1)	0	0	0	2 (3.1)
Fungal infection	2 (3.1)	0	2 (3.1)	0	0
Gastroenteritis viral	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Gingivitis	2 (3.1)	2 (3.1)	0	0	0
Human herpesvirus 6 infection	2 (3.1)	0	0	2 (3.1)	0
Metapneumovirus infection	2 (3.1)	0	0	2 (3.1)	0
Oral infection	2 (3.1)	0	2 (3.1)	0	0
Paronychia	2 (3.1)	0	2 (3.1)	0	0
Skin infection	2 (3.1)	0	2 (3.1)	0	0
Urinary tract infection	2 (3.1)	0	2 (3.1)	0	0
Varicella zoster virus infection	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Viral infection	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Anal abscess	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bk virus infection	1 (1.5)	1 (1.5)	0	0	0
Bronchiolitis	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.5)	0	1 (1.5)	0	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Coronavirus infection	1 (1.5)	0	0	1 (1.5)	0
Covid-19	1 (1.5)	0	0	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cystitis	1 (1.5)	0	1 (1.5)	0	0
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related infection	1 (1.5)	0	0	1 (1.5)	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Ear, nose and throat infection	1 (1.5)	0	1 (1.5)	0	0
Encephalitis viral	1 (1.5)	0	0	0	1 (1.5)
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal infection	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes simplex	1 (1.5)	0	0	1 (1.5)	0
Herpes virus infection	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	1 (1.5)	0	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	0	0	1 (1.5)
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection viral	1 (1.5)	0	1 (1.5)	0	0
Salmonellosis	1 (1.5)	0	1 (1.5)	0	0
Septic shock	1 (1.5)	0	0	0	1 (1.5)
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Staphylococcal skin infection	1 (1.5)	0	1 (1.5)	0	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Streptococcal sepsis	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Tinea pedis	1 (1.5)	1 (1.5)	0	0	0
Urinary tract infection pseudomonal	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection viral	1 (1.5)	1 (1.5)	0	0	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral skin infection	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	17 (26.2)	7 (10.8)	7 (10.8)	1 (1.5)	2 (3.1)
Infusion related reaction	4 (6.2)	2 (3.1)	1 (1.5)	1 (1.5)	0
Contusion	2 (3.1)	2 (3.1)	0	0	0
Fall	2 (3.1)	0	2 (3.1)	0	0
Ligament sprain	2 (3.1)	2 (3.1)	0	0	0
Procedural pain	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Wound	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Fibula fracture	1 (1.5)	0	1 (1.5)	0	0
Limb injury	1 (1.5)	0	1 (1.5)	0	0
Post-traumatic neck syndrome	1 (1.5)	0	1 (1.5)	0	0
Scratch	1 (1.5)	1 (1.5)	0	0	0
Skin abrasion	1 (1.5)	1 (1.5)	0	0	0
Skin injury	1 (1.5)	0	1 (1.5)	0	0
Skin wound	1 (1.5)	1 (1.5)	0	0	0
Transfusion reaction	1 (1.5)	1 (1.5)	0	0	0
Transplant failure	1 (1.5)	0	0	0	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (1.5)	0	0	0	1 (1.5)
Investigations					
-Total	49 (75.4)	3 (4.6)	8 (12.3)	16 (24.6)	22 (33.8)
White blood cell count decreased	22 (33.8)	3 (4.6)	4 (6.2)	2 (3.1)	13 (20.0)
Neutrophil count decreased	21 (32.3)	1 (1.5)	2 (3.1)	4 (6.2)	14 (21.5)
Platelet count decreased	21 (32.3)	6 (9.2)	3 (4.6)	7 (10.8)	5 (7.7)
Lymphocyte count decreased	17 (26.2)	1 (1.5)	1 (1.5)	10 (15.4)	5 (7.7)
Alanine aminotransferase increased	13 (20.0)	3 (4.6)	6 (9.2)	4 (6.2)	0
Aspartate aminotransferase increased	12 (18.5)	2 (3.1)	5 (7.7)	4 (6.2)	1 (1.5)
Blood bilirubin increased	9 (13.8)	1 (1.5)	3 (4.6)	5 (7.7)	0
Blood fibrinogen decreased	7 (10.8)	2 (3.1)	3 (4.6)	1 (1.5)	1 (1.5)
Blood immunoglobulin a decreased	7 (10.8)	5 (7.7)	1 (1.5)	1 (1.5)	0
Blood immunoglobulin m decreased	7 (10.8)	4 (6.2)	1 (1.5)	2 (3.1)	0
International normalised ratio increased	7 (10.8)	6 (9.2)	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	7 (10.8)	1 (1.5)	5 (7.7)	1 (1.5)	0
Activated partial thromboplastin time prolonged	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Blood lactate dehydrogenase increased	4 (6.2)	3 (4.6)	1 (1.5)	0	0
C-reactive protein increased	4 (6.2)	2 (3.1)	0	2 (3.1)	0
Electrocardiogram qt prolonged	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Blood immunoglobulin g decreased	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Oxygen saturation decreased	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Weight increased	3 (4.6)	1 (1.5)	0	2 (3.1)	0
Blood creatine phosphokinase increased	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Blood creatinine increased	2 (3.1)	0	1 (1.5)	0	1 (1.5)
Blood uric acid increased	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Fibrin d dimer increased	2 (3.1)	2 (3.1)	0	0	0
Gamma-glutamyltransferase increased	2 (3.1)	0	0	2 (3.1)	0
Immunoglobulins decreased	2 (3.1)	0	2 (3.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	2 (3.1)	1 (1.5)	0	0	1 (1.5)
Amylase increased	1 (1.5)	1 (1.5)	0	0	0
Bacterial test positive	1 (1.5)	0	0	1 (1.5)	0
Blood bicarbonate decreased	1 (1.5)	0	1 (1.5)	0	0
Blood glucose increased	1 (1.5)	0	0	0	1 (1.5)
Blood testosterone decreased	1 (1.5)	1 (1.5)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.5)	1 (1.5)	0	0	0
Blood urea increased	1 (1.5)	0	0	1 (1.5)	0
Bone density decreased	1 (1.5)	1 (1.5)	0	0	0
Breath sounds abnormal	1 (1.5)	0	1 (1.5)	0	0
Cardiac murmur	1 (1.5)	1 (1.5)	0	0	0
Coagulation test abnormal	1 (1.5)	1 (1.5)	0	0	0
Enterovirus test positive	1 (1.5)	0	1 (1.5)	0	0
Haemoglobin decreased	1 (1.5)	0	0	1 (1.5)	0
Haptoglobin decreased	1 (1.5)	1 (1.5)	0	0	0
Hepatitis b virus test positive	1 (1.5)	0	1 (1.5)	0	0
Prothrombin time prolonged	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urine output decreased	1 (1.5)	0	0	0	1 (1.5)
Weight decreased	1 (1.5)	0	0	1 (1.5)	0
Metabolism and nutrition disorders					
-Total	39 (60.0)	9 (13.8)	7 (10.8)	16 (24.6)	7 (10.8)
Decreased appetite	21 (32.3)	11 (16.9)	3 (4.6)	5 (7.7)	2 (3.1)
Hypophosphataemia	14 (21.5)	3 (4.6)	5 (7.7)	5 (7.7)	1 (1.5)
Hypokalaemia	13 (20.0)	2 (3.1)	3 (4.6)	7 (10.8)	1 (1.5)
Hypocalcaemia	8 (12.3)	2 (3.1)	4 (6.2)	2 (3.1)	0
Hypoalbuminaemia	6 (9.2)	0	6 (9.2)	0	0
Hyperuricaemia	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Hyperglycaemia	4 (6.2)	0	1 (1.5)	3 (4.6)	0
Hyperphosphataemia	4 (6.2)	3 (4.6)	0	0	1 (1.5)
Hypervolaemia	4 (6.2)	0	2 (3.1)	2 (3.1)	0
Hypernatraemia	3 (4.6)	1 (1.5)	0	1 (1.5)	1 (1.5)
Hypertriglyceridaemia	3 (4.6)	0	1 (1.5)	1 (1.5)	1 (1.5)
Hypomagnesaemia	3 (4.6)	3 (4.6)	0	0	0
Metabolic acidosis	3 (4.6)	1 (1.5)	0	0	2 (3.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	2 (3.1)	2 (3.1)	0	0	0
Iron overload	2 (3.1)	0	2 (3.1)	0	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0
Dehydration	1 (1.5)	0	1 (1.5)	0	0
Haemochromatosis	1 (1.5)	0	0	1 (1.5)	0
Haemosiderosis	1 (1.5)	0	1 (1.5)	0	0
Hypercalcaemia	1 (1.5)	0	0	1 (1.5)	0
Hyperchloraemia	1 (1.5)	1 (1.5)	0	0	0
Hypercholesterolaemia	1 (1.5)	0	1 (1.5)	0	0
Hyperkalaemia	1 (1.5)	0	0	0	1 (1.5)
Hyperlactacidaemia	1 (1.5)	1 (1.5)	0	0	0
Hyperlipidaemia	1 (1.5)	0	1 (1.5)	0	0
Hypermagnesaemia	1 (1.5)	1 (1.5)	0	0	0
Hypophagia	1 (1.5)	0	1 (1.5)	0	0
Metabolic syndrome	1 (1.5)	0	1 (1.5)	0	0
Polydipsia	1 (1.5)	0	0	1 (1.5)	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	35 (53.8)	14 (21.5)	15 (23.1)	5 (7.7)	1 (1.5)
Pain in extremity	15 (23.1)	7 (10.8)	7 (10.8)	1 (1.5)	0
Arthralgia	9 (13.8)	5 (7.7)	4 (6.2)	0	0
Back pain	8 (12.3)	2 (3.1)	4 (6.2)	2 (3.1)	0
Myalgia	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Bone pain	4 (6.2)	1 (1.5)	3 (4.6)	0	0
Muscular weakness	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Musculoskeletal chest pain	2 (3.1)	2 (3.1)	0	0	0
Pain in jaw	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Growth retardation	1 (1.5)	0	1 (1.5)	0	0
Joint effusion	1 (1.5)	0	1 (1.5)	0	0
Muscle rigidity	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal pain	1 (1.5)	0	1 (1.5)	0	0
Myositis	1 (1.5)	0	1 (1.5)	0	0
Neck pain	1 (1.5)	0	1 (1.5)	0	0
Osteonecrosis	1 (1.5)	1 (1.5)	0	0	0
Rhabdomyolysis	1 (1.5)	0	0	0	1 (1.5)
Synovitis	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (6.2)	1 (1.5)	1 (1.5)	2 (3.1)	0
Skin papilloma	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Bone giant cell tumour benign	1 (1.5)	0	0	1 (1.5)	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Nervous system disorders					
-Total	39 (60.0)	15 (23.1)	13 (20.0)	9 (13.8)	2 (3.1)
Headache	23 (35.4)	11 (16.9)	9 (13.8)	3 (4.6)	0
Encephalopathy	7 (10.8)	1 (1.5)	3 (4.6)	3 (4.6)	0
Tremor	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Dizziness	4 (6.2)	4 (6.2)	0	0	0
Seizure	4 (6.2)	0	1 (1.5)	3 (4.6)	0
Dysgeusia	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Lethargy	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Somnolence	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Dysarthria	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Autonomic neuropathy	1 (1.5)	0	0	1 (1.5)	0
Cerebral haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Hydrocephalus	1 (1.5)	0	0	0	1 (1.5)
Hypoaesthesia	1 (1.5)	1 (1.5)	0	0	0
Memory impairment	1 (1.5)	0	1 (1.5)	0	0
Migraine	1 (1.5)	0	1 (1.5)	0	0
Monoparesis	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorder	1 (1.5)	0	0	1 (1.5)	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Psychiatric disorders					
-Total	31 (47.7)	12 (18.5)	14 (21.5)	5 (7.7)	0
Anxiety	9 (13.8)	3 (4.6)	5 (7.7)	1 (1.5)	0
Confusional state	7 (10.8)	7 (10.8)	0	0	0
Delirium	7 (10.8)	2 (3.1)	3 (4.6)	2 (3.1)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	5 (7.7)	3 (4.6)	2 (3.1)	0	0
Hallucination	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Insomnia	3 (4.6)	1 (1.5)	2 (3.1)	0	0
Irritability	3 (4.6)	3 (4.6)	0	0	0
Mental status changes	3 (4.6)	1 (1.5)	0	2 (3.1)	0
Sleep disorder	3 (4.6)	0	3 (4.6)	0	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Automatism	1 (1.5)	1 (1.5)	0	0	0
Mood altered	1 (1.5)	1 (1.5)	0	0	0
Nightmare	1 (1.5)	1 (1.5)	0	0	0
Persistent depressive disorder	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tearfulness	1 (1.5)	1 (1.5)	0	0	0
Tic	1 (1.5)	0	1 (1.5)	0	0
Renal and urinary disorders					
-Total	19 (29.2)	6 (9.2)	6 (9.2)	3 (4.6)	4 (6.2)
Acute kidney injury	8 (12.3)	2 (3.1)	1 (1.5)	2 (3.1)	3 (4.6)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	3 (4.6)	3 (4.6)	0	0	0
Anuria	2 (3.1)	1 (1.5)	0	0	1 (1.5)
Haematuria	2 (3.1)	2 (3.1)	0	0	0
Pollakiuria	2 (3.1)	0	2 (3.1)	0	0
Azotaemia	1 (1.5)	0	1 (1.5)	0	0
Bladder dilatation	1 (1.5)	0	1 (1.5)	0	0
Cystitis haemorrhagic	1 (1.5)	0	1 (1.5)	0	0
Incontinence	1 (1.5)	0	1 (1.5)	0	0
Micturition urgency	1 (1.5)	0	1 (1.5)	0	0
Proteinuria	1 (1.5)	1 (1.5)	0	0	0
Renal failure	1 (1.5)	0	1 (1.5)	0	0
Renal tubular disorder	1 (1.5)	0	0	1 (1.5)	0
Renal tubular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Renal tubular necrosis	1 (1.5)	0	0	0	1 (1.5)
Urinary incontinence	1 (1.5)	0	1 (1.5)	0	0
Urinary retention	1 (1.5)	0	1 (1.5)	0	0
Urinary tract disorder	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	5 (7.7)	1 (1.5)	2 (3.1)	2 (3.1)	0
Dysmenorrhoea	1 (1.5)	0	1 (1.5)	0	0
Endometriosis	1 (1.5)	0	0	1 (1.5)	0
Heavy menstrual bleeding	1 (1.5)	1 (1.5)	0	0	0
Perineal rash	1 (1.5)	0	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Vaginal ulceration	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	44 (67.7)	17 (26.2)	6 (9.2)	9 (13.8)	12 (18.5)
Cough	21 (32.3)	17 (26.2)	4 (6.2)	0	0
Hypoxia	17 (26.2)	0	4 (6.2)	8 (12.3)	5 (7.7)
Pulmonary oedema	8 (12.3)	2 (3.1)	2 (3.1)	4 (6.2)	0
Tachypnoea	8 (12.3)	3 (4.6)	1 (1.5)	3 (4.6)	1 (1.5)
Dyspnoea	7 (10.8)	1 (1.5)	2 (3.1)	2 (3.1)	2 (3.1)
Epistaxis	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Oropharyngeal pain	7 (10.8)	6 (9.2)	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Nasal congestion	6 (9.2)	5 (7.7)	1 (1.5)	0	0
Respiratory failure	5 (7.7)	0	0	0	5 (7.7)
Rhinorrhoea	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Atelectasis	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Respiratory distress	3 (4.6)	0	2 (3.1)	0	1 (1.5)
Pharyngeal erythema	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Acute respiratory distress syndrome	1 (1.5)	0	0	0	1 (1.5)
Bradypnoea	1 (1.5)	0	0	1 (1.5)	0
Bronchospasm	1 (1.5)	0	1 (1.5)	0	0
Dyspnoea exertional	1 (1.5)	1 (1.5)	0	0	0
Haemoptysis	1 (1.5)	0	1 (1.5)	0	0
Laryngeal oedema	1 (1.5)	0	0	0	1 (1.5)
Lung disorder	1 (1.5)	1 (1.5)	0	0	0
Lung infiltration	1 (1.5)	0	0	1 (1.5)	0
Nasal discomfort	1 (1.5)	0	1 (1.5)	0	0
Nasal dryness	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (1.5)	0	1 (1.5)	0	0
Painful respiration	1 (1.5)	1 (1.5)	0	0	0
Paranasal sinus discomfort	1 (1.5)	0	1 (1.5)	0	0
Paranasal sinus inflammation	1 (1.5)	1 (1.5)	0	0	0
Pharyngeal exudate	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal oedema	1 (1.5)	0	1 (1.5)	0	0
Productive cough	1 (1.5)	1 (1.5)	0	0	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory acidosis	1 (1.5)	0	0	1 (1.5)	0
Respiratory disorder	1 (1.5)	0	1 (1.5)	0	0
Sleep apnoea syndrome	1 (1.5)	1 (1.5)	0	0	0
Upper respiratory tract inflammation	1 (1.5)	0	1 (1.5)	0	0
Wheezing	1 (1.5)	0	1 (1.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	33 (50.8)	14 (21.5)	13 (20.0)	6 (9.2)	0
Rash	7 (10.8)	3 (4.6)	4 (6.2)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	6 (9.2)	4 (6.2)	2 (3.1)	0	0
Erythema	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Pruritus	5 (7.7)	2 (3.1)	3 (4.6)	0	0
Dermatitis atopic	3 (4.6)	2 (3.1)	0	1 (1.5)	0
Eczema	3 (4.6)	2 (3.1)	0	1 (1.5)	0
Rash papular	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Blister	2 (3.1)	2 (3.1)	0	0	0
Hyperhidrosis	2 (3.1)	0	2 (3.1)	0	0
Ingrowing nail	2 (3.1)	0	2 (3.1)	0	0
Petechiae	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Rash maculo-papular	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Skin discolouration	2 (3.1)	2 (3.1)	0	0	0
Skin ulcer	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Decubitus ulcer	1 (1.5)	0	1 (1.5)	0	0
Dermatitis	1 (1.5)	1 (1.5)	0	0	0
Dermatitis allergic	1 (1.5)	1 (1.5)	0	0	0
Dermatitis diaper	1 (1.5)	0	1 (1.5)	0	0
Erythema nodosum	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hangnail	1 (1.5)	1 (1.5)	0	0	0
Miliaria	1 (1.5)	1 (1.5)	0	0	0
Night sweats	1 (1.5)	1 (1.5)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.5)	1 (1.5)	0	0	0
Papule	1 (1.5)	1 (1.5)	0	0	0
Photosensitivity reaction	1 (1.5)	0	1 (1.5)	0	0
Pruritus allergic	1 (1.5)	0	1 (1.5)	0	0
Purpura	1 (1.5)	1 (1.5)	0	0	0
Rash erythematous	1 (1.5)	1 (1.5)	0	0	0
Rash macular	1 (1.5)	0	0	1 (1.5)	0
Rash pruritic	1 (1.5)	1 (1.5)	0	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Skin lesion	1 (1.5)	0	1 (1.5)	0	0
Skin necrosis	1 (1.5)	0	0	1 (1.5)	0
Skin swelling	1 (1.5)	1 (1.5)	0	0	0
Urticaria	1 (1.5)	0	1 (1.5)	0	0
Vancomycin infusion reaction	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social circumstances					
-Total	1 (1.5)	0	1 (1.5)	0	0
Patient uncooperative	1 (1.5)	0	1 (1.5)	0	0
Vascular disorders					
-Total	24 (36.9)	4 (6.2)	7 (10.8)	7 (10.8)	6 (9.2)
Hypotension	17 (26.2)	2 (3.1)	5 (7.7)	5 (7.7)	5 (7.7)
Hypertension	12 (18.5)	2 (3.1)	7 (10.8)	3 (4.6)	0
Venoocclusive disease	2 (3.1)	0	0	1 (1.5)	1 (1.5)
Capillary leak syndrome	1 (1.5)	0	1 (1.5)	0	0
Flushing	1 (1.5)	1 (1.5)	0	0	0
Hot flush	1 (1.5)	1 (1.5)	0	0	0
Peripheral ischaemia	1 (1.5)	0	1 (1.5)	0	0
Thrombosis	1 (1.5)	0	1 (1.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	2 (33.3)	0	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Face oedema	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	1 (16.7)	1 (16.7)	0	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Nasal congestion	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	73 (98.6)	3 (4.1)	7 (9.5)	20 (27.0)	43 (58.1)
Blood and lymphatic system disorders					
-Total	46 (62.2)	3 (4.1)	8 (10.8)	24 (32.4)	11 (14.9)
Febrile neutropenia	23 (31.1)	0	0	22 (29.7)	1 (1.4)
Anaemia	19 (25.7)	4 (5.4)	7 (9.5)	8 (10.8)	0
Neutropenia	9 (12.2)	0	2 (2.7)	1 (1.4)	6 (8.1)
Thrombocytopenia	7 (9.5)	0	0	2 (2.7)	5 (6.8)
Disseminated intravascular coagulation	6 (8.1)	0	5 (6.8)	1 (1.4)	0
Coagulopathy	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Splenomegaly	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	21 (28.4)	9 (12.2)	5 (6.8)	5 (6.8)	2 (2.7)
Tachycardia	14 (18.9)	6 (8.1)	6 (8.1)	2 (2.7)	0
Bradycardia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Left ventricular dysfunction	3 (4.1)	0	0	3 (4.1)	0
Cardiac dysfunction	2 (2.7)	2 (2.7)	0	0	0
Sinus tachycardia	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	0	0	1 (1.4)
Cardiac failure	1 (1.4)	0	0	0	1 (1.4)
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Sinus bradycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	2 (2.7)	2 (2.7)	0	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Ear pruritus	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	5 (6.8)	0	5 (6.8)	0	0
Adrenal insufficiency	4 (5.4)	0	4 (5.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Conjunctival haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Ocular hyperaemia	2 (2.7)	2 (2.7)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Eye pain	1 (1.4)	1 (1.4)	0	0	0
Eyelid oedema	1 (1.4)	0	1 (1.4)	0	0
Periorbital oedema	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	49 (66.2)	18 (24.3)	18 (24.3)	12 (16.2)	1 (1.4)
Vomiting	21 (28.4)	12 (16.2)	8 (10.8)	1 (1.4)	0
Nausea	17 (23.0)	9 (12.2)	6 (8.1)	2 (2.7)	0
Diarrhoea	15 (20.3)	8 (10.8)	6 (8.1)	1 (1.4)	0
Abdominal pain	11 (14.9)	3 (4.1)	6 (8.1)	2 (2.7)	0
Constipation	10 (13.5)	5 (6.8)	5 (6.8)	0	0
Pancreatitis	4 (5.4)	0	3 (4.1)	1 (1.4)	0
Abdominal pain upper	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Mouth haemorrhage	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Abdominal distension	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Gastrointestinal sounds abnormal	2 (2.7)	2 (2.7)	0	0	0
Stomatitis	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (1.4)	0	0	0	1 (1.4)
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Enterocolitis	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingival bleeding	1 (1.4)	0	1 (1.4)	0	0
Gingival erythema	1 (1.4)	1 (1.4)	0	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Neutropenic colitis	1 (1.4)	0	0	1 (1.4)	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (1.4)	0	0	1 (1.4)	0
Trichoglossia	1 (1.4)	0	1 (1.4)	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	36 (48.6)	18 (24.3)	9 (12.2)	6 (8.1)	3 (4.1)
Pyrexia	21 (28.4)	10 (13.5)	4 (5.4)	5 (6.8)	2 (2.7)
Fatigue	10 (13.5)	8 (10.8)	2 (2.7)	0	0
Face oedema	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Chills	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Oedema peripheral	5 (6.8)	4 (5.4)	0	1 (1.4)	0
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Asthenia	2 (2.7)	2 (2.7)	0	0	0
Drug withdrawal syndrome	2 (2.7)	0	2 (2.7)	0	0
Influenza like illness	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Localised oedema	2 (2.7)	2 (2.7)	0	0	0
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (1.4)	0	0	1 (1.4)	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Malaise	1 (1.4)	0	1 (1.4)	0	0
Multiple organ dysfunction syndrome	1 (1.4)	0	0	0	1 (1.4)
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Pain	1 (1.4)	0	0	1 (1.4)	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	16 (21.6)	5 (6.8)	6 (8.1)	3 (4.1)	2 (2.7)
Hepatic function abnormal	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Hyperbilirubinaemia	5 (6.8)	1 (1.4)	3 (4.1)	1 (1.4)	0
Hepatomegaly	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Hypertransaminasaemia	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Cholelithiasis	1 (1.4)	0	1 (1.4)	0	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	62 (83.8)	3 (4.1)	18 (24.3)	22 (29.7)	19 (25.7)
Cytokine release syndrome	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Hypogammaglobulinaemia	21 (28.4)	2 (2.7)	13 (17.6)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Immunodeficiency	3 (4.1)	0	0	3 (4.1)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	34 (45.9)	6 (8.1)	10 (13.5)	16 (21.6)	2 (2.7)
Staphylococcal infection	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Conjunctivitis	4 (5.4)	1 (1.4)	3 (4.1)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Staphylococcal bacteraemia	3 (4.1)	0	0	3 (4.1)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Nail infection	2 (2.7)	2 (2.7)	0	0	0
Oral herpes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Rhinovirus infection	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	1 (1.4)	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes simplex	1 (1.4)	0	0	1 (1.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (12.2)	3 (4.1)	5 (6.8)	0	1 (1.4)
Fall	2 (2.7)	0	2 (2.7)	0	0
Procedural pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Transfusion reaction	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Infusion related reaction	1 (1.4)	0	1 (1.4)	0	0
Scratch	1 (1.4)	1 (1.4)	0	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Wound	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	54 (73.0)	4 (5.4)	8 (10.8)	16 (21.6)	26 (35.1)
White blood cell count decreased	22 (29.7)	3 (4.1)	2 (2.7)	2 (2.7)	15 (20.3)
Platelet count decreased	20 (27.0)	4 (5.4)	3 (4.1)	6 (8.1)	7 (9.5)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	7 (9.5)	3 (4.1)
Alanine aminotransferase increased	17 (23.0)	4 (5.4)	8 (10.8)	5 (6.8)	0
Neutrophil count decreased	17 (23.0)	0	3 (4.1)	1 (1.4)	13 (17.6)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	14 (18.9)	2 (2.7)	0	7 (9.5)	5 (6.8)
Blood bilirubin increased	11 (14.9)	1 (1.4)	2 (2.7)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Serum ferritin increased	8 (10.8)	1 (1.4)	5 (6.8)	2 (2.7)	0
Blood fibrinogen decreased	7 (9.5)	2 (2.7)	3 (4.1)	1 (1.4)	1 (1.4)
Activated partial thromboplastin time prolonged	6 (8.1)	3 (4.1)	2 (2.7)	1 (1.4)	0
Blood immunoglobulin a decreased	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Blood immunoglobulin m decreased	5 (6.8)	4 (5.4)	0	1 (1.4)	0
Blood lactate dehydrogenase increased	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Electrocardiogram qt prolonged	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Blood creatinine increased	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Fibrin d dimer increased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Weight increased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	2 (2.7)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gamma-glutamyltransferase increased	2 (2.7)	0	0	2 (2.7)	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
Urine output decreased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Amylase increased	1 (1.4)	1 (1.4)	0	0	0
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	1 (1.4)	0
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)
Blood immunoglobulin g decreased	1 (1.4)	1 (1.4)	0	0	0
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
Blood testosterone decreased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Electrocardiogram t wave abnormal	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0
Lipase increased	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Troponin increased	1 (1.4)	0	0	1 (1.4)	0
Weight decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	41 (55.4)	7 (9.5)	8 (10.8)	19 (25.7)	7 (9.5)
Decreased appetite	22 (29.7)	8 (10.8)	3 (4.1)	10 (13.5)	1 (1.4)
Hypokalaemia	18 (24.3)	3 (4.1)	5 (6.8)	9 (12.2)	1 (1.4)
Hypocalcaemia	14 (18.9)	2 (2.7)	8 (10.8)	4 (5.4)	0
Hypophosphataemia	14 (18.9)	3 (4.1)	4 (5.4)	6 (8.1)	1 (1.4)
Hypoalbuminaemia	10 (13.5)	0	9 (12.2)	1 (1.4)	0
Hyperglycaemia	7 (9.5)	0	3 (4.1)	4 (5.4)	0
Hypervolaemia	6 (8.1)	0	2 (2.7)	4 (5.4)	0
Hyperphosphataemia	5 (6.8)	4 (5.4)	0	0	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Hypomagnesaemia	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Tumour lysis syndrome	4 (5.4)	0	0	4 (5.4)	0
Hypercalcaemia	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Metabolic acidosis	3 (4.1)	1 (1.4)	0	0	2 (2.7)
Hyperkalaemia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypertriglyceridaemia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Acidosis	1 (1.4)	0	0	0	1 (1.4)
Calcium deficiency	1 (1.4)	1 (1.4)	0	0	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Hypernatraemia	1 (1.4)	1 (1.4)	0	0	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (41.9)	14 (18.9)	13 (17.6)	4 (5.4)	0
Pain in extremity	11 (14.9)	6 (8.1)	5 (6.8)	0	0
Arthralgia	10 (13.5)	4 (5.4)	5 (6.8)	1 (1.4)	0
Myalgia	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Back pain	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Bone pain	2 (2.7)	0	2 (2.7)	0	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Pain in jaw	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Haemarthrosis	1 (1.4)	0	0	1 (1.4)	0
Muscle rigidity	1 (1.4)	1 (1.4)	0	0	0
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Neck pain	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	36 (48.6)	13 (17.6)	14 (18.9)	7 (9.5)	2 (2.7)
Headache	20 (27.0)	10 (13.5)	8 (10.8)	2 (2.7)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Somnolence	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Dizziness	3 (4.1)	3 (4.1)	0	0	0
Dysgeusia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Seizure	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Paraesthesia	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	26 (35.1)	11 (14.9)	9 (12.2)	6 (8.1)	0
Delirium	7 (9.5)	2 (2.7)	2 (2.7)	3 (4.1)	0
Anxiety	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Agitation	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Insomnia	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Irritability	3 (4.1)	3 (4.1)	0	0	0
Mental status changes	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Automatism	1 (1.4)	1 (1.4)	0	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	18 (24.3)	5 (6.8)	6 (8.1)	2 (2.7)	5 (6.8)
Acute kidney injury	7 (9.5)	1 (1.4)	1 (1.4)	2 (2.7)	3 (4.1)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	3 (4.1)	3 (4.1)	0	0	0
Anuria	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Haematuria	2 (2.7)	2 (2.7)	0	0	0
Pollakiuria	2 (2.7)	0	2 (2.7)	0	0
Renal failure	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Azotaemia	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0
Heavy menstrual bleeding	1 (1.4)	1 (1.4)	0	0	0
Perineal rash	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	38 (51.4)	13 (17.6)	4 (5.4)	10 (13.5)	11 (14.9)
Hypoxia	16 (21.6)	0	5 (6.8)	5 (6.8)	6 (8.1)
Pulmonary oedema	12 (16.2)	2 (2.7)	3 (4.1)	6 (8.1)	1 (1.4)
Cough	10 (13.5)	9 (12.2)	1 (1.4)	0	0
Pleural effusion	7 (9.5)	4 (5.4)	0	2 (2.7)	1 (1.4)
Tachypnoea	6 (8.1)	3 (4.1)	1 (1.4)	2 (2.7)	0
Oropharyngeal pain	5 (6.8)	5 (6.8)	0	0	0
Epistaxis	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Respiratory failure	4 (5.4)	0	0	0	4 (5.4)
Respiratory distress	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Atelectasis	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Dyspnoea	2 (2.7)	0	0	2 (2.7)	0
Nasal congestion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinorrhoea	2 (2.7)	2 (2.7)	0	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal discomfort	1 (1.4)	0	1 (1.4)	0	0
Nasal dryness	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal erythema	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	24 (32.4)	11 (14.9)	11 (14.9)	2 (2.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Blister	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Erythema	3 (4.1)	3 (4.1)	0	0	0
Rash	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rash papular	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dermatitis atopic	2 (2.7)	2 (2.7)	0	0	0
Hyperhidrosis	2 (2.7)	0	2 (2.7)	0	0
Rash maculo-papular	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	0	1 (1.4)	0	0
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	1 (1.4)	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Scab	1 (1.4)	1 (1.4)	0	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin ulcer	1 (1.4)	0	1 (1.4)	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	26 (35.1)	4 (5.4)	7 (9.5)	10 (13.5)	5 (6.8)
Hypotension	19 (25.7)	1 (1.4)	6 (8.1)	7 (9.5)	5 (6.8)
Hypertension	12 (16.2)	4 (5.4)	5 (6.8)	3 (4.1)	0
Capillary leak syndrome	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0
Thrombosis	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Lymphocytosis	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	2 (40.0)	0	0
Gastroenteritis	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal infection	1 (20.0)	1 (20.0)	0	0	0
Otitis externa	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Fibula fracture	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	1 (20.0)	0
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Persistent depressive disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Dry skin	2 (40.0)	2 (40.0)	0	0	0
Skin hypopigmentation	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (92.9)	8 (11.4)	22 (31.4)	14 (20.0)	21 (30.0)
Blood and lymphatic system disorders					
-Total	16 (22.9)	3 (4.3)	3 (4.3)	6 (8.6)	4 (5.7)
Anaemia	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Neutropenia	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	7 (10.0)	3 (4.3)	1 (1.4)	0	3 (4.3)
Cardiac arrest	2 (2.9)	0	0	0	2 (2.9)
Cardiac failure	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Tachycardia	2 (2.9)	2 (2.9)	0	0	0
Left ventricular dysfunction	1 (1.4)	0	1 (1.4)	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	4 (5.7)	4 (5.7)	0	0	0
Cataract	2 (2.9)	2 (2.9)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	20 (28.6)	13 (18.6)	6 (8.6)	1 (1.4)	0
Diarrhoea	7 (10.0)	6 (8.6)	1 (1.4)	0	0
Vomiting	6 (8.6)	6 (8.6)	0	0	0
Nausea	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Constipation	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Abdominal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Pancreatitis	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Abdominal pain upper	1 (1.4)	1 (1.4)	0	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	1 (1.4)	0	0	0
Stomatitis	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	23 (32.9)	14 (20.0)	6 (8.6)	3 (4.3)	0
Pyrexia	15 (21.4)	7 (10.0)	6 (8.6)	2 (2.9)	0
Fatigue	5 (7.1)	5 (7.1)	0	0	0
Pain	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	1 (1.4)	0	0	0
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	16 (22.9)	1 (1.4)	11 (15.7)	4 (5.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	10 (14.3)	0	10 (14.3)	0	0
Allergy to immunoglobulin therapy	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Graft versus host disease	2 (2.9)	0	0	2 (2.9)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	37 (52.9)	5 (7.1)	12 (17.1)	12 (17.1)	8 (11.4)
Nasopharyngitis	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Upper respiratory tract infection	7 (10.0)	3 (4.3)	2 (2.9)	2 (2.9)	0
Rhinovirus infection	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Gastroenteritis	4 (5.7)	2 (2.9)	0	2 (2.9)	0
Parainfluenzae virus infection	4 (5.7)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.3)	0	0	3 (4.3)	0
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Pneumonia	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.3)	0	1 (1.4)	2 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Sinusitis	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Bacteraemia	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.9)	0	2 (2.9)	0	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	8 (11.4)	5 (7.1)	3 (4.3)	0	0
Infusion related reaction	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Ligament sprain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	28 (40.0)	6 (8.6)	7 (10.0)	10 (14.3)	5 (7.1)
White blood cell count decreased	9 (12.9)	4 (5.7)	2 (2.9)	2 (2.9)	1 (1.4)
Neutrophil count decreased	8 (11.4)	1 (1.4)	1 (1.4)	2 (2.9)	4 (5.7)
Platelet count decreased	5 (7.1)	3 (4.3)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Alanine aminotransferase increased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
C-reactive protein increased	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Weight decreased	1 (1.4)	0	0	1 (1.4)	0
Weight increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	14 (20.0)	3 (4.3)	4 (5.7)	4 (5.7)	3 (4.3)
Decreased appetite	6 (8.6)	2 (2.9)	3 (4.3)	1 (1.4)	0
Hypokalaemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hyperuricaemia	2 (2.9)	2 (2.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	15 (21.4)	5 (7.1)	7 (10.0)	3 (4.3)	0
Back pain	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Pain in extremity	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Arthralgia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Bone pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Growth retardation	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	13 (18.6)	6 (8.6)	5 (7.1)	0	2 (2.9)
Headache	9 (12.9)	5 (7.1)	4 (5.7)	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	9 (12.9)	1 (1.4)	7 (10.0)	1 (1.4)	0
Anxiety	6 (8.6)	1 (1.4)	5 (7.1)	0	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	5 (7.1)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Acute kidney injury	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	23 (32.9)	10 (14.3)	7 (10.0)	3 (4.3)	3 (4.3)
Cough	10 (14.3)	7 (10.0)	3 (4.3)	0	0
Nasal congestion	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Epistaxis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Hypoxia	3 (4.3)	0	0	3 (4.3)	0
Rhinorrhoea	3 (4.3)	3 (4.3)	0	0	0
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Rhinitis allergic	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal pain	1 (1.4)	0	1 (1.4)	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	18 (25.7)	10 (14.3)	7 (10.0)	1 (1.4)	0
Dry skin	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Rash	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Ingrowing nail	2 (2.9)	0	2 (2.9)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	6 (8.6)	1 (1.4)	0	2 (2.9)	3 (4.3)
Hypotension	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)
Venoocclusive disease	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Irritable bowel syndrome	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=3			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Rhinovirus infection	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (66.0)	3 (6.4)	10 (21.3)	11 (23.4)	7 (14.9)
Blood and lymphatic system disorders					
-Total	4 (8.5)	0	2 (4.3)	1 (2.1)	1 (2.1)
Agranulocytosis	1 (2.1)	0	0	1 (2.1)	0
Anaemia	1 (2.1)	0	1 (2.1)	0	0
Hypercoagulation	1 (2.1)	0	1 (2.1)	0	0
Lymphadenopathy	1 (2.1)	0	1 (2.1)	0	0
Neutropenia	1 (2.1)	0	0	0	1 (2.1)
Thrombocytopenia	1 (2.1)	0	1 (2.1)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.1)	1 (2.1)	0	0	0
Cerebral cavernous malformation	1 (2.1)	1 (2.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.1)	0	1 (2.1)	0	0
Deafness unilateral	1 (2.1)	0	1 (2.1)	0	0
Endocrine disorders					
-Total	1 (2.1)	0	1 (2.1)	0	0
Delayed puberty	1 (2.1)	0	1 (2.1)	0	0
Hypothyroidism	1 (2.1)	0	1 (2.1)	0	0
Eye disorders					
-Total	3 (6.4)	1 (2.1)	1 (2.1)	1 (2.1)	0
Dry eye	1 (2.1)	1 (2.1)	0	0	0
Eye pain	1 (2.1)	0	0	1 (2.1)	0
Eyelid oedema	1 (2.1)	1 (2.1)	0	0	0
Mydriasis	1 (2.1)	0	1 (2.1)	0	0
Gastrointestinal disorders					
-Total	6 (12.8)	4 (8.5)	1 (2.1)	1 (2.1)	0
Diarrhoea	5 (10.6)	3 (6.4)	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.1)	1 (2.1)	0	0	0
Nausea	1 (2.1)	1 (2.1)	0	0	0
Vomiting	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	8 (17.0)	4 (8.5)	2 (4.3)	1 (2.1)	1 (2.1)
Pyrexia	4 (8.5)	2 (4.3)	1 (2.1)	1 (2.1)	0
Pain	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Fatigue	1 (2.1)	0	1 (2.1)	0	0
Multiple organ dysfunction syndrome	1 (2.1)	0	0	0	1 (2.1)
Non-cardiac chest pain	1 (2.1)	1 (2.1)	0	0	0
Xerosis	1 (2.1)	1 (2.1)	0	0	0
Immune system disorders					
-Total	9 (19.1)	2 (4.3)	5 (10.6)	1 (2.1)	1 (2.1)
Hypogammaglobulinaemia	3 (6.4)	0	3 (6.4)	0	0
Seasonal allergy	3 (6.4)	2 (4.3)	1 (2.1)	0	0
Chronic graft versus host disease	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Drug hypersensitivity	1 (2.1)	0	0	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Infections and infestations					
-Total	22 (46.8)	2 (4.3)	7 (14.9)	9 (19.1)	4 (8.5)
Sinusitis	5 (10.6)	0	5 (10.6)	0	0
Upper respiratory tract infection	5 (10.6)	2 (4.3)	2 (4.3)	1 (2.1)	0
Conjunctivitis	4 (8.5)	2 (4.3)	2 (4.3)	0	0
Rhinovirus infection	3 (6.4)	0	2 (4.3)	1 (2.1)	0
Sepsis	3 (6.4)	0	0	1 (2.1)	2 (4.3)
Skin infection	3 (6.4)	0	3 (6.4)	0	0
Bronchitis	2 (4.3)	0	2 (4.3)	0	0
Covid-19	2 (4.3)	1 (2.1)	0	1 (2.1)	0
Fungal infection	2 (4.3)	0	2 (4.3)	0	0
Herpes zoster	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Influenza	2 (4.3)	0	1 (2.1)	0	1 (2.1)
Oral herpes	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Otitis media	2 (4.3)	0	2 (4.3)	0	0
Urinary tract infection	2 (4.3)	0	2 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (2.1)	0	1 (2.1)	0	0
Bronchiolitis	1 (2.1)	0	0	1 (2.1)	0
Candida infection	1 (2.1)	0	1 (2.1)	0	0
Covid-19 pneumonia	1 (2.1)	0	0	0	1 (2.1)
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Ear infection	1 (2.1)	0	0	1 (2.1)	0
Enterovirus infection	1 (2.1)	0	0	1 (2.1)	0
Folliculitis	1 (2.1)	0	1 (2.1)	0	0
Fungal skin infection	1 (2.1)	0	1 (2.1)	0	0
Gastroenteritis	1 (2.1)	1 (2.1)	0	0	0
Gastroenteritis viral	1 (2.1)	0	1 (2.1)	0	0
Herpes virus infection	1 (2.1)	0	1 (2.1)	0	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Nail infection	1 (2.1)	0	1 (2.1)	0	0
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Otitis media acute	1 (2.1)	0	1 (2.1)	0	0
Parainfluenzae virus infection	1 (2.1)	0	0	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.1)	0	0	0	1 (2.1)
Pneumonia respiratory syncytial viral	1 (2.1)	0	0	1 (2.1)	0
Rhinitis	1 (2.1)	1 (2.1)	0	0	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Streptococcal sepsis	1 (2.1)	0	1 (2.1)	0	0
Syphilis	1 (2.1)	0	1 (2.1)	0	0
Urinary tract infection pseudomonal	1 (2.1)	0	1 (2.1)	0	0
Varicella zoster virus infection	1 (2.1)	0	1 (2.1)	0	0
Viral skin infection	1 (2.1)	1 (2.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (6.4)	2 (4.3)	0	1 (2.1)	0
Abdominal injury	1 (2.1)	1 (2.1)	0	0	0
Infusion related reaction	1 (2.1)	0	0	1 (2.1)	0
Ligament sprain	1 (2.1)	1 (2.1)	0	0	0
Investigations					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (12.8)	3 (6.4)	1 (2.1)	1 (2.1)	1 (2.1)
Neutrophil count decreased	3 (6.4)	2 (4.3)	0	0	1 (2.1)
Platelet count decreased	2 (4.3)	2 (4.3)	0	0	0
Blood bilirubin increased	1 (2.1)	1 (2.1)	0	0	0
Blood immunoglobulin g decreased	1 (2.1)	0	1 (2.1)	0	0
Oxygen saturation decreased	1 (2.1)	0	0	1 (2.1)	0
Metabolism and nutrition disorders					
-Total	6 (12.8)	0	2 (4.3)	3 (6.4)	1 (2.1)
Decreased appetite	1 (2.1)	0	0	0	1 (2.1)
Hypercholesterolaemia	1 (2.1)	0	1 (2.1)	0	0
Hyperglycaemia	1 (2.1)	0	0	1 (2.1)	0
Hyperlipidaemia	1 (2.1)	0	1 (2.1)	0	0
Hypernatraemia	1 (2.1)	0	0	1 (2.1)	0
Hypertriglyceridaemia	1 (2.1)	0	1 (2.1)	0	0
Iron overload	1 (2.1)	0	1 (2.1)	0	0
Obesity	1 (2.1)	0	0	1 (2.1)	0
Musculoskeletal and connective tissue disorders					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (14.9)	2 (4.3)	5 (10.6)	0	0
Pain in extremity	2 (4.3)	0	2 (4.3)	0	0
Arthralgia	1 (2.1)	0	1 (2.1)	0	0
Growth retardation	1 (2.1)	0	1 (2.1)	0	0
Joint effusion	1 (2.1)	0	1 (2.1)	0	0
Osteonecrosis	1 (2.1)	1 (2.1)	0	0	0
Osteopenia	1 (2.1)	1 (2.1)	0	0	0
Synovitis	1 (2.1)	0	1 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.1)	0	0	1 (2.1)	0
Bone giant cell tumour benign	1 (2.1)	0	0	1 (2.1)	0
Nervous system disorders					
-Total	4 (8.5)	0	2 (4.3)	2 (4.3)	0
Headache	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Dysarthria	1 (2.1)	0	1 (2.1)	0	0
Nervous system disorder	1 (2.1)	0	0	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	3 (6.4)	1 (2.1)	2 (4.3)	0	0
Anxiety	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Tic	1 (2.1)	0	1 (2.1)	0	0
Reproductive system and breast disorders					
-Total	1 (2.1)	0	0	1 (2.1)	0
Endometriosis	1 (2.1)	0	0	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (21.3)	4 (8.5)	2 (4.3)	1 (2.1)	3 (6.4)
Cough	4 (8.5)	3 (6.4)	1 (2.1)	0	0
Dyspnoea	3 (6.4)	1 (2.1)	1 (2.1)	0	1 (2.1)
Rhinorrhoea	3 (6.4)	1 (2.1)	2 (4.3)	0	0
Sleep apnoea syndrome	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Dyspnoea exertional	1 (2.1)	1 (2.1)	0	0	0
Epistaxis	1 (2.1)	1 (2.1)	0	0	0
Hypoxia	1 (2.1)	0	0	1 (2.1)	0
Laryngeal oedema	1 (2.1)	0	0	0	1 (2.1)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (2.1)	1 (2.1)	0	0	0
Pharyngeal erythema	1 (2.1)	1 (2.1)	0	0	0
Pleural effusion	1 (2.1)	0	1 (2.1)	0	0
Respiratory failure	1 (2.1)	0	0	0	1 (2.1)
Tachypnoea	1 (2.1)	0	0	0	1 (2.1)
Wheezing	1 (2.1)	0	1 (2.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (14.9)	3 (6.4)	1 (2.1)	3 (6.4)	0
Rash	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Dermatitis atopic	1 (2.1)	0	0	1 (2.1)	0
Dry skin	1 (2.1)	1 (2.1)	0	0	0
Eczema	1 (2.1)	0	0	1 (2.1)	0
Papule	1 (2.1)	1 (2.1)	0	0	0
Rash erythematous	1 (2.1)	1 (2.1)	0	0	0
Rash macular	1 (2.1)	0	0	1 (2.1)	0
Rash maculo-papular	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					
-Total	2 (4.3)	0	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	2 (4.3)	0	1 (2.1)	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders					
-Total	5 (83.3)	0	1 (16.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Lymphocytosis	1 (16.7)	0	1 (16.7)	0	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Irritable bowel syndrome	1 (16.7)	0	1 (16.7)	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	0	2 (33.3)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	2 (33.3)	2 (33.3)	0	0	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Face oedema	1 (16.7)	0	1 (16.7)	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0	0	0
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0	0	0
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (50.0)	0	2 (33.3)	0	1 (16.7)
Fibula fracture	1 (16.7)	0	1 (16.7)	0	0
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Persistent depressive disorder	1 (16.7)	0	1 (16.7)	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Nasal congestion	2 (33.3)	2 (33.3)	0	0	0
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Cough	1 (16.7)	1 (16.7)	0	0	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	4 (66.7)	3 (50.0)	0	1 (16.7)	0
Dry skin	2 (33.3)	2 (33.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin hypopigmentation	1 (16.7)	1 (16.7)	0	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (100)	1 (1.4)	5 (6.8)	17 (23.0)	51 (68.9)
Blood and lymphatic system disorders					
-Total	50 (67.6)	1 (1.4)	10 (13.5)	27 (36.5)	12 (16.2)
Febrile neutropenia	24 (32.4)	0	0	23 (31.1)	1 (1.4)
Anaemia	23 (31.1)	6 (8.1)	8 (10.8)	9 (12.2)	0
Neutropenia	11 (14.9)	0	2 (2.7)	2 (2.7)	7 (9.5)
Thrombocytopenia	8 (10.8)	0	0	3 (4.1)	5 (6.8)
Disseminated intravascular coagulation	7 (9.5)	0	5 (6.8)	2 (2.7)	0
Coagulopathy	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Splenomegaly	4 (5.4)	3 (4.1)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Lymphadenopathy	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Lymphopenia	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypercoagulation	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Cardiac disorders					
-Total	25 (33.8)	9 (12.2)	6 (8.1)	5 (6.8)	5 (6.8)
Tachycardia	14 (18.9)	6 (8.1)	6 (8.1)	2 (2.7)	0
Left ventricular dysfunction	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Bradycardia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cardiac arrest	3 (4.1)	0	0	0	3 (4.1)
Cardiac failure	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Cardiac dysfunction	2 (2.7)	2 (2.7)	0	0	0
Sinus tachycardia	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Sinus bradycardia	1 (1.4)	0	0	1 (1.4)	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Cerebral cavernous malformation	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Ear pruritus	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	7 (9.5)	0	7 (9.5)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	4 (5.4)	0	4 (5.4)	0	0
Hypothyroidism	3 (4.1)	0	3 (4.1)	0	0
Delayed puberty	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	14 (18.9)	9 (12.2)	4 (5.4)	1 (1.4)	0
Ocular hyperaemia	3 (4.1)	3 (4.1)	0	0	0
Cataract	2 (2.7)	2 (2.7)	0	0	0
Conjunctival haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Eye pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Eyelid oedema	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Visual impairment	2 (2.7)	2 (2.7)	0	0	0
Dry eye	1 (1.4)	1 (1.4)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Mydriasis	1 (1.4)	0	1 (1.4)	0	0
Periorbital oedema	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0
Retinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	58 (78.4)	21 (28.4)	22 (29.7)	14 (18.9)	1 (1.4)
Diarrhoea	26 (35.1)	16 (21.6)	8 (10.8)	2 (2.7)	0
Vomiting	26 (35.1)	17 (23.0)	8 (10.8)	1 (1.4)	0
Nausea	21 (28.4)	11 (14.9)	8 (10.8)	2 (2.7)	0
Constipation	13 (17.6)	6 (8.1)	7 (9.5)	0	0
Abdominal pain	11 (14.9)	2 (2.7)	7 (9.5)	2 (2.7)	0
Pancreatitis	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Abdominal pain upper	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Mouth haemorrhage	4 (5.4)	2 (2.7)	0	2 (2.7)	0
Stomatitis	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Abdominal distension	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Gastrointestinal sounds abnormal	2 (2.7)	2 (2.7)	0	0	0
Proctalgia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Trichoglossia	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abdominal compartment syndrome	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Enterocolitis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingival bleeding	1 (1.4)	0	1 (1.4)	0	0
Gingival erythema	1 (1.4)	1 (1.4)	0	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Neutropenic colitis	1 (1.4)	0	0	1 (1.4)	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	49 (66.2)	24 (32.4)	12 (16.2)	9 (12.2)	4 (5.4)
Pyrexia	32 (43.2)	14 (18.9)	8 (10.8)	8 (10.8)	2 (2.7)
Fatigue	15 (20.3)	12 (16.2)	3 (4.1)	0	0
Face oedema	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Chills	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Oedema peripheral	6 (8.1)	5 (6.8)	0	1 (1.4)	0
Pain	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Asthenia	3 (4.1)	3 (4.1)	0	0	0
Drug withdrawal syndrome	2 (2.7)	0	2 (2.7)	0	0
Influenza like illness	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised oedema	2 (2.7)	2 (2.7)	0	0	0
Malaise	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	0	0	2 (2.7)
Non-cardiac chest pain	2 (2.7)	2 (2.7)	0	0	0
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Catheter site pain	1 (1.4)	0	0	1 (1.4)	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Xerosis	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	18 (24.3)	6 (8.1)	7 (9.5)	3 (4.1)	2 (2.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Hyperbilirubinaemia	5 (6.8)	1 (1.4)	3 (4.1)	1 (1.4)	0
Hepatomegaly	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Hypertransaminasaemia	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Cholelithiasis	1 (1.4)	0	1 (1.4)	0	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	66 (89.2)	2 (2.7)	20 (27.0)	24 (32.4)	20 (27.0)
Cytokine release syndrome	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Hypogammaglobulinaemia	31 (41.9)	2 (2.7)	23 (31.1)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Immunodeficiency	4 (5.4)	0	0	4 (5.4)	0
Seasonal allergy	3 (4.1)	2 (2.7)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Chronic graft versus host disease	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Graft versus host disease	2 (2.7)	0	0	2 (2.7)	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	57 (77.0)	8 (10.8)	12 (16.2)	24 (32.4)	13 (17.6)
Upper respiratory tract infection	12 (16.2)	5 (6.8)	4 (5.4)	3 (4.1)	0
Rhinovirus infection	8 (10.8)	0	6 (8.1)	2 (2.7)	0
Conjunctivitis	7 (9.5)	2 (2.7)	5 (6.8)	0	0
Nasopharyngitis	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Sinusitis	6 (8.1)	0	4 (5.4)	2 (2.7)	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Otitis media	5 (6.8)	0	4 (5.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Pneumonia	5 (6.8)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.7)
Staphylococcal bacteraemia	5 (6.8)	0	0	5 (6.8)	0
Staphylococcal infection	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Candida infection	4 (5.4)	0	3 (4.1)	0	1 (1.4)
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Nail infection	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Oral herpes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Bacteraemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Ear infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Herpes zoster	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Influenza	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Oral candidiasis	3 (4.1)	0	3 (4.1)	0	0
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rhinitis	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Sepsis	3 (4.1)	0	0	1 (1.4)	2 (2.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	3 (4.1)	0	3 (4.1)	0	0
Urinary tract infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Acute sinusitis	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	2 (2.7)	0	0	2 (2.7)	0
Bk virus infection	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Bronchitis	2 (2.7)	0	2 (2.7)	0	0
Bronchopulmonary aspergillosis	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Covid-19	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Fungal infection	2 (2.7)	0	2 (2.7)	0	0
Gastroenteritis viral	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Gingivitis	2 (2.7)	2 (2.7)	0	0	0
Herpes simplex	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.7)	0	0	2 (2.7)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Paronychia	2 (2.7)	0	2 (2.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Septic shock	2 (2.7)	0	0	0	2 (2.7)
Varicella zoster virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	18 (24.3)	9 (12.2)	7 (9.5)	1 (1.4)	1 (1.4)
Infusion related reaction	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Contusion	2 (2.7)	2 (2.7)	0	0	0
Fall	2 (2.7)	0	2 (2.7)	0	0
Ligament sprain	2 (2.7)	2 (2.7)	0	0	0
Procedural pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin abrasion	2 (2.7)	2 (2.7)	0	0	0
Transfusion reaction	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abdominal injury	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Scratch	1 (1.4)	1 (1.4)	0	0	0
Transplant failure	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	57 (77.0)	3 (4.1)	9 (12.2)	18 (24.3)	27 (36.5)
Platelet count decreased	23 (31.1)	6 (8.1)	3 (4.1)	7 (9.5)	7 (9.5)
White blood cell count decreased	23 (31.1)	3 (4.1)	3 (4.1)	2 (2.7)	15 (20.3)
Neutrophil count decreased	21 (28.4)	1 (1.4)	2 (2.7)	3 (4.1)	15 (20.3)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	7 (9.5)	3 (4.1)
Alanine aminotransferase increased	17 (23.0)	3 (4.1)	8 (10.8)	6 (8.1)	0
Lymphocyte count decreased	16 (21.6)	1 (1.4)	1 (1.4)	9 (12.2)	5 (6.8)
Blood bilirubin increased	12 (16.2)	1 (1.4)	3 (4.1)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Serum ferritin increased	8 (10.8)	1 (1.4)	5 (6.8)	2 (2.7)	0
Blood fibrinogen decreased	7 (9.5)	2 (2.7)	3 (4.1)	1 (1.4)	1 (1.4)
Blood immunoglobulin a decreased	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Activated partial thromboplastin time prolonged	6 (8.1)	3 (4.1)	2 (2.7)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Blood lactate dehydrogenase increased	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	5 (6.8)	2 (2.7)	0	3 (4.1)	0
Blood creatinine increased	4 (5.4)	0	1 (1.4)	2 (2.7)	1 (1.4)
Blood uric acid increased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Electrocardiogram qt prolonged	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Blood immunoglobulin g decreased	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Fibrin d dimer increased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Oxygen saturation decreased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Weight increased	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Gamma-glutamyltransferase increased	2 (2.7)	0	0	2 (2.7)	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
Urine output decreased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Weight decreased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Amylase increased	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	1 (1.4)	0
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
Blood testosterone decreased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Electrocardiogram t wave abnormal	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Lipase increased	1 (1.4)	1 (1.4)	0	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Troponin increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	47 (63.5)	8 (10.8)	9 (12.2)	20 (27.0)	10 (13.5)
Decreased appetite	28 (37.8)	10 (13.5)	6 (8.1)	10 (13.5)	2 (2.7)
Hypokalaemia	19 (25.7)	3 (4.1)	6 (8.1)	9 (12.2)	1 (1.4)
Hypophosphataemia	15 (20.3)	3 (4.1)	5 (6.8)	6 (8.1)	1 (1.4)
Hypocalcaemia	14 (18.9)	2 (2.7)	8 (10.8)	4 (5.4)	0
Hypoalbuminaemia	10 (13.5)	0	9 (12.2)	1 (1.4)	0
Hyperglycaemia	8 (10.8)	0	3 (4.1)	5 (6.8)	0
Hyperuricaemia	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Hypervolaemia	7 (9.5)	0	2 (2.7)	5 (6.8)	0
Hyperphosphataemia	5 (6.8)	4 (5.4)	0	0	1 (1.4)
Hypomagnesaemia	5 (6.8)	4 (5.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	5 (6.8)	0	0	4 (5.4)	1 (1.4)
Metabolic acidosis	4 (5.4)	1 (1.4)	0	0	3 (4.1)
Hypercalcaemia	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Hyperkalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hypertriglyceridaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hyperchloraemia	2 (2.7)	2 (2.7)	0	0	0
Hypernatraemia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Iron overload	2 (2.7)	0	2 (2.7)	0	0
Malnutrition	2 (2.7)	0	0	2 (2.7)	0
Acidosis	1 (1.4)	0	0	0	1 (1.4)
Calcium deficiency	1 (1.4)	1 (1.4)	0	0	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Hypercholesterolaemia	1 (1.4)	0	1 (1.4)	0	0
Hyperlipidaemia	1 (1.4)	0	1 (1.4)	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Obesity	1 (1.4)	0	0	1 (1.4)	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					
-Total	42 (56.8)	16 (21.6)	19 (25.7)	7 (9.5)	0
Pain in extremity	17 (23.0)	8 (10.8)	8 (10.8)	1 (1.4)	0
Arthralgia	12 (16.2)	5 (6.8)	6 (8.1)	1 (1.4)	0
Back pain	10 (13.5)	2 (2.7)	5 (6.8)	3 (4.1)	0
Myalgia	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Bone pain	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Growth retardation	2 (2.7)	0	2 (2.7)	0	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Musculoskeletal chest pain	2 (2.7)	2 (2.7)	0	0	0
Neck pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pain in jaw	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Haemarthrosis	1 (1.4)	0	0	1 (1.4)	0
Joint effusion	1 (1.4)	0	1 (1.4)	0	0
Muscle rigidity	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Osteonecrosis	1 (1.4)	1 (1.4)	0	0	0
Osteopenia	1 (1.4)	1 (1.4)	0	0	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Bone giant cell tumour benign	1 (1.4)	0	0	1 (1.4)	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	43 (58.1)	14 (18.9)	16 (21.6)	9 (12.2)	4 (5.4)
Headache	24 (32.4)	11 (14.9)	10 (13.5)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Dizziness	4 (5.4)	4 (5.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Somnolence	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Dysgeusia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cerebral haemorrhage	2 (2.7)	0	0	0	2 (2.7)
Dysarthria	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorder	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Paraesthesia	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	36 (48.6)	12 (16.2)	17 (23.0)	7 (9.5)	0
Anxiety	14 (18.9)	3 (4.1)	9 (12.2)	2 (2.7)	0
Delirium	8 (10.8)	2 (2.7)	3 (4.1)	3 (4.1)	0
Agitation	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Mental status changes	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Insomnia	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Irritability	3 (4.1)	3 (4.1)	0	0	0
Sleep disorder	2 (2.7)	0	2 (2.7)	0	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Automatism	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Tic	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	23 (31.1)	6 (8.1)	7 (9.5)	4 (5.4)	6 (8.1)
Acute kidney injury	10 (13.5)	2 (2.7)	2 (2.7)	2 (2.7)	4 (5.4)
Dysuria	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Haematuria	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Anuria	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Pollakiuria	2 (2.7)	0	2 (2.7)	0	0
Renal failure	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Azotaemia	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Endometriosis	1 (1.4)	0	0	1 (1.4)	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0
Heavy menstrual bleeding	1 (1.4)	1 (1.4)	0	0	0
Perineal rash	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	52 (70.3)	17 (23.0)	8 (10.8)	11 (14.9)	16 (21.6)
Cough	22 (29.7)	17 (23.0)	5 (6.8)	0	0
Hypoxia	19 (25.7)	0	4 (5.4)	9 (12.2)	6 (8.1)
Pulmonary oedema	12 (16.2)	2 (2.7)	3 (4.1)	6 (8.1)	1 (1.4)
Pleural effusion	9 (12.2)	4 (5.4)	2 (2.7)	2 (2.7)	1 (1.4)
Epistaxis	7 (9.5)	4 (5.4)	2 (2.7)	1 (1.4)	0
Nasal congestion	7 (9.5)	5 (6.8)	2 (2.7)	0	0
Oropharyngeal pain	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Tachypnoea	7 (9.5)	3 (4.1)	1 (1.4)	2 (2.7)	1 (1.4)
Dyspnoea	6 (8.1)	1 (1.4)	2 (2.7)	2 (2.7)	1 (1.4)
Respiratory failure	6 (8.1)	0	0	0	6 (8.1)
Rhinorrhoea	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Respiratory distress	4 (5.4)	0	2 (2.7)	0	2 (2.7)
Acute respiratory distress syndrome	2 (2.7)	0	0	0	2 (2.7)
Atelectasis	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pharyngeal erythema	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinitis allergic	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Sleep apnoea syndrome	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	2 (2.7)	0	2 (2.7)	0	0
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea exertional	1 (1.4)	1 (1.4)	0	0	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	0	0	1 (1.4)
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal discomfort	1 (1.4)	0	1 (1.4)	0	0
Nasal dryness	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	36 (48.6)	14 (18.9)	16 (21.6)	6 (8.1)	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Pruritus	6 (8.1)	2 (2.7)	4 (5.4)	0	0
Rash	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Erythema	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Blister	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dermatitis atopic	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Eczema	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Rash maculo-papular	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Rash papular	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Hyperhidrosis	2 (2.7)	0	2 (2.7)	0	0
Ingrowing nail	2 (2.7)	0	2 (2.7)	0	0
Skin discolouration	2 (2.7)	2 (2.7)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	0	1 (1.4)	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.4)	1 (1.4)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	1 (1.4)	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash erythematous	1 (1.4)	1 (1.4)	0	0	0
Rash macular	1 (1.4)	0	0	1 (1.4)	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scab	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Skin ulcer	1 (1.4)	0	1 (1.4)	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	32 (43.2)	5 (6.8)	8 (10.8)	11 (14.9)	8 (10.8)
Hypotension	22 (29.7)	2 (2.7)	6 (8.1)	7 (9.5)	7 (9.5)
Hypertension	15 (20.3)	4 (5.4)	7 (9.5)	4 (5.4)	0
Capillary leak syndrome	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Venoocclusive disease	2 (2.7)	0	0	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0
Thrombosis	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Immune system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	0	0	1 (50.0)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	1 (50.0)	0
Blood creatinine increased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypocalcaemia	1 (50.0)	0	0	1 (50.0)	0
Hypokalaemia	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Psychiatric disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Anxiety	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	0	1 (50.0)
Pleural effusion	1 (50.0)	0	0	0	1 (50.0)
Wheezing	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	0	0	1 (50.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	77 (98.7)	4 (5.1)	8 (10.3)	20 (25.6)	45 (57.7)
Blood and lymphatic system disorders					
-Total	48 (61.5)	3 (3.8)	8 (10.3)	24 (30.8)	13 (16.7)
Febrile neutropenia	25 (32.1)	0	0	23 (29.5)	2 (2.6)
Anaemia	21 (26.9)	5 (6.4)	8 (10.3)	8 (10.3)	0
Neutropenia	9 (11.5)	0	2 (2.6)	1 (1.3)	6 (7.7)
Thrombocytopenia	8 (10.3)	0	0	2 (2.6)	6 (7.7)
Disseminated intravascular coagulation	7 (9.0)	0	5 (6.4)	2 (2.6)	0
Coagulopathy	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					
-Total	24 (30.8)	10 (12.8)	6 (7.7)	5 (6.4)	3 (3.8)
Tachycardia	17 (21.8)	7 (9.0)	7 (9.0)	2 (2.6)	1 (1.3)
Bradycardia	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Sinus tachycardia	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Cardiac dysfunction	2 (2.6)	2 (2.6)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Ear and labyrinth disorders					
-Total	2 (2.6)	2 (2.6)	0	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					
-Total	5 (6.4)	0	5 (6.4)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	9 (11.5)	6 (7.7)	3 (3.8)	0	0
Conjunctival haemorrhage	2 (2.6)	2 (2.6)	0	0	0
Eyelid oedema	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Ocular hyperaemia	2 (2.6)	2 (2.6)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Visual impairment	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	51 (65.4)	19 (24.4)	18 (23.1)	13 (16.7)	1 (1.3)
Vomiting	21 (26.9)	12 (15.4)	8 (10.3)	1 (1.3)	0
Nausea	18 (23.1)	10 (12.8)	6 (7.7)	2 (2.6)	0
Diarrhoea	15 (19.2)	8 (10.3)	6 (7.7)	1 (1.3)	0
Abdominal pain	11 (14.1)	3 (3.8)	6 (7.7)	2 (2.6)	0
Constipation	11 (14.1)	6 (7.7)	5 (6.4)	0	0
Mouth haemorrhage	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.6)	0
Pancreatitis	4 (5.1)	0	3 (3.8)	1 (1.3)	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Abdominal pain upper	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Ascites	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Gastrointestinal sounds abnormal	2 (2.6)	2 (2.6)	0	0	0
Stomatitis	2 (2.6)	0	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
Trichoglossia	1 (1.3)	0	1 (1.3)	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	40 (51.3)	20 (25.6)	9 (11.5)	7 (9.0)	4 (5.1)
Pyrexia	24 (30.8)	11 (14.1)	5 (6.4)	6 (7.7)	2 (2.6)
Fatigue	11 (14.1)	9 (11.5)	2 (2.6)	0	0
Face oedema	8 (10.3)	5 (6.4)	2 (2.6)	1 (1.3)	0
Chills	6 (7.7)	4 (5.1)	2 (2.6)	0	0
Oedema peripheral	6 (7.7)	4 (5.1)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.4)	2 (2.6)	3 (3.8)	0	0
Asthenia	2 (2.6)	2 (2.6)	0	0	0
Catheter site pain	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Drug withdrawal syndrome	2 (2.6)	0	2 (2.6)	0	0
Influenza like illness	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.6)	2 (2.6)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	2 (2.6)	0	0	0	2 (2.6)
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Malaise	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Pain	1 (1.3)	0	0	1 (1.3)	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	17 (21.8)	5 (6.4)	6 (7.7)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.4)	0	2 (2.6)	2 (2.6)	1 (1.3)
Hyperbilirubinaemia	5 (6.4)	1 (1.3)	3 (3.8)	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	3 (3.8)	2 (2.6)	0	0	1 (1.3)
Cholelithiasis	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.6)	2 (2.6)	0	0	0
Hypertransaminasaemia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	65 (83.3)	3 (3.8)	21 (26.9)	21 (26.9)	20 (25.6)
Cytokine release syndrome	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Hypogammaglobulinaemia	23 (29.5)	2 (2.6)	14 (17.9)	7 (9.0)	0
Haemophagocytic lymphohistiocytosis	5 (6.4)	1 (1.3)	1 (1.3)	2 (2.6)	1 (1.3)
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	35 (44.9)	6 (7.7)	10 (12.8)	16 (20.5)	3 (3.8)
Conjunctivitis	5 (6.4)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	5 (6.4)	0	3 (3.8)	2 (2.6)	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Candida infection	3 (3.8)	0	2 (2.6)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.6)	2 (2.6)	0	0	0
Oral herpes	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Oral infection	2 (2.6)	0	2 (2.6)	0	0
Rhinovirus infection	2 (2.6)	0	2 (2.6)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	11 (14.1)	3 (3.8)	6 (7.7)	0	2 (2.6)
Fall	2 (2.6)	0	2 (2.6)	0	0
Infusion related reaction	2 (2.6)	0	2 (2.6)	0	0
Procedural pain	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Transfusion reaction	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Contusion	1 (1.3)	1 (1.3)	0	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin abrasion	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	56 (71.8)	4 (5.1)	8 (10.3)	17 (21.8)	27 (34.6)
White blood cell count decreased	24 (30.8)	3 (3.8)	3 (3.8)	2 (2.6)	16 (20.5)
Platelet count decreased	21 (26.9)	4 (5.1)	3 (3.8)	6 (7.7)	8 (10.3)
Neutrophil count decreased	20 (25.6)	0	3 (3.8)	2 (2.6)	15 (19.2)
Aspartate aminotransferase increased	18 (23.1)	2 (2.6)	6 (7.7)	8 (10.3)	2 (2.6)
Alanine aminotransferase increased	17 (21.8)	4 (5.1)	8 (10.3)	5 (6.4)	0
Lymphocyte count decreased	15 (19.2)	2 (2.6)	0	8 (10.3)	5 (6.4)
Blood bilirubin increased	11 (14.1)	1 (1.3)	2 (2.6)	8 (10.3)	0
International normalised ratio increased	9 (11.5)	6 (7.7)	3 (3.8)	0	0
Serum ferritin increased	8 (10.3)	1 (1.3)	5 (6.4)	2 (2.6)	0
Blood fibrinogen decreased	7 (9.0)	2 (2.6)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin m decreased	6 (7.7)	4 (5.1)	1 (1.3)	1 (1.3)	0
Activated partial thromboplastin time prolonged	5 (6.4)	3 (3.8)	2 (2.6)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (6.4)	4 (5.1)	1 (1.3)	0	0
Electrocardiogram qt prolonged	5 (6.4)	1 (1.3)	2 (2.6)	1 (1.3)	1 (1.3)
Blood lactate dehydrogenase increased	4 (5.1)	2 (2.6)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Weight increased	4 (5.1)	2 (2.6)	1 (1.3)	1 (1.3)	0
Blood creatinine increased	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Fibrin d dimer increased	3 (3.8)	2 (2.6)	0	1 (1.3)	0
Blood creatine phosphokinase increased	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Blood uric acid increased	2 (2.6)	2 (2.6)	0	0	0
Gamma-glutamyltransferase increased	2 (2.6)	0	0	2 (2.6)	0
Immunoglobulins decreased	2 (2.6)	0	2 (2.6)	0	0
Lipase increased	2 (2.6)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Amylase increased	1 (1.3)	1 (1.3)	0	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Oxygen saturation decreased	1 (1.3)	1 (1.3)	0	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	45 (57.7)	8 (10.3)	9 (11.5)	20 (25.6)	8 (10.3)
Decreased appetite	24 (30.8)	9 (11.5)	4 (5.1)	10 (12.8)	1 (1.3)
Hypokalaemia	18 (23.1)	3 (3.8)	5 (6.4)	8 (10.3)	2 (2.6)
Hypophosphataemia	17 (21.8)	3 (3.8)	5 (6.4)	8 (10.3)	1 (1.3)
Hypocalcaemia	15 (19.2)	2 (2.6)	9 (11.5)	4 (5.1)	0
Hypoalbuminaemia	11 (14.1)	0	10 (12.8)	1 (1.3)	0
Hyperglycaemia	8 (10.3)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (9.0)	5 (6.4)	1 (1.3)	1 (1.3)	0
Hypervolaemia	6 (7.7)	0	2 (2.6)	4 (5.1)	0
Hypomagnesaemia	6 (7.7)	5 (6.4)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.4)	4 (5.1)	0	0	1 (1.3)
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Metabolic acidosis	3 (3.8)	1 (1.3)	0	0	2 (2.6)
Tumour lysis syndrome	3 (3.8)	0	0	3 (3.8)	0
Acidosis	2 (2.6)	0	0	1 (1.3)	1 (1.3)

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Hypermagnesaemia	2 (2.6)	2 (2.6)	0	0	0
Hypernatraemia	2 (2.6)	1 (1.3)	0	0	1 (1.3)
Hypertriglyceridaemia	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hyperchloraemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Malnutrition	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	33 (42.3)	15 (19.2)	13 (16.7)	4 (5.1)	1 (1.3)
Pain in extremity	11 (14.1)	6 (7.7)	5 (6.4)	0	0
Arthralgia	10 (12.8)	4 (5.1)	5 (6.4)	1 (1.3)	0
Myalgia	9 (11.5)	6 (7.7)	3 (3.8)	0	0
Back pain	6 (7.7)	2 (2.6)	3 (3.8)	1 (1.3)	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	2 (2.6)	0	2 (2.6)	0	0
Muscular weakness	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Pain in jaw	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal chest pain	1 (1.3)	1 (1.3)	0	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Neck pain	1 (1.3)	0	1 (1.3)	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Nervous system disorders					
-Total	39 (50.0)	14 (17.9)	15 (19.2)	8 (10.3)	2 (2.6)
Headache	23 (29.5)	12 (15.4)	9 (11.5)	2 (2.6)	0
Encephalopathy	8 (10.3)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.7)	5 (6.4)	1 (1.3)	0	0
Somnolence	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Dizziness	3 (3.8)	3 (3.8)	0	0	0
Dysgeusia	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.6)	1 (1.3)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Seizure	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	27 (34.6)	12 (15.4)	9 (11.5)	6 (7.7)	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	7 (9.0)	7 (9.0)	0	0	0
Delirium	7 (9.0)	2 (2.6)	2 (2.6)	3 (3.8)	0
Agitation	5 (6.4)	2 (2.6)	3 (3.8)	0	0
Anxiety	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Insomnia	4 (5.1)	2 (2.6)	2 (2.6)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Sleep disorder	2 (2.6)	0	2 (2.6)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	20 (25.6)	5 (6.4)	6 (7.7)	3 (3.8)	6 (7.7)
Acute kidney injury	9 (11.5)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Dysuria	3 (3.8)	3 (3.8)	0	0	0
Anuria	2 (2.6)	1 (1.3)	0	0	1 (1.3)

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	2 (2.6)	2 (2.6)	0	0	0
Pollakiuria	2 (2.6)	0	2 (2.6)	0	0
Renal failure	2 (2.6)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.6)	0	2 (2.6)	0	0
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	5 (6.4)	2 (2.6)	2 (2.6)	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	40 (51.3)	14 (17.9)	4 (5.1)	11 (14.1)	11 (14.1)
Hypoxia	17 (21.8)	0	5 (6.4)	6 (7.7)	6 (7.7)
Pulmonary oedema	12 (15.4)	2 (2.6)	3 (3.8)	6 (7.7)	1 (1.3)
Cough	10 (12.8)	9 (11.5)	1 (1.3)	0	0
Tachypnoea	8 (10.3)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	6 (7.7)	4 (5.1)	0	2 (2.6)	0
Oropharyngeal pain	5 (6.4)	5 (6.4)	0	0	0
Epistaxis	4 (5.1)	2 (2.6)	1 (1.3)	1 (1.3)	0
Respiratory failure	4 (5.1)	0	0	0	4 (5.1)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Dyspnoea	3 (3.8)	0	0	2 (2.6)	1 (1.3)
Nasal congestion	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Respiratory distress	3 (3.8)	0	2 (2.6)	0	1 (1.3)
Acute respiratory distress syndrome	2 (2.6)	0	0	0	2 (2.6)

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (2.6)	2 (2.6)	0	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal erythema	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	27 (34.6)	13 (16.7)	11 (14.1)	3 (3.8)	0
Pruritus	6 (7.7)	2 (2.6)	4 (5.1)	0	0
Rash	5 (6.4)	2 (2.6)	3 (3.8)	0	0
Erythema	4 (5.1)	4 (5.1)	0	0	0
Blister	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Rash papular	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Dermatitis atopic	2 (2.6)	2 (2.6)	0	0	0
Petechiae	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Rash maculo-papular	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Skin ulcer	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Decubitus ulcer	1 (1.3)	0	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Eczema	1 (1.3)	1 (1.3)	0	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin discolouration	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	27 (34.6)	4 (5.1)	7 (9.0)	10 (12.8)	6 (7.7)
Hypotension	21 (26.9)	1 (1.3)	6 (7.7)	8 (10.3)	6 (7.7)
Hypertension	13 (16.7)	4 (5.1)	5 (6.4)	4 (5.1)	0
Capillary leak syndrome	1 (1.3)	0	1 (1.3)	0	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Pyrexia	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	1 (50.0)	0
Weight decreased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Decreased appetite	1 (50.0)	0	0	1 (50.0)	0
Haemochromatosis	1 (50.0)	0	0	1 (50.0)	0
Hypophosphataemia	1 (50.0)	0	1 (50.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Growth retardation	1 (50.0)	0	1 (50.0)	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	0	0	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Psychiatric disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Sleep disorder	1 (50.0)	0	1 (50.0)	0	0
Renal and urinary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Renal tubular disorder	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Lung disorder	1 (50.0)	1 (50.0)	0	0	0
Vascular disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hypotension	1 (50.0)	1 (50.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (91.8)	9 (12.3)	24 (32.9)	14 (19.2)	20 (27.4)
Blood and lymphatic system disorders					
-Total	16 (21.9)	3 (4.1)	4 (5.5)	5 (6.8)	4 (5.5)
Anaemia	6 (8.2)	4 (5.5)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Leukopenia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	6 (8.2)	3 (4.1)	0	0	3 (4.1)
Cardiac arrest	2 (2.7)	0	0	0	2 (2.7)
Cardiac failure	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	4 (5.5)	4 (5.5)	0	0	0
Cataract	2 (2.7)	2 (2.7)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (26.0)	12 (16.4)	6 (8.2)	1 (1.4)	0
Diarrhoea	7 (9.6)	6 (8.2)	1 (1.4)	0	0
Vomiting	6 (8.2)	6 (8.2)	0	0	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pancreatitis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Abdominal pain upper	1 (1.4)	1 (1.4)	0	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	1 (1.4)	0	0	0
Stomatitis	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (31.5)	15 (20.5)	6 (8.2)	2 (2.7)	0
Pyrexia	14 (19.2)	7 (9.6)	6 (8.2)	1 (1.4)	0
Fatigue	6 (8.2)	6 (8.2)	0	0	0
Pain	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	1 (1.4)	0	0	0
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	15 (20.5)	1 (1.4)	10 (13.7)	4 (5.5)	0
Hypogammaglobulinaemia	9 (12.3)	0	9 (12.3)	0	0
Allergy to immunoglobulin therapy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Graft versus host disease	2 (2.7)	0	0	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	37 (50.7)	5 (6.8)	14 (19.2)	11 (15.1)	7 (9.6)
Nasopharyngitis	7 (9.6)	4 (5.5)	3 (4.1)	0	0
Upper respiratory tract infection	7 (9.6)	3 (4.1)	3 (4.1)	1 (1.4)	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.5)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.5)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.3)	5 (6.8)	4 (5.5)	0	0
Infusion related reaction	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Ligament sprain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	29 (39.7)	7 (9.6)	7 (9.6)	10 (13.7)	5 (6.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (13.7)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.5)
White blood cell count decreased	10 (13.7)	4 (5.5)	2 (2.7)	3 (4.1)	1 (1.4)
Platelet count decreased	5 (6.8)	3 (4.1)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.5)	1 (1.4)	1 (1.4)	2 (2.7)	0
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Blood lactate dehydrogenase increased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
C-reactive protein increased	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Weight increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	14 (19.2)	4 (5.5)	4 (5.5)	3 (4.1)	3 (4.1)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	14 (19.2)	5 (6.8)	6 (8.2)	3 (4.1)	0
Back pain	6 (8.2)	2 (2.7)	2 (2.7)	2 (2.7)	0
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Bone pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.5)	1 (1.4)	2 (2.7)	1 (1.4)	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	13 (17.8)	7 (9.6)	5 (6.8)	0	1 (1.4)
Headache	10 (13.7)	6 (8.2)	4 (5.5)	0	0
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Migraine	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	9 (12.3)	1 (1.4)	7 (9.6)	1 (1.4)	0
Anxiety	6 (8.2)	1 (1.4)	5 (6.8)	0	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	4 (5.5)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	0	0	1 (1.4)	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	23 (31.5)	10 (13.7)	7 (9.6)	3 (4.1)	3 (4.1)
Cough	11 (15.1)	8 (11.0)	3 (4.1)	0	0
Nasal congestion	6 (8.2)	5 (6.8)	1 (1.4)	0	0
Epistaxis	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=73		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (4.1)	3 (4.1)	0	0	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinitis allergic	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (27.4)	12 (16.4)	7 (9.6)	1 (1.4)	0
Dry skin	6 (8.2)	4 (5.5)	2 (2.7)	0	0
Rash	4 (5.5)	3 (4.1)	1 (1.4)	0	0
Ingrowing nail	2 (2.7)	0	2 (2.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Hypotension	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Venoocclusive disease	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Endocrine disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Delayed puberty	1 (50.0)	0	1 (50.0)	0	0
Hypothyroidism	1 (50.0)	0	1 (50.0)	0	0
Eye disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Dry eye	1 (50.0)	1 (50.0)	0	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Nausea	1 (50.0)	1 (50.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Fatigue	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Seasonal allergy	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Decreased appetite	1 (50.0)	0	0	0	1 (50.0)
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Osteopenia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Cough	1 (50.0)	0	1 (50.0)	0	0
Rhinorrhoea	1 (50.0)	0	1 (50.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (62.5)	3 (6.3)	9 (18.8)	12 (25.0)	6 (12.5)
Blood and lymphatic system disorders					
-Total	4 (8.3)	0	2 (4.2)	1 (2.1)	1 (2.1)
Agranulocytosis	1 (2.1)	0	0	1 (2.1)	0
Anaemia	1 (2.1)	0	1 (2.1)	0	0
Hypercoagulation	1 (2.1)	0	1 (2.1)	0	0
Lymphadenopathy	1 (2.1)	0	1 (2.1)	0	0
Neutropenia	1 (2.1)	0	0	0	1 (2.1)
Thrombocytopenia	1 (2.1)	0	1 (2.1)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.1)	1 (2.1)	0	0	0
Cerebral cavernous malformation	1 (2.1)	1 (2.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.1)	0	1 (2.1)	0	0
Deafness unilateral	1 (2.1)	0	1 (2.1)	0	0
Eye disorders					
-Total	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Eye pain	1 (2.1)	0	0	1 (2.1)	0
Eyelid oedema	1 (2.1)	1 (2.1)	0	0	0
Mydriasis	1 (2.1)	0	1 (2.1)	0	0
Gastrointestinal disorders					
-Total	6 (12.5)	4 (8.3)	1 (2.1)	1 (2.1)	0
Diarrhoea	4 (8.3)	3 (6.3)	0	1 (2.1)	0
Constipation	1 (2.1)	1 (2.1)	0	0	0
Irritable bowel syndrome	1 (2.1)	0	1 (2.1)	0	0
General disorders and administration site conditions					
-Total	8 (16.7)	4 (8.3)	2 (4.2)	1 (2.1)	1 (2.1)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	5 (10.4)	2 (4.2)	2 (4.2)	1 (2.1)	0
Pain	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Multiple organ dysfunction syndrome	1 (2.1)	0	0	0	1 (2.1)
Non-cardiac chest pain	1 (2.1)	1 (2.1)	0	0	0
Xerosis	1 (2.1)	1 (2.1)	0	0	0
Immune system disorders					
-Total	8 (16.7)	1 (2.1)	5 (10.4)	1 (2.1)	1 (2.1)
Hypogammaglobulinaemia	3 (6.3)	0	3 (6.3)	0	0
Chronic graft versus host disease	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Seasonal allergy	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Drug hypersensitivity	1 (2.1)	0	0	1 (2.1)	0
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Infections and infestations					
-Total	22 (45.8)	2 (4.2)	7 (14.6)	9 (18.8)	4 (8.3)
Sinusitis	6 (12.5)	0	6 (12.5)	0	0
Upper respiratory tract infection	5 (10.4)	2 (4.2)	2 (4.2)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Rhinovirus infection	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Skin infection	3 (6.3)	0	3 (6.3)	0	0
Bronchitis	2 (4.2)	0	2 (4.2)	0	0
Covid-19	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Fungal infection	2 (4.2)	0	2 (4.2)	0	0
Herpes zoster	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Influenza	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Oral herpes	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Otitis media	2 (4.2)	0	2 (4.2)	0	0
Pneumonia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Sepsis	2 (4.2)	0	0	0	2 (4.2)
Urinary tract infection	2 (4.2)	0	2 (4.2)	0	0
Acute sinusitis	1 (2.1)	0	1 (2.1)	0	0
Bronchiolitis	1 (2.1)	0	0	1 (2.1)	0
Candida infection	1 (2.1)	0	1 (2.1)	0	0
Clostridium difficile colitis	1 (2.1)	0	0	1 (2.1)	0
Covid-19 pneumonia	1 (2.1)	0	0	0	1 (2.1)
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (2.1)	0	0	1 (2.1)	0
Enterovirus infection	1 (2.1)	0	0	1 (2.1)	0
Folliculitis	1 (2.1)	0	1 (2.1)	0	0
Fungal skin infection	1 (2.1)	0	1 (2.1)	0	0
Gastroenteritis	1 (2.1)	1 (2.1)	0	0	0
Gastroenteritis escherichia coli	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis salmonella	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis viral	1 (2.1)	0	1 (2.1)	0	0
Herpes virus infection	1 (2.1)	0	1 (2.1)	0	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Nail infection	1 (2.1)	0	1 (2.1)	0	0
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Otitis media acute	1 (2.1)	0	1 (2.1)	0	0
Parainfluenzae virus infection	1 (2.1)	0	0	1 (2.1)	0
Pneumonia respiratory syncytial viral	1 (2.1)	0	0	1 (2.1)	0
Rhinitis	1 (2.1)	1 (2.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Streptococcal sepsis	1 (2.1)	0	1 (2.1)	0	0
Syphilis	1 (2.1)	0	1 (2.1)	0	0
Urinary tract infection pseudomonal	1 (2.1)	0	1 (2.1)	0	0
Varicella zoster virus infection	1 (2.1)	0	1 (2.1)	0	0
Viral skin infection	1 (2.1)	1 (2.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (6.3)	2 (4.2)	0	1 (2.1)	0
Abdominal injury	1 (2.1)	1 (2.1)	0	0	0
Infusion related reaction	1 (2.1)	0	0	1 (2.1)	0
Ligament sprain	1 (2.1)	1 (2.1)	0	0	0
Investigations					
-Total	6 (12.5)	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)
Neutrophil count decreased	3 (6.3)	2 (4.2)	0	0	1 (2.1)
Platelet count decreased	2 (4.2)	2 (4.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (2.1)	1 (2.1)	0	0	0
Blood immunoglobulin g decreased	1 (2.1)	0	1 (2.1)	0	0
Oxygen saturation decreased	1 (2.1)	0	0	1 (2.1)	0
Metabolism and nutrition disorders					
-Total	5 (10.4)	0	2 (4.2)	3 (6.3)	0
Hypercholesterolaemia	1 (2.1)	0	1 (2.1)	0	0
Hyperglycaemia	1 (2.1)	0	0	1 (2.1)	0
Hyperlipidaemia	1 (2.1)	0	1 (2.1)	0	0
Hypernatraemia	1 (2.1)	0	0	1 (2.1)	0
Hypertriglyceridaemia	1 (2.1)	0	1 (2.1)	0	0
Iron overload	1 (2.1)	0	1 (2.1)	0	0
Obesity	1 (2.1)	0	0	1 (2.1)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (12.5)	1 (2.1)	5 (10.4)	0	0
Pain in extremity	2 (4.2)	0	2 (4.2)	0	0
Arthralgia	1 (2.1)	0	1 (2.1)	0	0
Growth retardation	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint effusion	1 (2.1)	0	1 (2.1)	0	0
Osteonecrosis	1 (2.1)	1 (2.1)	0	0	0
Synovitis	1 (2.1)	0	1 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.1)	0	0	1 (2.1)	0
Bone giant cell tumour benign	1 (2.1)	0	0	1 (2.1)	0
Nervous system disorders					
-Total	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Headache	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Nervous system disorder	1 (2.1)	0	0	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Psychiatric disorders					
-Total	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Anxiety	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Tic	1 (2.1)	0	1 (2.1)	0	0
Reproductive system and breast disorders					
-Total	1 (2.1)	0	0	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endometriosis	1 (2.1)	0	0	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (18.8)	4 (8.3)	1 (2.1)	1 (2.1)	3 (6.3)
Cough	3 (6.3)	3 (6.3)	0	0	0
Dyspnoea	3 (6.3)	1 (2.1)	1 (2.1)	0	1 (2.1)
Rhinorrhoea	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Sleep apnoea syndrome	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Dyspnoea exertional	1 (2.1)	1 (2.1)	0	0	0
Epistaxis	1 (2.1)	1 (2.1)	0	0	0
Hypoxia	1 (2.1)	0	0	1 (2.1)	0
Laryngeal oedema	1 (2.1)	0	0	0	1 (2.1)
Oropharyngeal pain	1 (2.1)	1 (2.1)	0	0	0
Pharyngeal erythema	1 (2.1)	1 (2.1)	0	0	0
Pleural effusion	1 (2.1)	0	1 (2.1)	0	0
Respiratory failure	1 (2.1)	0	0	0	1 (2.1)
Tachypnoea	1 (2.1)	0	0	0	1 (2.1)
Wheezing	1 (2.1)	0	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	7 (14.6)	3 (6.3)	1 (2.1)	3 (6.3)	0
Rash	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Dermatitis atopic	1 (2.1)	0	0	1 (2.1)	0
Dry skin	1 (2.1)	1 (2.1)	0	0	0
Eczema	1 (2.1)	0	0	1 (2.1)	0
Papule	1 (2.1)	1 (2.1)	0	0	0
Rash erythematous	1 (2.1)	1 (2.1)	0	0	0
Rash macular	1 (2.1)	0	0	1 (2.1)	0
Rash maculo-papular	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					
-Total	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Hypertension	2 (4.2)	0	1 (2.1)	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Delayed puberty	1 (50.0)	0	1 (50.0)	0	0
Hypothyroidism	1 (50.0)	0	1 (50.0)	0	0
Eye disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Dry eye	1 (50.0)	1 (50.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Nausea	1 (50.0)	1 (50.0)	0	0	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0	0	0
Vomiting	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Fatigue	1 (50.0)	0	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Seasonal allergy	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	0	0	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	1 (50.0)	0
Blood creatinine increased	1 (50.0)	0	0	1 (50.0)	0
Weight decreased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	0	0	1 (50.0)
Haemochromatosis	1 (50.0)	0	0	1 (50.0)	0
Hypocalcaemia	1 (50.0)	0	0	1 (50.0)	0
Hypokalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypophosphataemia	1 (50.0)	0	1 (50.0)	0	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Growth retardation	1 (50.0)	0	1 (50.0)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteopenia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	0	0	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Psychiatric disorders					
-Total	2 (100)	0	2 (100)	0	0
Anxiety	1 (50.0)	0	1 (50.0)	0	0
Sleep disorder	1 (50.0)	0	1 (50.0)	0	0
Renal and urinary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Renal tubular disorder	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (50.0)	0	1 (50.0)	0	0
Lung disorder	1 (50.0)	1 (50.0)	0	0	0
Pleural effusion	1 (50.0)	0	0	0	1 (50.0)
Rhinorrhoea	1 (50.0)	0	1 (50.0)	0	0
Wheezing	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	2 (100)	1 (50.0)	0	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (100)	1 (1.3)	6 (7.7)	19 (24.4)	52 (66.7)
Blood and lymphatic system disorders					
-Total	53 (67.9)	1 (1.3)	11 (14.1)	27 (34.6)	14 (17.9)
Febrile neutropenia	26 (33.3)	0	0	24 (30.8)	2 (2.6)
Anaemia	25 (32.1)	7 (9.0)	9 (11.5)	9 (11.5)	0
Neutropenia	11 (14.1)	0	2 (2.6)	2 (2.6)	7 (9.0)
Thrombocytopenia	9 (11.5)	0	0	3 (3.8)	6 (7.7)
Disseminated intravascular coagulation	7 (9.0)	0	5 (6.4)	2 (2.6)	0
Coagulopathy	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphadenopathy	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Lymphopenia	2 (2.6)	0	0	2 (2.6)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypercoagulation	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Leukocytosis	1 (1.3)	0	1 (1.3)	0	0
Lymphocytosis	1 (1.3)	0	1 (1.3)	0	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					
-Total	27 (34.6)	10 (12.8)	6 (7.7)	5 (6.4)	6 (7.7)
Tachycardia	17 (21.8)	7 (9.0)	7 (9.0)	2 (2.6)	1 (1.3)
Bradycardia	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Cardiac arrest	3 (3.8)	0	0	0	3 (3.8)
Cardiac failure	3 (3.8)	0	0	1 (1.3)	2 (2.6)
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Sinus tachycardia	3 (3.8)	2 (2.6)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.6)	2 (2.6)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Tricuspid valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.3)	1 (1.3)	0	0	0
Cerebral cavernous malformation	1 (1.3)	1 (1.3)	0	0	0
Ear and labyrinth disorders					
-Total	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (7.7)	0	6 (7.7)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	2 (2.6)	0	2 (2.6)	0	0
Eye disorders					
-Total	14 (17.9)	9 (11.5)	4 (5.1)	1 (1.3)	0
Eyelid oedema	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Ocular hyperaemia	3 (3.8)	3 (3.8)	0	0	0
Cataract	2 (2.6)	2 (2.6)	0	0	0
Conjunctival haemorrhage	2 (2.6)	2 (2.6)	0	0	0
Eye pain	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Visual impairment	2 (2.6)	2 (2.6)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Hypermetropia	1 (1.3)	1 (1.3)	0	0	0
Mydriasis	1 (1.3)	0	1 (1.3)	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	58 (74.4)	20 (25.6)	22 (28.2)	15 (19.2)	1 (1.3)
Diarrhoea	25 (32.1)	16 (20.5)	7 (9.0)	2 (2.6)	0
Vomiting	25 (32.1)	16 (20.5)	8 (10.3)	1 (1.3)	0
Nausea	21 (26.9)	11 (14.1)	8 (10.3)	2 (2.6)	0
Constipation	14 (17.9)	7 (9.0)	7 (9.0)	0	0
Abdominal pain	11 (14.1)	2 (2.6)	7 (9.0)	2 (2.6)	0
Pancreatitis	6 (7.7)	1 (1.3)	3 (3.8)	2 (2.6)	0
Mouth haemorrhage	5 (6.4)	2 (2.6)	1 (1.3)	2 (2.6)	0
Abdominal pain upper	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Ascites	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Stomatitis	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Gastrointestinal sounds abnormal	2 (2.6)	2 (2.6)	0	0	0
Proctalgia	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Trichoglossia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Abdominal rigidity	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dyspepsia	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enteritis	1 (1.3)	0	1 (1.3)	0	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal inflammation	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	52 (66.7)	25 (32.1)	13 (16.7)	9 (11.5)	5 (6.4)
Pyrexia	34 (43.6)	14 (17.9)	10 (12.8)	8 (10.3)	2 (2.6)
Fatigue	16 (20.5)	14 (17.9)	2 (2.6)	0	0
Face oedema	8 (10.3)	5 (6.4)	2 (2.6)	1 (1.3)	0
Chills	7 (9.0)	5 (6.4)	2 (2.6)	0	0
Oedema peripheral	7 (9.0)	5 (6.4)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.4)	2 (2.6)	3 (3.8)	0	0
Pain	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Asthenia	3 (3.8)	3 (3.8)	0	0	0
Multiple organ dysfunction syndrome	3 (3.8)	0	0	0	3 (3.8)
Catheter site pain	2 (2.6)	1 (1.3)	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	2 (2.6)	0	2 (2.6)	0	0
Influenza like illness	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.6)	2 (2.6)	0	0	0
Malaise	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Non-cardiac chest pain	2 (2.6)	2 (2.6)	0	0	0
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Xerosis	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (23.1)	5 (6.4)	7 (9.0)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.4)	0	2 (2.6)	2 (2.6)	1 (1.3)
Hyperbilirubinaemia	5 (6.4)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.6)	0	0	1 (1.3)
Cholelithiasis	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.6)	2 (2.6)	0	0	0
Hypertransaminasaemia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Liver disorder	1 (1.3)	0	1 (1.3)	0	0
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	69 (88.5)	2 (2.6)	23 (29.5)	23 (29.5)	21 (26.9)
Cytokine release syndrome	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Hypogammaglobulinaemia	32 (41.0)	2 (2.6)	23 (29.5)	7 (9.0)	0
Haemophagocytic lymphohistiocytosis	6 (7.7)	1 (1.3)	1 (1.3)	2 (2.6)	2 (2.6)
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Seasonal allergy	3 (3.8)	1 (1.3)	2 (2.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Chronic graft versus host disease	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Graft versus host disease	2 (2.6)	0	0	2 (2.6)	0
Engraftment syndrome	1 (1.3)	0	0	1 (1.3)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	58 (74.4)	8 (10.3)	13 (16.7)	24 (30.8)	13 (16.7)
Upper respiratory tract infection	12 (15.4)	5 (6.4)	5 (6.4)	2 (2.6)	0
Rhinovirus infection	9 (11.5)	0	7 (9.0)	2 (2.6)	0
Conjunctivitis	8 (10.3)	2 (2.6)	6 (7.7)	0	0
Nasopharyngitis	7 (9.0)	4 (5.1)	3 (3.8)	0	0
Sinusitis	7 (9.0)	0	5 (6.4)	2 (2.6)	0
Gastroenteritis	6 (7.7)	4 (5.1)	0	2 (2.6)	0
Pneumonia	6 (7.7)	1 (1.3)	1 (1.3)	2 (2.6)	2 (2.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	5 (6.4)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.4)	1 (1.3)	1 (1.3)	2 (2.6)	1 (1.3)
Staphylococcal bacteraemia	5 (6.4)	0	0	5 (6.4)	0
Staphylococcal infection	5 (6.4)	0	3 (3.8)	2 (2.6)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.6)	1 (1.3)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.6)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Influenza	3 (3.8)	0	2 (2.6)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.6)	1 (1.3)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Rhinitis	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.6)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	2 (2.6)	0	2 (2.6)	0	0
Adenovirus infection	2 (2.6)	0	0	2 (2.6)	0
Bk virus infection	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Bronchitis	2 (2.6)	0	2 (2.6)	0	0
Bronchopulmonary aspergillosis	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Encephalitis viral	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.6)	0	2 (2.6)	0	0
Gastroenteritis viral	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.6)	2 (2.6)	0	0	0
Herpes simplex	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.6)	0	0	2 (2.6)	0
Oral infection	2 (2.6)	0	2 (2.6)	0	0
Pneumocystis jirovecii pneumonia	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Respiratory syncytial virus infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Sepsis	2 (2.6)	0	0	0	2 (2.6)
Septic shock	2 (2.6)	0	0	0	2 (2.6)

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	21 (26.9)	9 (11.5)	9 (11.5)	1 (1.3)	2 (2.6)
Infusion related reaction	5 (6.4)	2 (2.6)	2 (2.6)	1 (1.3)	0
Contusion	2 (2.6)	2 (2.6)	0	0	0
Fall	2 (2.6)	0	2 (2.6)	0	0
Ligament sprain	2 (2.6)	2 (2.6)	0	0	0
Procedural pain	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Skin abrasion	2 (2.6)	2 (2.6)	0	0	0
Transfusion reaction	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Abdominal injury	1 (1.3)	1 (1.3)	0	0	0
Fibula fracture	1 (1.3)	0	1 (1.3)	0	0
Limb injury	1 (1.3)	0	1 (1.3)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post-traumatic neck syndrome	1 (1.3)	0	1 (1.3)	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					
-Total	58 (74.4)	3 (3.8)	9 (11.5)	18 (23.1)	28 (35.9)
White blood cell count decreased	25 (32.1)	3 (3.8)	4 (5.1)	2 (2.6)	16 (20.5)
Neutrophil count decreased	24 (30.8)	1 (1.3)	2 (2.6)	4 (5.1)	17 (21.8)
Platelet count decreased	24 (30.8)	6 (7.7)	3 (3.8)	7 (9.0)	8 (10.3)
Aspartate aminotransferase increased	18 (23.1)	2 (2.6)	6 (7.7)	8 (10.3)	2 (2.6)
Alanine aminotransferase increased	17 (21.8)	3 (3.8)	8 (10.3)	6 (7.7)	0
Lymphocyte count decreased	17 (21.8)	1 (1.3)	1 (1.3)	10 (12.8)	5 (6.4)
Blood bilirubin increased	12 (15.4)	1 (1.3)	3 (3.8)	8 (10.3)	0
International normalised ratio increased	9 (11.5)	6 (7.7)	3 (3.8)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	8 (10.3)	1 (1.3)	5 (6.4)	2 (2.6)	0
Blood fibrinogen decreased	7 (9.0)	2 (2.6)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin a decreased	7 (9.0)	5 (6.4)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (9.0)	4 (5.1)	1 (1.3)	2 (2.6)	0
Activated partial thromboplastin time prolonged	5 (6.4)	3 (3.8)	2 (2.6)	0	0
Blood lactate dehydrogenase increased	5 (6.4)	3 (3.8)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	5 (6.4)	2 (2.6)	0	3 (3.8)	0
Electrocardiogram qt prolonged	5 (6.4)	1 (1.3)	2 (2.6)	1 (1.3)	1 (1.3)
Blood creatinine increased	4 (5.1)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Blood uric acid increased	4 (5.1)	2 (2.6)	0	1 (1.3)	1 (1.3)
Weight increased	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.6)	0
Fibrin d dimer increased	3 (3.8)	2 (2.6)	0	1 (1.3)	0
Oxygen saturation decreased	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0

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	All patients N=78				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Gamma-glutamyltransferase increased	2 (2.6)	0	0	2 (2.6)	0
Immunoglobulins decreased	2 (2.6)	0	2 (2.6)	0	0
Lipase increased	2 (2.6)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.3)	1 (1.3)	0	0	0
Blood urea increased	1 (1.3)	0	0	1 (1.3)	0
Bone density decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Ejection fraction decreased	1 (1.3)	0	1 (1.3)	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Heart sounds abnormal	1 (1.3)	1 (1.3)	0	0	0
Hepatitis b virus test positive	1 (1.3)	0	1 (1.3)	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0
Weight decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	50 (64.1)	9 (11.5)	10 (12.8)	21 (26.9)	10 (12.8)
Decreased appetite	29 (37.2)	11 (14.1)	7 (9.0)	10 (12.8)	1 (1.3)
Hypokalaemia	19 (24.4)	3 (3.8)	6 (7.7)	8 (10.3)	2 (2.6)

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	17 (21.8)	3 (3.8)	5 (6.4)	8 (10.3)	1 (1.3)
Hypocalcaemia	15 (19.2)	2 (2.6)	9 (11.5)	4 (5.1)	0
Hypoalbuminaemia	11 (14.1)	0	10 (12.8)	1 (1.3)	0
Hyperglycaemia	9 (11.5)	0	4 (5.1)	5 (6.4)	0
Hyperuricaemia	9 (11.5)	7 (9.0)	1 (1.3)	1 (1.3)	0
Hypervolaemia	7 (9.0)	0	2 (2.6)	5 (6.4)	0
Hypomagnesaemia	6 (7.7)	5 (6.4)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.4)	4 (5.1)	0	0	1 (1.3)
Metabolic acidosis	4 (5.1)	1 (1.3)	0	0	3 (3.8)
Tumour lysis syndrome	4 (5.1)	0	0	3 (3.8)	1 (1.3)
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Hyperkalaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hypernatraemia	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Hypertriglyceridaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Acidosis	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Hyperchloraemia	2 (2.6)	2 (2.6)	0	0	0
Hypermagnesaemia	2 (2.6)	2 (2.6)	0	0	0
Iron overload	2 (2.6)	0	2 (2.6)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	2 (2.6)	0	0	2 (2.6)	0
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hypercholesterolaemia	1 (1.3)	0	1 (1.3)	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlipidaemia	1 (1.3)	0	1 (1.3)	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Hypophagia	1 (1.3)	0	1 (1.3)	0	0
Metabolic syndrome	1 (1.3)	0	1 (1.3)	0	0
Obesity	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	43 (55.1)	17 (21.8)	18 (23.1)	7 (9.0)	1 (1.3)
Pain in extremity	17 (21.8)	8 (10.3)	8 (10.3)	1 (1.3)	0
Arthralgia	12 (15.4)	5 (6.4)	6 (7.7)	1 (1.3)	0
Back pain	10 (12.8)	2 (2.6)	5 (6.4)	3 (3.8)	0
Myalgia	10 (12.8)	6 (7.7)	4 (5.1)	0	0

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			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Muscular weakness	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Musculoskeletal chest pain	2 (2.6)	2 (2.6)	0	0	0
Neck pain	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Pain in jaw	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Growth retardation	1 (1.3)	0	1 (1.3)	0	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Joint effusion	1 (1.3)	0	1 (1.3)	0	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal pain	1 (1.3)	0	1 (1.3)	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Osteonecrosis	1 (1.3)	1 (1.3)	0	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Synovitis	1 (1.3)	0	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bone giant cell tumour benign	1 (1.3)	0	0	1 (1.3)	0
Cancer pain	1 (1.3)	0	1 (1.3)	0	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	45 (57.7)	15 (19.2)	17 (21.8)	10 (12.8)	3 (3.8)
Headache	27 (34.6)	13 (16.7)	11 (14.1)	3 (3.8)	0
Encephalopathy	8 (10.3)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.7)	5 (6.4)	1 (1.3)	0	0
Somnolence	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Dizziness	4 (5.1)	4 (5.1)	0	0	0
Dysgeusia	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Seizure	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Cognitive disorder	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Extrapyramidal disorder	1 (1.3)	0	1 (1.3)	0	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hydrocephalus	1 (1.3)	0	0	0	1 (1.3)
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Migraine	1 (1.3)	0	1 (1.3)	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorder	1 (1.3)	0	0	1 (1.3)	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	37 (47.4)	13 (16.7)	17 (21.8)	7 (9.0)	0
Anxiety	13 (16.7)	3 (3.8)	8 (10.3)	2 (2.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	8 (10.3)	2 (2.6)	3 (3.8)	3 (3.8)	0
Confusional state	7 (9.0)	7 (9.0)	0	0	0
Agitation	6 (7.7)	3 (3.8)	3 (3.8)	0	0
Mental status changes	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Insomnia	4 (5.1)	2 (2.6)	2 (2.6)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Sleep disorder	2 (2.6)	0	2 (2.6)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Nightmare	1 (1.3)	1 (1.3)	0	0	0
Persistent depressive disorder	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tearfulness	1 (1.3)	1 (1.3)	0	0	0
Tic	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (30.8)	6 (7.7)	7 (9.0)	4 (5.1)	7 (9.0)
Acute kidney injury	12 (15.4)	2 (2.6)	2 (2.6)	3 (3.8)	5 (6.4)
Dysuria	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Haematuria	3 (3.8)	2 (2.6)	0	1 (1.3)	0
Anuria	2 (2.6)	1 (1.3)	0	0	1 (1.3)
Pollakiuria	2 (2.6)	0	2 (2.6)	0	0
Renal failure	2 (2.6)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.6)	0	2 (2.6)	0	0
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Cystitis haemorrhagic	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Kidney enlargement	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal mass	1 (1.3)	0	1 (1.3)	0	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	6 (7.7)	2 (2.6)	2 (2.6)	2 (2.6)	0
Dysmenorrhoea	1 (1.3)	0	1 (1.3)	0	0
Endometriosis	1 (1.3)	0	0	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	53 (67.9)	17 (21.8)	8 (10.3)	12 (15.4)	16 (20.5)
Cough	22 (28.2)	18 (23.1)	4 (5.1)	0	0
Hypoxia	20 (25.6)	0	4 (5.1)	10 (12.8)	6 (7.7)
Pulmonary oedema	12 (15.4)	2 (2.6)	3 (3.8)	6 (7.7)	1 (1.3)
Nasal congestion	9 (11.5)	7 (9.0)	2 (2.6)	0	0
Tachypnoea	9 (11.5)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	8 (10.3)	7 (9.0)	1 (1.3)	0	0
Pleural effusion	8 (10.3)	4 (5.1)	2 (2.6)	2 (2.6)	0
Dyspnoea	7 (9.0)	1 (1.3)	2 (2.6)	2 (2.6)	2 (2.6)
Epistaxis	7 (9.0)	4 (5.1)	2 (2.6)	1 (1.3)	0
Respiratory failure	6 (7.7)	0	0	0	6 (7.7)
Rhinorrhoea	5 (6.4)	4 (5.1)	1 (1.3)	0	0
Respiratory distress	4 (5.1)	0	2 (2.6)	0	2 (2.6)
Acute respiratory distress syndrome	3 (3.8)	0	0	0	3 (3.8)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.6)	0
Pharyngeal erythema	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Rhinitis allergic	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Sleep apnoea syndrome	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Bronchial oedema	1 (1.3)	1 (1.3)	0	0	0
Bronchospasm	1 (1.3)	0	1 (1.3)	0	0
Dyspnoea exertional	1 (1.3)	1 (1.3)	0	0	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (1.3)	0	0	0	1 (1.3)
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Paranasal sinus inflammation	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Upper respiratory tract inflammation	1 (1.3)	0	1 (1.3)	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	40 (51.3)	17 (21.8)	16 (20.5)	7 (9.0)	0
Dry skin	8 (10.3)	6 (7.7)	2 (2.6)	0	0
Rash	8 (10.3)	4 (5.1)	4 (5.1)	0	0
Pruritus	7 (9.0)	2 (2.6)	5 (6.4)	0	0
Erythema	5 (6.4)	4 (5.1)	1 (1.3)	0	0
Blister	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Dermatitis atopic	3 (3.8)	2 (2.6)	0	1 (1.3)	0
Eczema	3 (3.8)	2 (2.6)	0	1 (1.3)	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Rash maculo-papular	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Rash papular	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Decubitus ulcer	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Ingrowing nail	2 (2.6)	0	2 (2.6)	0	0
Petechiae	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Skin discolouration	2 (2.6)	2 (2.6)	0	0	0
Skin ulcer	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis allergic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0
Hangnail	1 (1.3)	1 (1.3)	0	0	0
Miliaria	1 (1.3)	1 (1.3)	0	0	0
Night sweats	1 (1.3)	1 (1.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Papule	1 (1.3)	1 (1.3)	0	0	0
Photosensitivity reaction	1 (1.3)	0	1 (1.3)	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash erythematous	1 (1.3)	1 (1.3)	0	0	0
Rash macular	1 (1.3)	0	0	1 (1.3)	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin hypopigmentation	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Skin swelling	1 (1.3)	1 (1.3)	0	0	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					
-Total	32 (41.0)	4 (5.1)	8 (10.3)	11 (14.1)	9 (11.5)
Hypotension	23 (29.5)	1 (1.3)	6 (7.7)	8 (10.3)	8 (10.3)
Hypertension	16 (20.5)	4 (5.1)	7 (9.0)	5 (6.4)	0
Venoocclusive disease	2 (2.6)	0	0	1 (1.3)	1 (1.3)
Capillary leak syndrome	1 (1.3)	0	1 (1.3)	0	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Anal haemorrhage	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0
Blood fibrinogen decreased	1 (100)	1 (100)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Blood uric acid increased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	1 (100)	0	0	0
Decreased appetite	1 (100)	1 (100)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Pain in extremity	1 (100)	1 (100)	0	0	0
Psychiatric disorders					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dry skin	1 (100)	1 (100)	0	0	0
Rash papular	1 (100)	1 (100)	0	0	0
Rash pruritic	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (98.7)	3 (3.8)	8 (10.1)	21 (26.6)	46 (58.2)
Blood and lymphatic system disorders					
-Total	49 (62.0)	2 (2.5)	8 (10.1)	26 (32.9)	13 (16.5)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
Anaemia	20 (25.3)	4 (5.1)	8 (10.1)	8 (10.1)	0
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Disseminated intravascular coagulation	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Coagulopathy	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					
-Total	24 (30.4)	10 (12.7)	6 (7.6)	5 (6.3)	3 (3.8)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Sinus tachycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Ear and labyrinth disorders					
-Total	2 (2.5)	2 (2.5)	0	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					
-Total	5 (6.3)	0	5 (6.3)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eyelid oedema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Ocular hyperaemia	2 (2.5)	2 (2.5)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Visual impairment	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	50 (63.3)	18 (22.8)	18 (22.8)	13 (16.5)	1 (1.3)
Vomiting	21 (26.6)	12 (15.2)	8 (10.1)	1 (1.3)	0
Nausea	18 (22.8)	10 (12.7)	6 (7.6)	2 (2.5)	0
Diarrhoea	15 (19.0)	8 (10.1)	6 (7.6)	1 (1.3)	0
Constipation	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Abdominal pain	10 (12.7)	2 (2.5)	6 (7.6)	2 (2.5)	0
Mouth haemorrhage	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.5)	0
Pancreatitis	4 (5.1)	0	3 (3.8)	1 (1.3)	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Abdominal pain upper	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Stomatitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
Trichoglossia	1 (1.3)	0	1 (1.3)	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	40 (50.6)	20 (25.3)	9 (11.4)	7 (8.9)	4 (5.1)
Pyrexia	24 (30.4)	11 (13.9)	5 (6.3)	6 (7.6)	2 (2.5)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Chills	6 (7.6)	4 (5.1)	2 (2.5)	0	0
Oedema peripheral	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Asthenia	2 (2.5)	2 (2.5)	0	0	0
Catheter site pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.5)	2 (2.5)	0	0	0
Multiple organ dysfunction syndrome	2 (2.5)	0	0	0	2 (2.5)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Malaise	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Pain	1 (1.3)	0	0	1 (1.3)	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	17 (21.5)	5 (6.3)	6 (7.6)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	67 (84.8)	3 (3.8)	21 (26.6)	22 (27.8)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	23 (29.1)	2 (2.5)	14 (17.7)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	35 (44.3)	6 (7.6)	10 (12.7)	16 (20.3)	3 (3.8)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.5)	2 (2.5)	0	0	0
Oral herpes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	11 (13.9)	3 (3.8)	6 (7.6)	0	2 (2.5)
Fall	2 (2.5)	0	2 (2.5)	0	0
Infusion related reaction	2 (2.5)	0	2 (2.5)	0	0
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Contusion	1 (1.3)	1 (1.3)	0	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin abrasion	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	56 (70.9)	3 (3.8)	8 (10.1)	17 (21.5)	28 (35.4)
White blood cell count decreased	24 (30.4)	3 (3.8)	3 (3.8)	2 (2.5)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Neutrophil count decreased	20 (25.3)	0	3 (3.8)	2 (2.5)	15 (19.0)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	4 (5.1)	8 (10.1)	6 (7.6)	0
Lymphocyte count decreased	15 (19.0)	2 (2.5)	0	8 (10.1)	5 (6.3)
Blood bilirubin increased	12 (15.2)	1 (1.3)	2 (2.5)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Activated partial thromboplastin time prolonged	6 (7.6)	3 (3.8)	2 (2.5)	1 (1.3)	0
Blood fibrinogen decreased	6 (7.6)	1 (1.3)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin m decreased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	5 (6.3)	1 (1.3)	2 (2.5)	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	4 (5.1)	1 (1.3)	0	2 (2.5)	1 (1.3)
Blood immunoglobulin a decreased	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Blood lactate dehydrogenase increased	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Weight increased	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
Fibrin d dimer increased	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gamma-glutamyltransferase increased	2 (2.5)	0	0	2 (2.5)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Blood uric acid increased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Oxygen saturation decreased	1 (1.3)	1 (1.3)	0	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0
Weight decreased	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	45 (57.0)	7 (8.9)	9 (11.4)	21 (26.6)	8 (10.1)
Decreased appetite	23 (29.1)	8 (10.1)	4 (5.1)	10 (12.7)	1 (1.3)
Hypokalaemia	19 (24.1)	3 (3.8)	5 (6.3)	9 (11.4)	2 (2.5)
Hypophosphataemia	17 (21.5)	3 (3.8)	5 (6.3)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	8 (10.1)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Hypervolaemia	6 (7.6)	0	2 (2.5)	4 (5.1)	0
Hypomagnesaemia	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.3)	4 (5.1)	0	0	1 (1.3)
Tumour lysis syndrome	4 (5.1)	0	0	4 (5.1)	0
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Metabolic acidosis	3 (3.8)	1 (1.3)	0	0	2 (2.5)
Acidosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hyperkalaemia	2 (2.5)	0	0	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Hypernatraemia	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Hypertriglyceridaemia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hyperchloraemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Malnutrition	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	32 (40.5)	14 (17.7)	13 (16.5)	4 (5.1)	1 (1.3)
Arthralgia	10 (12.7)	4 (5.1)	5 (6.3)	1 (1.3)	0
Pain in extremity	10 (12.7)	5 (6.3)	5 (6.3)	0	0
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Back pain	6 (7.6)	2 (2.5)	3 (3.8)	1 (1.3)	0
Bone pain	2 (2.5)	0	2 (2.5)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal chest pain	1 (1.3)	1 (1.3)	0	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Neck pain	1 (1.3)	0	1 (1.3)	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Nervous system disorders					
-Total	40 (50.6)	14 (17.7)	16 (20.3)	8 (10.1)	2 (2.5)
Headache	23 (29.1)	12 (15.2)	9 (11.4)	2 (2.5)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Dizziness	3 (3.8)	3 (3.8)	0	0	0
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	27 (34.2)	11 (13.9)	10 (12.7)	6 (7.6)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Anxiety	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Agitation	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Insomnia	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Irritability	2 (2.5)	2 (2.5)	0	0	0
Sleep disorder	2 (2.5)	0	2 (2.5)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	20 (25.3)	5 (6.3)	6 (7.6)	3 (3.8)	6 (7.6)
Acute kidney injury	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Dysuria	3 (3.8)	3 (3.8)	0	0	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Haematuria	2 (2.5)	2 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal failure	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	40 (50.6)	13 (16.5)	4 (5.1)	11 (13.9)	12 (15.2)
Hypoxia	17 (21.5)	0	5 (6.3)	6 (7.6)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Cough	9 (11.4)	8 (10.1)	1 (1.3)	0	0
Tachypnoea	8 (10.1)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	7 (8.9)	4 (5.1)	0	2 (2.5)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0	0	0
Epistaxis	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
Respiratory failure	4 (5.1)	0	0	0	4 (5.1)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Dyspnoea	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Respiratory distress	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Acute respiratory distress syndrome	2 (2.5)	0	0	0	2 (2.5)
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal erythema	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Rhinorrhoea	1 (1.3)	1 (1.3)	0	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	26 (32.9)	12 (15.2)	11 (13.9)	3 (3.8)	0
Pruritus	6 (7.6)	2 (2.5)	4 (5.1)	0	0
Rash	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Erythema	4 (5.1)	4 (5.1)	0	0	0
Blister	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Dermatitis atopic	2 (2.5)	2 (2.5)	0	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Rash maculo-papular	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Rash papular	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Skin ulcer	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Decubitus ulcer	1 (1.3)	0	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Eczema	1 (1.3)	1 (1.3)	0	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin discolouration	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	28 (35.4)	4 (5.1)	7 (8.9)	11 (13.9)	6 (7.6)
Hypotension	21 (26.6)	1 (1.3)	6 (7.6)	8 (10.1)	6 (7.6)
Hypertension	13 (16.5)	4 (5.1)	5 (6.3)	4 (5.1)	0
Capillary leak syndrome	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Diarrhoea	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0
Proctalgia	1 (100)	1 (100)	0	0	0
Vomiting	1 (100)	1 (100)	0	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Rhinorrhoea	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (91.9)	9 (12.2)	23 (31.1)	15 (20.3)	21 (28.4)
Blood and lymphatic system disorders					
-Total	17 (23.0)	3 (4.1)	4 (5.4)	6 (8.1)	4 (5.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	7 (9.5)	3 (4.1)	1 (1.4)	0	3 (4.1)
Cardiac arrest	2 (2.7)	0	0	0	2 (2.7)
Cardiac failure	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Left ventricular dysfunction	1 (1.4)	0	1 (1.4)	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	4 (5.4)	4 (5.4)	0	0	0
Cataract	2 (2.7)	2 (2.7)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	19 (25.7)	12 (16.2)	6 (8.1)	1 (1.4)	0
Diarrhoea	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Vomiting	5 (6.8)	5 (6.8)	0	0	0
Nausea	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pancreatitis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Abdominal pain upper	1 (1.4)	1 (1.4)	0	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Stomatitis	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	24 (32.4)	15 (20.3)	6 (8.1)	3 (4.1)	0
Pyrexia	15 (20.3)	7 (9.5)	6 (8.1)	2 (2.7)	0
Fatigue	6 (8.1)	6 (8.1)	0	0	0
Pain	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	1 (1.4)	0	0	0
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	15 (20.3)	1 (1.4)	10 (13.5)	4 (5.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	9 (12.2)	0	9 (12.2)	0	0
Allergy to immunoglobulin therapy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Graft versus host disease	2 (2.7)	0	0	2 (2.7)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	39 (52.7)	5 (6.8)	14 (18.9)	12 (16.2)	8 (10.8)
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Infusion related reaction	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ligament sprain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	29 (39.2)	6 (8.1)	7 (9.5)	11 (14.9)	5 (6.8)
Neutrophil count decreased	10 (13.5)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.4)
White blood cell count decreased	9 (12.2)	3 (4.1)	2 (2.7)	3 (4.1)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Platelet count decreased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Blood lactate dehydrogenase increased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
C-reactive protein increased	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Weight decreased	1 (1.4)	0	0	1 (1.4)	0
Weight increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	15 (20.3)	4 (5.4)	4 (5.4)	4 (5.4)	3 (4.1)
Decreased appetite	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	15 (20.3)	5 (6.8)	7 (9.5)	3 (4.1)	0
Back pain	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Growth retardation	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	14 (18.9)	7 (9.5)	5 (6.8)	0	2 (2.7)
Headache	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Dizziness	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	10 (13.5)	1 (1.4)	8 (10.8)	1 (1.4)	0
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	0	0	1 (1.4)	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	23 (31.1)	10 (13.5)	7 (9.5)	3 (4.1)	3 (4.1)
Cough	10 (13.5)	7 (9.5)	3 (4.1)	0	0
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Epistaxis	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinorrhoea	2 (2.7)	2 (2.7)	0	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (27.0)	12 (16.2)	7 (9.5)	1 (1.4)	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Rash	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Ingrowing nail	2 (2.7)	0	2 (2.7)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	6 (8.1)	1 (1.4)	0	2 (2.7)	3 (4.1)
Hypotension	4 (5.4)	1 (1.4)	0	1 (1.4)	2 (2.7)
Venoocclusive disease	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (64.0)	3 (6.0)	10 (20.0)	12 (24.0)	7 (14.0)
Blood and lymphatic system disorders					
-Total	4 (8.0)	0	2 (4.0)	1 (2.0)	1 (2.0)
Agranulocytosis	1 (2.0)	0	0	1 (2.0)	0
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Hypercoagulation	1 (2.0)	0	1 (2.0)	0	0
Lymphadenopathy	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	1 (2.0)	0	0	0
Cerebral cavernous malformation	1 (2.0)	1 (2.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Deafness unilateral	1 (2.0)	0	1 (2.0)	0	0
Endocrine disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Delayed puberty	1 (2.0)	0	1 (2.0)	0	0
Hypothyroidism	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	3 (6.0)	1 (2.0)	1 (2.0)	1 (2.0)	0
Dry eye	1 (2.0)	1 (2.0)	0	0	0
Eye pain	1 (2.0)	0	0	1 (2.0)	0
Eyelid oedema	1 (2.0)	1 (2.0)	0	0	0
Mydriasis	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	7 (14.0)	4 (8.0)	2 (4.0)	1 (2.0)	0
Diarrhoea	5 (10.0)	3 (6.0)	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.0)	1 (2.0)	0	0	0
Irritable bowel syndrome	1 (2.0)	0	1 (2.0)	0	0
Nausea	1 (2.0)	1 (2.0)	0	0	0
Vomiting	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	9 (18.0)	4 (8.0)	3 (6.0)	1 (2.0)	1 (2.0)
Pyrexia	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Fatigue	1 (2.0)	0	1 (2.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	0	0	1 (2.0)
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0
Xerosis	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	9 (18.0)	2 (4.0)	5 (10.0)	1 (2.0)	1 (2.0)
Hypogammaglobulinaemia	3 (6.0)	0	3 (6.0)	0	0
Seasonal allergy	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Chronic graft versus host disease	2 (4.0)	0	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug hypersensitivity	1 (2.0)	0	0	1 (2.0)	0
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Infections and infestations					
-Total	23 (46.0)	2 (4.0)	7 (14.0)	10 (20.0)	4 (8.0)
Sinusitis	6 (12.0)	0	6 (12.0)	0	0
Upper respiratory tract infection	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Conjunctivitis	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Rhinovirus infection	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Sepsis	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Skin infection	3 (6.0)	0	3 (6.0)	0	0
Bronchitis	2 (4.0)	0	2 (4.0)	0	0
Covid-19	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Fungal infection	2 (4.0)	0	2 (4.0)	0	0
Herpes zoster	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Influenza	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Oral herpes	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Otitis media	2 (4.0)	0	2 (4.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.0)	0	2 (4.0)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Bronchiolitis	1 (2.0)	0	0	1 (2.0)	0
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Folliculitis	1 (2.0)	0	1 (2.0)	0	0
Fungal skin infection	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis	1 (2.0)	1 (2.0)	0	0	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis viral	1 (2.0)	0	1 (2.0)	0	0
Herpes virus infection	1 (2.0)	0	1 (2.0)	0	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Streptococcal sepsis	1 (2.0)	0	1 (2.0)	0	0
Syphilis	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection pseudomonal	1 (2.0)	0	1 (2.0)	0	0
Varicella zoster virus infection	1 (2.0)	0	1 (2.0)	0	0
Viral skin infection	1 (2.0)	1 (2.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (6.0)	2 (4.0)	0	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal injury	1 (2.0)	1 (2.0)	0	0	0
Infusion related reaction	1 (2.0)	0	0	1 (2.0)	0
Ligament sprain	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	6 (12.0)	3 (6.0)	1 (2.0)	1 (2.0)	1 (2.0)
Neutrophil count decreased	3 (6.0)	2 (4.0)	0	0	1 (2.0)
Platelet count decreased	2 (4.0)	2 (4.0)	0	0	0
Blood bilirubin increased	1 (2.0)	1 (2.0)	0	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Oxygen saturation decreased	1 (2.0)	0	0	1 (2.0)	0
Metabolism and nutrition disorders					
-Total	6 (12.0)	0	2 (4.0)	3 (6.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	0	0	1 (2.0)
Hypercholesterolaemia	1 (2.0)	0	1 (2.0)	0	0
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Hyperlipidaemia	1 (2.0)	0	1 (2.0)	0	0
Hypernatraemia	1 (2.0)	0	0	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	1 (2.0)	0	1 (2.0)	0	0
Iron overload	1 (2.0)	0	1 (2.0)	0	0
Obesity	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (14.0)	2 (4.0)	5 (10.0)	0	0
Pain in extremity	2 (4.0)	0	2 (4.0)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Growth retardation	1 (2.0)	0	1 (2.0)	0	0
Joint effusion	1 (2.0)	0	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	1 (2.0)	0	0	0
Osteopenia	1 (2.0)	1 (2.0)	0	0	0
Synovitis	1 (2.0)	0	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.0)	0	0	1 (2.0)	0
Bone giant cell tumour benign	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					
-Total	4 (8.0)	0	2 (4.0)	2 (4.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Dysarthria	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorder	1 (2.0)	0	0	1 (2.0)	0
Seizure	1 (2.0)	0	0	1 (2.0)	0
Psychiatric disorders					
-Total	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Anxiety	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Tic	1 (2.0)	0	1 (2.0)	0	0
Reproductive system and breast disorders					
-Total	1 (2.0)	0	0	1 (2.0)	0
Endometriosis	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (20.0)	4 (8.0)	2 (4.0)	1 (2.0)	3 (6.0)
Cough	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Dyspnoea	3 (6.0)	1 (2.0)	1 (2.0)	0	1 (2.0)
Rhinorrhoea	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Sleep apnoea syndrome	2 (4.0)	1 (2.0)	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (2.0)	1 (2.0)	0	0	0
Epistaxis	1 (2.0)	1 (2.0)	0	0	0
Hypoxia	1 (2.0)	0	0	1 (2.0)	0
Laryngeal oedema	1 (2.0)	0	0	0	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Pharyngeal erythema	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Tachypnoea	1 (2.0)	0	0	0	1 (2.0)
Wheezing	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (14.0)	3 (6.0)	1 (2.0)	3 (6.0)	0
Rash	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Dermatitis atopic	1 (2.0)	0	0	1 (2.0)	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Eczema	1 (2.0)	0	0	1 (2.0)	0
Papule	1 (2.0)	1 (2.0)	0	0	0
Rash erythematous	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (2.0)	0	0	1 (2.0)	0
Rash maculo-papular	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hypertension	2 (4.0)	0	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Anal haemorrhage	1 (100)	1 (100)	0	0	0
Diarrhoea	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0
Proctalgia	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (100)	1 (100)	0	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0
Blood fibrinogen decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Blood uric acid increased	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	1 (100)	0	0	0
Decreased appetite	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Pain in extremity	1 (100)	1 (100)	0	0	0
Psychiatric disorders					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Rhinorrhoea	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dry skin	1 (100)	1 (100)	0	0	0
Rash papular	1 (100)	1 (100)	0	0	0
Rash pruritic	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	1 (1.3)	5 (6.3)	19 (24.1)	54 (68.4)
Blood and lymphatic system disorders					
-Total	54 (68.4)	0	11 (13.9)	29 (36.7)	14 (17.7)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	24 (30.4)	6 (7.6)	9 (11.4)	9 (11.4)	0
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Disseminated intravascular coagulation	8 (10.1)	0	5 (6.3)	3 (3.8)	0
Coagulopathy	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphadenopathy	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Lymphopenia	2 (2.5)	0	0	2 (2.5)	0
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypercoagulation	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Leukocytosis	1 (1.3)	0	1 (1.3)	0	0
Lymphocytosis	1 (1.3)	0	1 (1.3)	0	0
Cardiac disorders					
-Total	28 (35.4)	10 (12.7)	7 (8.9)	5 (6.3)	6 (7.6)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Left ventricular dysfunction	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac arrest	3 (3.8)	0	0	0	3 (3.8)
Cardiac failure	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Sinus tachycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Tricuspid valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.3)	1 (1.3)	0	0	0
Cerebral cavernous malformation	1 (1.3)	1 (1.3)	0	0	0
Ear and labyrinth disorders					
-Total	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (8.9)	0	7 (8.9)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	3 (3.8)	0	3 (3.8)	0	0
Delayed puberty	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	15 (19.0)	10 (12.7)	4 (5.1)	1 (1.3)	0
Eyelid oedema	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Ocular hyperaemia	3 (3.8)	3 (3.8)	0	0	0
Cataract	2 (2.5)	2 (2.5)	0	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eye pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Visual impairment	2 (2.5)	2 (2.5)	0	0	0
Dry eye	1 (1.3)	1 (1.3)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Hypermetropia	1 (1.3)	1 (1.3)	0	0	0
Mydriasis	1 (1.3)	0	1 (1.3)	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					
-Total	59 (74.7)	20 (25.3)	23 (29.1)	15 (19.0)	1 (1.3)
Diarrhoea	25 (31.6)	15 (19.0)	8 (10.1)	2 (2.5)	0
Vomiting	25 (31.6)	16 (20.3)	8 (10.1)	1 (1.3)	0
Nausea	21 (26.6)	11 (13.9)	8 (10.1)	2 (2.5)	0
Constipation	14 (17.7)	7 (8.9)	7 (8.9)	0	0
Abdominal pain	10 (12.7)	1 (1.3)	7 (8.9)	2 (2.5)	0
Pancreatitis	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Mouth haemorrhage	5 (6.3)	2 (2.5)	1 (1.3)	2 (2.5)	0
Abdominal pain upper	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Stomatitis	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Trichoglossia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (1.3)	0	1 (1.3)	0	0
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dyspepsia	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enteritis	1 (1.3)	0	1 (1.3)	0	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal inflammation	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Peritoneal haematoma	1 (1.3)	1 (1.3)	0	0	0
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	53 (67.1)	25 (31.6)	13 (16.5)	10 (12.7)	5 (6.3)
Pyrexia	35 (44.3)	14 (17.7)	10 (12.7)	9 (11.4)	2 (2.5)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Chills	7 (8.9)	5 (6.3)	2 (2.5)	0	0
Oedema peripheral	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Pain	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Asthenia	3 (3.8)	3 (3.8)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (3.8)	0	0	0	3 (3.8)
Catheter site pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.5)	2 (2.5)	0	0	0
Malaise	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Non-cardiac chest pain	2 (2.5)	2 (2.5)	0	0	0
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Xerosis	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	19 (24.1)	6 (7.6)	7 (8.9)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Hepatic cytolysis	1 (1.3)	1 (1.3)	0	0	0
Liver disorder	1 (1.3)	0	1 (1.3)	0	0
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	70 (88.6)	2 (2.5)	22 (27.8)	24 (30.4)	22 (27.8)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	32 (40.5)	2 (2.5)	23 (29.1)	7 (8.9)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Seasonal allergy	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Allergy to immunoglobulin therapy	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Chronic graft versus host disease	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Graft versus host disease	2 (2.5)	0	0	2 (2.5)	0
Engraftment syndrome	1 (1.3)	0	0	1 (1.3)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	60 (75.9)	8 (10.1)	13 (16.5)	25 (31.6)	14 (17.7)
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	7 (8.9)	4 (5.1)	3 (3.8)	0	0
Sinusitis	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Gastroenteritis	6 (7.6)	4 (5.1)	0	2 (2.5)	0
Pneumonia	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Otitis media	5 (6.3)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.5)	1 (1.3)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Bronchitis	2 (2.5)	0	2 (2.5)	0	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.5)	2 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Paronychia	2 (2.5)	0	2 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	21 (26.6)	9 (11.4)	9 (11.4)	1 (1.3)	2 (2.5)
Infusion related reaction	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Contusion	2 (2.5)	2 (2.5)	0	0	0
Fall	2 (2.5)	0	2 (2.5)	0	0
Ligament sprain	2 (2.5)	2 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Skin abrasion	2 (2.5)	2 (2.5)	0	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Abdominal injury	1 (1.3)	1 (1.3)	0	0	0
Fibula fracture	1 (1.3)	0	1 (1.3)	0	0
Limb injury	1 (1.3)	0	1 (1.3)	0	0
Post-traumatic neck syndrome	1 (1.3)	0	1 (1.3)	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					
-Total	59 (74.7)	2 (2.5)	9 (11.4)	19 (24.1)	29 (36.7)
Neutrophil count decreased	24 (30.4)	1 (1.3)	2 (2.5)	4 (5.1)	17 (21.5)
White blood cell count decreased	24 (30.4)	2 (2.5)	4 (5.1)	2 (2.5)	16 (20.3)
Platelet count decreased	23 (29.1)	5 (6.3)	3 (3.8)	7 (8.9)	8 (10.1)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	3 (3.8)	8 (10.1)	7 (8.9)	0
Lymphocyte count decreased	17 (21.5)	1 (1.3)	1 (1.3)	10 (12.7)	5 (6.3)
Blood bilirubin increased	13 (16.5)	1 (1.3)	3 (3.8)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Activated partial thromboplastin time prolonged	6 (7.6)	3 (3.8)	2 (2.5)	1 (1.3)	0
Blood fibrinogen decreased	6 (7.6)	1 (1.3)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin a decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	6 (7.6)	3 (3.8)	1 (1.3)	2 (2.5)	0
Blood creatinine increased	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Blood lactate dehydrogenase increased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	5 (6.3)	2 (2.5)	0	3 (3.8)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	5 (6.3)	1 (1.3)	2 (2.5)	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Weight increased	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.5)	0
Blood uric acid increased	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Fibrin d dimer increased	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Oxygen saturation decreased	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Gamma-glutamyltransferase increased	2 (2.5)	0	0	2 (2.5)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Weight decreased	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.3)	1 (1.3)	0	0	0
Blood urea increased	1 (1.3)	0	0	1 (1.3)	0
Bone density decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Ejection fraction decreased	1 (1.3)	0	1 (1.3)	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Heart sounds abnormal	1 (1.3)	1 (1.3)	0	0	0
Hepatitis b virus test positive	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	51 (64.6)	8 (10.1)	10 (12.7)	22 (27.8)	11 (13.9)
Decreased appetite	29 (36.7)	10 (12.7)	7 (8.9)	10 (12.7)	2 (2.5)
Hypokalaemia	20 (25.3)	3 (3.8)	6 (7.6)	9 (11.4)	2 (2.5)
Hypophosphataemia	18 (22.8)	3 (3.8)	6 (7.6)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	9 (11.4)	0	4 (5.1)	5 (6.3)	0
Hyperuricaemia	9 (11.4)	7 (8.9)	1 (1.3)	1 (1.3)	0
Hypervolaemia	7 (8.9)	0	2 (2.5)	5 (6.3)	0
Hypomagnesaemia	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.3)	4 (5.1)	0	0	1 (1.3)
Tumour lysis syndrome	5 (6.3)	0	0	4 (5.1)	1 (1.3)
Metabolic acidosis	4 (5.1)	1 (1.3)	0	0	3 (3.8)
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hypernatraemia	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Hypertriglyceridaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Acidosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hyperchloraemia	2 (2.5)	2 (2.5)	0	0	0
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Iron overload	2 (2.5)	0	2 (2.5)	0	0
Malnutrition	2 (2.5)	0	0	2 (2.5)	0
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemochromatosis	1 (1.3)	0	0	1 (1.3)	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hypercholesterolaemia	1 (1.3)	0	1 (1.3)	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlipidaemia	1 (1.3)	0	1 (1.3)	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Hypophagia	1 (1.3)	0	1 (1.3)	0	0
Metabolic syndrome	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Obesity	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	43 (54.4)	16 (20.3)	19 (24.1)	7 (8.9)	1 (1.3)
Pain in extremity	16 (20.3)	7 (8.9)	8 (10.1)	1 (1.3)	0
Arthralgia	12 (15.2)	5 (6.3)	6 (7.6)	1 (1.3)	0
Back pain	10 (12.7)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)	0	0
Bone pain	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Growth retardation	2 (2.5)	0	2 (2.5)	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Musculoskeletal chest pain	2 (2.5)	2 (2.5)	0	0	0
Neck pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Joint effusion	1 (1.3)	0	1 (1.3)	0	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal pain	1 (1.3)	0	1 (1.3)	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Osteonecrosis	1 (1.3)	1 (1.3)	0	0	0
Osteopenia	1 (1.3)	1 (1.3)	0	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Synovitis	1 (1.3)	0	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Bone giant cell tumour benign	1 (1.3)	0	0	1 (1.3)	0
Cancer pain	1 (1.3)	0	1 (1.3)	0	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	47 (59.5)	15 (19.0)	18 (22.8)	10 (12.7)	4 (5.1)
Headache	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Dizziness	4 (5.1)	4 (5.1)	0	0	0
Seizure	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cerebral haemorrhage	2 (2.5)	0	0	0	2 (2.5)
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Autonomic neuropathy	1 (1.3)	0	0	1 (1.3)	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Extrapyramidal disorder	1 (1.3)	0	1 (1.3)	0	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hydrocephalus	1 (1.3)	0	0	0	1 (1.3)
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Migraine	1 (1.3)	0	1 (1.3)	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorder	1 (1.3)	0	0	1 (1.3)	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	38 (48.1)	12 (15.2)	19 (24.1)	7 (8.9)	0
Anxiety	14 (17.7)	3 (3.8)	9 (11.4)	2 (2.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Agitation	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Mental status changes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Insomnia	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Sleep disorder	3 (3.8)	0	3 (3.8)	0	0
Irritability	2 (2.5)	2 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Nightmare	1 (1.3)	1 (1.3)	0	0	0
Persistent depressive disorder	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tearfulness	1 (1.3)	1 (1.3)	0	0	0
Tic	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	25 (31.6)	6 (7.6)	7 (8.9)	5 (6.3)	7 (8.9)
Acute kidney injury	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Dysuria	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Haematuria	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal failure	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Cystitis haemorrhagic	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Kidney enlargement	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal mass	1 (1.3)	0	1 (1.3)	0	0
Renal tubular disorder	1 (1.3)	0	0	1 (1.3)	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	6 (7.6)	2 (2.5)	2 (2.5)	2 (2.5)	0
Dysmenorrhoea	1 (1.3)	0	1 (1.3)	0	0
Endometriosis	1 (1.3)	0	0	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	54 (68.4)	17 (21.5)	8 (10.1)	12 (15.2)	17 (21.5)
Cough	22 (27.8)	17 (21.5)	5 (6.3)	0	0
Hypoxia	20 (25.3)	0	4 (5.1)	10 (12.7)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)	0	0
Pleural effusion	9 (11.4)	4 (5.1)	2 (2.5)	2 (2.5)	1 (1.3)
Tachypnoea	9 (11.4)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)	0	0
Dyspnoea	7 (8.9)	1 (1.3)	2 (2.5)	2 (2.5)	2 (2.5)
Epistaxis	7 (8.9)	4 (5.1)	2 (2.5)	1 (1.3)	0
Respiratory failure	6 (7.6)	0	0	0	6 (7.6)
Rhinorrhoea	5 (6.3)	3 (3.8)	2 (2.5)	0	0
Respiratory distress	4 (5.1)	0	2 (2.5)	0	2 (2.5)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	3 (3.8)	0	0	0	3 (3.8)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Pharyngeal erythema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Rhinitis allergic	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Sleep apnoea syndrome	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wheezing	2 (2.5)	0	2 (2.5)	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Bronchial oedema	1 (1.3)	1 (1.3)	0	0	0
Bronchospasm	1 (1.3)	0	1 (1.3)	0	0
Dyspnoea exertional	1 (1.3)	1 (1.3)	0	0	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Laryngeal oedema	1 (1.3)	0	0	0	1 (1.3)
Lung disorder	1 (1.3)	1 (1.3)	0	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Paranasal sinus inflammation	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Upper respiratory tract inflammation	1 (1.3)	0	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	39 (49.4)	16 (20.3)	16 (20.3)	7 (8.9)	0
Rash	8 (10.1)	4 (5.1)	4 (5.1)	0	0
Dry skin	7 (8.9)	5 (6.3)	2 (2.5)	0	0
Pruritus	7 (8.9)	2 (2.5)	5 (6.3)	0	0
Erythema	5 (6.3)	4 (5.1)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dermatitis atopic	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Eczema	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rash maculo-papular	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Decubitus ulcer	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Ingrowing nail	2 (2.5)	0	2 (2.5)	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Rash papular	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Skin discolouration	2 (2.5)	2 (2.5)	0	0	0
Skin ulcer	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis allergic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0
Hangnail	1 (1.3)	1 (1.3)	0	0	0
Miliaria	1 (1.3)	1 (1.3)	0	0	0
Night sweats	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Papule	1 (1.3)	1 (1.3)	0	0	0
Photosensitivity reaction	1 (1.3)	0	1 (1.3)	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash erythematous	1 (1.3)	1 (1.3)	0	0	0
Rash macular	1 (1.3)	0	0	1 (1.3)	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin hypopigmentation	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Skin swelling	1 (1.3)	1 (1.3)	0	0	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					
-Total	34 (43.0)	5 (6.3)	8 (10.1)	12 (15.2)	9 (11.4)
Hypotension	24 (30.4)	2 (2.5)	6 (7.6)	8 (10.1)	8 (10.1)
Hypertension	16 (20.3)	4 (5.1)	7 (8.9)	5 (6.3)	0
Capillary leak syndrome	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Venoocclusive disease	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Constipation	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	1 (100)	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dermatitis atopic	1 (100)	1 (100)	0	0	0
Rash vesicular	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (98.7)	4 (5.1)	8 (10.1)	21 (26.6)	45 (57.0)
Blood and lymphatic system disorders					
-Total	50 (63.3)	3 (3.8)	8 (10.1)	26 (32.9)	13 (16.5)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
Anaemia	21 (26.6)	5 (6.3)	8 (10.1)	8 (10.1)	0
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Disseminated intravascular coagulation	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Coagulopathy	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					
-Total	24 (30.4)	10 (12.7)	6 (7.6)	5 (6.3)	3 (3.8)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Sinus tachycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Ear and labyrinth disorders					
-Total	2 (2.5)	2 (2.5)	0	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					
-Total	5 (6.3)	0	5 (6.3)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eyelid oedema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Ocular hyperaemia	2 (2.5)	2 (2.5)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Visual impairment	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	50 (63.3)	19 (24.1)	17 (21.5)	13 (16.5)	1 (1.3)
Vomiting	21 (26.6)	12 (15.2)	8 (10.1)	1 (1.3)	0
Nausea	18 (22.8)	10 (12.7)	6 (7.6)	2 (2.5)	0
Diarrhoea	15 (19.0)	8 (10.1)	6 (7.6)	1 (1.3)	0
Abdominal pain	11 (13.9)	3 (3.8)	6 (7.6)	2 (2.5)	0
Constipation	10 (12.7)	6 (7.6)	4 (5.1)	0	0
Mouth haemorrhage	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.5)	0
Pancreatitis	4 (5.1)	0	3 (3.8)	1 (1.3)	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Abdominal pain upper	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Stomatitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
Trichoglossia	1 (1.3)	0	1 (1.3)	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	40 (50.6)	20 (25.3)	9 (11.4)	7 (8.9)	4 (5.1)
Pyrexia	24 (30.4)	11 (13.9)	5 (6.3)	6 (7.6)	2 (2.5)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Chills	6 (7.6)	4 (5.1)	2 (2.5)	0	0
Oedema peripheral	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Asthenia	2 (2.5)	2 (2.5)	0	0	0
Catheter site pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.5)	2 (2.5)	0	0	0
Multiple organ dysfunction syndrome	2 (2.5)	0	0	0	2 (2.5)
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Malaise	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Pain	1 (1.3)	0	0	1 (1.3)	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	17 (21.5)	5 (6.3)	6 (7.6)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	66 (83.5)	3 (3.8)	20 (25.3)	22 (27.8)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	22 (27.8)	2 (2.5)	13 (16.5)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	35 (44.3)	6 (7.6)	10 (12.7)	16 (20.3)	3 (3.8)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.5)	2 (2.5)	0	0	0
Oral herpes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	11 (13.9)	3 (3.8)	6 (7.6)	0	2 (2.5)
Fall	2 (2.5)	0	2 (2.5)	0	0
Infusion related reaction	2 (2.5)	0	2 (2.5)	0	0
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Contusion	1 (1.3)	1 (1.3)	0	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin abrasion	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					
-Total	56 (70.9)	4 (5.1)	8 (10.1)	17 (21.5)	27 (34.2)
White blood cell count decreased	23 (29.1)	3 (3.8)	3 (3.8)	1 (1.3)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Neutrophil count decreased	19 (24.1)	0	3 (3.8)	2 (2.5)	14 (17.7)
Alanine aminotransferase increased	18 (22.8)	4 (5.1)	8 (10.1)	6 (7.6)	0
Lymphocyte count decreased	14 (17.7)	2 (2.5)	0	7 (8.9)	5 (6.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	12 (15.2)	1 (1.3)	2 (2.5)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Blood fibrinogen decreased	7 (8.9)	2 (2.5)	3 (3.8)	1 (1.3)	1 (1.3)
Activated partial thromboplastin time prolonged	6 (7.6)	3 (3.8)	2 (2.5)	1 (1.3)	0
Blood immunoglobulin m decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin a decreased	5 (6.3)	4 (5.1)	1 (1.3)	0	0
Electrocardiogram qt prolonged	5 (6.3)	1 (1.3)	2 (2.5)	1 (1.3)	1 (1.3)
Blood creatinine increased	4 (5.1)	1 (1.3)	0	2 (2.5)	1 (1.3)
Blood lactate dehydrogenase increased	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Weight increased	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
Fibrin d dimer increased	3 (3.8)	2 (2.5)	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Blood uric acid increased	2 (2.5)	2 (2.5)	0	0	0
Gamma-glutamyltransferase increased	2 (2.5)	0	0	2 (2.5)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Oxygen saturation decreased	1 (1.3)	1 (1.3)	0	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0
Weight decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	46 (58.2)	8 (10.1)	9 (11.4)	21 (26.6)	8 (10.1)
Decreased appetite	24 (30.4)	9 (11.4)	4 (5.1)	10 (12.7)	1 (1.3)
Hypokalaemia	19 (24.1)	3 (3.8)	5 (6.3)	9 (11.4)	2 (2.5)
Hypophosphataemia	17 (21.5)	3 (3.8)	5 (6.3)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	8 (10.1)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Hypervolaemia	6 (7.6)	0	2 (2.5)	4 (5.1)	0
Hypomagnesaemia	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.3)	4 (5.1)	0	0	1 (1.3)
Tumour lysis syndrome	4 (5.1)	0	0	4 (5.1)	0
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Metabolic acidosis	3 (3.8)	1 (1.3)	0	0	2 (2.5)
Acidosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hyperkalaemia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Hypernatraemia	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Hypertriglyceridaemia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Malnutrition	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	33 (41.8)	15 (19.0)	13 (16.5)	4 (5.1)	1 (1.3)
Pain in extremity	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Arthralgia	10 (12.7)	4 (5.1)	5 (6.3)	1 (1.3)	0
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Back pain	6 (7.6)	2 (2.5)	3 (3.8)	1 (1.3)	0
Bone pain	2 (2.5)	0	2 (2.5)	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (1.3)	1 (1.3)	0	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Neck pain	1 (1.3)	0	1 (1.3)	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Nervous system disorders					
-Total	40 (50.6)	14 (17.7)	16 (20.3)	8 (10.1)	2 (2.5)
Headache	23 (29.1)	12 (15.2)	9 (11.4)	2 (2.5)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Dizziness	3 (3.8)	3 (3.8)	0	0	0
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	28 (35.4)	12 (15.2)	10 (12.7)	6 (7.6)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Anxiety	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Agitation	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Insomnia	4 (5.1)	2 (2.5)	2 (2.5)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Sleep disorder	2 (2.5)	0	2 (2.5)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	20 (25.3)	5 (6.3)	6 (7.6)	3 (3.8)	6 (7.6)
Acute kidney injury	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Dysuria	3 (3.8)	3 (3.8)	0	0	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Haematuria	2 (2.5)	2 (2.5)	0	0	0
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal failure	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	41 (51.9)	14 (17.7)	4 (5.1)	11 (13.9)	12 (15.2)
Hypoxia	17 (21.5)	0	5 (6.3)	6 (7.6)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Cough	10 (12.7)	9 (11.4)	1 (1.3)	0	0
Tachypnoea	8 (10.1)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	7 (8.9)	4 (5.1)	0	2 (2.5)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0	0	0
Epistaxis	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
Respiratory failure	4 (5.1)	0	0	0	4 (5.1)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Dyspnoea	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Respiratory distress	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Acute respiratory distress syndrome	2 (2.5)	0	0	0	2 (2.5)
Rhinorrhoea	2 (2.5)	2 (2.5)	0	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal erythema	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	26 (32.9)	12 (15.2)	11 (13.9)	3 (3.8)	0
Pruritus	6 (7.6)	2 (2.5)	4 (5.1)	0	0
Rash	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Erythema	4 (5.1)	4 (5.1)	0	0	0
Blister	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rash papular	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Rash maculo-papular	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Skin ulcer	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Decubitus ulcer	1 (1.3)	0	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis atopic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Eczema	1 (1.3)	1 (1.3)	0	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin discolouration	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					

Timing: within 8 weeks post infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	28 (35.4)	4 (5.1)	7 (8.9)	11 (13.9)	6 (7.6)
Hypotension	21 (26.6)	1 (1.3)	6 (7.6)	8 (10.1)	6 (7.6)
Hypertension	13 (16.5)	4 (5.1)	5 (6.3)	4 (5.1)	0
Capillary leak syndrome	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Cystitis	1 (100)	0	1 (100)	0	0
Nasopharyngitis	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	0	0	1 (100)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dermatitis atopic	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (91.9)	9 (12.2)	24 (32.4)	15 (20.3)	20 (27.0)
Blood and lymphatic system disorders					
-Total	17 (23.0)	3 (4.1)	4 (5.4)	6 (8.1)	4 (5.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	7 (9.5)	3 (4.1)	1 (1.4)	0	3 (4.1)
Cardiac arrest	2 (2.7)	0	0	0	2 (2.7)
Cardiac failure	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Left ventricular dysfunction	1 (1.4)	0	1 (1.4)	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	4 (5.4)	4 (5.4)	0	0	0
Cataract	2 (2.7)	2 (2.7)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	20 (27.0)	13 (17.6)	6 (8.1)	1 (1.4)	0
Diarrhoea	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Vomiting	6 (8.1)	6 (8.1)	0	0	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pancreatitis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Abdominal pain upper	1 (1.4)	1 (1.4)	0	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	24 (32.4)	15 (20.3)	6 (8.1)	3 (4.1)	0
Pyrexia	15 (20.3)	7 (9.5)	6 (8.1)	2 (2.7)	0
Fatigue	6 (8.1)	6 (8.1)	0	0	0
Pain	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	1 (1.4)	0	0	0
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (21.6)	1 (1.4)	11 (14.9)	4 (5.4)	0
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)	0	0
Allergy to immunoglobulin therapy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Graft versus host disease	2 (2.7)	0	0	2 (2.7)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	38 (51.4)	5 (6.8)	13 (17.6)	12 (16.2)	8 (10.8)
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Infusion related reaction	3 (4.1)	2 (2.7)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Ligament sprain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	29 (39.2)	7 (9.5)	7 (9.5)	11 (14.9)	4 (5.4)
Neutrophil count decreased	9 (12.2)	2 (2.7)	1 (1.4)	3 (4.1)	3 (4.1)
White blood cell count decreased	9 (12.2)	4 (5.4)	2 (2.7)	2 (2.7)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Platelet count decreased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Blood lactate dehydrogenase increased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
C-reactive protein increased	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Weight decreased	1 (1.4)	0	0	1 (1.4)	0
Weight increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (20.3)	4 (5.4)	4 (5.4)	4 (5.4)	3 (4.1)
Decreased appetite	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	15 (20.3)	5 (6.8)	7 (9.5)	3 (4.1)	0
Back pain	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Bone pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Growth retardation	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	14 (18.9)	7 (9.5)	5 (6.8)	0	2 (2.7)
Headache	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	10 (13.5)	1 (1.4)	8 (10.8)	1 (1.4)	0
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	0	0	1 (1.4)	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	23 (31.1)	10 (13.5)	7 (9.5)	3 (4.1)	3 (4.1)
Cough	10 (13.5)	7 (9.5)	3 (4.1)	0	0
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Epistaxis	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (4.1)	3 (4.1)	0	0	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinitis allergic	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (25.7)	11 (14.9)	7 (9.5)	1 (1.4)	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Rash	4 (5.4)	3 (4.1)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	2 (2.7)	0	2 (2.7)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	6 (8.1)	1 (1.4)	0	2 (2.7)	3 (4.1)
Hypotension	4 (5.4)	1 (1.4)	0	1 (1.4)	2 (2.7)
Venoocclusive disease	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

		All patients N=1			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	1 (100)	0	0
Lymphadenopathy	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Bronchitis	1 (100)	0	1 (100)	0	0
Gastroenteritis	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (63.3)	3 (6.1)	9 (18.4)	12 (24.5)	7 (14.3)
Blood and lymphatic system disorders					
-Total	3 (6.1)	0	1 (2.0)	1 (2.0)	1 (2.0)
Agranulocytosis	1 (2.0)	0	0	1 (2.0)	0
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Hypercoagulation	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral cavernous malformation	1 (2.0)	1 (2.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Deafness unilateral	1 (2.0)	0	1 (2.0)	0	0
Endocrine disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Delayed puberty	1 (2.0)	0	1 (2.0)	0	0
Hypothyroidism	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	3 (6.1)	1 (2.0)	1 (2.0)	1 (2.0)	0
Dry eye	1 (2.0)	1 (2.0)	0	0	0
Eye pain	1 (2.0)	0	0	1 (2.0)	0
Eyelid oedema	1 (2.0)	1 (2.0)	0	0	0
Mydriasis	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	7 (14.3)	4 (8.2)	2 (4.1)	1 (2.0)	0
Diarrhoea	5 (10.2)	3 (6.1)	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.0)	1 (2.0)	0	0	0
Irritable bowel syndrome	1 (2.0)	0	1 (2.0)	0	0
Nausea	1 (2.0)	1 (2.0)	0	0	0
Vomiting	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	9 (18.4)	4 (8.2)	3 (6.1)	1 (2.0)	1 (2.0)
Pyrexia	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Pain	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Fatigue	1 (2.0)	0	1 (2.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	0	0	1 (2.0)
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0
Xerosis	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	9 (18.4)	2 (4.1)	5 (10.2)	1 (2.0)	1 (2.0)
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)	0	0
Seasonal allergy	3 (6.1)	2 (4.1)	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Drug hypersensitivity	1 (2.0)	0	0	1 (2.0)	0
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Infections and infestations					
-Total	22 (44.9)	2 (4.1)	6 (12.2)	10 (20.4)	4 (8.2)
Sinusitis	6 (12.2)	0	6 (12.2)	0	0
Upper respiratory tract infection	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)	0	0
Rhinovirus infection	4 (8.2)	0	3 (6.1)	1 (2.0)	0
Sepsis	3 (6.1)	0	0	1 (2.0)	2 (4.1)
Skin infection	3 (6.1)	0	3 (6.1)	0	0
Covid-19	2 (4.1)	1 (2.0)	0	1 (2.0)	0
Fungal infection	2 (4.1)	0	2 (4.1)	0	0
Herpes zoster	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Influenza	2 (4.1)	0	1 (2.0)	0	1 (2.0)
Oral herpes	2 (4.1)	1 (2.0)	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	2 (4.1)	0	2 (4.1)	0	0
Pneumonia	2 (4.1)	0	0	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.1)	0	2 (4.1)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Bronchiolitis	1 (2.0)	0	0	1 (2.0)	0
Bronchitis	1 (2.0)	0	1 (2.0)	0	0
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Folliculitis	1 (2.0)	0	1 (2.0)	0	0
Fungal skin infection	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis viral	1 (2.0)	0	1 (2.0)	0	0
Herpes virus infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	0	1 (2.0)	0	0
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Streptococcal sepsis	1 (2.0)	0	1 (2.0)	0	0
Syphilis	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection pseudomonal	1 (2.0)	0	1 (2.0)	0	0
Varicella zoster virus infection	1 (2.0)	0	1 (2.0)	0	0
Viral skin infection	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (6.1)	2 (4.1)	0	1 (2.0)	0
Abdominal injury	1 (2.0)	1 (2.0)	0	0	0
Infusion related reaction	1 (2.0)	0	0	1 (2.0)	0
Ligament sprain	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	5 (10.2)	2 (4.1)	1 (2.0)	1 (2.0)	1 (2.0)
Neutrophil count decreased	3 (6.1)	2 (4.1)	0	0	1 (2.0)
Blood bilirubin increased	1 (2.0)	1 (2.0)	0	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Oxygen saturation decreased	1 (2.0)	0	0	1 (2.0)	0
Platelet count decreased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (12.2)	0	2 (4.1)	3 (6.1)	1 (2.0)
Decreased appetite	1 (2.0)	0	0	0	1 (2.0)
Hypercholesterolaemia	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Hyperlipidaemia	1 (2.0)	0	1 (2.0)	0	0
Hypernatraemia	1 (2.0)	0	0	1 (2.0)	0
Hypertriglyceridaemia	1 (2.0)	0	1 (2.0)	0	0
Iron overload	1 (2.0)	0	1 (2.0)	0	0
Obesity	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (14.3)	2 (4.1)	5 (10.2)	0	0
Pain in extremity	2 (4.1)	0	2 (4.1)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Growth retardation	1 (2.0)	0	1 (2.0)	0	0
Joint effusion	1 (2.0)	0	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	1 (2.0)	0	0	0
Osteopenia	1 (2.0)	1 (2.0)	0	0	0
Synovitis	1 (2.0)	0	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	0	0	1 (2.0)	0
Bone giant cell tumour benign	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					
-Total	4 (8.2)	0	2 (4.1)	2 (4.1)	0
Headache	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Dysarthria	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorder	1 (2.0)	0	0	1 (2.0)	0
Seizure	1 (2.0)	0	0	1 (2.0)	0
Psychiatric disorders					
-Total	3 (6.1)	1 (2.0)	2 (4.1)	0	0
Anxiety	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Tic	1 (2.0)	0	1 (2.0)	0	0
Reproductive system and breast disorders					
-Total	1 (2.0)	0	0	1 (2.0)	0
Endometriosis	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (20.4)	4 (8.2)	2 (4.1)	1 (2.0)	3 (6.1)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	4 (8.2)	3 (6.1)	1 (2.0)	0	0
Dyspnoea	3 (6.1)	1 (2.0)	1 (2.0)	0	1 (2.0)
Rhinorrhoea	3 (6.1)	1 (2.0)	2 (4.1)	0	0
Sleep apnoea syndrome	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Dyspnoea exertional	1 (2.0)	1 (2.0)	0	0	0
Epistaxis	1 (2.0)	1 (2.0)	0	0	0
Hypoxia	1 (2.0)	0	0	1 (2.0)	0
Laryngeal oedema	1 (2.0)	0	0	0	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Pharyngeal erythema	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Tachypnoea	1 (2.0)	0	0	0	1 (2.0)
Wheezing	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (14.3)	3 (6.1)	1 (2.0)	3 (6.1)	0
Rash	2 (4.1)	1 (2.0)	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=49 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dermatitis atopic	1 (2.0)	0	0	1 (2.0)	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Eczema	1 (2.0)	0	0	1 (2.0)	0
Papule	1 (2.0)	1 (2.0)	0	0	0
Rash erythematous	1 (2.0)	1 (2.0)	0	0	0
Rash macular	1 (2.0)	0	0	1 (2.0)	0
Rash maculo-papular	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Hypertension	2 (4.1)	0	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Blood and lymphatic system disorders					
-Total	1 (100)	0	1 (100)	0	0
Lymphadenopathy	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Constipation	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (100)	0	1 (100)	0	0
Bronchitis	1 (100)	0	1 (100)	0	0
Cystitis	1 (100)	0	1 (100)	0	0
Gastroenteritis	1 (100)	1 (100)	0	0	0
Nasopharyngitis	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	1 (100)	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dermatitis atopic	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash vesicular	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	1 (1.3)	6 (7.6)	19 (24.1)	53 (67.1)
Blood and lymphatic system disorders					
-Total	54 (68.4)	1 (1.3)	10 (12.7)	29 (36.7)	14 (17.7)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	25 (31.6)	7 (8.9)	9 (11.4)	9 (11.4)	0
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Disseminated intravascular coagulation	8 (10.1)	0	5 (6.3)	3 (3.8)	0
Coagulopathy	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphopenia	2 (2.5)	0	0	2 (2.5)	0
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypercoagulation	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Leukocytosis	1 (1.3)	0	1 (1.3)	0	0
Lymphadenopathy	1 (1.3)	1 (1.3)	0	0	0
Lymphocytosis	1 (1.3)	0	1 (1.3)	0	0
Cardiac disorders					
-Total	28 (35.4)	10 (12.7)	7 (8.9)	5 (6.3)	6 (7.6)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Left ventricular dysfunction	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac arrest	3 (3.8)	0	0	0	3 (3.8)
Cardiac failure	3 (3.8)	0	0	1 (1.3)	2 (2.5)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Tricuspid valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.3)	1 (1.3)	0	0	0
Cerebral cavernous malformation	1 (1.3)	1 (1.3)	0	0	0
Ear and labyrinth disorders					
-Total	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					
-Total	7 (8.9)	0	7 (8.9)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	3 (3.8)	0	3 (3.8)	0	0
Delayed puberty	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	15 (19.0)	10 (12.7)	4 (5.1)	1 (1.3)	0
Eyelid oedema	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Ocular hyperaemia	3 (3.8)	3 (3.8)	0	0	0
Cataract	2 (2.5)	2 (2.5)	0	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eye pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Visual impairment	2 (2.5)	2 (2.5)	0	0	0
Dry eye	1 (1.3)	1 (1.3)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Hypermetropia	1 (1.3)	1 (1.3)	0	0	0
Mydriasis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					
-Total	59 (74.7)	21 (26.6)	22 (27.8)	15 (19.0)	1 (1.3)
Diarrhoea	26 (32.9)	16 (20.3)	8 (10.1)	2 (2.5)	0
Vomiting	26 (32.9)	17 (21.5)	8 (10.1)	1 (1.3)	0
Nausea	22 (27.8)	12 (15.2)	8 (10.1)	2 (2.5)	0
Constipation	13 (16.5)	7 (8.9)	6 (7.6)	0	0
Abdominal pain	11 (13.9)	2 (2.5)	7 (8.9)	2 (2.5)	0
Pancreatitis	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Mouth haemorrhage	5 (6.3)	2 (2.5)	1 (1.3)	2 (2.5)	0
Abdominal pain upper	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Stomatitis	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Proctalgia	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Trichoglossia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Abdominal rigidity	1 (1.3)	0	1 (1.3)	0	0
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dyspepsia	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enteritis	1 (1.3)	0	1 (1.3)	0	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal inflammation	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Peritoneal haematoma	1 (1.3)	1 (1.3)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	53 (67.1)	25 (31.6)	13 (16.5)	10 (12.7)	5 (6.3)
Pyrexia	35 (44.3)	14 (17.7)	10 (12.7)	9 (11.4)	2 (2.5)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Chills	7 (8.9)	5 (6.3)	2 (2.5)	0	0
Oedema peripheral	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Pain	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Asthenia	3 (3.8)	3 (3.8)	0	0	0
Multiple organ dysfunction syndrome	3 (3.8)	0	0	0	3 (3.8)
Catheter site pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.5)	2 (2.5)	0	0	0
Malaise	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Non-cardiac chest pain	2 (2.5)	2 (2.5)	0	0	0
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Xerosis	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	19 (24.1)	6 (7.6)	7 (8.9)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic cytolysis	1 (1.3)	1 (1.3)	0	0	0
Liver disorder	1 (1.3)	0	1 (1.3)	0	0
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	70 (88.6)	2 (2.5)	22 (27.8)	24 (30.4)	22 (27.8)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	32 (40.5)	2 (2.5)	23 (29.1)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Seasonal allergy	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Allergy to immunoglobulin therapy	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Chronic graft versus host disease	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Graft versus host disease	2 (2.5)	0	0	2 (2.5)	0
Engraftment syndrome	1 (1.3)	0	0	1 (1.3)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	59 (74.7)	8 (10.1)	12 (15.2)	25 (31.6)	14 (17.7)
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Sinusitis	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Nasopharyngitis	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Pneumonia	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Gastroenteritis	5 (6.3)	3 (3.8)	0	2 (2.5)	0
Otitis media	5 (6.3)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Staphylococcal infection	5 (6.3)	0	3 (3.8)	2 (2.5)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	4 (5.1)	1 (1.3)	2 (2.5)	1 (1.3)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Respiratory syncytial virus infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.5)	2 (2.5)	0	0	0
Herpes simplex	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Paronychia	2 (2.5)	0	2 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Bronchitis	1 (1.3)	0	1 (1.3)	0	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	21 (26.6)	9 (11.4)	9 (11.4)	1 (1.3)	2 (2.5)
Infusion related reaction	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Contusion	2 (2.5)	2 (2.5)	0	0	0
Fall	2 (2.5)	0	2 (2.5)	0	0
Ligament sprain	2 (2.5)	2 (2.5)	0	0	0
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Skin abrasion	2 (2.5)	2 (2.5)	0	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Abdominal injury	1 (1.3)	1 (1.3)	0	0	0
Fibula fracture	1 (1.3)	0	1 (1.3)	0	0
Limb injury	1 (1.3)	0	1 (1.3)	0	0
Post-traumatic neck syndrome	1 (1.3)	0	1 (1.3)	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					
-Total	59 (74.7)	3 (3.8)	9 (11.4)	19 (24.1)	28 (35.4)
White blood cell count decreased	24 (30.4)	3 (3.8)	4 (5.1)	1 (1.3)	16 (20.3)
Neutrophil count decreased	23 (29.1)	1 (1.3)	2 (2.5)	4 (5.1)	16 (20.3)
Platelet count decreased	23 (29.1)	5 (6.3)	3 (3.8)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	3 (3.8)	8 (10.1)	7 (8.9)	0
Lymphocyte count decreased	16 (20.3)	1 (1.3)	1 (1.3)	9 (11.4)	5 (6.3)
Blood bilirubin increased	13 (16.5)	1 (1.3)	3 (3.8)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	7 (8.9)	2 (2.5)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin a decreased	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (8.9)	4 (5.1)	1 (1.3)	2 (2.5)	0
Activated partial thromboplastin time prolonged	6 (7.6)	3 (3.8)	2 (2.5)	1 (1.3)	0
Blood creatinine increased	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Blood lactate dehydrogenase increased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	5 (6.3)	2 (2.5)	0	3 (3.8)	0
Electrocardiogram qt prolonged	5 (6.3)	1 (1.3)	2 (2.5)	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Blood uric acid increased	4 (5.1)	2 (2.5)	0	1 (1.3)	1 (1.3)
Weight increased	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.5)	0
Fibrin d dimer increased	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Oxygen saturation decreased	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Gamma-glutamyltransferase increased	2 (2.5)	0	0	2 (2.5)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Weight decreased	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.3)	1 (1.3)	0	0	0
Blood urea increased	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone density decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Ejection fraction decreased	1 (1.3)	0	1 (1.3)	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Heart sounds abnormal	1 (1.3)	1 (1.3)	0	0	0
Hepatitis b virus test positive	1 (1.3)	0	1 (1.3)	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	52 (65.8)	9 (11.4)	10 (12.7)	22 (27.8)	11 (13.9)
Decreased appetite	30 (38.0)	11 (13.9)	7 (8.9)	10 (12.7)	2 (2.5)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	20 (25.3)	3 (3.8)	6 (7.6)	9 (11.4)	2 (2.5)
Hypophosphataemia	18 (22.8)	3 (3.8)	6 (7.6)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	9 (11.4)	0	4 (5.1)	5 (6.3)	0
Hyperuricaemia	9 (11.4)	7 (8.9)	1 (1.3)	1 (1.3)	0
Hypervolaemia	7 (8.9)	0	2 (2.5)	5 (6.3)	0
Hypomagnesaemia	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.3)	4 (5.1)	0	0	1 (1.3)
Tumour lysis syndrome	5 (6.3)	0	0	4 (5.1)	1 (1.3)
Metabolic acidosis	4 (5.1)	1 (1.3)	0	0	3 (3.8)
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Hyperkalaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hypernatraemia	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Hypertriglyceridaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Acidosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hyperchloraemia	2 (2.5)	2 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Iron overload	2 (2.5)	0	2 (2.5)	0	0
Malnutrition	2 (2.5)	0	0	2 (2.5)	0
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemochromatosis	1 (1.3)	0	0	1 (1.3)	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hypercholesterolaemia	1 (1.3)	0	1 (1.3)	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlipidaemia	1 (1.3)	0	1 (1.3)	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Hypophagia	1 (1.3)	0	1 (1.3)	0	0
Metabolic syndrome	1 (1.3)	0	1 (1.3)	0	0
Obesity	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	44 (55.7)	17 (21.5)	19 (24.1)	7 (8.9)	1 (1.3)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	17 (21.5)	8 (10.1)	8 (10.1)	1 (1.3)	0
Arthralgia	12 (15.2)	5 (6.3)	6 (7.6)	1 (1.3)	0
Back pain	10 (12.7)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)	0	0
Bone pain	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Growth retardation	2 (2.5)	0	2 (2.5)	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Musculoskeletal chest pain	2 (2.5)	2 (2.5)	0	0	0
Neck pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Joint effusion	1 (1.3)	0	1 (1.3)	0	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal pain	1 (1.3)	0	1 (1.3)	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Osteonecrosis	1 (1.3)	1 (1.3)	0	0	0
Osteopenia	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Synovitis	1 (1.3)	0	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Bone giant cell tumour benign	1 (1.3)	0	0	1 (1.3)	0
Cancer pain	1 (1.3)	0	1 (1.3)	0	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	47 (59.5)	15 (19.0)	18 (22.8)	10 (12.7)	4 (5.1)
Headache	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Dizziness	4 (5.1)	4 (5.1)	0	0	0
Seizure	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cerebral haemorrhage	2 (2.5)	0	0	0	2 (2.5)
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Autonomic neuropathy	1 (1.3)	0	0	1 (1.3)	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Extrapyramidal disorder	1 (1.3)	0	1 (1.3)	0	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hydrocephalus	1 (1.3)	0	0	0	1 (1.3)
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Migraine	1 (1.3)	0	1 (1.3)	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorder	1 (1.3)	0	0	1 (1.3)	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	39 (49.4)	13 (16.5)	19 (24.1)	7 (8.9)	0
Anxiety	14 (17.7)	3 (3.8)	9 (11.4)	2 (2.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Agitation	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Mental status changes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Insomnia	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Sleep disorder	3 (3.8)	0	3 (3.8)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Nightmare	1 (1.3)	1 (1.3)	0	0	0
Persistent depressive disorder	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tearfulness	1 (1.3)	1 (1.3)	0	0	0
Tic	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	25 (31.6)	6 (7.6)	7 (8.9)	5 (6.3)	7 (8.9)
Acute kidney injury	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Dysuria	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Haematuria	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal failure	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Kidney enlargement	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal mass	1 (1.3)	0	1 (1.3)	0	0
Renal tubular disorder	1 (1.3)	0	0	1 (1.3)	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	6 (7.6)	2 (2.5)	2 (2.5)	2 (2.5)	0
Dysmenorrhoea	1 (1.3)	0	1 (1.3)	0	0
Endometriosis	1 (1.3)	0	0	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	54 (68.4)	17 (21.5)	8 (10.1)	12 (15.2)	17 (21.5)
Cough	22 (27.8)	17 (21.5)	5 (6.3)	0	0
Hypoxia	20 (25.3)	0	4 (5.1)	10 (12.7)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)	0	0
Pleural effusion	9 (11.4)	4 (5.1)	2 (2.5)	2 (2.5)	1 (1.3)
Tachypnoea	9 (11.4)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)	0	0
Dyspnoea	7 (8.9)	1 (1.3)	2 (2.5)	2 (2.5)	2 (2.5)
Epistaxis	7 (8.9)	4 (5.1)	2 (2.5)	1 (1.3)	0
Respiratory failure	6 (7.6)	0	0	0	6 (7.6)
Rhinorrhoea	6 (7.6)	4 (5.1)	2 (2.5)	0	0
Respiratory distress	4 (5.1)	0	2 (2.5)	0	2 (2.5)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	3 (3.8)	0	0	0	3 (3.8)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Pharyngeal erythema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Rhinitis allergic	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Sleep apnoea syndrome	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wheezing	2 (2.5)	0	2 (2.5)	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Bronchial oedema	1 (1.3)	1 (1.3)	0	0	0
Bronchospasm	1 (1.3)	0	1 (1.3)	0	0
Dyspnoea exertional	1 (1.3)	1 (1.3)	0	0	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Laryngeal oedema	1 (1.3)	0	0	0	1 (1.3)
Lung disorder	1 (1.3)	1 (1.3)	0	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Paranasal sinus inflammation	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Upper respiratory tract inflammation	1 (1.3)	0	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	39 (49.4)	16 (20.3)	16 (20.3)	7 (8.9)	0
Dry skin	8 (10.1)	6 (7.6)	2 (2.5)	0	0
Rash	8 (10.1)	4 (5.1)	4 (5.1)	0	0
Pruritus	7 (8.9)	2 (2.5)	5 (6.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	5 (6.3)	4 (5.1)	1 (1.3)	0	0
Blister	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Eczema	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rash maculo-papular	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Rash papular	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Decubitus ulcer	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Dermatitis atopic	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Ingrowing nail	2 (2.5)	0	2 (2.5)	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Skin discolouration	2 (2.5)	2 (2.5)	0	0	0
Skin ulcer	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis allergic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0
Hangnail	1 (1.3)	1 (1.3)	0	0	0
Miliaria	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Night sweats	1 (1.3)	1 (1.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Papule	1 (1.3)	1 (1.3)	0	0	0
Photosensitivity reaction	1 (1.3)	0	1 (1.3)	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash erythematous	1 (1.3)	1 (1.3)	0	0	0
Rash macular	1 (1.3)	0	0	1 (1.3)	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin hypopigmentation	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Skin swelling	1 (1.3)	1 (1.3)	0	0	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					
-Total	34 (43.0)	5 (6.3)	8 (10.1)	12 (15.2)	9 (11.4)
Hypotension	24 (30.4)	2 (2.5)	6 (7.6)	8 (10.1)	8 (10.1)
Hypertension	16 (20.3)	4 (5.1)	7 (8.9)	5 (6.3)	0
Capillary leak syndrome	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Venoocclusive disease	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
General disorders and administration site conditions					
-Total	1 (100)	1 (100)	0	0	0
Pyrexia	1 (100)	1 (100)	0	0	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Gamma-glutamyltransferase increased	1 (100)	0	0	1 (100)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (98.7)	4 (5.1)	8 (10.1)	20 (25.3)	46 (58.2)
Blood and lymphatic system disorders					
-Total	50 (63.3)	3 (3.8)	8 (10.1)	26 (32.9)	13 (16.5)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
Anaemia	21 (26.6)	5 (6.3)	8 (10.1)	8 (10.1)	0
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Disseminated intravascular coagulation	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Coagulopathy	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Lymphopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					
-Total	24 (30.4)	10 (12.7)	6 (7.6)	5 (6.3)	3 (3.8)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Sinus tachycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure	1 (1.3)	0	0	0	1 (1.3)
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Ear and labyrinth disorders					
-Total	2 (2.5)	2 (2.5)	0	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					
-Total	5 (6.3)	0	5 (6.3)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eyelid oedema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Ocular hyperaemia	2 (2.5)	2 (2.5)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Visual impairment	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	51 (64.6)	19 (24.1)	18 (22.8)	13 (16.5)	1 (1.3)
Vomiting	21 (26.6)	12 (15.2)	8 (10.1)	1 (1.3)	0
Nausea	18 (22.8)	10 (12.7)	6 (7.6)	2 (2.5)	0
Diarrhoea	15 (19.0)	8 (10.1)	6 (7.6)	1 (1.3)	0
Abdominal pain	11 (13.9)	3 (3.8)	6 (7.6)	2 (2.5)	0
Constipation	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Mouth haemorrhage	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.5)	0
Pancreatitis	4 (5.1)	0	3 (3.8)	1 (1.3)	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Abdominal pain upper	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Stomatitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
Trichoglossia	1 (1.3)	0	1 (1.3)	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	39 (49.4)	19 (24.1)	9 (11.4)	7 (8.9)	4 (5.1)
Pyrexia	23 (29.1)	10 (12.7)	5 (6.3)	6 (7.6)	2 (2.5)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Chills	6 (7.6)	4 (5.1)	2 (2.5)	0	0
Oedema peripheral	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Asthenia	2 (2.5)	2 (2.5)	0	0	0
Catheter site pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.5)	2 (2.5)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	2 (2.5)	0	0	0	2 (2.5)
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Malaise	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Pain	1 (1.3)	0	0	1 (1.3)	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	17 (21.5)	5 (6.3)	6 (7.6)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	67 (84.8)	3 (3.8)	21 (26.6)	22 (27.8)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	23 (29.1)	2 (2.5)	14 (17.7)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Immunodeficiency	3 (3.8)	0	0	3 (3.8)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	34 (43.0)	6 (7.6)	9 (11.4)	16 (20.3)	3 (3.8)
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Staphylococcal infection	4 (5.1)	0	2 (2.5)	2 (2.5)	0
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Nail infection	2 (2.5)	2 (2.5)	0	0	0
Oral herpes	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	1 (1.3)	0	0	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	0	0	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Oral candidiasis	1 (1.3)	0	1 (1.3)	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Pneumonia	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Varicella zoster virus infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	11 (13.9)	3 (3.8)	6 (7.6)	0	2 (2.5)
Fall	2 (2.5)	0	2 (2.5)	0	0
Infusion related reaction	2 (2.5)	0	2 (2.5)	0	0
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Contusion	1 (1.3)	1 (1.3)	0	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin abrasion	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	56 (70.9)	4 (5.1)	8 (10.1)	16 (20.3)	28 (35.4)
White blood cell count decreased	24 (30.4)	3 (3.8)	3 (3.8)	2 (2.5)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Neutrophil count decreased	20 (25.3)	0	3 (3.8)	2 (2.5)	15 (19.0)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	4 (5.1)	8 (10.1)	6 (7.6)	0
Lymphocyte count decreased	15 (19.0)	2 (2.5)	0	8 (10.1)	5 (6.3)
Blood bilirubin increased	12 (15.2)	1 (1.3)	2 (2.5)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Blood fibrinogen decreased	7 (8.9)	2 (2.5)	3 (3.8)	1 (1.3)	1 (1.3)
Activated partial thromboplastin time prolonged	6 (7.6)	3 (3.8)	2 (2.5)	1 (1.3)	0
Blood immunoglobulin m decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (6.3)	4 (5.1)	1 (1.3)	0	0
Electrocardiogram qt prolonged	5 (6.3)	1 (1.3)	2 (2.5)	1 (1.3)	1 (1.3)
Blood creatinine increased	4 (5.1)	1 (1.3)	0	2 (2.5)	1 (1.3)
Blood lactate dehydrogenase increased	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Weight increased	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
Fibrin d dimer increased	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Blood uric acid increased	2 (2.5)	2 (2.5)	0	0	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Gamma-glutamyltransferase increased	1 (1.3)	0	0	1 (1.3)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Oxygen saturation decreased	1 (1.3)	1 (1.3)	0	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	46 (58.2)	8 (10.1)	9 (11.4)	21 (26.6)	8 (10.1)
Decreased appetite	24 (30.4)	9 (11.4)	4 (5.1)	10 (12.7)	1 (1.3)
Hypokalaemia	19 (24.1)	3 (3.8)	5 (6.3)	9 (11.4)	2 (2.5)
Hypophosphataemia	17 (21.5)	3 (3.8)	5 (6.3)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	8 (10.1)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Hypervolaemia	6 (7.6)	0	2 (2.5)	4 (5.1)	0
Hypomagnesaemia	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.3)	4 (5.1)	0	0	1 (1.3)
Tumour lysis syndrome	4 (5.1)	0	0	4 (5.1)	0
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Metabolic acidosis	3 (3.8)	1 (1.3)	0	0	2 (2.5)
Acidosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Hypernatraemia	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Hypertriglyceridaemia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hyperchloraemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Malnutrition	1 (1.3)	0	0	1 (1.3)	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	33 (41.8)	15 (19.0)	13 (16.5)	4 (5.1)	1 (1.3)
Pain in extremity	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Arthralgia	10 (12.7)	4 (5.1)	5 (6.3)	1 (1.3)	0
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Back pain	6 (7.6)	2 (2.5)	3 (3.8)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	2 (2.5)	0	2 (2.5)	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal chest pain	1 (1.3)	1 (1.3)	0	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Neck pain	1 (1.3)	0	1 (1.3)	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Nervous system disorders					
-Total	40 (50.6)	14 (17.7)	16 (20.3)	8 (10.1)	2 (2.5)
Headache	23 (29.1)	12 (15.2)	9 (11.4)	2 (2.5)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Dizziness	3 (3.8)	3 (3.8)	0	0	0
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Seizure	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	28 (35.4)	12 (15.2)	10 (12.7)	6 (7.6)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Anxiety	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Agitation	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Insomnia	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Mental status changes	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Sleep disorder	2 (2.5)	0	2 (2.5)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	20 (25.3)	5 (6.3)	6 (7.6)	3 (3.8)	6 (7.6)
Acute kidney injury	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Dysuria	3 (3.8)	3 (3.8)	0	0	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	2 (2.5)	2 (2.5)	0	0	0
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal failure	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	41 (51.9)	14 (17.7)	4 (5.1)	11 (13.9)	12 (15.2)
Hypoxia	17 (21.5)	0	5 (6.3)	6 (7.6)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Cough	10 (12.7)	9 (11.4)	1 (1.3)	0	0
Tachypnoea	8 (10.1)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	7 (8.9)	4 (5.1)	0	2 (2.5)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0	0	0
Epistaxis	4 (5.1)	2 (2.5)	1 (1.3)	1 (1.3)	0
Respiratory failure	4 (5.1)	0	0	0	4 (5.1)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Dyspnoea	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Respiratory distress	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Acute respiratory distress syndrome	2 (2.5)	0	0	0	2 (2.5)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

		All patients N=79			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (2.5)	2 (2.5)	0	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal erythema	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Pruritus	6 (7.6)	2 (2.5)	4 (5.1)	0	0
Rash	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Erythema	4 (5.1)	4 (5.1)	0	0	0
Blister	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rash papular	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dermatitis atopic	2 (2.5)	2 (2.5)	0	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Rash maculo-papular	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Skin ulcer	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Decubitus ulcer	1 (1.3)	0	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Eczema	1 (1.3)	1 (1.3)	0	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin discolouration	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	28 (35.4)	4 (5.1)	7 (8.9)	11 (13.9)	6 (7.6)
Hypotension	21 (26.6)	1 (1.3)	6 (7.6)	8 (10.1)	6 (7.6)
Hypertension	13 (16.5)	4 (5.1)	5 (6.3)	4 (5.1)	0
Capillary leak syndrome	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=1			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Photosensitivity reaction	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (91.9)	9 (12.2)	23 (31.1)	15 (20.3)	21 (28.4)
Blood and lymphatic system disorders					
-Total	17 (23.0)	3 (4.1)	4 (5.4)	6 (8.1)	4 (5.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	7 (9.5)	3 (4.1)	1 (1.4)	0	3 (4.1)
Cardiac arrest	2 (2.7)	0	0	0	2 (2.7)
Cardiac failure	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Left ventricular dysfunction	1 (1.4)	0	1 (1.4)	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	4 (5.4)	4 (5.4)	0	0	0
Cataract	2 (2.7)	2 (2.7)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	20 (27.0)	13 (17.6)	6 (8.1)	1 (1.4)	0
Diarrhoea	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Vomiting	6 (8.1)	6 (8.1)	0	0	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pancreatitis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Abdominal pain upper	1 (1.4)	1 (1.4)	0	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	24 (32.4)	15 (20.3)	6 (8.1)	3 (4.1)	0
Pyrexia	15 (20.3)	7 (9.5)	6 (8.1)	2 (2.7)	0
Fatigue	6 (8.1)	6 (8.1)	0	0	0
Pain	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	1 (1.4)	0	0	0
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (21.6)	1 (1.4)	11 (14.9)	4 (5.4)	0
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)	0	0
Allergy to immunoglobulin therapy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Graft versus host disease	2 (2.7)	0	0	2 (2.7)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	39 (52.7)	5 (6.8)	14 (18.9)	12 (16.2)	8 (10.8)
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Metapneumovirus infection	3 (4.1)	0	0	3 (4.1)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pneumonia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Sinusitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Bacteraemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Ear infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Infusion related reaction	3 (4.1)	2 (2.7)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Ligament sprain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	30 (40.5)	7 (9.5)	7 (9.5)	11 (14.9)	5 (6.8)
Neutrophil count decreased	10 (13.5)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.4)
White blood cell count decreased	10 (13.5)	4 (5.4)	2 (2.7)	3 (4.1)	1 (1.4)
Platelet count decreased	5 (6.8)	3 (4.1)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Blood lactate dehydrogenase increased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
C-reactive protein increased	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Weight decreased	1 (1.4)	0	0	1 (1.4)	0
Weight increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (20.3)	4 (5.4)	4 (5.4)	4 (5.4)	3 (4.1)
Decreased appetite	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	15 (20.3)	5 (6.8)	7 (9.5)	3 (4.1)	0
Back pain	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Bone pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Growth retardation	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	14 (18.9)	7 (9.5)	5 (6.8)	0	2 (2.7)
Headache	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	10 (13.5)	1 (1.4)	8 (10.8)	1 (1.4)	0
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Mental status changes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	0	0	1 (1.4)	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	24 (32.4)	11 (14.9)	7 (9.5)	3 (4.1)	3 (4.1)
Cough	11 (14.9)	8 (10.8)	3 (4.1)	0	0
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Epistaxis	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (4.1)	3 (4.1)	0	0	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinitis allergic	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (25.7)	12 (16.2)	6 (8.1)	1 (1.4)	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Rash	4 (5.4)	3 (4.1)	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	2 (2.7)	0	2 (2.7)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	6 (8.1)	1 (1.4)	0	2 (2.7)	3 (4.1)
Hypotension	4 (5.4)	1 (1.4)	0	1 (1.4)	2 (2.7)
Venoocclusive disease	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

			All patients N=49		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (65.3)	3 (6.1)	10 (20.4)	12 (24.5)	7 (14.3)
Blood and lymphatic system disorders					
-Total	4 (8.2)	0	2 (4.1)	1 (2.0)	1 (2.0)
Agranulocytosis	1 (2.0)	0	0	1 (2.0)	0
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Hypercoagulation	1 (2.0)	0	1 (2.0)	0	0
Lymphadenopathy	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	1 (2.0)	0	0	0
Cerebral cavernous malformation	1 (2.0)	1 (2.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Deafness unilateral	1 (2.0)	0	1 (2.0)	0	0
Endocrine disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Delayed puberty	1 (2.0)	0	1 (2.0)	0	0
Hypothyroidism	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	3 (6.1)	1 (2.0)	1 (2.0)	1 (2.0)	0
Dry eye	1 (2.0)	1 (2.0)	0	0	0
Eye pain	1 (2.0)	0	0	1 (2.0)	0
Eyelid oedema	1 (2.0)	1 (2.0)	0	0	0
Mydriasis	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	7 (14.3)	4 (8.2)	2 (4.1)	1 (2.0)	0
Diarrhoea	5 (10.2)	3 (6.1)	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

			All patients N=49		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.0)	1 (2.0)	0	0	0
Irritable bowel syndrome	1 (2.0)	0	1 (2.0)	0	0
Nausea	1 (2.0)	1 (2.0)	0	0	0
Vomiting	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	9 (18.4)	4 (8.2)	3 (6.1)	1 (2.0)	1 (2.0)
Pyrexia	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Pain	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Fatigue	1 (2.0)	0	1 (2.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	0	0	1 (2.0)
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0
Xerosis	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	9 (18.4)	2 (4.1)	5 (10.2)	1 (2.0)	1 (2.0)
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)	0	0
Seasonal allergy	3 (6.1)	2 (4.1)	1 (2.0)	0	0
Chronic graft versus host disease	2 (4.1)	0	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

			All patients N=49		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug hypersensitivity	1 (2.0)	0	0	1 (2.0)	0
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	0	0	1 (2.0)
Infections and infestations					
-Total	23 (46.9)	2 (4.1)	7 (14.3)	10 (20.4)	4 (8.2)
Sinusitis	6 (12.2)	0	6 (12.2)	0	0
Upper respiratory tract infection	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)	0	0
Rhinovirus infection	4 (8.2)	0	3 (6.1)	1 (2.0)	0
Sepsis	3 (6.1)	0	0	1 (2.0)	2 (4.1)
Skin infection	3 (6.1)	0	3 (6.1)	0	0
Bronchitis	2 (4.1)	0	2 (4.1)	0	0
Covid-19	2 (4.1)	1 (2.0)	0	1 (2.0)	0
Fungal infection	2 (4.1)	0	2 (4.1)	0	0
Herpes zoster	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Influenza	2 (4.1)	0	1 (2.0)	0	1 (2.0)
Oral herpes	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Otitis media	2 (4.1)	0	2 (4.1)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (4.1)	0	0	1 (2.0)	1 (2.0)
Urinary tract infection	2 (4.1)	0	2 (4.1)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Bronchiolitis	1 (2.0)	0	0	1 (2.0)	0
Candida infection	1 (2.0)	0	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	0	0	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	0	0	1 (2.0)
Device related sepsis	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	0	1 (2.0)	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Folliculitis	1 (2.0)	0	1 (2.0)	0	0
Fungal skin infection	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis	1 (2.0)	1 (2.0)	0	0	0
Gastroenteritis escherichia coli	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis viral	1 (2.0)	0	1 (2.0)	0	0
Herpes virus infection	1 (2.0)	0	1 (2.0)	0	0
Meningitis pneumococcal	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.0)	0	0	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	0	0	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal abscess	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Streptococcal sepsis	1 (2.0)	0	1 (2.0)	0	0
Syphilis	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection pseudomonal	1 (2.0)	0	1 (2.0)	0	0
Varicella zoster virus infection	1 (2.0)	0	1 (2.0)	0	0
Viral skin infection	1 (2.0)	1 (2.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (6.1)	2 (4.1)	0	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal injury	1 (2.0)	1 (2.0)	0	0	0
Infusion related reaction	1 (2.0)	0	0	1 (2.0)	0
Ligament sprain	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	6 (12.2)	3 (6.1)	1 (2.0)	1 (2.0)	1 (2.0)
Neutrophil count decreased	3 (6.1)	2 (4.1)	0	0	1 (2.0)
Platelet count decreased	2 (4.1)	2 (4.1)	0	0	0
Blood bilirubin increased	1 (2.0)	1 (2.0)	0	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Oxygen saturation decreased	1 (2.0)	0	0	1 (2.0)	0
Metabolism and nutrition disorders					
-Total	6 (12.2)	0	2 (4.1)	3 (6.1)	1 (2.0)
Decreased appetite	1 (2.0)	0	0	0	1 (2.0)
Hypercholesterolaemia	1 (2.0)	0	1 (2.0)	0	0
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Hyperlipidaemia	1 (2.0)	0	1 (2.0)	0	0
Hypernatraemia	1 (2.0)	0	0	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	1 (2.0)	0	1 (2.0)	0	0
Iron overload	1 (2.0)	0	1 (2.0)	0	0
Obesity	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (14.3)	2 (4.1)	5 (10.2)	0	0
Pain in extremity	2 (4.1)	0	2 (4.1)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Growth retardation	1 (2.0)	0	1 (2.0)	0	0
Joint effusion	1 (2.0)	0	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	1 (2.0)	0	0	0
Osteopenia	1 (2.0)	1 (2.0)	0	0	0
Synovitis	1 (2.0)	0	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.0)	0	0	1 (2.0)	0
Bone giant cell tumour benign	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					
-Total	4 (8.2)	0	2 (4.1)	2 (4.1)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Dysarthria	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorder	1 (2.0)	0	0	1 (2.0)	0
Seizure	1 (2.0)	0	0	1 (2.0)	0
Psychiatric disorders					
-Total	3 (6.1)	1 (2.0)	2 (4.1)	0	0
Anxiety	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Tic	1 (2.0)	0	1 (2.0)	0	0
Reproductive system and breast disorders					
-Total	1 (2.0)	0	0	1 (2.0)	0
Endometriosis	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (20.4)	4 (8.2)	2 (4.1)	1 (2.0)	3 (6.1)
Cough	4 (8.2)	3 (6.1)	1 (2.0)	0	0
Dyspnoea	3 (6.1)	1 (2.0)	1 (2.0)	0	1 (2.0)
Rhinorrhoea	3 (6.1)	1 (2.0)	2 (4.1)	0	0
Sleep apnoea syndrome	2 (4.1)	1 (2.0)	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (2.0)	1 (2.0)	0	0	0
Epistaxis	1 (2.0)	1 (2.0)	0	0	0
Hypoxia	1 (2.0)	0	0	1 (2.0)	0
Laryngeal oedema	1 (2.0)	0	0	0	1 (2.0)
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Pharyngeal erythema	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Tachypnoea	1 (2.0)	0	0	0	1 (2.0)
Wheezing	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (14.3)	3 (6.1)	1 (2.0)	3 (6.1)	0
Rash	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Dermatitis atopic	1 (2.0)	0	0	1 (2.0)	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Eczema	1 (2.0)	0	0	1 (2.0)	0
Papule	1 (2.0)	1 (2.0)	0	0	0
Rash erythematous	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (2.0)	0	0	1 (2.0)	0
Rash maculo-papular	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Hypertension	2 (4.1)	0	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
General disorders and administration site conditions					
-Total	1 (100)	1 (100)	0	0	0
Pyrexia	1 (100)	1 (100)	0	0	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Gamma-glutamyltransferase increased	1 (100)	0	0	1 (100)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Photosensitivity reaction	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	1 (1.3)	6 (7.6)	18 (22.8)	54 (68.4)
Blood and lymphatic system disorders					
-Total	55 (69.6)	1 (1.3)	11 (13.9)	29 (36.7)	14 (17.7)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	25 (31.6)	7 (8.9)	9 (11.4)	9 (11.4)	0
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Disseminated intravascular coagulation	8 (10.1)	0	5 (6.3)	3 (3.8)	0
Coagulopathy	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Splenomegaly	4 (5.1)	3 (3.8)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Lymphadenopathy	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Lymphopenia	2 (2.5)	0	0	2 (2.5)	0
Pancytopenia	2 (2.5)	0	0	2 (2.5)	0
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypercoagulation	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Leukocytosis	1 (1.3)	0	1 (1.3)	0	0
Lymphocytosis	1 (1.3)	0	1 (1.3)	0	0
Cardiac disorders					
-Total	28 (35.4)	10 (12.7)	7 (8.9)	5 (6.3)	6 (7.6)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Left ventricular dysfunction	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac arrest	3 (3.8)	0	0	0	3 (3.8)
Cardiac failure	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Sinus tachycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0	0	0
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus bradycardia	1 (1.3)	0	0	1 (1.3)	0
Tricuspid valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.3)	1 (1.3)	0	0	0
Cerebral cavernous malformation	1 (1.3)	1 (1.3)	0	0	0
Ear and labyrinth disorders					
-Total	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (8.9)	0	7 (8.9)	0	0
Adrenal insufficiency	4 (5.1)	0	4 (5.1)	0	0
Hypothyroidism	3 (3.8)	0	3 (3.8)	0	0
Delayed puberty	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	15 (19.0)	10 (12.7)	4 (5.1)	1 (1.3)	0
Eyelid oedema	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Ocular hyperaemia	3 (3.8)	3 (3.8)	0	0	0
Cataract	2 (2.5)	2 (2.5)	0	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eye pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Visual impairment	2 (2.5)	2 (2.5)	0	0	0
Dry eye	1 (1.3)	1 (1.3)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Hypermetropia	1 (1.3)	1 (1.3)	0	0	0
Mydriasis	1 (1.3)	0	1 (1.3)	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					
-Total	60 (75.9)	21 (26.6)	23 (29.1)	15 (19.0)	1 (1.3)
Diarrhoea	26 (32.9)	16 (20.3)	8 (10.1)	2 (2.5)	0
Vomiting	26 (32.9)	17 (21.5)	8 (10.1)	1 (1.3)	0
Nausea	22 (27.8)	12 (15.2)	8 (10.1)	2 (2.5)	0
Constipation	14 (17.7)	7 (8.9)	7 (8.9)	0	0
Abdominal pain	11 (13.9)	2 (2.5)	7 (8.9)	2 (2.5)	0
Pancreatitis	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Mouth haemorrhage	5 (6.3)	2 (2.5)	1 (1.3)	2 (2.5)	0
Abdominal pain upper	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Stomatitis	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Proctalgia	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Trichoglossia	2 (2.5)	1 (1.3)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Abdominal rigidity	1 (1.3)	0	1 (1.3)	0	0
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Dyspepsia	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enteritis	1 (1.3)	0	1 (1.3)	0	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal inflammation	1 (1.3)	0	1 (1.3)	0	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0
Gingival bleeding	1 (1.3)	0	1 (1.3)	0	0
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Neutropenic colitis	1 (1.3)	0	0	1 (1.3)	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Peritoneal haematoma	1 (1.3)	1 (1.3)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	52 (65.8)	24 (30.4)	13 (16.5)	10 (12.7)	5 (6.3)
Pyrexia	34 (43.0)	13 (16.5)	10 (12.7)	9 (11.4)	2 (2.5)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Chills	7 (8.9)	5 (6.3)	2 (2.5)	0	0
Oedema peripheral	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Generalised oedema	5 (6.3)	2 (2.5)	3 (3.8)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Asthenia	3 (3.8)	3 (3.8)	0	0	0
Multiple organ dysfunction syndrome	3 (3.8)	0	0	0	3 (3.8)
Catheter site pain	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Localised oedema	2 (2.5)	2 (2.5)	0	0	0
Malaise	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Non-cardiac chest pain	2 (2.5)	2 (2.5)	0	0	0
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Xerosis	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	19 (24.1)	6 (7.6)	7 (8.9)	3 (3.8)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Biliary tract disorder	1 (1.3)	1 (1.3)	0	0	0
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Hepatic cytolysis	1 (1.3)	1 (1.3)	0	0	0
Liver disorder	1 (1.3)	0	1 (1.3)	0	0
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	71 (89.9)	2 (2.5)	23 (29.1)	24 (30.4)	22 (27.8)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	33 (41.8)	2 (2.5)	24 (30.4)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Immunodeficiency	4 (5.1)	0	0	4 (5.1)	0
Seasonal allergy	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Allergy to immunoglobulin therapy	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Chronic graft versus host disease	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Graft versus host disease	2 (2.5)	0	0	2 (2.5)	0
Engraftment syndrome	1 (1.3)	0	0	1 (1.3)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Selective igg subclass deficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	59 (74.7)	8 (10.1)	12 (15.2)	25 (31.6)	14 (17.7)
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Nasopharyngitis	7 (8.9)	4 (5.1)	3 (3.8)	0	0
Sinusitis	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Gastroenteritis	6 (7.6)	4 (5.1)	0	2 (2.5)	0
Pneumonia	6 (7.6)	1 (1.3)	1 (1.3)	2 (2.5)	2 (2.5)
Otitis media	5 (6.3)	0	4 (5.1)	1 (1.3)	0
Parainfluenzae virus infection	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Candida infection	4 (5.1)	0	3 (3.8)	0	1 (1.3)
Clostridium difficile infection	4 (5.1)	1 (1.3)	0	3 (3.8)	0
Nail infection	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Oral herpes	4 (5.1)	1 (1.3)	2 (2.5)	1 (1.3)	0
Staphylococcal infection	4 (5.1)	0	2 (2.5)	2 (2.5)	0
Bacteraemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Herpes zoster	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Metapneumovirus infection	3 (3.8)	0	0	3 (3.8)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Respiratory syncytial virus infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory tract infection	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Sepsis	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Skin infection	3 (3.8)	0	3 (3.8)	0	0
Urinary tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Bronchitis	2 (2.5)	0	2 (2.5)	0	0
Bronchopulmonary aspergillosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Covid-19	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Gingivitis	2 (2.5)	2 (2.5)	0	0	0
Herpes simplex	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Paronychia	2 (2.5)	0	2 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Atypical pneumonia	1 (1.3)	1 (1.3)	0	0	0
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis	1 (1.3)	0	1 (1.3)	0	0
Cytomegalovirus infection reactivation	1 (1.3)	0	0	1 (1.3)	0
Device related infection	1 (1.3)	0	0	1 (1.3)	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis clostridial	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	1 (1.3)	0	0	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	1 (1.3)	1 (1.3)	0	0	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Otitis media acute	1 (1.3)	0	1 (1.3)	0	0
Pharyngitis streptococcal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Sinusitis fungal	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal skin infection	1 (1.3)	0	1 (1.3)	0	0
Stomatococcal infection	1 (1.3)	0	1 (1.3)	0	0
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Syphilis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Viral upper respiratory tract infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	21 (26.6)	9 (11.4)	9 (11.4)	1 (1.3)	2 (2.5)
Infusion related reaction	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Contusion	2 (2.5)	2 (2.5)	0	0	0
Fall	2 (2.5)	0	2 (2.5)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ligament sprain	2 (2.5)	2 (2.5)	0	0	0
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Skin abrasion	2 (2.5)	2 (2.5)	0	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wound	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Abdominal injury	1 (1.3)	1 (1.3)	0	0	0
Fibula fracture	1 (1.3)	0	1 (1.3)	0	0
Limb injury	1 (1.3)	0	1 (1.3)	0	0
Post-traumatic neck syndrome	1 (1.3)	0	1 (1.3)	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					
-Total	59 (74.7)	3 (3.8)	9 (11.4)	18 (22.8)	29 (36.7)
White blood cell count decreased	25 (31.6)	3 (3.8)	4 (5.1)	2 (2.5)	16 (20.3)
Neutrophil count decreased	24 (30.4)	1 (1.3)	2 (2.5)	4 (5.1)	17 (21.5)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	24 (30.4)	6 (7.6)	3 (3.8)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	3 (3.8)	8 (10.1)	7 (8.9)	0
Lymphocyte count decreased	17 (21.5)	1 (1.3)	1 (1.3)	10 (12.7)	5 (6.3)
Blood bilirubin increased	13 (16.5)	1 (1.3)	3 (3.8)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Blood fibrinogen decreased	7 (8.9)	2 (2.5)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin a decreased	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (8.9)	4 (5.1)	1 (1.3)	2 (2.5)	0
Activated partial thromboplastin time prolonged	6 (7.6)	3 (3.8)	2 (2.5)	1 (1.3)	0
Blood creatinine increased	5 (6.3)	1 (1.3)	1 (1.3)	2 (2.5)	1 (1.3)
Blood lactate dehydrogenase increased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
C-reactive protein increased	5 (6.3)	2 (2.5)	0	3 (3.8)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	5 (6.3)	1 (1.3)	2 (2.5)	1 (1.3)	1 (1.3)
Blood immunoglobulin g decreased	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Blood uric acid increased	4 (5.1)	2 (2.5)	0	1 (1.3)	1 (1.3)
Weight increased	4 (5.1)	1 (1.3)	1 (1.3)	2 (2.5)	0
Fibrin d dimer increased	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Oxygen saturation decreased	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Urine output decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Weight decreased	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amylase increased	1 (1.3)	1 (1.3)	0	0	0
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood glucose increased	1 (1.3)	0	0	0	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.3)	1 (1.3)	0	0	0
Blood urea increased	1 (1.3)	0	0	1 (1.3)	0
Bone density decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Ejection fraction decreased	1 (1.3)	0	1 (1.3)	0	0
Electrocardiogram t wave abnormal	1 (1.3)	0	1 (1.3)	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Gamma-glutamyltransferase increased	1 (1.3)	0	0	1 (1.3)	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Heart sounds abnormal	1 (1.3)	1 (1.3)	0	0	0
Hepatitis b virus test positive	1 (1.3)	0	1 (1.3)	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcus test positive	1 (1.3)	1 (1.3)	0	0	0
Troponin increased	1 (1.3)	0	0	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	52 (65.8)	9 (11.4)	10 (12.7)	22 (27.8)	11 (13.9)
Decreased appetite	30 (38.0)	11 (13.9)	7 (8.9)	10 (12.7)	2 (2.5)
Hypokalaemia	20 (25.3)	3 (3.8)	6 (7.6)	9 (11.4)	2 (2.5)
Hypophosphataemia	18 (22.8)	3 (3.8)	6 (7.6)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	9 (11.4)	0	4 (5.1)	5 (6.3)	0
Hyperuricaemia	9 (11.4)	7 (8.9)	1 (1.3)	1 (1.3)	0
Hypervolaemia	7 (8.9)	0	2 (2.5)	5 (6.3)	0
Hypomagnesaemia	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Hyperphosphataemia	5 (6.3)	4 (5.1)	0	0	1 (1.3)
Tumour lysis syndrome	5 (6.3)	0	0	4 (5.1)	1 (1.3)
Metabolic acidosis	4 (5.1)	1 (1.3)	0	0	3 (3.8)
Hypercalcaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Hyperkalaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Hypertriglyceridaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hyponatraemia	3 (3.8)	3 (3.8)	0	0	0
Acidosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Hyperchloraemia	2 (2.5)	2 (2.5)	0	0	0
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Iron overload	2 (2.5)	0	2 (2.5)	0	0
Malnutrition	2 (2.5)	0	0	2 (2.5)	0
Calcium deficiency	1 (1.3)	1 (1.3)	0	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Haemochromatosis	1 (1.3)	0	0	1 (1.3)	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hypercholesterolaemia	1 (1.3)	0	1 (1.3)	0	0
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlipidaemia	1 (1.3)	0	1 (1.3)	0	0
Hypoglycaemia	1 (1.3)	0	1 (1.3)	0	0
Hypophagia	1 (1.3)	0	1 (1.3)	0	0
Metabolic syndrome	1 (1.3)	0	1 (1.3)	0	0
Obesity	1 (1.3)	0	0	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	44 (55.7)	17 (21.5)	19 (24.1)	7 (8.9)	1 (1.3)
Pain in extremity	17 (21.5)	8 (10.1)	8 (10.1)	1 (1.3)	0
Arthralgia	12 (15.2)	5 (6.3)	6 (7.6)	1 (1.3)	0
Back pain	10 (12.7)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)	0	0
Bone pain	4 (5.1)	1 (1.3)	3 (3.8)	0	0
Growth retardation	2 (2.5)	0	2 (2.5)	0	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Musculoskeletal chest pain	2 (2.5)	2 (2.5)	0	0	0
Neck pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Haemarthrosis	1 (1.3)	0	0	1 (1.3)	0
Joint effusion	1 (1.3)	0	1 (1.3)	0	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Muscle spasms	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal pain	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (1.3)	0	1 (1.3)	0	0
Osteonecrosis	1 (1.3)	1 (1.3)	0	0	0
Osteopenia	1 (1.3)	1 (1.3)	0	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Synovitis	1 (1.3)	0	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Bone giant cell tumour benign	1 (1.3)	0	0	1 (1.3)	0
Cancer pain	1 (1.3)	0	1 (1.3)	0	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	47 (59.5)	15 (19.0)	18 (22.8)	10 (12.7)	4 (5.1)
Headache	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Tremor	6 (7.6)	5 (6.3)	1 (1.3)	0	0
Somnolence	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	4 (5.1)	4 (5.1)	0	0	0
Seizure	4 (5.1)	0	1 (1.3)	3 (3.8)	0
Cognitive disorder	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cerebral haemorrhage	2 (2.5)	0	0	0	2 (2.5)
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Amnesia	1 (1.3)	0	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Autonomic neuropathy	1 (1.3)	0	0	1 (1.3)	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Extrapyramidal disorder	1 (1.3)	0	1 (1.3)	0	0
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Hydrocephalus	1 (1.3)	0	0	0	1 (1.3)
Hyperaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Migraine	1 (1.3)	0	1 (1.3)	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorder	1 (1.3)	0	0	1 (1.3)	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neurological decompensation	1 (1.3)	0	0	0	1 (1.3)
Paraesthesia	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	39 (49.4)	13 (16.5)	19 (24.1)	7 (8.9)	0
Anxiety	14 (17.7)	3 (3.8)	9 (11.4)	2 (2.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Confusional state	7 (8.9)	7 (8.9)	0	0	0
Agitation	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Mental status changes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Insomnia	4 (5.1)	2 (2.5)	2 (2.5)	0	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Irritability	3 (3.8)	3 (3.8)	0	0	0
Sleep disorder	3 (3.8)	0	3 (3.8)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Automatism	1 (1.3)	1 (1.3)	0	0	0
Hallucination, visual	1 (1.3)	0	1 (1.3)	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Nightmare	1 (1.3)	1 (1.3)	0	0	0
Persistent depressive disorder	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tearfulness	1 (1.3)	1 (1.3)	0	0	0
Tic	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	25 (31.6)	6 (7.6)	7 (8.9)	5 (6.3)	7 (8.9)
Acute kidney injury	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Dysuria	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Haematuria	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal failure	2 (2.5)	0	1 (1.3)	0	1 (1.3)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0
Azotaemia	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Cystitis haemorrhagic	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Kidney enlargement	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal mass	1 (1.3)	0	1 (1.3)	0	0
Renal tubular disorder	1 (1.3)	0	0	1 (1.3)	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	0	1 (1.3)
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	6 (7.6)	2 (2.5)	2 (2.5)	2 (2.5)	0
Dysmenorrhoea	1 (1.3)	0	1 (1.3)	0	0
Endometriosis	1 (1.3)	0	0	1 (1.3)	0
Female genital tract fistula	1 (1.3)	1 (1.3)	0	0	0
Heavy menstrual bleeding	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	55 (69.6)	18 (22.8)	8 (10.1)	12 (15.2)	17 (21.5)
Cough	23 (29.1)	18 (22.8)	5 (6.3)	0	0
Hypoxia	20 (25.3)	0	4 (5.1)	10 (12.7)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)	0	0
Pleural effusion	9 (11.4)	4 (5.1)	2 (2.5)	2 (2.5)	1 (1.3)
Tachypnoea	9 (11.4)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)	0	0
Dyspnoea	7 (8.9)	1 (1.3)	2 (2.5)	2 (2.5)	2 (2.5)
Epistaxis	7 (8.9)	4 (5.1)	2 (2.5)	1 (1.3)	0
Respiratory failure	6 (7.6)	0	0	0	6 (7.6)
Rhinorrhoea	6 (7.6)	4 (5.1)	2 (2.5)	0	0
Respiratory distress	4 (5.1)	0	2 (2.5)	0	2 (2.5)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

			All patients N=79		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	3 (3.8)	0	0	0	3 (3.8)
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Pharyngeal erythema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Rhinitis allergic	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Sleep apnoea syndrome	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Wheezing	2 (2.5)	0	2 (2.5)	0	0
Acute respiratory failure	1 (1.3)	0	0	1 (1.3)	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Bronchial oedema	1 (1.3)	1 (1.3)	0	0	0
Bronchospasm	1 (1.3)	0	1 (1.3)	0	0
Dyspnoea exertional	1 (1.3)	1 (1.3)	0	0	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Laryngeal oedema	1 (1.3)	0	0	0	1 (1.3)
Lung disorder	1 (1.3)	1 (1.3)	0	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Paranasal sinus inflammation	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Upper respiratory tract inflammation	1 (1.3)	0	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	39 (49.4)	17 (21.5)	15 (19.0)	7 (8.9)	0
Dry skin	8 (10.1)	6 (7.6)	2 (2.5)	0	0
Rash	8 (10.1)	4 (5.1)	4 (5.1)	0	0
Pruritus	7 (8.9)	2 (2.5)	5 (6.3)	0	0
Erythema	5 (6.3)	4 (5.1)	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dermatitis atopic	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Eczema	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Hyperhidrosis	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Rash maculo-papular	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Rash papular	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Decubitus ulcer	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Ingrowing nail	2 (2.5)	0	2 (2.5)	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Skin discolouration	2 (2.5)	2 (2.5)	0	0	0
Skin ulcer	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis allergic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0
Hangnail	1 (1.3)	1 (1.3)	0	0	0
Miliaria	1 (1.3)	1 (1.3)	0	0	0
Night sweats	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Papule	1 (1.3)	1 (1.3)	0	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash erythematous	1 (1.3)	1 (1.3)	0	0	0
Rash macular	1 (1.3)	0	0	1 (1.3)	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Scab	1 (1.3)	1 (1.3)	0	0	0
Skin hypopigmentation	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Skin swelling	1 (1.3)	1 (1.3)	0	0	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Surgical and medical procedures					
-Total	1 (1.3)	0	0	1 (1.3)	0
Thrombolysis	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					
-Total	34 (43.0)	5 (6.3)	8 (10.1)	12 (15.2)	9 (11.4)
Hypotension	24 (30.4)	2 (2.5)	6 (7.6)	8 (10.1)	8 (10.1)
Hypertension	16 (20.3)	4 (5.1)	7 (8.9)	5 (6.3)	0
Capillary leak syndrome	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Venoocclusive disease	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (96.3)	2 (7.4)	4 (14.8)	7 (25.9)	13 (48.1)
Blood and lymphatic system disorders					
-Total	12 (44.4)	2 (7.4)	3 (11.1)	3 (11.1)	4 (14.8)
Anaemia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Disseminated intravascular coagulation	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Febrile neutropenia	3 (11.1)	0	0	3 (11.1)	0
Neutropenia	3 (11.1)	0	1 (3.7)	0	2 (7.4)
Thrombocytopenia	2 (7.4)	0	0	0	2 (7.4)
Coagulopathy	1 (3.7)	1 (3.7)	0	0	0
Splenomegaly	1 (3.7)	1 (3.7)	0	0	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (25.9)	3 (11.1)	2 (7.4)	1 (3.7)	1 (3.7)
Tachycardia	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
Bradycardia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Sinus tachycardia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Cardiac dysfunction	1 (3.7)	1 (3.7)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Ear pruritus	1 (3.7)	1 (3.7)	0	0	0
Eye disorders					
-Total	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Eyelid oedema	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Conjunctival haemorrhage	1 (3.7)	1 (3.7)	0	0	0
Eye pain	1 (3.7)	1 (3.7)	0	0	0
Periorbital oedema	1 (3.7)	1 (3.7)	0	0	0
Gastrointestinal disorders					
-Total	20 (74.1)	8 (29.6)	7 (25.9)	5 (18.5)	0
Vomiting	7 (25.9)	6 (22.2)	1 (3.7)	0	0
Diarrhoea	6 (22.2)	3 (11.1)	2 (7.4)	1 (3.7)	0
Abdominal pain	5 (18.5)	1 (3.7)	4 (14.8)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Abdominal pain upper	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Pancreatitis	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Constipation	2 (7.4)	2 (7.4)	0	0	0
Abdominal distension	1 (3.7)	0	1 (3.7)	0	0
Anal haemorrhage	1 (3.7)	1 (3.7)	0	0	0
Ascites	1 (3.7)	1 (3.7)	0	0	0
Dysphagia	1 (3.7)	0	0	1 (3.7)	0
Enterocolitis	1 (3.7)	0	1 (3.7)	0	0
Gastrooesophageal reflux disease	1 (3.7)	0	1 (3.7)	0	0
Gingival erythema	1 (3.7)	1 (3.7)	0	0	0
Melaena	1 (3.7)	0	0	1 (3.7)	0
Mouth haemorrhage	1 (3.7)	0	1 (3.7)	0	0
Proctalgia	1 (3.7)	0	0	1 (3.7)	0
General disorders and administration site conditions					
-Total	12 (44.4)	8 (29.6)	2 (7.4)	0	2 (7.4)
Pyrexia	6 (22.2)	4 (14.8)	1 (3.7)	0	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Face oedema	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Oedema peripheral	2 (7.4)	2 (7.4)	0	0	0
Asthenia	1 (3.7)	1 (3.7)	0	0	0
Catheter site erythema	1 (3.7)	1 (3.7)	0	0	0
Catheter site haemorrhage	1 (3.7)	1 (3.7)	0	0	0
Generalised oedema	1 (3.7)	1 (3.7)	0	0	0
Localised oedema	1 (3.7)	1 (3.7)	0	0	0
Multiple organ dysfunction syndrome	1 (3.7)	0	0	0	1 (3.7)
Oedema due to hepatic disease	1 (3.7)	0	1 (3.7)	0	0
Systemic inflammatory response syndrome	1 (3.7)	0	0	1 (3.7)	0
Hepatobiliary disorders					
-Total	6 (22.2)	0	2 (7.4)	2 (7.4)	2 (7.4)
Hepatic function abnormal	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hyperbilirubinaemia	2 (7.4)	0	2 (7.4)	0	0
Cholelithiasis	1 (3.7)	1 (3.7)	0	0	0
Cholestasis	1 (3.7)	0	0	0	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gallbladder enlargement	1 (3.7)	1 (3.7)	0	0	0
Hypertransaminasaemia	1 (3.7)	0	1 (3.7)	0	0
Immune system disorders					
-Total	21 (77.8)	0	3 (11.1)	9 (33.3)	9 (33.3)
Cytokine release syndrome	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Hypogammaglobulinaemia	7 (25.9)	1 (3.7)	3 (11.1)	3 (11.1)	0
Haemophagocytic lymphohistiocytosis	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Immunodeficiency	1 (3.7)	0	0	1 (3.7)	0
Infections and infestations					
-Total	16 (59.3)	4 (14.8)	5 (18.5)	5 (18.5)	2 (7.4)
Clostridium difficile infection	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Conjunctivitis	2 (7.4)	0	2 (7.4)	0	0
Oral infection	2 (7.4)	0	2 (7.4)	0	0
Staphylococcal infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Anal abscess	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Bk virus infection	1 (3.7)	1 (3.7)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (3.7)	0	0	1 (3.7)	0
Cholecystitis infective	1 (3.7)	0	1 (3.7)	0	0
Encephalitis	1 (3.7)	0	0	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	0	0	1 (3.7)
Gastroenteritis norovirus	1 (3.7)	1 (3.7)	0	0	0
Localised infection	1 (3.7)	1 (3.7)	0	0	0
Meningitis bacterial	1 (3.7)	0	0	1 (3.7)	0
Myringitis	1 (3.7)	1 (3.7)	0	0	0
Nail infection	1 (3.7)	1 (3.7)	0	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Paronychia	1 (3.7)	0	1 (3.7)	0	0
Pneumonia	1 (3.7)	0	0	1 (3.7)	0
Injury, poisoning and procedural complications					
-Total	6 (22.2)	2 (7.4)	3 (11.1)	0	1 (3.7)
Procedural pain	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Wound	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Contusion	1 (3.7)	1 (3.7)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fall	1 (3.7)	0	1 (3.7)	0	0
Scratch	1 (3.7)	1 (3.7)	0	0	0
Skin abrasion	1 (3.7)	1 (3.7)	0	0	0
Skin injury	1 (3.7)	0	1 (3.7)	0	0
Skin wound	1 (3.7)	1 (3.7)	0	0	0
Vasoplegia syndrome	1 (3.7)	0	0	0	1 (3.7)
Investigations					
-Total	19 (70.4)	2 (7.4)	4 (14.8)	4 (14.8)	9 (33.3)
Neutrophil count decreased	7 (25.9)	0	1 (3.7)	0	6 (22.2)
White blood cell count decreased	7 (25.9)	0	1 (3.7)	1 (3.7)	5 (18.5)
Alanine aminotransferase increased	6 (22.2)	1 (3.7)	2 (7.4)	3 (11.1)	0
Lymphocyte count decreased	6 (22.2)	2 (7.4)	0	2 (7.4)	2 (7.4)
Aspartate aminotransferase increased	5 (18.5)	0	4 (14.8)	1 (3.7)	0
Blood fibrinogen decreased	5 (18.5)	1 (3.7)	3 (11.1)	0	1 (3.7)
Platelet count decreased	5 (18.5)	1 (3.7)	1 (3.7)	1 (3.7)	2 (7.4)
Blood bilirubin increased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Serum ferritin increased	4 (14.8)	0	4 (14.8)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Activated partial thromboplastin time prolonged	2 (7.4)	2 (7.4)	0	0	0
Blood creatine phosphokinase increased	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Blood immunoglobulin m decreased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Blood lactate dehydrogenase increased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
International normalised ratio increased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Lipase increased	2 (7.4)	1 (3.7)	0	0	1 (3.7)
Amylase increased	1 (3.7)	1 (3.7)	0	0	0
Bacterial test positive	1 (3.7)	0	0	1 (3.7)	0
Blood bicarbonate decreased	1 (3.7)	0	1 (3.7)	0	0
Blood creatinine increased	1 (3.7)	0	0	0	1 (3.7)
Blood immunoglobulin a decreased	1 (3.7)	1 (3.7)	0	0	0
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (3.7)	1 (3.7)	0	0	0
C-reactive protein increased	1 (3.7)	1 (3.7)	0	0	0
Cardiac murmur	1 (3.7)	1 (3.7)	0	0	0
Coagulation test abnormal	1 (3.7)	1 (3.7)	0	0	0
Fibrin d dimer increased	1 (3.7)	1 (3.7)	0	0	0
Haemoglobin decreased	1 (3.7)	0	0	1 (3.7)	0
Immunoglobulins decreased	1 (3.7)	0	1 (3.7)	0	0
Urine output decreased	1 (3.7)	0	0	0	1 (3.7)
Weight decreased	1 (3.7)	0	1 (3.7)	0	0
Weight increased	1 (3.7)	1 (3.7)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (63.0)	4 (14.8)	2 (7.4)	8 (29.6)	3 (11.1)
Hypokalaemia	9 (33.3)	1 (3.7)	2 (7.4)	5 (18.5)	1 (3.7)
Decreased appetite	7 (25.9)	4 (14.8)	0	3 (11.1)	0
Hypophosphataemia	7 (25.9)	2 (7.4)	2 (7.4)	2 (7.4)	1 (3.7)
Hypocalcaemia	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Hypoalbuminaemia	3 (11.1)	0	3 (11.1)	0	0
Hypernatraemia	2 (7.4)	1 (3.7)	0	0	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (7.4)	2 (7.4)	0	0	0
Hypomagnesaemia	2 (7.4)	2 (7.4)	0	0	0
Tumour lysis syndrome	2 (7.4)	0	0	2 (7.4)	0
Haemosiderosis	1 (3.7)	0	1 (3.7)	0	0
Hyperchloraemia	1 (3.7)	1 (3.7)	0	0	0
Hyperlactacidaemia	1 (3.7)	1 (3.7)	0	0	0
Hypertriglyceridaemia	1 (3.7)	0	0	0	1 (3.7)
Hyperuricaemia	1 (3.7)	0	1 (3.7)	0	0
Hypervolaemia	1 (3.7)	0	1 (3.7)	0	0
Hyponatraemia	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (44.4)	6 (22.2)	5 (18.5)	0	1 (3.7)
Pain in extremity	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Arthralgia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Myalgia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Back pain	1 (3.7)	0	1 (3.7)	0	0
Muscle rigidity	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal chest pain	1 (3.7)	1 (3.7)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (3.7)	0	1 (3.7)	0	0
Rhabdomyolysis	1 (3.7)	0	0	0	1 (3.7)
Nervous system disorders					
-Total	12 (44.4)	5 (18.5)	5 (18.5)	2 (7.4)	0
Headache	7 (25.9)	3 (11.1)	4 (14.8)	0	0
Encephalopathy	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Tremor	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Dizziness	2 (7.4)	2 (7.4)	0	0	0
Generalised tonic-clonic seizure	1 (3.7)	0	1 (3.7)	0	0
Hypoaesthesia	1 (3.7)	1 (3.7)	0	0	0
Monoparesis	1 (3.7)	0	1 (3.7)	0	0
Neuralgia	1 (3.7)	0	1 (3.7)	0	0
Seizure	1 (3.7)	0	1 (3.7)	0	0
Somnolence	1 (3.7)	0	0	1 (3.7)	0
Psychiatric disorders					
-Total	10 (37.0)	6 (22.2)	2 (7.4)	2 (7.4)	0
Delirium	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Insomnia	3 (11.1)	1 (3.7)	2 (7.4)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Confusional state	2 (7.4)	2 (7.4)	0	0	0
Mental status changes	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Agitation	1 (3.7)	0	1 (3.7)	0	0
Automatism	1 (3.7)	1 (3.7)	0	0	0
Irritability	1 (3.7)	1 (3.7)	0	0	0
Sleep disorder	1 (3.7)	0	1 (3.7)	0	0
Renal and urinary disorders					
-Total	8 (29.6)	2 (7.4)	2 (7.4)	1 (3.7)	3 (11.1)
Acute kidney injury	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Anuria	1 (3.7)	1 (3.7)	0	0	0
Azotaemia	1 (3.7)	0	1 (3.7)	0	0
Bladder dilatation	1 (3.7)	0	1 (3.7)	0	0
Dysuria	1 (3.7)	1 (3.7)	0	0	0
Haematuria	1 (3.7)	1 (3.7)	0	0	0
Micturition urgency	1 (3.7)	0	1 (3.7)	0	0
Pollakiuria	1 (3.7)	0	1 (3.7)	0	0
Proteinuria	1 (3.7)	1 (3.7)	0	0	0
Renal failure	1 (3.7)	0	1 (3.7)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (3.7)	0	0	0	1 (3.7)
Urinary retention	1 (3.7)	0	1 (3.7)	0	0
Reproductive system and breast disorders					
-Total	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Perineal rash	1 (3.7)	0	1 (3.7)	0	0
Vaginal ulceration	1 (3.7)	0	0	1 (3.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (48.1)	4 (14.8)	1 (3.7)	3 (11.1)	5 (18.5)
Hypoxia	8 (29.6)	0	2 (7.4)	2 (7.4)	4 (14.8)
Pleural effusion	4 (14.8)	3 (11.1)	0	1 (3.7)	0
Pulmonary oedema	4 (14.8)	2 (7.4)	1 (3.7)	1 (3.7)	0
Cough	3 (11.1)	3 (11.1)	0	0	0
Tachypnoea	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Atelectasis	2 (7.4)	0	0	2 (7.4)	0
Oropharyngeal pain	2 (7.4)	2 (7.4)	0	0	0
Acute respiratory distress syndrome	1 (3.7)	0	0	0	1 (3.7)
Bradypnoea	1 (3.7)	0	0	1 (3.7)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (3.7)	0	0	0	1 (3.7)
Epistaxis	1 (3.7)	0	1 (3.7)	0	0
Nasal discomfort	1 (3.7)	0	1 (3.7)	0	0
Pharyngeal haemorrhage	1 (3.7)	0	1 (3.7)	0	0
Productive cough	1 (3.7)	1 (3.7)	0	0	0
Respiratory acidosis	1 (3.7)	0	0	1 (3.7)	0
Respiratory distress	1 (3.7)	0	1 (3.7)	0	0
Rhinorrhoea	1 (3.7)	1 (3.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (29.6)	2 (7.4)	4 (14.8)	2 (7.4)	0
Petechiae	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Pruritus	2 (7.4)	0	2 (7.4)	0	0
Rash	2 (7.4)	0	2 (7.4)	0	0
Skin ulcer	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Blister	1 (3.7)	1 (3.7)	0	0	0
Decubitus ulcer	1 (3.7)	0	1 (3.7)	0	0
Dermatitis diaper	1 (3.7)	0	1 (3.7)	0	0
Dry skin	1 (3.7)	1 (3.7)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (3.7)	1 (3.7)	0	0	0
Erythema nodosum	1 (3.7)	1 (3.7)	0	0	0
Pruritus allergic	1 (3.7)	0	1 (3.7)	0	0
Rash papular	1 (3.7)	1 (3.7)	0	0	0
Rash pruritic	1 (3.7)	1 (3.7)	0	0	0
Skin necrosis	1 (3.7)	0	0	1 (3.7)	0
Urticaria	1 (3.7)	0	1 (3.7)	0	0
Vancomycin infusion reaction	1 (3.7)	0	0	1 (3.7)	0
Vascular disorders					
-Total	10 (37.0)	1 (3.7)	3 (11.1)	3 (11.1)	3 (11.1)
Hypotension	7 (25.9)	0	2 (7.4)	2 (7.4)	3 (11.1)
Hypertension	5 (18.5)	1 (3.7)	2 (7.4)	2 (7.4)	0
Capillary leak syndrome	1 (3.7)	0	1 (3.7)	0	0
Thrombosis	1 (3.7)	0	1 (3.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (100)	2 (3.8)	4 (7.5)	14 (26.4)	33 (62.3)
Blood and lymphatic system disorders					
-Total	38 (71.7)	1 (1.9)	5 (9.4)	23 (43.4)	9 (17.0)
Febrile neutropenia	23 (43.4)	0	0	21 (39.6)	2 (3.8)
Anaemia	17 (32.1)	3 (5.7)	6 (11.3)	8 (15.1)	0
Neutropenia	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Coagulopathy	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Disseminated intravascular coagulation	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Leukopenia	3 (5.7)	0	1 (1.9)	1 (1.9)	1 (1.9)
Splenomegaly	3 (5.7)	2 (3.8)	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (3.8)	0	0	2 (3.8)	0
B-cell aplasia	1 (1.9)	0	1 (1.9)	0	0
Eosinophilia	1 (1.9)	0	1 (1.9)	0	0
Hypofibrinogenaemia	1 (1.9)	0	1 (1.9)	0	0
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Cardiac disorders					
-Total	17 (32.1)	7 (13.2)	4 (7.5)	4 (7.5)	2 (3.8)
Tachycardia	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0
Left ventricular dysfunction	3 (5.7)	0	0	3 (5.7)	0
Atrioventricular block first degree	1 (1.9)	0	1 (1.9)	0	0
Bradycardia	1 (1.9)	1 (1.9)	0	0	0
Cardiac arrest	1 (1.9)	0	0	0	1 (1.9)
Cardiac dysfunction	1 (1.9)	1 (1.9)	0	0	0
Cardiac failure	1 (1.9)	0	0	0	1 (1.9)
Cardiac failure congestive	1 (1.9)	0	1 (1.9)	0	0
Mitral valve incompetence	1 (1.9)	1 (1.9)	0	0	0
Pericardial effusion	1 (1.9)	1 (1.9)	0	0	0
Right ventricular dysfunction	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (1.9)	0	0	1 (1.9)	0
Sinus tachycardia	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Ear pain	1 (1.9)	1 (1.9)	0	0	0
Endocrine disorders					
-Total	5 (9.4)	0	5 (9.4)	0	0
Adrenal insufficiency	4 (7.5)	0	4 (7.5)	0	0
Hypothyroidism	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	6 (11.3)	4 (7.5)	2 (3.8)	0	0
Ocular hyperaemia	2 (3.8)	2 (3.8)	0	0	0
Conjunctival haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Eye oedema	1 (1.9)	1 (1.9)	0	0	0
Periorbital swelling	1 (1.9)	0	1 (1.9)	0	0
Retinal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Visual impairment	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (58.5)	11 (20.8)	11 (20.8)	8 (15.1)	1 (1.9)
Nausea	14 (26.4)	7 (13.2)	5 (9.4)	2 (3.8)	0
Vomiting	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0
Constipation	9 (17.0)	4 (7.5)	5 (9.4)	0	0
Diarrhoea	9 (17.0)	5 (9.4)	4 (7.5)	0	0
Abdominal pain	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
Mouth haemorrhage	3 (5.7)	1 (1.9)	0	2 (3.8)	0
Abdominal distension	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Ascites	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Gastrointestinal sounds abnormal	2 (3.8)	2 (3.8)	0	0	0
Stomatitis	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Abdominal compartment syndrome	1 (1.9)	0	0	0	1 (1.9)
Anal fissure	1 (1.9)	0	1 (1.9)	0	0
Dry mouth	1 (1.9)	0	1 (1.9)	0	0
Gingival bleeding	1 (1.9)	0	1 (1.9)	0	0
Gingivitis ulcerative	1 (1.9)	0	0	1 (1.9)	0
Haematemesis	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (1.9)	0	1 (1.9)	0	0
Lip dry	1 (1.9)	0	1 (1.9)	0	0
Lip oedema	1 (1.9)	1 (1.9)	0	0	0
Mouth swelling	1 (1.9)	1 (1.9)	0	0	0
Neutropenic colitis	1 (1.9)	0	0	1 (1.9)	0
Odynophagia	1 (1.9)	1 (1.9)	0	0	0
Pancreatitis	1 (1.9)	0	1 (1.9)	0	0
Trichoglossia	1 (1.9)	0	1 (1.9)	0	0
Upper gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	28 (52.8)	12 (22.6)	7 (13.2)	7 (13.2)	2 (3.8)
Pyrexia	18 (34.0)	7 (13.2)	4 (7.5)	6 (11.3)	1 (1.9)
Fatigue	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Chills	6 (11.3)	4 (7.5)	2 (3.8)	0	0
Face oedema	5 (9.4)	3 (5.7)	1 (1.9)	1 (1.9)	0
Generalised oedema	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Oedema peripheral	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Drug withdrawal syndrome	2 (3.8)	0	2 (3.8)	0	0
Influenza like illness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Asthenia	1 (1.9)	1 (1.9)	0	0	0
Chest discomfort	1 (1.9)	0	0	1 (1.9)	0
Crying	1 (1.9)	0	1 (1.9)	0	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Localised oedema	1 (1.9)	1 (1.9)	0	0	0
Malaise	1 (1.9)	0	1 (1.9)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	0	0	1 (1.9)
Pain	1 (1.9)	0	0	1 (1.9)	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0
Swelling face	1 (1.9)	1 (1.9)	0	0	0
Vascular device occlusion	1 (1.9)	1 (1.9)	0	0	0
Hepatobiliary disorders					
-Total	11 (20.8)	5 (9.4)	4 (7.5)	1 (1.9)	1 (1.9)
Hepatomegaly	3 (5.7)	2 (3.8)	0	0	1 (1.9)
Hyperbilirubinaemia	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	2 (3.8)	0	2 (3.8)	0	0
Biliary tract disorder	1 (1.9)	1 (1.9)	0	0	0
Cholelithiasis	1 (1.9)	0	1 (1.9)	0	0
Gallbladder enlargement	1 (1.9)	1 (1.9)	0	0	0
Hypertransaminasaemia	1 (1.9)	1 (1.9)	0	0	0
Ocular icterus	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	46 (86.8)	3 (5.7)	18 (34.0)	13 (24.5)	12 (22.6)
Cytokine release syndrome	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Hypogammaglobulinaemia	16 (30.2)	1 (1.9)	11 (20.8)	4 (7.5)	0
Immunodeficiency	2 (3.8)	0	0	2 (3.8)	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	0	1 (1.9)	0
Hypersensitivity	1 (1.9)	1 (1.9)	0	0	0
Seasonal allergy	1 (1.9)	0	1 (1.9)	0	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	19 (35.8)	2 (3.8)	5 (9.4)	11 (20.8)	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	3 (5.7)	0	2 (3.8)	0	1 (1.9)
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Staphylococcal bacteraemia	3 (5.7)	0	0	3 (5.7)	0
Staphylococcal infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Clostridium difficile infection	2 (3.8)	0	0	2 (3.8)	0
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Rhinovirus infection	2 (3.8)	0	2 (3.8)	0	0
Adenovirus infection	1 (1.9)	0	0	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Encephalitis viral	1 (1.9)	0	0	1 (1.9)	0
Gingivitis	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes simplex	1 (1.9)	0	0	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	0	0	1 (1.9)	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Oral candidiasis	1 (1.9)	0	1 (1.9)	0	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	0	0	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	5 (9.4)	1 (1.9)	3 (5.7)	0	1 (1.9)
Infusion related reaction	2 (3.8)	0	2 (3.8)	0	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Fall	1 (1.9)	0	1 (1.9)	0	0
Transplant failure	1 (1.9)	0	0	0	1 (1.9)
Investigations					
-Total	38 (71.7)	2 (3.8)	4 (7.5)	13 (24.5)	19 (35.8)
White blood cell count decreased	17 (32.1)	3 (5.7)	2 (3.8)	1 (1.9)	11 (20.8)
Platelet count decreased	16 (30.2)	3 (5.7)	2 (3.8)	5 (9.4)	6 (11.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	14 (26.4)	2 (3.8)	2 (3.8)	7 (13.2)	3 (5.7)
Neutrophil count decreased	13 (24.5)	0	2 (3.8)	2 (3.8)	9 (17.0)
Alanine aminotransferase increased	12 (22.6)	3 (5.7)	6 (11.3)	3 (5.7)	0
Lymphocyte count decreased	9 (17.0)	0	0	6 (11.3)	3 (5.7)
Blood bilirubin increased	8 (15.1)	0	1 (1.9)	7 (13.2)	0
International normalised ratio increased	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Activated partial thromboplastin time prolonged	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Blood immunoglobulin a decreased	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Blood immunoglobulin m decreased	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Serum ferritin increased	4 (7.5)	1 (1.9)	1 (1.9)	2 (3.8)	0
Blood creatinine increased	3 (5.7)	1 (1.9)	0	2 (3.8)	0
C-reactive protein increased	3 (5.7)	0	0	3 (5.7)	0
Weight increased	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Blood fibrinogen decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Electrocardiogram qt prolonged	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Fibrin d dimer increased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Gamma-glutamyltransferase increased	2 (3.8)	0	0	2 (3.8)	0
Blood alkaline phosphatase increased	1 (1.9)	1 (1.9)	0	0	0
Blood glucose increased	1 (1.9)	0	0	0	1 (1.9)
Blood immunoglobulin g decreased	1 (1.9)	1 (1.9)	0	0	0
Blood phosphorus increased	1 (1.9)	0	1 (1.9)	0	0
Blood testosterone decreased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Breath sounds abnormal	1 (1.9)	0	1 (1.9)	0	0
Electrocardiogram t wave abnormal	1 (1.9)	0	1 (1.9)	0	0
Enterovirus test positive	1 (1.9)	0	1 (1.9)	0	0
Haptoglobin decreased	1 (1.9)	1 (1.9)	0	0	0
Immunoglobulins decreased	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Prothrombin time prolonged	1 (1.9)	0	1 (1.9)	0	0
Staphylococcus test positive	1 (1.9)	1 (1.9)	0	0	0
Troponin increased	1 (1.9)	0	0	1 (1.9)	0
Urine output decreased	1 (1.9)	0	0	1 (1.9)	0
Metabolism and nutrition disorders					
-Total	29 (54.7)	4 (7.5)	7 (13.2)	13 (24.5)	5 (9.4)
Decreased appetite	17 (32.1)	5 (9.4)	4 (7.5)	7 (13.2)	1 (1.9)
Hypocalcaemia	12 (22.6)	1 (1.9)	8 (15.1)	3 (5.7)	0
Hypokalaemia	10 (18.9)	2 (3.8)	3 (5.7)	4 (7.5)	1 (1.9)
Hypophosphataemia	10 (18.9)	1 (1.9)	3 (5.7)	6 (11.3)	0
Hyperglycaemia	8 (15.1)	0	4 (7.5)	4 (7.5)	0
Hypoalbuminaemia	8 (15.1)	0	7 (13.2)	1 (1.9)	0
Hyperuricaemia	6 (11.3)	5 (9.4)	0	1 (1.9)	0
Hypervolaemia	5 (9.4)	0	1 (1.9)	4 (7.5)	0
Hypomagnesaemia	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Hypercalcaemia	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Hyperphosphataemia	3 (5.7)	2 (3.8)	0	0	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	3 (5.7)	1 (1.9)	0	0	2 (3.8)
Acidosis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Hyperkalaemia	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Hypermagnesaemia	2 (3.8)	2 (3.8)	0	0	0
Hyponatraemia	2 (3.8)	2 (3.8)	0	0	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0
Calcium deficiency	1 (1.9)	1 (1.9)	0	0	0
Dehydration	1 (1.9)	0	1 (1.9)	0	0
Hypertriglyceridaemia	1 (1.9)	0	0	1 (1.9)	0
Hypoglycaemia	1 (1.9)	0	1 (1.9)	0	0
Malnutrition	1 (1.9)	0	0	1 (1.9)	0
Polydipsia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	21 (39.6)	9 (17.0)	8 (15.1)	4 (7.5)	0
Myalgia	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Arthralgia	6 (11.3)	2 (3.8)	3 (5.7)	1 (1.9)	0
Pain in extremity	6 (11.3)	4 (7.5)	2 (3.8)	0	0
Back pain	5 (9.4)	2 (3.8)	2 (3.8)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	2 (3.8)	0	2 (3.8)	0	0
Muscular weakness	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pain in jaw	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Haemarthrosis	1 (1.9)	0	0	1 (1.9)	0
Muscle spasms	1 (1.9)	0	1 (1.9)	0	0
Neck pain	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	28 (52.8)	9 (17.0)	11 (20.8)	6 (11.3)	2 (3.8)
Headache	16 (30.2)	9 (17.0)	5 (9.4)	2 (3.8)	0
Encephalopathy	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Somnolence	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Cognitive disorder	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Dysgeusia	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Lethargy	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Tremor	3 (5.7)	3 (5.7)	0	0	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Cerebral haemorrhage	1 (1.9)	0	0	0	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dizziness	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Hyperaesthesia	1 (1.9)	1 (1.9)	0	0	0
Neurological decompensation	1 (1.9)	0	0	0	1 (1.9)
Paraesthesia	1 (1.9)	1 (1.9)	0	0	0
Seizure	1 (1.9)	0	0	1 (1.9)	0
Psychiatric disorders					
-Total	18 (34.0)	6 (11.3)	8 (15.1)	4 (7.5)	0
Confusional state	5 (9.4)	5 (9.4)	0	0	0
Agitation	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Anxiety	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Delirium	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Hallucination	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (1.9)	1 (1.9)	0	0	0
Mental status changes	1 (1.9)	0	1 (1.9)	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	12 (22.6)	3 (5.7)	4 (7.5)	2 (3.8)	3 (5.7)
Acute kidney injury	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Dysuria	2 (3.8)	2 (3.8)	0	0	0
Anuria	1 (1.9)	0	0	0	1 (1.9)
Haematuria	1 (1.9)	1 (1.9)	0	0	0
Incontinence	1 (1.9)	0	1 (1.9)	0	0
Pollakiuria	1 (1.9)	0	1 (1.9)	0	0
Renal failure	1 (1.9)	0	0	0	1 (1.9)
Renal tubular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Urinary incontinence	1 (1.9)	0	1 (1.9)	0	0
Urinary retention	1 (1.9)	0	1 (1.9)	0	0
Urinary tract disorder	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Female genital tract fistula	1 (1.9)	1 (1.9)	0	0	0
Heavy menstrual bleeding	1 (1.9)	1 (1.9)	0	0	0
Vaginal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (52.8)	10 (18.9)	3 (5.7)	8 (15.1)	7 (13.2)
Hypoxia	9 (17.0)	0	3 (5.7)	4 (7.5)	2 (3.8)
Pulmonary oedema	8 (15.1)	0	2 (3.8)	5 (9.4)	1 (1.9)
Cough	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Tachypnoea	5 (9.4)	2 (3.8)	1 (1.9)	2 (3.8)	0
Respiratory failure	4 (7.5)	0	0	0	4 (7.5)
Epistaxis	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Nasal congestion	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Oropharyngeal pain	3 (5.7)	3 (5.7)	0	0	0
Pleural effusion	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)
Dyspnoea	2 (3.8)	0	0	2 (3.8)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Acute respiratory distress syndrome	1 (1.9)	0	0	0	1 (1.9)
Acute respiratory failure	1 (1.9)	0	0	1 (1.9)	0
Atelectasis	1 (1.9)	0	1 (1.9)	0	0
Haemoptysis	1 (1.9)	0	1 (1.9)	0	0
Lung infiltration	1 (1.9)	0	0	1 (1.9)	0
Nasal dryness	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal plaque	1 (1.9)	0	1 (1.9)	0	0
Painful respiration	1 (1.9)	1 (1.9)	0	0	0
Paranasal sinus discomfort	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal erythema	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal exudate	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal oedema	1 (1.9)	0	1 (1.9)	0	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Respiratory disorder	1 (1.9)	0	1 (1.9)	0	0
Rhinorrhoea	1 (1.9)	1 (1.9)	0	0	0
Wheezing	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	19 (35.8)	11 (20.8)	7 (13.2)	1 (1.9)	0
Pruritus	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Erythema	3 (5.7)	3 (5.7)	0	0	0
Hyperhidrosis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Rash	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Blister	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Dermatitis atopic	2 (3.8)	2 (3.8)	0	0	0
Rash maculo-papular	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Rash papular	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.9)	1 (1.9)	0	0	0
Purpura	1 (1.9)	1 (1.9)	0	0	0
Rash vesicular	1 (1.9)	1 (1.9)	0	0	0
Scab	1 (1.9)	1 (1.9)	0	0	0
Skin discolouration	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin lesion	1 (1.9)	0	1 (1.9)	0	0
Social circumstances					
-Total	1 (1.9)	0	1 (1.9)	0	0
Patient uncooperative	1 (1.9)	0	1 (1.9)	0	0
Surgical and medical procedures					
-Total	1 (1.9)	0	0	1 (1.9)	0
Thrombolysis	1 (1.9)	0	0	1 (1.9)	0
Vascular disorders					
-Total	18 (34.0)	3 (5.7)	4 (7.5)	8 (15.1)	3 (5.7)
Hypotension	14 (26.4)	1 (1.9)	4 (7.5)	6 (11.3)	3 (5.7)
Hypertension	8 (15.1)	3 (5.7)	3 (5.7)	2 (3.8)	0
Capillary leak syndrome	1 (1.9)	0	0	1 (1.9)	0
Flushing	1 (1.9)	1 (1.9)	0	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0
Peripheral ischaemia	1 (1.9)	0	1 (1.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (88.0)	3 (12.0)	5 (20.0)	6 (24.0)	8 (32.0)
Blood and lymphatic system disorders					
-Total	4 (16.0)	0	0	3 (12.0)	1 (4.0)
Neutropenia	3 (12.0)	0	0	2 (8.0)	1 (4.0)
Anaemia	1 (4.0)	1 (4.0)	0	0	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Thrombocytopenia	1 (4.0)	0	0	1 (4.0)	0
Cardiac disorders					
-Total	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Cardiac failure	1 (4.0)	0	0	0	1 (4.0)
Tachycardia	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Hypothyroidism	1 (4.0)	0	1 (4.0)	0	0
Gastrointestinal disorders					
-Total	6 (24.0)	3 (12.0)	2 (8.0)	1 (4.0)	0
Constipation	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Diarrhoea	2 (8.0)	2 (8.0)	0	0	0
Nausea	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Enteritis	1 (4.0)	0	1 (4.0)	0	0
Pancreatitis	1 (4.0)	0	0	1 (4.0)	0
Proctalgia	1 (4.0)	1 (4.0)	0	0	0
Trichoglossia	1 (4.0)	1 (4.0)	0	0	0
Vomiting	1 (4.0)	1 (4.0)	0	0	0
General disorders and administration site conditions					
-Total	7 (28.0)	4 (16.0)	2 (8.0)	1 (4.0)	0
Pyrexia	5 (20.0)	2 (8.0)	2 (8.0)	1 (4.0)	0
Asthenia	1 (4.0)	1 (4.0)	0	0	0
Fatigue	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (4.0)	1 (4.0)	0	0	0
Hepatobiliary disorders					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Hypertransaminasaemia	1 (4.0)	1 (4.0)	0	0	0
Liver disorder	1 (4.0)	0	1 (4.0)	0	0
Immune system disorders					
-Total	6 (24.0)	1 (4.0)	3 (12.0)	2 (8.0)	0
Hypogammaglobulinaemia	3 (12.0)	0	3 (12.0)	0	0
Allergy to immunoglobulin therapy	1 (4.0)	1 (4.0)	0	0	0
Engraftment syndrome	1 (4.0)	0	0	1 (4.0)	0
Graft versus host disease	1 (4.0)	0	0	1 (4.0)	0
Immunodeficiency	1 (4.0)	0	0	1 (4.0)	0
Infections and infestations					
-Total	12 (48.0)	2 (8.0)	4 (16.0)	3 (12.0)	3 (12.0)
Nasopharyngitis	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Sinusitis	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Gastroenteritis	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Respiratory tract infection	2 (8.0)	1 (4.0)	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (8.0)	0	2 (8.0)	0	0
Coronavirus infection	1 (4.0)	0	0	1 (4.0)	0
Device related infection	1 (4.0)	0	0	1 (4.0)	0
Ear infection	1 (4.0)	0	1 (4.0)	0	0
Gastroenteritis viral	1 (4.0)	1 (4.0)	0	0	0
Influenza	1 (4.0)	0	1 (4.0)	0	0
Metapneumovirus infection	1 (4.0)	0	0	1 (4.0)	0
Nail infection	1 (4.0)	1 (4.0)	0	0	0
Pneumocystis jirovecii pneumonia	1 (4.0)	0	0	0	1 (4.0)
Pneumonia	1 (4.0)	1 (4.0)	0	0	0
Salmonellosis	1 (4.0)	0	1 (4.0)	0	0
Septic shock	1 (4.0)	0	0	0	1 (4.0)
Staphylococcal sepsis	1 (4.0)	0	0	0	1 (4.0)
Tinea pedis	1 (4.0)	1 (4.0)	0	0	0
Viral infection	1 (4.0)	0	1 (4.0)	0	0
Investigations					
-Total	9 (36.0)	1 (4.0)	1 (4.0)	5 (20.0)	2 (8.0)
Blood uric acid increased	2 (8.0)	0	0	1 (4.0)	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Alanine aminotransferase increased	1 (4.0)	1 (4.0)	0	0	0
Blood bilirubin increased	1 (4.0)	0	0	1 (4.0)	0
Blood creatinine increased	1 (4.0)	0	1 (4.0)	0	0
Blood immunoglobulin a decreased	1 (4.0)	0	0	1 (4.0)	0
Blood immunoglobulin m decreased	1 (4.0)	0	0	1 (4.0)	0
Blood thyroid stimulating hormone increased	1 (4.0)	1 (4.0)	0	0	0
Blood urea increased	1 (4.0)	0	0	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	0	1 (4.0)	0	0
Neutrophil count decreased	1 (4.0)	0	0	0	1 (4.0)
Oxygen saturation decreased	1 (4.0)	0	1 (4.0)	0	0
Weight increased	1 (4.0)	0	0	1 (4.0)	0
White blood cell count decreased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (24.0)	1 (4.0)	2 (8.0)	1 (4.0)	2 (8.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (8.0)	2 (8.0)	0	0	0
Decreased appetite	1 (4.0)	0	1 (4.0)	0	0
Hyperchloraemia	1 (4.0)	1 (4.0)	0	0	0
Hypervolaemia	1 (4.0)	0	0	1 (4.0)	0
Hypokalaemia	1 (4.0)	0	1 (4.0)	0	0
Metabolic acidosis	1 (4.0)	0	0	0	1 (4.0)
Metabolic syndrome	1 (4.0)	0	1 (4.0)	0	0
Tumour lysis syndrome	1 (4.0)	0	0	0	1 (4.0)
Musculoskeletal and connective tissue disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Pain in extremity	1 (4.0)	1 (4.0)	0	0	0
Nervous system disorders					
-Total	4 (16.0)	3 (12.0)	0	0	1 (4.0)
Headache	3 (12.0)	3 (12.0)	0	0	0
Hydrocephalus	1 (4.0)	0	0	0	1 (4.0)
Psychiatric disorders					
-Total	2 (8.0)	0	2 (8.0)	0	0
Anxiety	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (4.0)	0	1 (4.0)	0	0
Renal and urinary disorders					
-Total	3 (12.0)	1 (4.0)	1 (4.0)	0	1 (4.0)
Acute kidney injury	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Cystitis haemorrhagic	1 (4.0)	0	1 (4.0)	0	0
Reproductive system and breast disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Dysmenorrhoea	1 (4.0)	0	1 (4.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (32.0)	3 (12.0)	2 (8.0)	1 (4.0)	2 (8.0)
Cough	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Nasal congestion	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Pleural effusion	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Acute respiratory distress syndrome	1 (4.0)	0	0	0	1 (4.0)
Epistaxis	1 (4.0)	0	1 (4.0)	0	0
Hypoxia	1 (4.0)	0	0	1 (4.0)	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paranasal sinus inflammation	1 (4.0)	1 (4.0)	0	0	0
Respiratory distress	1 (4.0)	0	0	0	1 (4.0)
Rhinorrhoea	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (24.0)	4 (16.0)	2 (8.0)	0	0
Dry skin	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Eczema	1 (4.0)	1 (4.0)	0	0	0
Hangnail	1 (4.0)	1 (4.0)	0	0	0
Ingrowing nail	1 (4.0)	0	1 (4.0)	0	0
Skin discolouration	1 (4.0)	1 (4.0)	0	0	0
Skin swelling	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	4 (16.0)	0	0	1 (4.0)	3 (12.0)
Hypotension	2 (8.0)	0	0	0	2 (8.0)
Venoocclusive disease	2 (8.0)	0	0	1 (4.0)	1 (4.0)
Hypertension	1 (4.0)	0	1 (4.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (94.0)	6 (12.0)	19 (38.0)	9 (18.0)	13 (26.0)
Blood and lymphatic system disorders					
-Total	13 (26.0)	3 (6.0)	4 (8.0)	3 (6.0)	3 (6.0)
Anaemia	5 (10.0)	3 (6.0)	0	2 (4.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Neutropenia	2 (4.0)	0	0	0	2 (4.0)
B-cell aplasia	1 (2.0)	0	1 (2.0)	0	0
Disseminated intravascular coagulation	1 (2.0)	0	0	1 (2.0)	0
Eosinophilia	1 (2.0)	0	1 (2.0)	0	0
Leukocytosis	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (2.0)	0	1 (2.0)	0	0
Lymphadenopathy	1 (2.0)	1 (2.0)	0	0	0
Lymphocytosis	1 (2.0)	0	1 (2.0)	0	0
Lymphopenia	1 (2.0)	0	0	1 (2.0)	0
Thrombocytopenia	1 (2.0)	0	0	0	1 (2.0)
Cardiac disorders					
-Total	5 (10.0)	2 (4.0)	1 (2.0)	0	2 (4.0)
Cardiac arrest	2 (4.0)	0	0	0	2 (4.0)
Cardiac failure	1 (2.0)	0	0	1 (2.0)	0
Left ventricular dysfunction	1 (2.0)	0	1 (2.0)	0	0
Tachycardia	1 (2.0)	1 (2.0)	0	0	0
Tricuspid valve incompetence	1 (2.0)	1 (2.0)	0	0	0
Eye disorders					
-Total	4 (8.0)	4 (8.0)	0	0	0
Cataract	2 (4.0)	2 (4.0)	0	0	0
Hypermetropia	1 (2.0)	1 (2.0)	0	0	0
Ocular hyperaemia	1 (2.0)	1 (2.0)	0	0	0
Visual impairment	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (28.0)	10 (20.0)	4 (8.0)	0	0
Diarrhoea	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Vomiting	5 (10.0)	5 (10.0)	0	0	0
Nausea	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Abdominal pain upper	1 (2.0)	1 (2.0)	0	0	0
Abdominal rigidity	1 (2.0)	0	1 (2.0)	0	0
Constipation	1 (2.0)	0	1 (2.0)	0	0
Dyspepsia	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal haemorrhage	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal inflammation	1 (2.0)	0	1 (2.0)	0	0
Mouth haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Pancreatitis	1 (2.0)	1 (2.0)	0	0	0
Peritoneal haematoma	1 (2.0)	1 (2.0)	0	0	0
Stomatitis	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	17 (34.0)	11 (22.0)	4 (8.0)	2 (4.0)	0
Pyrexia	10 (20.0)	5 (10.0)	4 (8.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	5 (10.0)	5 (10.0)	0	0	0
Pain	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Malaise	1 (2.0)	1 (2.0)	0	0	0
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Hepatic cytolysis	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	10 (20.0)	0	8 (16.0)	2 (4.0)	0
Hypogammaglobulinaemia	7 (14.0)	0	7 (14.0)	0	0
Allergy to immunoglobulin therapy	1 (2.0)	0	0	1 (2.0)	0
Drug hypersensitivity	1 (2.0)	0	1 (2.0)	0	0
Graft versus host disease	1 (2.0)	0	0	1 (2.0)	0
Infections and infestations					
-Total	27 (54.0)	3 (6.0)	10 (20.0)	9 (18.0)	5 (10.0)
Upper respiratory tract infection	8 (16.0)	3 (6.0)	3 (6.0)	2 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Parainfluenzae virus infection	4 (8.0)	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)
Gastroenteritis	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Otitis media	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Respiratory syncytial virus infection	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Rhinovirus infection	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Bacteraemia	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Metapneumovirus infection	2 (4.0)	0	0	2 (4.0)	0
Otitis externa	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Pneumonia	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Rhinitis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Adenovirus infection	1 (2.0)	0	0	1 (2.0)	0
Bk virus infection	1 (2.0)	0	0	1 (2.0)	0
Bronchopulmonary aspergillosis	1 (2.0)	0	0	0	1 (2.0)
Cellulitis	1 (2.0)	0	1 (2.0)	0	0
Conjunctivitis	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis	1 (2.0)	0	1 (2.0)	0	0
Cytomegalovirus infection reactivation	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0
Ear, nose and throat infection	1 (2.0)	0	1 (2.0)	0	0
Encephalitis	1 (2.0)	0	0	0	1 (2.0)
Enterobacter infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis clostridial	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal infection	1 (2.0)	1 (2.0)	0	0	0
Gingivitis	1 (2.0)	1 (2.0)	0	0	0
Herpes simplex	1 (2.0)	0	1 (2.0)	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	0	0	1 (2.0)	0
Klebsiella infection	1 (2.0)	0	0	1 (2.0)	0
Mastoiditis	1 (2.0)	0	0	1 (2.0)	0
Molluscum contagiosum	1 (2.0)	1 (2.0)	0	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Paronychia	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	1 (2.0)	0	0	1 (2.0)	0
Pneumocystis jirovecii pneumonia	1 (2.0)	0	0	1 (2.0)	0
Respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Respiratory tract infection viral	1 (2.0)	0	1 (2.0)	0	0
Sinusitis fungal	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal skin infection	1 (2.0)	0	1 (2.0)	0	0
Urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Viral haemorrhagic cystitis	1 (2.0)	0	0	1 (2.0)	0
Viral infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Injury, poisoning and procedural complications					
-Total	9 (18.0)	5 (10.0)	4 (8.0)	0	0
Infusion related reaction	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Contusion	1 (2.0)	1 (2.0)	0	0	0
Fibula fracture	1 (2.0)	0	1 (2.0)	0	0
Ligament sprain	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (2.0)	0	1 (2.0)	0	0
Post-traumatic neck syndrome	1 (2.0)	0	1 (2.0)	0	0
Skin abrasion	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	21 (42.0)	6 (12.0)	6 (12.0)	6 (12.0)	3 (6.0)
Neutrophil count decreased	9 (18.0)	2 (4.0)	1 (2.0)	3 (6.0)	3 (6.0)
White blood cell count decreased	9 (18.0)	3 (6.0)	2 (4.0)	3 (6.0)	1 (2.0)
Lymphocyte count decreased	3 (6.0)	1 (2.0)	0	2 (4.0)	0
Platelet count decreased	3 (6.0)	2 (4.0)	0	0	1 (2.0)
Alanine aminotransferase increased	1 (2.0)	0	0	1 (2.0)	0
Blood bilirubin increased	1 (2.0)	0	1 (2.0)	0	0
Blood immunoglobulin a decreased	1 (2.0)	1 (2.0)	0	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Blood lactate dehydrogenase increased	1 (2.0)	1 (2.0)	0	0	0
Bone density decreased	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (2.0)	1 (2.0)	0	0	0
Ejection fraction decreased	1 (2.0)	0	1 (2.0)	0	0
Heart sounds abnormal	1 (2.0)	1 (2.0)	0	0	0
Hepatitis b virus test positive	1 (2.0)	0	1 (2.0)	0	0
Immunoglobulins decreased	1 (2.0)	0	1 (2.0)	0	0
Weight decreased	1 (2.0)	0	0	1 (2.0)	0
Metabolism and nutrition disorders					
-Total	9 (18.0)	3 (6.0)	2 (4.0)	3 (6.0)	1 (2.0)
Decreased appetite	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Hypokalaemia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Haemochromatosis	1 (2.0)	0	0	1 (2.0)	0
Hyperkalaemia	1 (2.0)	0	1 (2.0)	0	0
Hyperuricaemia	1 (2.0)	1 (2.0)	0	0	0
Hypophagia	1 (2.0)	0	1 (2.0)	0	0
Hypophosphataemia	1 (2.0)	0	1 (2.0)	0	0
Iron overload	1 (2.0)	0	1 (2.0)	0	0
Malnutrition	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	14 (28.0)	4 (8.0)	7 (14.0)	3 (6.0)	0
Back pain	6 (12.0)	2 (4.0)	2 (4.0)	2 (4.0)	0
Pain in extremity	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Arthralgia	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Bone pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Growth retardation	1 (2.0)	0	1 (2.0)	0	0
Musculoskeletal chest pain	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal pain	1 (2.0)	0	1 (2.0)	0	0
Myalgia	1 (2.0)	0	1 (2.0)	0	0
Neck pain	1 (2.0)	1 (2.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Skin papilloma	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Cancer pain	1 (2.0)	0	1 (2.0)	0	0
Myelodysplastic syndrome	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (20.0)	4 (8.0)	5 (10.0)	0	1 (2.0)
Headache	7 (14.0)	3 (6.0)	4 (8.0)	0	0
Autonomic neuropathy	1 (2.0)	0	0	1 (2.0)	0
Cerebral haemorrhage	1 (2.0)	0	0	0	1 (2.0)
Dizziness	1 (2.0)	1 (2.0)	0	0	0
Extrapyramidal disorder	1 (2.0)	0	1 (2.0)	0	0
Memory impairment	1 (2.0)	0	1 (2.0)	0	0
Migraine	1 (2.0)	0	1 (2.0)	0	0
Seizure	1 (2.0)	0	0	1 (2.0)	0
Psychiatric disorders					
-Total	8 (16.0)	1 (2.0)	6 (12.0)	1 (2.0)	0
Anxiety	5 (10.0)	1 (2.0)	4 (8.0)	0	0
Agitation	1 (2.0)	1 (2.0)	0	0	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Mental status changes	1 (2.0)	0	0	1 (2.0)	0
Mood altered	1 (2.0)	1 (2.0)	0	0	0
Nightmare	1 (2.0)	1 (2.0)	0	0	0
Persistent depressive disorder	1 (2.0)	0	1 (2.0)	0	0
Sleep disorder	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tearfulness	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	2 (4.0)	0	0	2 (4.0)	0
Acute kidney injury	1 (2.0)	0	1 (2.0)	0	0
Dysuria	1 (2.0)	0	1 (2.0)	0	0
Haematuria	1 (2.0)	0	0	1 (2.0)	0
Kidney enlargement	1 (2.0)	0	1 (2.0)	0	0
Renal mass	1 (2.0)	0	1 (2.0)	0	0
Renal tubular disorder	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (32.0)	8 (16.0)	5 (10.0)	2 (4.0)	1 (2.0)
Cough	7 (14.0)	5 (10.0)	2 (4.0)	0	0
Nasal congestion	4 (8.0)	4 (8.0)	0	0	0
Epistaxis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Hypoxia	2 (4.0)	0	0	2 (4.0)	0
Rhinitis allergic	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Rhinorrhoea	2 (4.0)	2 (4.0)	0	0	0
Bronchial oedema	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchospasm	1 (2.0)	0	1 (2.0)	0	0
Dyspnoea	1 (2.0)	0	1 (2.0)	0	0
Lung disorder	1 (2.0)	1 (2.0)	0	0	0
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Upper respiratory tract inflammation	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (28.0)	8 (16.0)	5 (10.0)	1 (2.0)	0
Dry skin	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Rash	2 (4.0)	2 (4.0)	0	0	0
Decubitus ulcer	1 (2.0)	0	0	1 (2.0)	0
Dermatitis allergic	1 (2.0)	1 (2.0)	0	0	0
Dermatitis atopic	1 (2.0)	1 (2.0)	0	0	0
Erythema	1 (2.0)	0	1 (2.0)	0	0
Ingrowing nail	1 (2.0)	0	1 (2.0)	0	0
Miliaria	1 (2.0)	1 (2.0)	0	0	0
Night sweats	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photosensitivity reaction	1 (2.0)	0	1 (2.0)	0	0
Pruritus	1 (2.0)	0	1 (2.0)	0	0
Skin hypopigmentation	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Hypotension	2 (4.0)	1 (2.0)	0	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (62.5)	1 (6.3)	1 (6.3)	6 (37.5)	2 (12.5)
Blood and lymphatic system disorders					
-Total	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Agranulocytosis	1 (6.3)	0	0	1 (6.3)	0
Anaemia	1 (6.3)	0	1 (6.3)	0	0
Neutropenia	1 (6.3)	0	0	0	1 (6.3)
Thrombocytopenia	1 (6.3)	0	1 (6.3)	0	0
Eye disorders					
-Total	1 (6.3)	0	0	1 (6.3)	0
Eye pain	1 (6.3)	0	0	1 (6.3)	0
Eyelid oedema	1 (6.3)	1 (6.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Diarrhoea	2 (12.5)	1 (6.3)	0	1 (6.3)	0
General disorders and administration site conditions					
-Total	3 (18.8)	2 (12.5)	0	1 (6.3)	0
Pyrexia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Xerosis	1 (6.3)	1 (6.3)	0	0	0
Immune system disorders					
-Total	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Drug hypersensitivity	1 (6.3)	0	0	1 (6.3)	0
Hypogammaglobulinaemia	1 (6.3)	0	1 (6.3)	0	0
Seasonal allergy	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					
-Total	9 (56.3)	1 (6.3)	0	6 (37.5)	2 (12.5)
Conjunctivitis	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Sinusitis	3 (18.8)	0	3 (18.8)	0	0
Herpes zoster	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Oral herpes	2 (12.5)	1 (6.3)	1 (6.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=16			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	2 (12.5)	0	2 (12.5)	0	0
Sepsis	2 (12.5)	0	0	0	2 (12.5)
Skin infection	2 (12.5)	0	2 (12.5)	0	0
Upper respiratory tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Bronchiolitis	1 (6.3)	0	0	1 (6.3)	0
Bronchitis	1 (6.3)	0	1 (6.3)	0	0
Candida infection	1 (6.3)	0	1 (6.3)	0	0
Covid-19	1 (6.3)	0	0	1 (6.3)	0
Device related sepsis	1 (6.3)	0	0	1 (6.3)	0
Ear infection	1 (6.3)	0	0	1 (6.3)	0
Folliculitis	1 (6.3)	0	1 (6.3)	0	0
Gastroenteritis viral	1 (6.3)	0	1 (6.3)	0	0
Herpes virus infection	1 (6.3)	0	1 (6.3)	0	0
Nail infection	1 (6.3)	0	1 (6.3)	0	0
Ophthalmic herpes zoster	1 (6.3)	0	1 (6.3)	0	0
Pneumonia respiratory syncytial viral	1 (6.3)	0	0	1 (6.3)	0
Rhinitis	1 (6.3)	1 (6.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (6.3)	0	1 (6.3)	0	0
Staphylococcal bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Streptococcal sepsis	1 (6.3)	0	1 (6.3)	0	0
Injury, poisoning and procedural complications					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Infusion related reaction	1 (6.3)	0	0	1 (6.3)	0
Ligament sprain	1 (6.3)	1 (6.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Hyperlipidaemia	1 (6.3)	0	1 (6.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Osteonecrosis	1 (6.3)	1 (6.3)	0	0	0
Pain in extremity	1 (6.3)	0	1 (6.3)	0	0
Nervous system disorders					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Headache	2 (12.5)	0	1 (6.3)	1 (6.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	4 (25.0)	3 (18.8)	0	1 (6.3)	0
Cough	1 (6.3)	1 (6.3)	0	0	0
Dyspnoea	1 (6.3)	0	1 (6.3)	0	0
Epistaxis	1 (6.3)	1 (6.3)	0	0	0
Hypoxia	1 (6.3)	0	0	1 (6.3)	0
Oropharyngeal pain	1 (6.3)	1 (6.3)	0	0	0
Rhinorrhoea	1 (6.3)	0	1 (6.3)	0	0
Sleep apnoea syndrome	1 (6.3)	1 (6.3)	0	0	0
Wheezing	1 (6.3)	0	1 (6.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (25.0)	1 (6.3)	1 (6.3)	2 (12.5)	0
Eczema	1 (6.3)	0	0	1 (6.3)	0
Papule	1 (6.3)	1 (6.3)	0	0	0
Rash	1 (6.3)	0	1 (6.3)	0	0
Rash erythematous	1 (6.3)	1 (6.3)	0	0	0
Rash macular	1 (6.3)	0	0	1 (6.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (64.7)	2 (5.9)	9 (26.5)	6 (17.6)	5 (14.7)
Blood and lymphatic system disorders					
-Total	2 (5.9)	0	2 (5.9)	0	0
Hypercoagulation	1 (2.9)	0	1 (2.9)	0	0
Lymphadenopathy	1 (2.9)	0	1 (2.9)	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Cerebral cavernous malformation	1 (2.9)	1 (2.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Deafness unilateral	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Delayed puberty	1 (2.9)	0	1 (2.9)	0	0
Hypothyroidism	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Dry eye	1 (2.9)	1 (2.9)	0	0	0
Mydriasis	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Diarrhoea	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Constipation	1 (2.9)	1 (2.9)	0	0	0
Irritable bowel syndrome	1 (2.9)	0	1 (2.9)	0	0
Nausea	1 (2.9)	1 (2.9)	0	0	0
Vomiting	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	6 (17.6)	2 (5.9)	3 (8.8)	0	1 (2.9)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Fatigue	1 (2.9)	0	1 (2.9)	0	0
Multiple organ dysfunction syndrome	1 (2.9)	0	0	0	1 (2.9)
Non-cardiac chest pain	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	6 (17.6)	2 (5.9)	3 (8.8)	0	1 (2.9)
Chronic graft versus host disease	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hypogammaglobulinaemia	2 (5.9)	0	2 (5.9)	0	0
Seasonal allergy	2 (5.9)	2 (5.9)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	0	0	1 (2.9)
Infections and infestations					
-Total	14 (41.2)	1 (2.9)	7 (20.6)	4 (11.8)	2 (5.9)
Rhinovirus infection	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Sinusitis	3 (8.8)	0	3 (8.8)	0	0
Upper respiratory tract infection	3 (8.8)	2 (5.9)	1 (2.9)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal infection	2 (5.9)	0	2 (5.9)	0	0
Influenza	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Pneumonia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Urinary tract infection	2 (5.9)	0	2 (5.9)	0	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Bronchitis	1 (2.9)	0	1 (2.9)	0	0
Clostridium difficile colitis	1 (2.9)	0	0	1 (2.9)	0
Conjunctivitis	1 (2.9)	1 (2.9)	0	0	0
Covid-19	1 (2.9)	1 (2.9)	0	0	0
Covid-19 pneumonia	1 (2.9)	0	0	0	1 (2.9)
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis escherichia coli	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis salmonella	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Otitis media acute	1 (2.9)	0	1 (2.9)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	1 (2.9)	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal abscess	1 (2.9)	0	0	1 (2.9)	0
Syphilis	1 (2.9)	0	1 (2.9)	0	0
Urinary tract infection pseudomonal	1 (2.9)	0	1 (2.9)	0	0
Varicella zoster virus infection	1 (2.9)	0	1 (2.9)	0	0
Viral skin infection	1 (2.9)	1 (2.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.9)	1 (2.9)	0	0	0
Abdominal injury	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	6 (17.6)	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)
Neutrophil count decreased	3 (8.8)	2 (5.9)	0	0	1 (2.9)
Platelet count decreased	2 (5.9)	2 (5.9)	0	0	0
Blood bilirubin increased	1 (2.9)	1 (2.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Oxygen saturation decreased	1 (2.9)	0	0	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	5 (14.7)	0	1 (2.9)	3 (8.8)	1 (2.9)
Decreased appetite	1 (2.9)	0	0	0	1 (2.9)
Hypercholesterolaemia	1 (2.9)	0	1 (2.9)	0	0
Hyperglycaemia	1 (2.9)	0	0	1 (2.9)	0
Hypernatraemia	1 (2.9)	0	0	1 (2.9)	0
Hypertriglyceridaemia	1 (2.9)	0	1 (2.9)	0	0
Iron overload	1 (2.9)	0	1 (2.9)	0	0
Obesity	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (14.7)	1 (2.9)	4 (11.8)	0	0
Arthralgia	1 (2.9)	0	1 (2.9)	0	0
Growth retardation	1 (2.9)	0	1 (2.9)	0	0
Joint effusion	1 (2.9)	0	1 (2.9)	0	0
Osteopenia	1 (2.9)	1 (2.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (2.9)	0	1 (2.9)	0	0
Synovitis	1 (2.9)	0	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.9)	0	0	1 (2.9)	0
Bone giant cell tumour benign	1 (2.9)	0	0	1 (2.9)	0
Nervous system disorders					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Dysarthria	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorder	1 (2.9)	0	0	1 (2.9)	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Psychiatric disorders					
-Total	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Anxiety	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Tic	1 (2.9)	0	1 (2.9)	0	0
Reproductive system and breast disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Endometriosis	1 (2.9)	0	0	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	6 (17.6)	1 (2.9)	2 (5.9)	0	3 (8.8)
Cough	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Dyspnoea	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Rhinorrhoea	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Dyspnoea exertional	1 (2.9)	1 (2.9)	0	0	0
Laryngeal oedema	1 (2.9)	0	0	0	1 (2.9)
Pharyngeal erythema	1 (2.9)	1 (2.9)	0	0	0
Pleural effusion	1 (2.9)	0	1 (2.9)	0	0
Respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Sleep apnoea syndrome	1 (2.9)	0	1 (2.9)	0	0
Tachypnoea	1 (2.9)	0	0	0	1 (2.9)
Skin and subcutaneous tissue disorders					
-Total	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Dermatitis atopic	1 (2.9)	0	0	1 (2.9)	0
Dry skin	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hypertension	2 (5.9)	0	1 (2.9)	1 (2.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (100)	1 (3.7)	3 (11.1)	7 (25.9)	16 (59.3)
Blood and lymphatic system disorders					
-Total	14 (51.9)	1 (3.7)	3 (11.1)	5 (18.5)	5 (18.5)
Anaemia	6 (22.2)	3 (11.1)	3 (11.1)	0	0
Neutropenia	5 (18.5)	0	1 (3.7)	1 (3.7)	3 (11.1)
Disseminated intravascular coagulation	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Febrile neutropenia	4 (14.8)	0	0	4 (14.8)	0
Thrombocytopenia	3 (11.1)	0	0	1 (3.7)	2 (7.4)
Agranulocytosis	1 (3.7)	0	0	1 (3.7)	0
Coagulopathy	1 (3.7)	1 (3.7)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	1 (3.7)	1 (3.7)	0	0	0
Cardiac disorders					
-Total	8 (29.6)	3 (11.1)	2 (7.4)	1 (3.7)	2 (7.4)
Tachycardia	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
Bradycardia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Sinus tachycardia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Cardiac dysfunction	1 (3.7)	1 (3.7)	0	0	0
Cardiac failure	1 (3.7)	0	0	0	1 (3.7)
Ear and labyrinth disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Ear pruritus	1 (3.7)	1 (3.7)	0	0	0
Endocrine disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Hypothyroidism	1 (3.7)	0	1 (3.7)	0	0
Eye disorders					
-Total	4 (14.8)	2 (7.4)	1 (3.7)	1 (3.7)	0
Eyelid oedema	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Eye pain	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Conjunctival haemorrhage	1 (3.7)	1 (3.7)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	1 (3.7)	1 (3.7)	0	0	0
Gastrointestinal disorders					
-Total	21 (77.8)	6 (22.2)	8 (29.6)	7 (25.9)	0
Diarrhoea	10 (37.0)	6 (22.2)	2 (7.4)	2 (7.4)	0
Vomiting	8 (29.6)	7 (25.9)	1 (3.7)	0	0
Abdominal pain	5 (18.5)	1 (3.7)	4 (14.8)	0	0
Nausea	5 (18.5)	3 (11.1)	2 (7.4)	0	0
Constipation	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Pancreatitis	4 (14.8)	0	2 (7.4)	2 (7.4)	0
Abdominal pain upper	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Proctalgia	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Abdominal distension	1 (3.7)	0	1 (3.7)	0	0
Anal haemorrhage	1 (3.7)	1 (3.7)	0	0	0
Ascites	1 (3.7)	1 (3.7)	0	0	0
Dysphagia	1 (3.7)	0	0	1 (3.7)	0
Enteritis	1 (3.7)	0	1 (3.7)	0	0
Enterocolitis	1 (3.7)	0	1 (3.7)	0	0
Gastrooesophageal reflux disease	1 (3.7)	0	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival erythema	1 (3.7)	1 (3.7)	0	0	0
Melaena	1 (3.7)	0	0	1 (3.7)	0
Mouth haemorrhage	1 (3.7)	0	1 (3.7)	0	0
Trichoglossia	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	15 (55.6)	9 (33.3)	2 (7.4)	2 (7.4)	2 (7.4)
Pyrexia	10 (37.0)	5 (18.5)	2 (7.4)	2 (7.4)	1 (3.7)
Fatigue	5 (18.5)	4 (14.8)	1 (3.7)	0	0
Face oedema	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Oedema peripheral	3 (11.1)	3 (11.1)	0	0	0
Asthenia	2 (7.4)	2 (7.4)	0	0	0
Catheter site erythema	1 (3.7)	1 (3.7)	0	0	0
Catheter site haemorrhage	1 (3.7)	1 (3.7)	0	0	0
Generalised oedema	1 (3.7)	1 (3.7)	0	0	0
Localised oedema	1 (3.7)	1 (3.7)	0	0	0
Multiple organ dysfunction syndrome	1 (3.7)	0	0	0	1 (3.7)
Oedema due to hepatic disease	1 (3.7)	0	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (3.7)	0	0	1 (3.7)	0
Xerosis	1 (3.7)	1 (3.7)	0	0	0
Hepatobiliary disorders					
-Total	7 (25.9)	0	3 (11.1)	2 (7.4)	2 (7.4)
Hepatic function abnormal	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hyperbilirubinaemia	2 (7.4)	0	2 (7.4)	0	0
Cholelithiasis	1 (3.7)	1 (3.7)	0	0	0
Cholestasis	1 (3.7)	0	0	0	1 (3.7)
Gallbladder enlargement	1 (3.7)	1 (3.7)	0	0	0
Hypertransaminasaemia	1 (3.7)	0	1 (3.7)	0	0
Liver disorder	1 (3.7)	0	1 (3.7)	0	0
Immune system disorders					
-Total	24 (88.9)	0	5 (18.5)	10 (37.0)	9 (33.3)
Cytokine release syndrome	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Hypogammaglobulinaemia	11 (40.7)	1 (3.7)	7 (25.9)	3 (11.1)	0
Haemophagocytic lymphohistiocytosis	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Immunodeficiency	2 (7.4)	0	0	2 (7.4)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	1 (3.7)	1 (3.7)	0	0	0
Drug hypersensitivity	1 (3.7)	0	0	1 (3.7)	0
Engraftment syndrome	1 (3.7)	0	0	1 (3.7)	0
Graft versus host disease	1 (3.7)	0	0	1 (3.7)	0
Seasonal allergy	1 (3.7)	0	1 (3.7)	0	0
Infections and infestations					
-Total	21 (77.8)	4 (14.8)	1 (3.7)	10 (37.0)	6 (22.2)
Conjunctivitis	5 (18.5)	1 (3.7)	4 (14.8)	0	0
Nail infection	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Nasopharyngitis	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Rhinovirus infection	3 (11.1)	0	3 (11.1)	0	0
Sinusitis	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Clostridium difficile infection	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Ear infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Gastroenteritis	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Gastroenteritis viral	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Herpes zoster	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Oral herpes	2 (7.4)	1 (3.7)	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (7.4)	0	2 (7.4)	0	0
Otitis media	2 (7.4)	0	2 (7.4)	0	0
Pneumonia	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Respiratory tract infection	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Sepsis	2 (7.4)	0	0	0	2 (7.4)
Skin infection	2 (7.4)	0	2 (7.4)	0	0
Staphylococcal infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Upper respiratory tract infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Anal abscess	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Bk virus infection	1 (3.7)	1 (3.7)	0	0	0
Bronchiolitis	1 (3.7)	0	0	1 (3.7)	0
Bronchitis	1 (3.7)	0	1 (3.7)	0	0
Bronchopulmonary aspergillosis	1 (3.7)	0	0	1 (3.7)	0
Candida infection	1 (3.7)	0	1 (3.7)	0	0
Cholecystitis infective	1 (3.7)	0	1 (3.7)	0	0
Coronavirus infection	1 (3.7)	0	0	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (3.7)	0	0	1 (3.7)	0
Device related infection	1 (3.7)	0	0	1 (3.7)	0
Device related sepsis	1 (3.7)	0	0	1 (3.7)	0
Encephalitis	1 (3.7)	0	0	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	0	0	1 (3.7)
Folliculitis	1 (3.7)	0	1 (3.7)	0	0
Gastroenteritis norovirus	1 (3.7)	1 (3.7)	0	0	0
Herpes virus infection	1 (3.7)	0	1 (3.7)	0	0
Influenza	1 (3.7)	0	1 (3.7)	0	0
Localised infection	1 (3.7)	1 (3.7)	0	0	0
Meningitis bacterial	1 (3.7)	0	0	1 (3.7)	0
Metapneumovirus infection	1 (3.7)	0	0	1 (3.7)	0
Myringitis	1 (3.7)	1 (3.7)	0	0	0
Ophthalmic herpes zoster	1 (3.7)	0	1 (3.7)	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Paronychia	1 (3.7)	0	1 (3.7)	0	0
Pneumocystis jirovecii pneumonia	1 (3.7)	0	0	0	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (3.7)	0	0	1 (3.7)	0
Rhinitis	1 (3.7)	1 (3.7)	0	0	0
Salmonellosis	1 (3.7)	0	1 (3.7)	0	0
Septic shock	1 (3.7)	0	0	0	1 (3.7)
Staphylococcal bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Staphylococcal sepsis	1 (3.7)	0	0	0	1 (3.7)
Streptococcal sepsis	1 (3.7)	0	1 (3.7)	0	0
Tinea pedis	1 (3.7)	1 (3.7)	0	0	0
Viral infection	1 (3.7)	0	1 (3.7)	0	0
Injury, poisoning and procedural complications					
-Total	8 (29.6)	3 (11.1)	3 (11.1)	1 (3.7)	1 (3.7)
Procedural pain	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Wound	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Contusion	1 (3.7)	1 (3.7)	0	0	0
Fall	1 (3.7)	0	1 (3.7)	0	0
Infusion related reaction	1 (3.7)	0	0	1 (3.7)	0
Ligament sprain	1 (3.7)	1 (3.7)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scratch	1 (3.7)	1 (3.7)	0	0	0
Skin abrasion	1 (3.7)	1 (3.7)	0	0	0
Skin injury	1 (3.7)	0	1 (3.7)	0	0
Skin wound	1 (3.7)	1 (3.7)	0	0	0
Vasoplegia syndrome	1 (3.7)	0	0	0	1 (3.7)
Investigations					
-Total	19 (70.4)	2 (7.4)	2 (7.4)	5 (18.5)	10 (37.0)
White blood cell count decreased	8 (29.6)	1 (3.7)	1 (3.7)	1 (3.7)	5 (18.5)
Neutrophil count decreased	7 (25.9)	0	1 (3.7)	0	6 (22.2)
Platelet count decreased	7 (25.9)	2 (7.4)	1 (3.7)	2 (7.4)	2 (7.4)
Alanine aminotransferase increased	6 (22.2)	1 (3.7)	2 (7.4)	3 (11.1)	0
Lymphocyte count decreased	6 (22.2)	1 (3.7)	1 (3.7)	2 (7.4)	2 (7.4)
Aspartate aminotransferase increased	5 (18.5)	0	4 (14.8)	1 (3.7)	0
Blood fibrinogen decreased	5 (18.5)	1 (3.7)	3 (11.1)	0	1 (3.7)
Blood bilirubin increased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Serum ferritin increased	4 (14.8)	0	4 (14.8)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Blood uric acid increased	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
Electrocardiogram qt prolonged	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Activated partial thromboplastin time prolonged	2 (7.4)	2 (7.4)	0	0	0
Blood creatine phosphokinase increased	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Blood creatinine increased	2 (7.4)	0	1 (3.7)	0	1 (3.7)
Blood immunoglobulin a decreased	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Blood lactate dehydrogenase increased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
International normalised ratio increased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Lipase increased	2 (7.4)	1 (3.7)	0	0	1 (3.7)
Amylase increased	1 (3.7)	1 (3.7)	0	0	0
Bacterial test positive	1 (3.7)	0	0	1 (3.7)	0
Blood bicarbonate decreased	1 (3.7)	0	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0
Blood thyroid stimulating hormone increased	1 (3.7)	1 (3.7)	0	0	0
Blood urea increased	1 (3.7)	0	0	1 (3.7)	0
C-reactive protein increased	1 (3.7)	1 (3.7)	0	0	0
Cardiac murmur	1 (3.7)	1 (3.7)	0	0	0
Coagulation test abnormal	1 (3.7)	1 (3.7)	0	0	0
Fibrin d dimer increased	1 (3.7)	1 (3.7)	0	0	0
Haemoglobin decreased	1 (3.7)	0	0	1 (3.7)	0
Immunoglobulins decreased	1 (3.7)	0	1 (3.7)	0	0
Oxygen saturation decreased	1 (3.7)	0	1 (3.7)	0	0
Urine output decreased	1 (3.7)	0	0	0	1 (3.7)
Weight decreased	1 (3.7)	0	1 (3.7)	0	0
Weight increased	1 (3.7)	0	0	1 (3.7)	0
Metabolism and nutrition disorders					
-Total	17 (63.0)	4 (14.8)	2 (7.4)	6 (22.2)	5 (18.5)
Hypokalaemia	10 (37.0)	1 (3.7)	3 (11.1)	5 (18.5)	1 (3.7)
Decreased appetite	8 (29.6)	4 (14.8)	1 (3.7)	3 (11.1)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	7 (25.9)	2 (7.4)	2 (7.4)	2 (7.4)	1 (3.7)
Hypocalcaemia	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Hyperuricaemia	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Hypoalbuminaemia	3 (11.1)	0	3 (11.1)	0	0
Tumour lysis syndrome	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hyperchloraemia	2 (7.4)	2 (7.4)	0	0	0
Hypernatraemia	2 (7.4)	1 (3.7)	0	0	1 (3.7)
Hyperphosphataemia	2 (7.4)	2 (7.4)	0	0	0
Hypervolaemia	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Hypomagnesaemia	2 (7.4)	2 (7.4)	0	0	0
Haemosiderosis	1 (3.7)	0	1 (3.7)	0	0
Hyperlactacidaemia	1 (3.7)	1 (3.7)	0	0	0
Hyperlipidaemia	1 (3.7)	0	1 (3.7)	0	0
Hypertriglyceridaemia	1 (3.7)	0	0	0	1 (3.7)
Hyponatraemia	1 (3.7)	1 (3.7)	0	0	0
Metabolic acidosis	1 (3.7)	0	0	0	1 (3.7)
Metabolic syndrome	1 (3.7)	0	1 (3.7)	0	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (48.1)	7 (25.9)	5 (18.5)	0	1 (3.7)
Pain in extremity	7 (25.9)	3 (11.1)	4 (14.8)	0	0
Arthralgia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Myalgia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Back pain	1 (3.7)	0	1 (3.7)	0	0
Muscle rigidity	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal chest pain	1 (3.7)	1 (3.7)	0	0	0
Myositis	1 (3.7)	0	1 (3.7)	0	0
Osteonecrosis	1 (3.7)	1 (3.7)	0	0	0
Rhabdomyolysis	1 (3.7)	0	0	0	1 (3.7)
Nervous system disorders					
-Total	14 (51.9)	5 (18.5)	5 (18.5)	3 (11.1)	1 (3.7)
Headache	8 (29.6)	3 (11.1)	4 (14.8)	1 (3.7)	0
Encephalopathy	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Tremor	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Dizziness	2 (7.4)	2 (7.4)	0	0	0
Generalised tonic-clonic seizure	1 (3.7)	0	1 (3.7)	0	0
Hydrocephalus	1 (3.7)	0	0	0	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoaesthesia	1 (3.7)	1 (3.7)	0	0	0
Monoparesis	1 (3.7)	0	1 (3.7)	0	0
Neuralgia	1 (3.7)	0	1 (3.7)	0	0
Seizure	1 (3.7)	0	1 (3.7)	0	0
Somnolence	1 (3.7)	0	0	1 (3.7)	0
Psychiatric disorders					
-Total	12 (44.4)	6 (22.2)	4 (14.8)	2 (7.4)	0
Anxiety	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Delirium	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Insomnia	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Mental status changes	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Confusional state	2 (7.4)	2 (7.4)	0	0	0
Agitation	1 (3.7)	0	1 (3.7)	0	0
Automatism	1 (3.7)	1 (3.7)	0	0	0
Irritability	1 (3.7)	1 (3.7)	0	0	0
Sleep disorder	1 (3.7)	0	1 (3.7)	0	0
Renal and urinary disorders					
-Total	11 (40.7)	3 (11.1)	3 (11.1)	1 (3.7)	4 (14.8)
Acute kidney injury	6 (22.2)	1 (3.7)	0	1 (3.7)	4 (14.8)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anuria	1 (3.7)	1 (3.7)	0	0	0
Azotaemia	1 (3.7)	0	1 (3.7)	0	0
Bladder dilatation	1 (3.7)	0	1 (3.7)	0	0
Cystitis haemorrhagic	1 (3.7)	0	1 (3.7)	0	0
Dysuria	1 (3.7)	1 (3.7)	0	0	0
Haematuria	1 (3.7)	1 (3.7)	0	0	0
Micturition urgency	1 (3.7)	0	1 (3.7)	0	0
Pollakiuria	1 (3.7)	0	1 (3.7)	0	0
Proteinuria	1 (3.7)	1 (3.7)	0	0	0
Renal failure	1 (3.7)	0	1 (3.7)	0	0
Renal tubular necrosis	1 (3.7)	0	0	0	1 (3.7)
Urinary retention	1 (3.7)	0	1 (3.7)	0	0
Reproductive system and breast disorders					
-Total	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Dysmenorrhoea	1 (3.7)	0	1 (3.7)	0	0
Perineal rash	1 (3.7)	0	1 (3.7)	0	0
Vaginal ulceration	1 (3.7)	0	0	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	19 (70.4)	8 (29.6)	2 (7.4)	3 (11.1)	6 (22.2)
Hypoxia	9 (33.3)	0	1 (3.7)	4 (14.8)	4 (14.8)
Cough	7 (25.9)	6 (22.2)	1 (3.7)	0	0
Pleural effusion	5 (18.5)	3 (11.1)	1 (3.7)	1 (3.7)	0
Oropharyngeal pain	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Pulmonary oedema	4 (14.8)	2 (7.4)	1 (3.7)	1 (3.7)	0
Epistaxis	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Tachypnoea	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Acute respiratory distress syndrome	2 (7.4)	0	0	0	2 (7.4)
Atelectasis	2 (7.4)	0	0	2 (7.4)	0
Dyspnoea	2 (7.4)	0	1 (3.7)	0	1 (3.7)
Nasal congestion	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Respiratory distress	2 (7.4)	0	1 (3.7)	0	1 (3.7)
Rhinorrhoea	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Bradypnoea	1 (3.7)	0	0	1 (3.7)	0
Nasal discomfort	1 (3.7)	0	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paranasal sinus inflammation	1 (3.7)	1 (3.7)	0	0	0
Pharyngeal haemorrhage	1 (3.7)	0	1 (3.7)	0	0
Productive cough	1 (3.7)	1 (3.7)	0	0	0
Respiratory acidosis	1 (3.7)	0	0	1 (3.7)	0
Sleep apnoea syndrome	1 (3.7)	1 (3.7)	0	0	0
Wheezing	1 (3.7)	0	1 (3.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (44.4)	3 (11.1)	5 (18.5)	4 (14.8)	0
Dry skin	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Rash	3 (11.1)	0	3 (11.1)	0	0
Eczema	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Petechiae	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Pruritus	2 (7.4)	0	2 (7.4)	0	0
Skin ulcer	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Blister	1 (3.7)	1 (3.7)	0	0	0
Decubitus ulcer	1 (3.7)	0	1 (3.7)	0	0
Dermatitis diaper	1 (3.7)	0	1 (3.7)	0	0
Erythema	1 (3.7)	1 (3.7)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema nodosum	1 (3.7)	1 (3.7)	0	0	0
Hangnail	1 (3.7)	1 (3.7)	0	0	0
Ingrowing nail	1 (3.7)	0	1 (3.7)	0	0
Papule	1 (3.7)	1 (3.7)	0	0	0
Pruritus allergic	1 (3.7)	0	1 (3.7)	0	0
Rash erythematous	1 (3.7)	1 (3.7)	0	0	0
Rash macular	1 (3.7)	0	0	1 (3.7)	0
Rash papular	1 (3.7)	1 (3.7)	0	0	0
Rash pruritic	1 (3.7)	1 (3.7)	0	0	0
Skin discolouration	1 (3.7)	1 (3.7)	0	0	0
Skin necrosis	1 (3.7)	0	0	1 (3.7)	0
Skin swelling	1 (3.7)	1 (3.7)	0	0	0
Urticaria	1 (3.7)	0	1 (3.7)	0	0
Vancomycin infusion reaction	1 (3.7)	0	0	1 (3.7)	0
Vascular disorders					
-Total	12 (44.4)	1 (3.7)	3 (11.1)	2 (7.4)	6 (22.2)
Hypotension	8 (29.6)	0	2 (7.4)	1 (3.7)	5 (18.5)
Hypertension	6 (22.2)	1 (3.7)	3 (11.1)	2 (7.4)	0
Venoocclusive disease	2 (7.4)	0	0	1 (3.7)	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Capillary leak syndrome	1 (3.7)	0	1 (3.7)	0	0
Thrombosis	1 (3.7)	0	1 (3.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (100)	0	3 (5.7)	12 (22.6)	38 (71.7)
Blood and lymphatic system disorders					
-Total	41 (77.4)	0	8 (15.1)	24 (45.3)	9 (17.0)
Febrile neutropenia	23 (43.4)	0	0	21 (39.6)	2 (3.8)
Anaemia	19 (35.8)	4 (7.5)	6 (11.3)	9 (17.0)	0
Neutropenia	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Coagulopathy	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Disseminated intravascular coagulation	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Leukopenia	3 (5.7)	0	1 (1.9)	1 (1.9)	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Lymphadenopathy	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Lymphopenia	2 (3.8)	0	0	2 (3.8)	0
Pancytopenia	2 (3.8)	0	0	2 (3.8)	0
B-cell aplasia	1 (1.9)	0	1 (1.9)	0	0
Eosinophilia	1 (1.9)	0	1 (1.9)	0	0
Hypercoagulation	1 (1.9)	0	1 (1.9)	0	0
Hypofibrinogenaemia	1 (1.9)	0	1 (1.9)	0	0
Leukocytosis	1 (1.9)	0	1 (1.9)	0	0
Lymphocytosis	1 (1.9)	0	1 (1.9)	0	0
Cardiac disorders					
-Total	20 (37.7)	7 (13.2)	5 (9.4)	4 (7.5)	4 (7.5)
Tachycardia	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0
Left ventricular dysfunction	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Cardiac arrest	3 (5.7)	0	0	0	3 (5.7)
Cardiac failure	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Atrioventricular block first degree	1 (1.9)	0	1 (1.9)	0	0
Bradycardia	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	1 (1.9)	1 (1.9)	0	0	0
Cardiac failure congestive	1 (1.9)	0	1 (1.9)	0	0
Mitral valve incompetence	1 (1.9)	1 (1.9)	0	0	0
Pericardial effusion	1 (1.9)	1 (1.9)	0	0	0
Right ventricular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Sinus bradycardia	1 (1.9)	0	0	1 (1.9)	0
Sinus tachycardia	1 (1.9)	1 (1.9)	0	0	0
Tricuspid valve incompetence	1 (1.9)	1 (1.9)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Cerebral cavernous malformation	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Deafness unilateral	1 (1.9)	0	1 (1.9)	0	0
Ear pain	1 (1.9)	1 (1.9)	0	0	0
Endocrine disorders					
-Total	6 (11.3)	0	6 (11.3)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	4 (7.5)	0	4 (7.5)	0	0
Hypothyroidism	2 (3.8)	0	2 (3.8)	0	0
Delayed puberty	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	11 (20.8)	8 (15.1)	3 (5.7)	0	0
Ocular hyperaemia	3 (5.7)	3 (5.7)	0	0	0
Cataract	2 (3.8)	2 (3.8)	0	0	0
Visual impairment	2 (3.8)	2 (3.8)	0	0	0
Conjunctival haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Dry eye	1 (1.9)	1 (1.9)	0	0	0
Eye oedema	1 (1.9)	1 (1.9)	0	0	0
Hypermetropia	1 (1.9)	1 (1.9)	0	0	0
Mydriasis	1 (1.9)	0	1 (1.9)	0	0
Periorbital swelling	1 (1.9)	0	1 (1.9)	0	0
Retinal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	39 (73.6)	15 (28.3)	15 (28.3)	8 (15.1)	1 (1.9)
Vomiting	18 (34.0)	10 (18.9)	7 (13.2)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	17 (32.1)	9 (17.0)	6 (11.3)	2 (3.8)	0
Diarrhoea	16 (30.2)	10 (18.9)	6 (11.3)	0	0
Constipation	10 (18.9)	4 (7.5)	6 (11.3)	0	0
Abdominal pain	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Mouth haemorrhage	4 (7.5)	2 (3.8)	0	2 (3.8)	0
Stomatitis	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Abdominal distension	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Ascites	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Gastrointestinal sounds abnormal	2 (3.8)	2 (3.8)	0	0	0
Pancreatitis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal compartment syndrome	1 (1.9)	0	0	0	1 (1.9)
Abdominal pain upper	1 (1.9)	1 (1.9)	0	0	0
Abdominal rigidity	1 (1.9)	0	1 (1.9)	0	0
Anal fissure	1 (1.9)	0	1 (1.9)	0	0
Dry mouth	1 (1.9)	0	1 (1.9)	0	0
Dyspepsia	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal haemorrhage	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal inflammation	1 (1.9)	0	1 (1.9)	0	0
Gingival bleeding	1 (1.9)	0	1 (1.9)	0	0
Gingivitis ulcerative	1 (1.9)	0	0	1 (1.9)	0
Haematemesis	1 (1.9)	1 (1.9)	0	0	0
Ileus	1 (1.9)	0	1 (1.9)	0	0
Irritable bowel syndrome	1 (1.9)	0	1 (1.9)	0	0
Lip dry	1 (1.9)	0	1 (1.9)	0	0
Lip oedema	1 (1.9)	1 (1.9)	0	0	0
Mouth swelling	1 (1.9)	1 (1.9)	0	0	0
Neutropenic colitis	1 (1.9)	0	0	1 (1.9)	0
Odynophagia	1 (1.9)	1 (1.9)	0	0	0
Peritoneal haematoma	1 (1.9)	1 (1.9)	0	0	0
Trichoglossia	1 (1.9)	0	1 (1.9)	0	0
Upper gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	38 (71.7)	16 (30.2)	11 (20.8)	8 (15.1)	3 (5.7)
Pyrexia	25 (47.2)	9 (17.0)	8 (15.1)	7 (13.2)	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	12 (22.6)	10 (18.9)	2 (3.8)	0	0
Chills	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Face oedema	5 (9.4)	3 (5.7)	1 (1.9)	1 (1.9)	0
Pain	5 (9.4)	1 (1.9)	2 (3.8)	2 (3.8)	0
Generalised oedema	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Oedema peripheral	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Catheter site pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Drug withdrawal syndrome	2 (3.8)	0	2 (3.8)	0	0
Influenza like illness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Malaise	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Multiple organ dysfunction syndrome	2 (3.8)	0	0	0	2 (3.8)
Non-cardiac chest pain	2 (3.8)	2 (3.8)	0	0	0
Asthenia	1 (1.9)	1 (1.9)	0	0	0
Chest discomfort	1 (1.9)	0	0	1 (1.9)	0
Crying	1 (1.9)	0	1 (1.9)	0	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Localised oedema	1 (1.9)	1 (1.9)	0	0	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Swelling face	1 (1.9)	1 (1.9)	0	0	0
Vascular device occlusion	1 (1.9)	1 (1.9)	0	0	0
Hepatobiliary disorders					
-Total	12 (22.6)	6 (11.3)	4 (7.5)	1 (1.9)	1 (1.9)
Hepatomegaly	3 (5.7)	2 (3.8)	0	0	1 (1.9)
Hyperbilirubinaemia	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Hepatic function abnormal	2 (3.8)	0	2 (3.8)	0	0
Biliary tract disorder	1 (1.9)	1 (1.9)	0	0	0
Cholelithiasis	1 (1.9)	0	1 (1.9)	0	0
Gallbladder enlargement	1 (1.9)	1 (1.9)	0	0	0
Hepatic cytolysis	1 (1.9)	1 (1.9)	0	0	0
Hypertransaminasaemia	1 (1.9)	1 (1.9)	0	0	0
Ocular icterus	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	47 (88.7)	2 (3.8)	18 (34.0)	14 (26.4)	13 (24.5)
Cytokine release syndrome	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Hypogammaglobulinaemia	22 (41.5)	1 (1.9)	17 (32.1)	4 (7.5)	0
Seasonal allergy	3 (5.7)	2 (3.8)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Haemophagocytic lymphohistiocytosis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Immunodeficiency	2 (3.8)	0	0	2 (3.8)	0
Allergy to immunoglobulin therapy	1 (1.9)	0	0	1 (1.9)	0
Drug hypersensitivity	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease	1 (1.9)	0	0	1 (1.9)	0
Hypersensitivity	1 (1.9)	1 (1.9)	0	0	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	39 (73.6)	4 (7.5)	12 (22.6)	15 (28.3)	8 (15.1)
Upper respiratory tract infection	11 (20.8)	5 (9.4)	4 (7.5)	2 (3.8)	0
Rhinovirus infection	6 (11.3)	0	4 (7.5)	2 (3.8)	0
Parainfluenzae virus infection	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Gastroenteritis	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Nasopharyngitis	4 (7.5)	2 (3.8)	2 (3.8)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (7.5)	0	1 (1.9)	1 (1.9)	2 (3.8)
Sinusitis	4 (7.5)	0	3 (5.7)	1 (1.9)	0
Staphylococcal bacteraemia	4 (7.5)	0	0	4 (7.5)	0
Candida infection	3 (5.7)	0	2 (3.8)	0	1 (1.9)
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Oral candidiasis	3 (5.7)	0	3 (5.7)	0	0
Otitis media	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Respiratory syncytial virus infection	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Staphylococcal infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Urinary tract infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Acute sinusitis	2 (3.8)	0	2 (3.8)	0	0
Adenovirus infection	2 (3.8)	0	0	2 (3.8)	0
Bacteraemia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Clostridium difficile infection	2 (3.8)	0	0	2 (3.8)	0
Fungal infection	2 (3.8)	0	2 (3.8)	0	0
Gingivitis	2 (3.8)	2 (3.8)	0	0	0
Herpes simplex	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Human herpesvirus 6 infection	2 (3.8)	0	0	2 (3.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Metapneumovirus infection	2 (3.8)	0	0	2 (3.8)	0
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Otitis externa	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Rhinitis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Varicella zoster virus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Bk virus infection	1 (1.9)	0	0	1 (1.9)	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis	1 (1.9)	0	1 (1.9)	0	0
Clostridium difficile colitis	1 (1.9)	0	0	1 (1.9)	0
Covid-19	1 (1.9)	1 (1.9)	0	0	0
Covid-19 pneumonia	1 (1.9)	0	0	0	1 (1.9)
Cystitis	1 (1.9)	0	1 (1.9)	0	0
Cytomegalovirus infection reactivation	1 (1.9)	0	0	1 (1.9)	0
Ear infection	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear, nose and throat infection	1 (1.9)	0	1 (1.9)	0	0
Encephalitis	1 (1.9)	0	0	0	1 (1.9)
Encephalitis viral	1 (1.9)	0	0	1 (1.9)	0
Enterobacter infection	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis clostridial	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis escherichia coli	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis salmonella	1 (1.9)	0	0	1 (1.9)	0
Gastrointestinal infection	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Mastoiditis	1 (1.9)	0	0	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Neutropenic infection	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	0	1 (1.9)	0	0
Pharyngitis streptococcal	1 (1.9)	0	0	1 (1.9)	0
Pneumocystis jirovecii pneumonia	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Respiratory tract infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory tract infection viral	1 (1.9)	0	1 (1.9)	0	0
Sepsis	1 (1.9)	0	0	1 (1.9)	0
Septic shock	1 (1.9)	0	0	0	1 (1.9)
Sinusitis fungal	1 (1.9)	0	0	1 (1.9)	0
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal skin infection	1 (1.9)	0	1 (1.9)	0	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0
Syphilis	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection pseudomonal	1 (1.9)	0	1 (1.9)	0	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Viral haemorrhagic cystitis	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	0	0	1 (1.9)	0
Viral skin infection	1 (1.9)	1 (1.9)	0	0	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	13 (24.5)	6 (11.3)	6 (11.3)	0	1 (1.9)
Infusion related reaction	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal injury	1 (1.9)	1 (1.9)	0	0	0
Contusion	1 (1.9)	1 (1.9)	0	0	0
Fall	1 (1.9)	0	1 (1.9)	0	0
Fibula fracture	1 (1.9)	0	1 (1.9)	0	0
Ligament sprain	1 (1.9)	1 (1.9)	0	0	0
Limb injury	1 (1.9)	0	1 (1.9)	0	0
Post-traumatic neck syndrome	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Transplant failure	1 (1.9)	0	0	0	1 (1.9)
Investigations					
-Total	41 (77.4)	1 (1.9)	7 (13.2)	14 (26.4)	19 (35.8)
Neutrophil count decreased	17 (32.1)	1 (1.9)	1 (1.9)	4 (7.5)	11 (20.8)
Platelet count decreased	17 (32.1)	4 (7.5)	2 (3.8)	5 (9.4)	6 (11.3)
White blood cell count decreased	17 (32.1)	2 (3.8)	3 (5.7)	1 (1.9)	11 (20.8)
Aspartate aminotransferase increased	14 (26.4)	2 (3.8)	2 (3.8)	7 (13.2)	3 (5.7)
Alanine aminotransferase increased	12 (22.6)	2 (3.8)	6 (11.3)	4 (7.5)	0
Lymphocyte count decreased	11 (20.8)	0	0	8 (15.1)	3 (5.7)
Blood bilirubin increased	9 (17.0)	0	2 (3.8)	7 (13.2)	0
International normalised ratio increased	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Blood immunoglobulin a decreased	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Activated partial thromboplastin time prolonged	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	4 (7.5)	3 (5.7)	0	1 (1.9)	0
C-reactive protein increased	4 (7.5)	1 (1.9)	0	3 (5.7)	0
Serum ferritin increased	4 (7.5)	1 (1.9)	1 (1.9)	2 (3.8)	0
Blood creatinine increased	3 (5.7)	1 (1.9)	0	2 (3.8)	0
Blood immunoglobulin g decreased	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Blood lactate dehydrogenase increased	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Weight increased	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Blood fibrinogen decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Electrocardiogram qt prolonged	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Fibrin d dimer increased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Gamma-glutamyltransferase increased	2 (3.8)	0	0	2 (3.8)	0
Oxygen saturation decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Blood alkaline phosphatase increased	1 (1.9)	1 (1.9)	0	0	0
Blood glucose increased	1 (1.9)	0	0	0	1 (1.9)
Blood phosphorus increased	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood testosterone decreased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Bone density decreased	1 (1.9)	1 (1.9)	0	0	0
Breath sounds abnormal	1 (1.9)	0	1 (1.9)	0	0
Ejection fraction decreased	1 (1.9)	0	1 (1.9)	0	0
Electrocardiogram t wave abnormal	1 (1.9)	0	1 (1.9)	0	0
Enterovirus test positive	1 (1.9)	0	1 (1.9)	0	0
Haptoglobin decreased	1 (1.9)	1 (1.9)	0	0	0
Heart sounds abnormal	1 (1.9)	1 (1.9)	0	0	0
Hepatitis b virus test positive	1 (1.9)	0	1 (1.9)	0	0
Immunoglobulins decreased	1 (1.9)	0	1 (1.9)	0	0
Prothrombin time prolonged	1 (1.9)	0	1 (1.9)	0	0
Staphylococcus test positive	1 (1.9)	1 (1.9)	0	0	0
Troponin increased	1 (1.9)	0	0	1 (1.9)	0
Urine output decreased	1 (1.9)	0	0	1 (1.9)	0
Weight decreased	1 (1.9)	0	0	1 (1.9)	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	35 (66.0)	5 (9.4)	8 (15.1)	16 (30.2)	6 (11.3)
Decreased appetite	22 (41.5)	7 (13.2)	6 (11.3)	7 (13.2)	2 (3.8)
Hypocalcaemia	12 (22.6)	1 (1.9)	8 (15.1)	3 (5.7)	0
Hypophosphataemia	11 (20.8)	1 (1.9)	4 (7.5)	6 (11.3)	0
Hypokalaemia	10 (18.9)	2 (3.8)	3 (5.7)	4 (7.5)	1 (1.9)
Hyperglycaemia	9 (17.0)	0	4 (7.5)	5 (9.4)	0
Hypoalbuminaemia	8 (15.1)	0	7 (13.2)	1 (1.9)	0
Hyperuricaemia	6 (11.3)	5 (9.4)	0	1 (1.9)	0
Hypervolaemia	5 (9.4)	0	1 (1.9)	4 (7.5)	0
Hypomagnesaemia	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Hypercalcaemia	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Hyperkalaemia	3 (5.7)	0	1 (1.9)	1 (1.9)	1 (1.9)
Hyperphosphataemia	3 (5.7)	2 (3.8)	0	0	1 (1.9)
Metabolic acidosis	3 (5.7)	1 (1.9)	0	0	2 (3.8)
Acidosis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Hypermagnesaemia	2 (3.8)	2 (3.8)	0	0	0
Hypertriglyceridaemia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Hyponatraemia	2 (3.8)	2 (3.8)	0	0	0
Iron overload	2 (3.8)	0	2 (3.8)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	2 (3.8)	0	0	2 (3.8)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0
Calcium deficiency	1 (1.9)	1 (1.9)	0	0	0
Dehydration	1 (1.9)	0	1 (1.9)	0	0
Haemochromatosis	1 (1.9)	0	0	1 (1.9)	0
Hypercholesterolaemia	1 (1.9)	0	1 (1.9)	0	0
Hypernatraemia	1 (1.9)	0	0	1 (1.9)	0
Hypoglycaemia	1 (1.9)	0	1 (1.9)	0	0
Hypophagia	1 (1.9)	0	1 (1.9)	0	0
Obesity	1 (1.9)	0	0	1 (1.9)	0
Polydipsia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	31 (58.5)	10 (18.9)	14 (26.4)	7 (13.2)	0
Pain in extremity	10 (18.9)	5 (9.4)	4 (7.5)	1 (1.9)	0
Back pain	9 (17.0)	2 (3.8)	4 (7.5)	3 (5.7)	0
Arthralgia	8 (15.1)	3 (5.7)	4 (7.5)	1 (1.9)	0
Myalgia	8 (15.1)	5 (9.4)	3 (5.7)	0	0
Bone pain	4 (7.5)	1 (1.9)	3 (5.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Growth retardation	2 (3.8)	0	2 (3.8)	0	0
Muscular weakness	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Neck pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Pain in jaw	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Haemarthrosis	1 (1.9)	0	0	1 (1.9)	0
Joint effusion	1 (1.9)	0	1 (1.9)	0	0
Muscle spasms	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal pain	1 (1.9)	0	1 (1.9)	0	0
Osteopenia	1 (1.9)	1 (1.9)	0	0	0
Synovitis	1 (1.9)	0	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (9.4)	1 (1.9)	2 (3.8)	2 (3.8)	0
Skin papilloma	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Bone giant cell tumour benign	1 (1.9)	0	0	1 (1.9)	0
Cancer pain	1 (1.9)	0	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	33 (62.3)	10 (18.9)	13 (24.5)	7 (13.2)	3 (5.7)
Headache	19 (35.8)	10 (18.9)	7 (13.2)	2 (3.8)	0
Encephalopathy	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Somnolence	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Cognitive disorder	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Dysgeusia	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Lethargy	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Seizure	3 (5.7)	0	0	3 (5.7)	0
Tremor	3 (5.7)	3 (5.7)	0	0	0
Cerebral haemorrhage	2 (3.8)	0	0	0	2 (3.8)
Dizziness	2 (3.8)	2 (3.8)	0	0	0
Dysarthria	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Autonomic neuropathy	1 (1.9)	0	0	1 (1.9)	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extrapyramidal disorder	1 (1.9)	0	1 (1.9)	0	0
Hyperaesthesia	1 (1.9)	1 (1.9)	0	0	0
Memory impairment	1 (1.9)	0	1 (1.9)	0	0
Migraine	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorder	1 (1.9)	0	0	1 (1.9)	0
Neurological decompensation	1 (1.9)	0	0	0	1 (1.9)
Paraesthesia	1 (1.9)	1 (1.9)	0	0	0
Psychiatric disorders					
-Total	27 (50.9)	7 (13.2)	15 (28.3)	5 (9.4)	0
Anxiety	11 (20.8)	3 (5.7)	7 (13.2)	1 (1.9)	0
Agitation	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Confusional state	5 (9.4)	5 (9.4)	0	0	0
Delirium	5 (9.4)	0	2 (3.8)	3 (5.7)	0
Hallucination	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Mental status changes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Sleep disorder	2 (3.8)	0	2 (3.8)	0	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (1.9)	1 (1.9)	0	0	0
Mood altered	1 (1.9)	1 (1.9)	0	0	0
Nightmare	1 (1.9)	1 (1.9)	0	0	0
Persistent depressive disorder	1 (1.9)	0	1 (1.9)	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Tearfulness	1 (1.9)	1 (1.9)	0	0	0
Tic	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	14 (26.4)	3 (5.7)	4 (7.5)	4 (7.5)	3 (5.7)
Acute kidney injury	6 (11.3)	1 (1.9)	2 (3.8)	2 (3.8)	1 (1.9)
Dysuria	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Haematuria	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Anuria	1 (1.9)	0	0	0	1 (1.9)
Incontinence	1 (1.9)	0	1 (1.9)	0	0
Kidney enlargement	1 (1.9)	0	1 (1.9)	0	0
Pollakiuria	1 (1.9)	0	1 (1.9)	0	0
Renal failure	1 (1.9)	0	0	0	1 (1.9)
Renal mass	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular disorder	1 (1.9)	0	0	1 (1.9)	0
Renal tubular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Urinary incontinence	1 (1.9)	0	1 (1.9)	0	0
Urinary retention	1 (1.9)	0	1 (1.9)	0	0
Urinary tract disorder	1 (1.9)	0	1 (1.9)	0	0
Reproductive system and breast disorders					
-Total	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Endometriosis	1 (1.9)	0	0	1 (1.9)	0
Female genital tract fistula	1 (1.9)	1 (1.9)	0	0	0
Heavy menstrual bleeding	1 (1.9)	1 (1.9)	0	0	0
Vaginal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (67.9)	10 (18.9)	6 (11.3)	9 (17.0)	11 (20.8)
Cough	16 (30.2)	12 (22.6)	4 (7.5)	0	0
Hypoxia	11 (20.8)	0	3 (5.7)	6 (11.3)	2 (3.8)
Pulmonary oedema	8 (15.1)	0	2 (3.8)	5 (9.4)	1 (1.9)
Nasal congestion	7 (13.2)	6 (11.3)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	6 (11.3)	0	0	0	6 (11.3)
Tachypnoea	6 (11.3)	2 (3.8)	1 (1.9)	2 (3.8)	1 (1.9)
Dyspnoea	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Epistaxis	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Oropharyngeal pain	4 (7.5)	4 (7.5)	0	0	0
Pleural effusion	4 (7.5)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Rhinorrhoea	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Pharyngeal erythema	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Respiratory distress	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Rhinitis allergic	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Acute respiratory distress syndrome	1 (1.9)	0	0	0	1 (1.9)
Acute respiratory failure	1 (1.9)	0	0	1 (1.9)	0
Atelectasis	1 (1.9)	0	1 (1.9)	0	0
Bronchial oedema	1 (1.9)	1 (1.9)	0	0	0
Bronchospasm	1 (1.9)	0	1 (1.9)	0	0
Dyspnoea exertional	1 (1.9)	1 (1.9)	0	0	0
Haemoptysis	1 (1.9)	0	1 (1.9)	0	0
Laryngeal oedema	1 (1.9)	0	0	0	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lung disorder	1 (1.9)	1 (1.9)	0	0	0
Lung infiltration	1 (1.9)	0	0	1 (1.9)	0
Nasal dryness	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal plaque	1 (1.9)	0	1 (1.9)	0	0
Painful respiration	1 (1.9)	1 (1.9)	0	0	0
Paranasal sinus discomfort	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal exudate	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal oedema	1 (1.9)	0	1 (1.9)	0	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Respiratory disorder	1 (1.9)	0	1 (1.9)	0	0
Sleep apnoea syndrome	1 (1.9)	0	1 (1.9)	0	0
Upper respiratory tract inflammation	1 (1.9)	0	1 (1.9)	0	0
Wheezing	1 (1.9)	0	1 (1.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	28 (52.8)	14 (26.4)	11 (20.8)	3 (5.7)	0
Dry skin	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Pruritus	5 (9.4)	2 (3.8)	3 (5.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Erythema	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Dermatitis atopic	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Hyperhidrosis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Rash maculo-papular	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Blister	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Rash papular	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Decubitus ulcer	1 (1.9)	0	0	1 (1.9)	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Dermatitis allergic	1 (1.9)	1 (1.9)	0	0	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	0	1 (1.9)	0	0
Miliaria	1 (1.9)	1 (1.9)	0	0	0
Night sweats	1 (1.9)	1 (1.9)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.9)	1 (1.9)	0	0	0
Photosensitivity reaction	1 (1.9)	0	1 (1.9)	0	0
Purpura	1 (1.9)	1 (1.9)	0	0	0
Rash vesicular	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scab	1 (1.9)	1 (1.9)	0	0	0
Skin discolouration	1 (1.9)	1 (1.9)	0	0	0
Skin hypopigmentation	1 (1.9)	1 (1.9)	0	0	0
Skin lesion	1 (1.9)	0	1 (1.9)	0	0
Social circumstances					
-Total	1 (1.9)	0	1 (1.9)	0	0
Patient uncooperative	1 (1.9)	0	1 (1.9)	0	0
Surgical and medical procedures					
-Total	1 (1.9)	0	0	1 (1.9)	0
Thrombolysis	1 (1.9)	0	0	1 (1.9)	0
Vascular disorders					
-Total	22 (41.5)	4 (7.5)	5 (9.4)	10 (18.9)	3 (5.7)
Hypotension	16 (30.2)	2 (3.8)	4 (7.5)	7 (13.2)	3 (5.7)
Hypertension	10 (18.9)	3 (5.7)	4 (7.5)	3 (5.7)	0
Capillary leak syndrome	1 (1.9)	0	0	1 (1.9)	0
Flushing	1 (1.9)	1 (1.9)	0	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0
Peripheral ischaemia	1 (1.9)	0	1 (1.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	2 (7.1)	3 (10.7)	8 (28.6)	14 (50.0)
Blood and lymphatic system disorders					
-Total	15 (53.6)	2 (7.1)	2 (7.1)	9 (32.1)	2 (7.1)
Febrile neutropenia	6 (21.4)	0	0	6 (21.4)	0
Anaemia	5 (17.9)	1 (3.6)	0	4 (14.3)	0
Neutropenia	3 (10.7)	0	1 (3.6)	1 (3.6)	1 (3.6)
Coagulopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Disseminated intravascular coagulation	2 (7.1)	0	2 (7.1)	0	0
Pancytopenia	2 (7.1)	0	0	2 (7.1)	0
Thrombocytopenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (3.6)	0	1 (3.6)	0	0
Leukopenia	1 (3.6)	0	0	1 (3.6)	0
Splenomegaly	1 (3.6)	0	1 (3.6)	0	0
Cardiac disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Pericardial effusion	1 (3.6)	1 (3.6)	0	0	0
Sinus tachycardia	1 (3.6)	0	1 (3.6)	0	0
Endocrine disorders					
-Total	2 (7.1)	0	2 (7.1)	0	0
Adrenal insufficiency	1 (3.6)	0	1 (3.6)	0	0
Hypothyroidism	1 (3.6)	0	1 (3.6)	0	0
Eye disorders					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Eye oedema	1 (3.6)	1 (3.6)	0	0	0
Eye pain	1 (3.6)	1 (3.6)	0	0	0
Eyelid oedema	1 (3.6)	0	1 (3.6)	0	0
Retinal haemorrhage	1 (3.6)	0	1 (3.6)	0	0
Visual field defect	1 (3.6)	0	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	16 (57.1)	6 (21.4)	8 (28.6)	2 (7.1)	0
Vomiting	7 (25.0)	5 (17.9)	2 (7.1)	0	0
Abdominal pain	5 (17.9)	0	5 (17.9)	0	0
Diarrhoea	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Nausea	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Constipation	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Abdominal pain upper	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Ascites	1 (3.6)	0	1 (3.6)	0	0
Mouth swelling	1 (3.6)	1 (3.6)	0	0	0
Odynophagia	1 (3.6)	1 (3.6)	0	0	0
Stomatitis	1 (3.6)	0	0	1 (3.6)	0
General disorders and administration site conditions					
-Total	11 (39.3)	7 (25.0)	3 (10.7)	1 (3.6)	0
Pyrexia	5 (17.9)	3 (10.7)	2 (7.1)	0	0
Face oedema	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Asthenia	2 (7.1)	2 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Catheter site erythema	1 (3.6)	1 (3.6)	0	0	0
Fatigue	1 (3.6)	1 (3.6)	0	0	0
Generalised oedema	1 (3.6)	0	1 (3.6)	0	0
Influenza like illness	1 (3.6)	0	1 (3.6)	0	0
Localised oedema	1 (3.6)	1 (3.6)	0	0	0
Hepatobiliary disorders					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Cholelithiasis	1 (3.6)	0	1 (3.6)	0	0
Hepatomegaly	1 (3.6)	1 (3.6)	0	0	0
Hyperbilirubinaemia	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					
-Total	21 (75.0)	0	5 (17.9)	8 (28.6)	8 (28.6)
Cytokine release syndrome	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Hypogammaglobulinaemia	10 (35.7)	1 (3.6)	5 (17.9)	4 (14.3)	0
Immunodeficiency	3 (10.7)	0	0	3 (10.7)	0
Haemophagocytic lymphohistiocytosis	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (3.6)	1 (3.6)	0	0	0
Infections and infestations					
-Total	12 (42.9)	2 (7.1)	5 (17.9)	5 (17.9)	0
Conjunctivitis	3 (10.7)	0	3 (10.7)	0	0
Nail infection	2 (7.1)	2 (7.1)	0	0	0
Oral infection	2 (7.1)	0	2 (7.1)	0	0
Staphylococcal infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Adenovirus infection	1 (3.6)	0	0	1 (3.6)	0
Bronchopulmonary aspergillosis	1 (3.6)	0	0	1 (3.6)	0
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Myringitis	1 (3.6)	1 (3.6)	0	0	0
Pneumonia fungal	1 (3.6)	0	0	1 (3.6)	0
Pneumonia viral	1 (3.6)	0	0	1 (3.6)	0
Injury, poisoning and procedural complications					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Fall	1 (3.6)	0	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (3.6)	0	1 (3.6)	0	0
Procedural pain	1 (3.6)	1 (3.6)	0	0	0
Investigations					
-Total	16 (57.1)	1 (3.6)	4 (14.3)	4 (14.3)	7 (25.0)
Lymphocyte count decreased	7 (25.0)	1 (3.6)	0	3 (10.7)	3 (10.7)
Neutrophil count decreased	6 (21.4)	0	1 (3.6)	0	5 (17.9)
White blood cell count decreased	6 (21.4)	1 (3.6)	0	1 (3.6)	4 (14.3)
Platelet count decreased	5 (17.9)	1 (3.6)	1 (3.6)	1 (3.6)	2 (7.1)
Alanine aminotransferase increased	2 (7.1)	0	0	2 (7.1)	0
Immunoglobulins decreased	2 (7.1)	0	2 (7.1)	0	0
Aspartate aminotransferase increased	1 (3.6)	0	0	1 (3.6)	0
Blood bilirubin increased	1 (3.6)	0	0	1 (3.6)	0
Blood fibrinogen decreased	1 (3.6)	0	0	0	1 (3.6)
Blood lactate dehydrogenase increased	1 (3.6)	0	1 (3.6)	0	0
C-reactive protein increased	1 (3.6)	0	0	1 (3.6)	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gamma-glutamyltransferase increased	1 (3.6)	0	0	1 (3.6)	0
Prothrombin time prolonged	1 (3.6)	0	1 (3.6)	0	0
Serum ferritin increased	1 (3.6)	1 (3.6)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (35.7)	3 (10.7)	2 (7.1)	4 (14.3)	1 (3.6)
Hypokalaemia	5 (17.9)	1 (3.6)	1 (3.6)	3 (10.7)	0
Decreased appetite	4 (14.3)	2 (7.1)	1 (3.6)	1 (3.6)	0
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Hypophosphataemia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Hyperglycaemia	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Hypernatraemia	1 (3.6)	1 (3.6)	0	0	0
Hyperuricaemia	1 (3.6)	0	1 (3.6)	0	0
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)	0	0
Hypocalcaemia	1 (3.6)	0	0	1 (3.6)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (39.3)	5 (17.9)	5 (17.9)	1 (3.6)	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Back pain	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Pain in extremity	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Muscular weakness	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal chest pain	1 (3.6)	1 (3.6)	0	0	0
Myalgia	1 (3.6)	1 (3.6)	0	0	0
Pain in jaw	1 (3.6)	1 (3.6)	0	0	0
Nervous system disorders					
-Total	14 (50.0)	6 (21.4)	6 (21.4)	2 (7.1)	0
Headache	9 (32.1)	7 (25.0)	2 (7.1)	0	0
Encephalopathy	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Tremor	2 (7.1)	2 (7.1)	0	0	0
Amnesia	1 (3.6)	0	1 (3.6)	0	0
Dysgeusia	1 (3.6)	1 (3.6)	0	0	0
Hyperaesthesia	1 (3.6)	1 (3.6)	0	0	0
Neuralgia	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Psychiatric disorders					

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (32.1)	3 (10.7)	5 (17.9)	1 (3.6)	0
Anxiety	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Hallucination	2 (7.1)	0	2 (7.1)	0	0
Insomnia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hallucination, visual	1 (3.6)	0	1 (3.6)	0	0
Sleep disorder	1 (3.6)	0	1 (3.6)	0	0
Renal and urinary disorders					
-Total	5 (17.9)	2 (7.1)	2 (7.1)	0	1 (3.6)
Dysuria	2 (7.1)	2 (7.1)	0	0	0
Anuria	1 (3.6)	0	0	0	1 (3.6)
Renal failure	1 (3.6)	0	1 (3.6)	0	0
Urinary tract disorder	1 (3.6)	0	1 (3.6)	0	0
Reproductive system and breast disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Female genital tract fistula	1 (3.6)	1 (3.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (32.1)	4 (14.3)	2 (7.1)	3 (10.7)	0
Cough	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Pulmonary oedema	4 (14.3)	1 (3.6)	0	3 (10.7)	0
Hypoxia	3 (10.7)	0	3 (10.7)	0	0
Oropharyngeal pain	2 (7.1)	2 (7.1)	0	0	0
Painful respiration	1 (3.6)	1 (3.6)	0	0	0
Productive cough	1 (3.6)	1 (3.6)	0	0	0
Respiratory disorder	1 (3.6)	0	1 (3.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (25.0)	2 (7.1)	5 (17.9)	0	0
Dermatitis atopic	2 (7.1)	2 (7.1)	0	0	0
Pruritus	2 (7.1)	0	2 (7.1)	0	0
Rash	2 (7.1)	0	2 (7.1)	0	0
Erythema	1 (3.6)	1 (3.6)	0	0	0
Pruritus allergic	1 (3.6)	0	1 (3.6)	0	0
Rash maculo-papular	1 (3.6)	0	1 (3.6)	0	0
Rash vesicular	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Region: Europe

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urticaria	1 (3.6)	0	1 (3.6)	0	0
Vascular disorders					
-Total	5 (17.9)	1 (3.6)	2 (7.1)	2 (7.1)	0
Hypotension	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Hypertension	2 (7.1)	1 (3.6)	0	1 (3.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (100)	2 (4.4)	5 (11.1)	12 (26.7)	26 (57.8)
Blood and lymphatic system disorders					
-Total	29 (64.4)	1 (2.2)	4 (8.9)	17 (37.8)	7 (15.6)
Febrile neutropenia	20 (44.4)	0	0	18 (40.0)	2 (4.4)
Anaemia	15 (33.3)	4 (8.9)	7 (15.6)	4 (8.9)	0
Thrombocytopenia	5 (11.1)	0	0	1 (2.2)	4 (8.9)
Coagulopathy	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Disseminated intravascular coagulation	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Neutropenia	3 (6.7)	0	1 (2.2)	0	2 (4.4)
Splenomegaly	3 (6.7)	3 (6.7)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (2.2)	0	1 (2.2)	0	0
Lymphopenia	1 (2.2)	0	0	1 (2.2)	0
Cardiac disorders					
-Total	20 (44.4)	7 (15.6)	5 (11.1)	5 (11.1)	3 (6.7)
Tachycardia	17 (37.8)	7 (15.6)	7 (15.6)	2 (4.4)	1 (2.2)
Bradycardia	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Left ventricular dysfunction	3 (6.7)	0	0	3 (6.7)	0
Sinus tachycardia	2 (4.4)	2 (4.4)	0	0	0
Atrioventricular block first degree	1 (2.2)	0	1 (2.2)	0	0
Cardiac arrest	1 (2.2)	0	0	0	1 (2.2)
Cardiac failure	1 (2.2)	0	0	0	1 (2.2)
Cardiac failure congestive	1 (2.2)	0	1 (2.2)	0	0
Mitral valve incompetence	1 (2.2)	1 (2.2)	0	0	0
Right ventricular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Sinus bradycardia	1 (2.2)	0	0	1 (2.2)	0
Ear and labyrinth disorders					
-Total	2 (4.4)	2 (4.4)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear pain	1 (2.2)	1 (2.2)	0	0	0
Ear pruritus	1 (2.2)	1 (2.2)	0	0	0
Endocrine disorders					
-Total	3 (6.7)	0	3 (6.7)	0	0
Adrenal insufficiency	3 (6.7)	0	3 (6.7)	0	0
Eye disorders					
-Total	6 (13.3)	5 (11.1)	1 (2.2)	0	0
Conjunctival haemorrhage	2 (4.4)	2 (4.4)	0	0	0
Ocular hyperaemia	2 (4.4)	2 (4.4)	0	0	0
Eyelid oedema	1 (2.2)	1 (2.2)	0	0	0
Periorbital oedema	1 (2.2)	1 (2.2)	0	0	0
Periorbital swelling	1 (2.2)	0	1 (2.2)	0	0
Visual impairment	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal disorders					
-Total	29 (64.4)	10 (22.2)	7 (15.6)	11 (24.4)	1 (2.2)
Vomiting	14 (31.1)	7 (15.6)	6 (13.3)	1 (2.2)	0
Nausea	12 (26.7)	7 (15.6)	4 (8.9)	1 (2.2)	0
Diarrhoea	9 (20.0)	7 (15.6)	1 (2.2)	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	7 (15.6)	4 (8.9)	3 (6.7)	0	0
Abdominal pain	5 (11.1)	2 (4.4)	1 (2.2)	2 (4.4)	0
Mouth haemorrhage	4 (8.9)	1 (2.2)	1 (2.2)	2 (4.4)	0
Abdominal distension	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Ascites	2 (4.4)	2 (4.4)	0	0	0
Gastrointestinal sounds abnormal	2 (4.4)	2 (4.4)	0	0	0
Pancreatitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Abdominal compartment syndrome	1 (2.2)	0	0	0	1 (2.2)
Abdominal pain upper	1 (2.2)	1 (2.2)	0	0	0
Anal fissure	1 (2.2)	0	1 (2.2)	0	0
Anal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Dry mouth	1 (2.2)	0	1 (2.2)	0	0
Dysphagia	1 (2.2)	0	0	1 (2.2)	0
Gastrooesophageal reflux disease	1 (2.2)	0	1 (2.2)	0	0
Gingival bleeding	1 (2.2)	0	1 (2.2)	0	0
Gingival erythema	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis ulcerative	1 (2.2)	0	0	1 (2.2)	0
Haematemesis	1 (2.2)	1 (2.2)	0	0	0
Ileus	1 (2.2)	0	1 (2.2)	0	0
Lip dry	1 (2.2)	0	1 (2.2)	0	0
Lip oedema	1 (2.2)	1 (2.2)	0	0	0
Melaena	1 (2.2)	0	0	1 (2.2)	0
Neutropenic colitis	1 (2.2)	0	0	1 (2.2)	0
Proctalgia	1 (2.2)	0	0	1 (2.2)	0
Stomatitis	1 (2.2)	0	1 (2.2)	0	0
Trichoglossia	1 (2.2)	0	1 (2.2)	0	0
Upper gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	28 (62.2)	12 (26.7)	6 (13.3)	6 (13.3)	4 (8.9)
Pyrexia	18 (40.0)	7 (15.6)	3 (6.7)	6 (13.3)	2 (4.4)
Fatigue	10 (22.2)	8 (17.8)	2 (4.4)	0	0
Chills	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Face oedema	4 (8.9)	3 (6.7)	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	4 (8.9)	2 (4.4)	2 (4.4)	0	0
Oedema peripheral	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Catheter site pain	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Drug withdrawal syndrome	2 (4.4)	0	2 (4.4)	0	0
Multiple organ dysfunction syndrome	2 (4.4)	0	0	0	2 (4.4)
Catheter site haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Chest discomfort	1 (2.2)	0	0	1 (2.2)	0
Crying	1 (2.2)	0	1 (2.2)	0	0
Facial pain	1 (2.2)	0	1 (2.2)	0	0
Localised oedema	1 (2.2)	1 (2.2)	0	0	0
Malaise	1 (2.2)	0	1 (2.2)	0	0
Oedema due to hepatic disease	1 (2.2)	0	1 (2.2)	0	0
Pain	1 (2.2)	0	0	1 (2.2)	0
Sluggishness	1 (2.2)	0	1 (2.2)	0	0
Swelling face	1 (2.2)	1 (2.2)	0	0	0
Systemic inflammatory response syndrome	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device occlusion	1 (2.2)	1 (2.2)	0	0	0
Hepatobiliary disorders					
-Total	10 (22.2)	4 (8.9)	3 (6.7)	1 (2.2)	2 (4.4)
Hyperbilirubinaemia	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Gallbladder enlargement	2 (4.4)	2 (4.4)	0	0	0
Hepatomegaly	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Hypertransaminasaemia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Biliary tract disorder	1 (2.2)	1 (2.2)	0	0	0
Cholelithiasis	1 (2.2)	1 (2.2)	0	0	0
Cholestasis	1 (2.2)	0	0	0	1 (2.2)
Hepatic function abnormal	1 (2.2)	0	1 (2.2)	0	0
Ocular icterus	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	39 (86.7)	2 (4.4)	15 (33.3)	12 (26.7)	10 (22.2)
Cytokine release syndrome	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Hypogammaglobulinaemia	11 (24.4)	1 (2.2)	7 (15.6)	3 (6.7)	0
Haemophagocytic lymphohistiocytosis	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (2.2)	0	1 (2.2)	0	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Infections and infestations					
-Total	18 (40.0)	2 (4.4)	4 (8.9)	10 (22.2)	2 (4.4)
Clostridium difficile infection	4 (8.9)	1 (2.2)	0	3 (6.7)	0
Candida infection	3 (6.7)	0	2 (4.4)	0	1 (2.2)
Staphylococcal bacteraemia	3 (6.7)	0	0	3 (6.7)	0
Staphylococcal infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Conjunctivitis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Oral herpes	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Rhinovirus infection	2 (4.4)	0	2 (4.4)	0	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)
Gastroenteritis norovirus	1 (2.2)	1 (2.2)	0	0	0
Granulicatella infection	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (2.2)	0	0	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Localised infection	1 (2.2)	1 (2.2)	0	0	0
Oral candidiasis	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Sinusitis	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Stomatococcal infection	1 (2.2)	0	1 (2.2)	0	0
Systemic candida	1 (2.2)	0	0	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	0	0	1 (2.2)	0
Injury, poisoning and procedural complications					
-Total	8 (17.8)	2 (4.4)	4 (8.9)	0	2 (4.4)
Transfusion reaction	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Wound	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Contusion	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fall	1 (2.2)	0	1 (2.2)	0	0
Infusion related reaction	1 (2.2)	0	1 (2.2)	0	0
Procedural pain	1 (2.2)	0	1 (2.2)	0	0
Scratch	1 (2.2)	1 (2.2)	0	0	0
Skin abrasion	1 (2.2)	1 (2.2)	0	0	0
Skin injury	1 (2.2)	0	1 (2.2)	0	0
Skin wound	1 (2.2)	1 (2.2)	0	0	0
Transplant failure	1 (2.2)	0	0	0	1 (2.2)
Vasoplegia syndrome	1 (2.2)	0	0	0	1 (2.2)
Investigations					
-Total	36 (80.0)	3 (6.7)	4 (8.9)	13 (28.9)	16 (35.6)
Aspartate aminotransferase increased	18 (40.0)	2 (4.4)	6 (13.3)	7 (15.6)	3 (6.7)
Alanine aminotransferase increased	16 (35.6)	4 (8.9)	8 (17.8)	4 (8.9)	0
Platelet count decreased	14 (31.1)	3 (6.7)	2 (4.4)	4 (8.9)	5 (11.1)
White blood cell count decreased	14 (31.1)	2 (4.4)	3 (6.7)	1 (2.2)	8 (17.8)
Blood bilirubin increased	11 (24.4)	1 (2.2)	2 (4.4)	8 (17.8)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	11 (24.4)	0	2 (4.4)	2 (4.4)	7 (15.6)
International normalised ratio increased	9 (20.0)	6 (13.3)	3 (6.7)	0	0
Lymphocyte count decreased	8 (17.8)	1 (2.2)	0	5 (11.1)	2 (4.4)
Activated partial thromboplastin time prolonged	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Blood immunoglobulin m decreased	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin a decreased	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Electrocardiogram qt prolonged	5 (11.1)	1 (2.2)	2 (4.4)	1 (2.2)	1 (2.2)
Blood creatinine increased	4 (8.9)	1 (2.2)	0	2 (4.4)	1 (2.2)
Blood fibrinogen decreased	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Serum ferritin increased	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Weight increased	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Blood lactate dehydrogenase increased	3 (6.7)	2 (4.4)	0	1 (2.2)	0
C-reactive protein increased	3 (6.7)	1 (2.2)	0	2 (4.4)	0
Fibrin d dimer increased	3 (6.7)	2 (4.4)	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Blood uric acid increased	2 (4.4)	2 (4.4)	0	0	0
Lipase increased	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Urine output decreased	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Amylase increased	1 (2.2)	1 (2.2)	0	0	0
Bacterial test positive	1 (2.2)	0	0	1 (2.2)	0
Blood alkaline phosphatase increased	1 (2.2)	1 (2.2)	0	0	0
Blood bicarbonate decreased	1 (2.2)	0	1 (2.2)	0	0
Blood creatine phosphokinase increased	1 (2.2)	0	0	0	1 (2.2)
Blood glucose increased	1 (2.2)	0	0	0	1 (2.2)
Blood phosphorus increased	1 (2.2)	0	1 (2.2)	0	0
Blood testosterone decreased	1 (2.2)	1 (2.2)	0	0	0
Breath sounds abnormal	1 (2.2)	0	1 (2.2)	0	0
Cardiac murmur	1 (2.2)	1 (2.2)	0	0	0
Coagulation test abnormal	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram t wave abnormal	1 (2.2)	0	1 (2.2)	0	0
Enterovirus test positive	1 (2.2)	0	1 (2.2)	0	0
Gamma-glutamyltransferase increased	1 (2.2)	0	0	1 (2.2)	0
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Haptoglobin decreased	1 (2.2)	1 (2.2)	0	0	0
Oxygen saturation decreased	1 (2.2)	1 (2.2)	0	0	0
Staphylococcus test positive	1 (2.2)	1 (2.2)	0	0	0
Troponin increased	1 (2.2)	0	0	1 (2.2)	0
Weight decreased	1 (2.2)	0	1 (2.2)	0	0
Metabolism and nutrition disorders					
-Total	34 (75.6)	5 (11.1)	7 (15.6)	15 (33.3)	7 (15.6)
Decreased appetite	20 (44.4)	7 (15.6)	3 (6.7)	9 (20.0)	1 (2.2)
Hypocalcaemia	15 (33.3)	2 (4.4)	9 (20.0)	4 (8.9)	0
Hypokalaemia	14 (31.1)	2 (4.4)	4 (8.9)	6 (13.3)	2 (4.4)
Hypophosphataemia	14 (31.1)	3 (6.7)	5 (11.1)	6 (13.3)	0
Hypoalbuminaemia	9 (20.0)	0	8 (17.8)	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	6 (13.3)	0	3 (6.7)	3 (6.7)	0
Hyperuricaemia	6 (13.3)	5 (11.1)	0	1 (2.2)	0
Hypervolaemia	6 (13.3)	0	2 (4.4)	4 (8.9)	0
Hyperphosphataemia	5 (11.1)	4 (8.9)	0	0	1 (2.2)
Hypercalcaemia	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Hypomagnesaemia	3 (6.7)	3 (6.7)	0	0	0
Hyponatraemia	3 (6.7)	3 (6.7)	0	0	0
Metabolic acidosis	3 (6.7)	1 (2.2)	0	0	2 (4.4)
Acidosis	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Hyperkalaemia	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Hypermagnesaemia	2 (4.4)	2 (4.4)	0	0	0
Hypertriglyceridaemia	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Tumour lysis syndrome	2 (4.4)	0	0	2 (4.4)	0
Calcium deficiency	1 (2.2)	1 (2.2)	0	0	0
Dehydration	1 (2.2)	0	1 (2.2)	0	0
Haemosiderosis	1 (2.2)	0	1 (2.2)	0	0
Hyperchloraemia	1 (2.2)	1 (2.2)	0	0	0
Hyperlactacidaemia	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (2.2)	0	0	0	1 (2.2)
Hypoglycaemia	1 (2.2)	0	1 (2.2)	0	0
Malnutrition	1 (2.2)	0	0	1 (2.2)	0
Polydipsia	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	21 (46.7)	10 (22.2)	7 (15.6)	3 (6.7)	1 (2.2)
Myalgia	8 (17.8)	5 (11.1)	3 (6.7)	0	0
Arthralgia	6 (13.3)	2 (4.4)	3 (6.7)	1 (2.2)	0
Pain in extremity	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Back pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Bone pain	2 (4.4)	0	2 (4.4)	0	0
Haemarthrosis	1 (2.2)	0	0	1 (2.2)	0
Muscle rigidity	1 (2.2)	1 (2.2)	0	0	0
Muscle spasms	1 (2.2)	0	1 (2.2)	0	0
Muscular weakness	1 (2.2)	0	0	1 (2.2)	0
Myositis	1 (2.2)	0	1 (2.2)	0	0
Neck pain	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	1 (2.2)	0	0	1 (2.2)	0
Rhabdomyolysis	1 (2.2)	0	0	0	1 (2.2)
Nervous system disorders					
-Total	24 (53.3)	7 (15.6)	9 (20.0)	6 (13.3)	2 (4.4)
Headache	13 (28.9)	4 (8.9)	7 (15.6)	2 (4.4)	0
Encephalopathy	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0
Somnolence	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Tremor	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Cognitive disorder	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Dizziness	3 (6.7)	3 (6.7)	0	0	0
Lethargy	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Dysgeusia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Aphasia	1 (2.2)	1 (2.2)	0	0	0
Cerebral haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Disturbance in attention	1 (2.2)	1 (2.2)	0	0	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised tonic-clonic seizure	1 (2.2)	0	1 (2.2)	0	0
Hypoaesthesia	1 (2.2)	1 (2.2)	0	0	0
Monoparesis	1 (2.2)	0	1 (2.2)	0	0
Neurological decompensation	1 (2.2)	0	0	0	1 (2.2)
Paraesthesia	1 (2.2)	1 (2.2)	0	0	0
Psychiatric disorders					
-Total	19 (42.2)	9 (20.0)	5 (11.1)	5 (11.1)	0
Delirium	7 (15.6)	2 (4.4)	2 (4.4)	3 (6.7)	0
Agitation	5 (11.1)	2 (4.4)	3 (6.7)	0	0
Confusional state	5 (11.1)	5 (11.1)	0	0	0
Anxiety	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Irritability	3 (6.7)	3 (6.7)	0	0	0
Mental status changes	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Insomnia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Affect lability	1 (2.2)	0	1 (2.2)	0	0
Automatism	1 (2.2)	1 (2.2)	0	0	0
Hallucination	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Sleep disorder	1 (2.2)	0	1 (2.2)	0	0
Social avoidant behaviour	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	12 (26.7)	2 (4.4)	4 (8.9)	3 (6.7)	3 (6.7)
Acute kidney injury	7 (15.6)	1 (2.2)	1 (2.2)	3 (6.7)	2 (4.4)
Pollakiuria	2 (4.4)	0	2 (4.4)	0	0
Urinary retention	2 (4.4)	0	2 (4.4)	0	0
Anuria	1 (2.2)	1 (2.2)	0	0	0
Azotaemia	1 (2.2)	0	1 (2.2)	0	0
Bladder dilatation	1 (2.2)	0	1 (2.2)	0	0
Dysuria	1 (2.2)	1 (2.2)	0	0	0
Haematuria	1 (2.2)	1 (2.2)	0	0	0
Incontinence	1 (2.2)	0	1 (2.2)	0	0
Micturition urgency	1 (2.2)	0	1 (2.2)	0	0
Renal failure	1 (2.2)	0	0	0	1 (2.2)
Renal tubular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Renal tubular necrosis	1 (2.2)	0	0	0	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (2.2)	0	1 (2.2)	0	0
Reproductive system and breast disorders					
-Total	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Perineal rash	1 (2.2)	0	1 (2.2)	0	0
Vaginal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Vaginal ulceration	1 (2.2)	0	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (60.0)	8 (17.8)	2 (4.4)	8 (17.8)	9 (20.0)
Hypoxia	11 (24.4)	0	2 (4.4)	6 (13.3)	3 (6.7)
Pulmonary oedema	8 (17.8)	1 (2.2)	3 (6.7)	3 (6.7)	1 (2.2)
Tachypnoea	8 (17.8)	3 (6.7)	1 (2.2)	4 (8.9)	0
Cough	6 (13.3)	6 (13.3)	0	0	0
Pleural effusion	6 (13.3)	3 (6.7)	0	2 (4.4)	1 (2.2)
Respiratory failure	4 (8.9)	0	0	0	4 (8.9)
Atelectasis	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Dyspnoea	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Epistaxis	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Respiratory distress	3 (6.7)	0	2 (4.4)	0	1 (2.2)
Acute respiratory distress syndrome	2 (4.4)	0	0	0	2 (4.4)
Oropharyngeal pain	2 (4.4)	2 (4.4)	0	0	0
Rhinorrhoea	2 (4.4)	2 (4.4)	0	0	0
Acute respiratory failure	1 (2.2)	0	0	1 (2.2)	0
Bradypnoea	1 (2.2)	0	0	1 (2.2)	0
Haemoptysis	1 (2.2)	0	1 (2.2)	0	0
Lung infiltration	1 (2.2)	0	0	1 (2.2)	0
Nasal discomfort	1 (2.2)	0	1 (2.2)	0	0
Nasal dryness	1 (2.2)	1 (2.2)	0	0	0
Oropharyngeal plaque	1 (2.2)	0	1 (2.2)	0	0
Paranasal sinus discomfort	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal erythema	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal exudate	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal oedema	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary mass	1 (2.2)	0	1 (2.2)	0	0
Respiratory acidosis	1 (2.2)	0	0	1 (2.2)	0
Wheezing	1 (2.2)	0	1 (2.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (35.6)	8 (17.8)	5 (11.1)	3 (6.7)	0
Blister	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Erythema	3 (6.7)	3 (6.7)	0	0	0
Hyperhidrosis	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Pruritus	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Rash	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Rash papular	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Petechiae	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Decubitus ulcer	1 (2.2)	0	1 (2.2)	0	0
Dermatitis	1 (2.2)	1 (2.2)	0	0	0
Dermatitis diaper	1 (2.2)	0	1 (2.2)	0	0
Dry skin	1 (2.2)	1 (2.2)	0	0	0
Eczema	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Purpura	1 (2.2)	1 (2.2)	0	0	0
Rash maculo-papular	1 (2.2)	0	0	1 (2.2)	0
Rash pruritic	1 (2.2)	1 (2.2)	0	0	0
Scab	1 (2.2)	1 (2.2)	0	0	0
Skin discolouration	1 (2.2)	1 (2.2)	0	0	0
Skin lesion	1 (2.2)	0	1 (2.2)	0	0
Skin necrosis	1 (2.2)	0	0	1 (2.2)	0
Skin ulcer	1 (2.2)	1 (2.2)	0	0	0
Vancomycin infusion reaction	1 (2.2)	0	0	1 (2.2)	0
Social circumstances					
-Total	1 (2.2)	0	1 (2.2)	0	0
Patient uncooperative	1 (2.2)	0	1 (2.2)	0	0
Surgical and medical procedures					
-Total	1 (2.2)	0	0	1 (2.2)	0
Thrombolysis	1 (2.2)	0	0	1 (2.2)	0
Vascular disorders					
-Total	22 (48.9)	3 (6.7)	4 (8.9)	9 (20.0)	6 (13.3)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	18 (40.0)	1 (2.2)	4 (8.9)	7 (15.6)	6 (13.3)
Hypertension	10 (22.2)	3 (6.7)	4 (8.9)	3 (6.7)	0
Capillary leak syndrome	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Flushing	1 (2.2)	1 (2.2)	0	0	0
Hot flush	1 (2.2)	1 (2.2)	0	0	0
Peripheral ischaemia	1 (2.2)	0	1 (2.2)	0	0
Thrombosis	1 (2.2)	0	1 (2.2)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders					
-Total	6 (85.7)	0	2 (28.6)	0	4 (57.1)
Neutropenia	3 (42.9)	0	0	0	3 (42.9)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)	0	0
Anaemia	1 (14.3)	0	1 (14.3)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Hypofibrinogenaemia	1 (14.3)	0	1 (14.3)	0	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Cardiac dysfunction	2 (28.6)	2 (28.6)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	3 (42.9)	3 (42.9)	0	0
Nausea	2 (28.6)	2 (28.6)	0	0	0
Pancreatitis	2 (28.6)	0	2 (28.6)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Enterocolitis	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Face oedema	1 (14.3)	1 (14.3)	0	0	0
Influenza like illness	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)
Immune system disorders					
-Total	7 (100)	1 (14.3)	1 (14.3)	2 (28.6)	3 (42.9)
Cytokine release syndrome	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)	0	0
Infections and infestations					
-Total	5 (71.4)	2 (28.6)	1 (14.3)	1 (14.3)	1 (14.3)
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bk virus infection	1 (14.3)	1 (14.3)	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Pneumonia	1 (14.3)	0	0	1 (14.3)	0
Urinary tract infection viral	1 (14.3)	1 (14.3)	0	0	0
Investigations					
-Total	5 (71.4)	0	0	0	5 (71.4)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	3 (42.9)	0	3 (42.9)	0	0
Blood fibrinogen decreased	2 (28.6)	0	2 (28.6)	0	0
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Blood creatine phosphokinase increased	1 (14.3)	0	0	1 (14.3)	0
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	3 (42.9)	1 (14.3)	0	0	2 (28.6)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (28.6)	0	0	0	2 (28.6)
Haematuria	1 (14.3)	1 (14.3)	0	0	0
Proteinuria	1 (14.3)	1 (14.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Heavy menstrual bleeding	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (71.4)	2 (28.6)	0	0	3 (42.9)
Hypoxia	3 (42.9)	0	0	0	3 (42.9)
Epistaxis	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0	0	0
Pleural effusion	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Erythema nodosum	1 (14.3)	1 (14.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Region: Rest of World

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Skin ulcer	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	4 (14.3)	10 (35.7)	4 (14.3)	10 (35.7)
Blood and lymphatic system disorders					
-Total	7 (25.0)	2 (7.1)	1 (3.6)	3 (10.7)	1 (3.6)
Anaemia	2 (7.1)	2 (7.1)	0	0	0
Neutropenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Disseminated intravascular coagulation	1 (3.6)	0	0	1 (3.6)	0
Eosinophilia	1 (3.6)	0	1 (3.6)	0	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Lymphadenopathy	1 (3.6)	1 (3.6)	0	0	0
Thrombocytopenia	1 (3.6)	0	0	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Left ventricular dysfunction	1 (3.6)	0	1 (3.6)	0	0
Gastrointestinal disorders					
-Total	7 (25.0)	5 (17.9)	1 (3.6)	1 (3.6)	0
Constipation	2 (7.1)	0	2 (7.1)	0	0
Pancreatitis	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Vomiting	2 (7.1)	2 (7.1)	0	0	0
Abdominal pain upper	1 (3.6)	1 (3.6)	0	0	0
Abdominal rigidity	1 (3.6)	0	1 (3.6)	0	0
Diarrhoea	1 (3.6)	1 (3.6)	0	0	0
Dyspepsia	1 (3.6)	1 (3.6)	0	0	0
Mouth haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Nausea	1 (3.6)	1 (3.6)	0	0	0
Peritoneal haematoma	1 (3.6)	1 (3.6)	0	0	0
General disorders and administration site conditions					
-Total	5 (17.9)	2 (7.1)	3 (10.7)	0	0
Pyrexia	4 (14.3)	1 (3.6)	3 (10.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Asthenia	1 (3.6)	1 (3.6)	0	0	0
Non-cardiac chest pain	1 (3.6)	1 (3.6)	0	0	0
Hepatobiliary disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hepatic cytolysis	1 (3.6)	1 (3.6)	0	0	0
Liver disorder	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					
-Total	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Allergy to immunoglobulin therapy	1 (3.6)	1 (3.6)	0	0	0
Graft versus host disease	1 (3.6)	0	0	1 (3.6)	0
Immunodeficiency	1 (3.6)	0	0	1 (3.6)	0
Infections and infestations					
-Total	20 (71.4)	4 (14.3)	7 (25.0)	3 (10.7)	6 (21.4)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)	0	0
Gastroenteritis	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Pneumonia	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Rhinitis	2 (7.1)	1 (3.6)	1 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (7.1)	2 (7.1)	0	0	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Conjunctivitis	1 (3.6)	0	1 (3.6)	0	0
Cystitis	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	0	1 (3.6)	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Ear, nose and throat infection	1 (3.6)	0	1 (3.6)	0	0
Encephalitis	1 (3.6)	0	0	0	1 (3.6)
Herpes zoster	1 (3.6)	0	0	1 (3.6)	0
Molluscum contagiosum	1 (3.6)	1 (3.6)	0	0	0
Nail infection	1 (3.6)	1 (3.6)	0	0	0
Oral candidiasis	1 (3.6)	0	1 (3.6)	0	0
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0
Paronychia	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	0	1 (3.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (3.6)	0	1 (3.6)	0	0
Rhinovirus infection	1 (3.6)	0	1 (3.6)	0	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	0	0	1 (3.6)
Staphylococcal skin infection	1 (3.6)	0	1 (3.6)	0	0
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Viral infection	1 (3.6)	0	1 (3.6)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.6)	0	1 (3.6)	0	0
Infusion related reaction	1 (3.6)	0	1 (3.6)	0	0
Investigations					
-Total	8 (28.6)	2 (7.1)	2 (7.1)	2 (7.1)	2 (7.1)
White blood cell count decreased	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Neutrophil count decreased	2 (7.1)	0	0	0	2 (7.1)
Platelet count decreased	2 (7.1)	2 (7.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (3.6)	0	0	1 (3.6)	0
Bone density decreased	1 (3.6)	1 (3.6)	0	0	0
Hepatitis b virus test positive	1 (3.6)	0	1 (3.6)	0	0
Immunoglobulins decreased	1 (3.6)	0	1 (3.6)	0	0
Weight decreased	1 (3.6)	0	0	1 (3.6)	0
Metabolism and nutrition disorders					
-Total	2 (7.1)	0	0	2 (7.1)	0
Decreased appetite	1 (3.6)	0	0	1 (3.6)	0
Haemochromatosis	1 (3.6)	0	0	1 (3.6)	0
Hypophosphataemia	1 (3.6)	0	1 (3.6)	0	0
Malnutrition	1 (3.6)	0	0	1 (3.6)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Back pain	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Arthralgia	1 (3.6)	1 (3.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Skin papilloma	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Myelodysplastic syndrome	1 (3.6)	0	0	1 (3.6)	0
Nervous system disorders					
-Total	4 (14.3)	1 (3.6)	1 (3.6)	0	2 (7.1)
Headache	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Autonomic neuropathy	1 (3.6)	0	0	1 (3.6)	0
Cerebral haemorrhage	1 (3.6)	0	0	0	1 (3.6)
Hydrocephalus	1 (3.6)	0	0	0	1 (3.6)
Memory impairment	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Psychiatric disorders					
-Total	3 (10.7)	0	3 (10.7)	0	0
Anxiety	2 (7.1)	0	2 (7.1)	0	0
Sleep disorder	1 (3.6)	0	1 (3.6)	0	0
Renal and urinary disorders					
-Total	1 (3.6)	0	0	1 (3.6)	0
Renal tubular disorder	1 (3.6)	0	0	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	8 (28.6)	5 (17.9)	2 (7.1)	0	1 (3.6)
Cough	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Bronchial oedema	1 (3.6)	1 (3.6)	0	0	0
Bronchospasm	1 (3.6)	0	1 (3.6)	0	0
Lung disorder	1 (3.6)	1 (3.6)	0	0	0
Respiratory failure	1 (3.6)	0	0	0	1 (3.6)
Skin and subcutaneous tissue disorders					
-Total	7 (25.0)	3 (10.7)	3 (10.7)	1 (3.6)	0
Decubitus ulcer	1 (3.6)	0	0	1 (3.6)	0
Dermatitis allergic	1 (3.6)	1 (3.6)	0	0	0
Dermatitis atopic	1 (3.6)	1 (3.6)	0	0	0
Dry skin	1 (3.6)	0	1 (3.6)	0	0
Erythema	1 (3.6)	0	1 (3.6)	0	0
Hangnail	1 (3.6)	1 (3.6)	0	0	0
Photosensitivity reaction	1 (3.6)	0	1 (3.6)	0	0
Rash	1 (3.6)	0	1 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=28 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Hypotension	1 (3.6)	1 (3.6)	0	0	0
Venoocclusive disease	1 (3.6)	0	0	0	1 (3.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	5 (12.5)	13 (32.5)	10 (25.0)	7 (17.5)
Blood and lymphatic system disorders					
-Total	6 (15.0)	1 (2.5)	2 (5.0)	2 (5.0)	1 (2.5)
Anaemia	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Leukocytosis	1 (2.5)	0	1 (2.5)	0	0
Leukopenia	1 (2.5)	0	1 (2.5)	0	0
Lymphocytosis	1 (2.5)	0	1 (2.5)	0	0
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.5)	3 (7.5)	0	0	2 (5.0)
Cardiac arrest	2 (5.0)	0	0	0	2 (5.0)
Tachycardia	2 (5.0)	2 (5.0)	0	0	0
Cardiac failure	1 (2.5)	0	0	1 (2.5)	0
Tricuspid valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	4 (10.0)	4 (10.0)	0	0	0
Cataract	2 (5.0)	2 (5.0)	0	0	0
Hypermetropia	1 (2.5)	1 (2.5)	0	0	0
Ocular hyperaemia	1 (2.5)	1 (2.5)	0	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	10 (25.0)	6 (15.0)	4 (10.0)	0	0
Diarrhoea	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Nausea	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Vomiting	4 (10.0)	4 (10.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Gastrointestinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal inflammation	1 (2.5)	0	1 (2.5)	0	0
Proctalgia	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	18 (45.0)	12 (30.0)	3 (7.5)	3 (7.5)	0
Pyrexia	10 (25.0)	5 (12.5)	3 (7.5)	2 (5.0)	0
Fatigue	6 (15.0)	6 (15.0)	0	0	0
Pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Chills	1 (2.5)	1 (2.5)	0	0	0
Malaise	1 (2.5)	1 (2.5)	0	0	0
Oedema peripheral	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Hypertransaminasaemia	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	11 (27.5)	0	9 (22.5)	2 (5.0)	0
Hypogammaglobulinaemia	8 (20.0)	0	8 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	1 (2.5)	0	0	1 (2.5)	0
Drug hypersensitivity	1 (2.5)	0	1 (2.5)	0	0
Engraftment syndrome	1 (2.5)	0	0	1 (2.5)	0
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Infections and infestations					
-Total	17 (42.5)	0	7 (17.5)	8 (20.0)	2 (5.0)
Upper respiratory tract infection	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Metapneumovirus infection	3 (7.5)	0	0	3 (7.5)	0
Rhinovirus infection	3 (7.5)	0	3 (7.5)	0	0
Gastroenteritis	2 (5.0)	2 (5.0)	0	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Otitis media	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinusitis	2 (5.0)	0	2 (5.0)	0	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis viral	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0	0	0
Salmonellosis	1 (2.5)	0	1 (2.5)	0	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Tinea pedis	1 (2.5)	1 (2.5)	0	0	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	8 (20.0)	5 (12.5)	3 (7.5)	0	0
Infusion related reaction	2 (5.0)	2 (5.0)	0	0	0
Contusion	1 (2.5)	1 (2.5)	0	0	0
Fibula fracture	1 (2.5)	0	1 (2.5)	0	0
Ligament sprain	1 (2.5)	1 (2.5)	0	0	0
Limb injury	1 (2.5)	0	1 (2.5)	0	0
Post-traumatic neck syndrome	1 (2.5)	0	1 (2.5)	0	0
Skin abrasion	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	20 (50.0)	5 (12.5)	5 (12.5)	8 (20.0)	2 (5.0)
Neutrophil count decreased	7 (17.5)	2 (5.0)	1 (2.5)	3 (7.5)	1 (2.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	2 (5.0)	1 (2.5)	1 (2.5)
Lymphocyte count decreased	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Platelet count decreased	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Alanine aminotransferase increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood bilirubin increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Blood lactate dehydrogenase increased	1 (2.5)	1 (2.5)	0	0	0
Blood thyroid stimulating hormone increased	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (2.5)	0	0	1 (2.5)	0
Blood uric acid increased	1 (2.5)	0	0	0	1 (2.5)
C-reactive protein increased	1 (2.5)	1 (2.5)	0	0	0
Ejection fraction decreased	1 (2.5)	0	1 (2.5)	0	0
Heart sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Oxygen saturation decreased	1 (2.5)	0	1 (2.5)	0	0
Weight increased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	12 (30.0)	4 (10.0)	4 (10.0)	2 (5.0)	2 (5.0)
Decreased appetite	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Hyperuricaemia	3 (7.5)	3 (7.5)	0	0	0
Hypokalaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hyperchloraemia	1 (2.5)	1 (2.5)	0	0	0
Hyperkalaemia	1 (2.5)	0	1 (2.5)	0	0
Hypervolaemia	1 (2.5)	0	0	1 (2.5)	0
Hypophagia	1 (2.5)	0	1 (2.5)	0	0
Iron overload	1 (2.5)	0	1 (2.5)	0	0
Metabolic syndrome	1 (2.5)	0	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (2.5)	0	0	0	1 (2.5)
Musculoskeletal and connective tissue disorders					
-Total	13 (32.5)	4 (10.0)	6 (15.0)	3 (7.5)	0
Pain in extremity	5 (12.5)	2 (5.0)	2 (5.0)	1 (2.5)	0
Back pain	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Arthralgia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Bone pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Growth retardation	1 (2.5)	0	1 (2.5)	0	0
Musculoskeletal chest pain	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal pain	1 (2.5)	0	1 (2.5)	0	0
Myalgia	1 (2.5)	0	1 (2.5)	0	0
Neck pain	1 (2.5)	1 (2.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	1 (2.5)	0	0
Cancer pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	9 (22.5)	5 (12.5)	4 (10.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Extrapyramidal disorder	1 (2.5)	0	1 (2.5)	0	0
Migraine	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Mental status changes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Nightmare	1 (2.5)	1 (2.5)	0	0	0
Persistent depressive disorder	1 (2.5)	0	1 (2.5)	0	0
Tearfulness	1 (2.5)	1 (2.5)	0	0	0
Renal and urinary disorders					
-Total	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Acute kidney injury	3 (7.5)	1 (2.5)	1 (2.5)	0	1 (2.5)
Dysuria	1 (2.5)	0	1 (2.5)	0	0
Haematuria	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Kidney enlargement	1 (2.5)	0	1 (2.5)	0	0
Renal mass	1 (2.5)	0	1 (2.5)	0	0
Reproductive system and breast disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Dysmenorrhoea	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (35.0)	6 (15.0)	3 (7.5)	3 (7.5)	2 (5.0)
Cough	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Nasal congestion	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Hypoxia	3 (7.5)	0	0	3 (7.5)	0
Rhinorrhoea	3 (7.5)	3 (7.5)	0	0	0
Oropharyngeal pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rhinitis allergic	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Acute respiratory distress syndrome	1 (2.5)	0	0	0	1 (2.5)
Dyspnoea	1 (2.5)	0	1 (2.5)	0	0
Paranasal sinus inflammation	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (2.5)	1 (2.5)	0	0	0
Respiratory distress	1 (2.5)	0	0	0	1 (2.5)
Skin and subcutaneous tissue disorders					
-Total	11 (27.5)	7 (17.5)	4 (10.0)	0	0
Dry skin	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Rash	3 (7.5)	3 (7.5)	0	0	0
Ingrowing nail	2 (5.0)	0	2 (5.0)	0	0
Eczema	1 (2.5)	1 (2.5)	0	0	0
Miliaria	1 (2.5)	1 (2.5)	0	0	0
Night sweats	1 (2.5)	1 (2.5)	0	0	0
Pruritus	1 (2.5)	0	1 (2.5)	0	0
Skin discolouration	1 (2.5)	1 (2.5)	0	0	0
Skin hypopigmentation	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Hypotension	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Hypertension	1 (2.5)	0	1 (2.5)	0	0
Venoocclusive disease	1 (2.5)	0	0	1 (2.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	1 (14.3)	1 (14.3)	4 (57.1)
Blood and lymphatic system disorders					
-Total	4 (57.1)	0	1 (14.3)	1 (14.3)	2 (28.6)
Neutropenia	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Anaemia	1 (14.3)	1 (14.3)	0	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Cardiac disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Cardiac failure	1 (14.3)	0	0	0	1 (14.3)
Gastrointestinal disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (14.3)	1 (14.3)	0	0	0
Enteritis	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	1 (14.3)	0	0	0
Trichoglossia	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)	0	0
Infections and infestations					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	0	1 (14.3)	0
Metabolism and nutrition disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Metabolic acidosis	1 (14.3)	0	0	0	1 (14.3)
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Cystitis haemorrhagic	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract inflammation	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Skin swelling	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Hypotension	1 (14.3)	0	0	0	1 (14.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (63.6)	2 (9.1)	3 (13.6)	5 (22.7)	4 (18.2)
Blood and lymphatic system disorders					
-Total	4 (18.2)	0	2 (9.1)	1 (4.5)	1 (4.5)
Agranulocytosis	1 (4.5)	0	0	1 (4.5)	0
Anaemia	1 (4.5)	0	1 (4.5)	0	0
Hypercoagulation	1 (4.5)	0	1 (4.5)	0	0
Lymphadenopathy	1 (4.5)	0	1 (4.5)	0	0
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Thrombocytopenia	1 (4.5)	0	1 (4.5)	0	0
Eye disorders					

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	0	0	1 (4.5)	0
Eye pain	1 (4.5)	0	0	1 (4.5)	0
Eyelid oedema	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Diarrhoea	3 (13.6)	2 (9.1)	0	1 (4.5)	0
General disorders and administration site conditions					
-Total	3 (13.6)	1 (4.5)	0	1 (4.5)	1 (4.5)
Pyrexia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Multiple organ dysfunction syndrome	1 (4.5)	0	0	0	1 (4.5)
Immune system disorders					
-Total	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Chronic graft versus host disease	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Drug hypersensitivity	1 (4.5)	0	0	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	0	0	1 (4.5)

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	11 (50.0)	2 (9.1)	2 (9.1)	4 (18.2)	3 (13.6)
Conjunctivitis	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Sepsis	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Candida infection	1 (4.5)	0	1 (4.5)	0	0
Covid-19	1 (4.5)	0	0	1 (4.5)	0
Covid-19 pneumonia	1 (4.5)	0	0	0	1 (4.5)
Device related sepsis	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Fungal infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis	1 (4.5)	1 (4.5)	0	0	0
Herpes virus infection	1 (4.5)	0	1 (4.5)	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Influenza	1 (4.5)	0	0	0	1 (4.5)
Neutropenic infection	1 (4.5)	0	0	1 (4.5)	0
Ophthalmic herpes zoster	1 (4.5)	0	1 (4.5)	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (4.5)	0	0	1 (4.5)	0
Pneumonia	1 (4.5)	0	0	0	1 (4.5)
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Rhinovirus infection	1 (4.5)	0	0	1 (4.5)	0
Sinusitis	1 (4.5)	0	1 (4.5)	0	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Streptococcal sepsis	1 (4.5)	0	1 (4.5)	0	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Viral skin infection	1 (4.5)	1 (4.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.5)	1 (4.5)	0	0	0
Ligament sprain	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Blood immunoglobulin g decreased	1 (4.5)	0	1 (4.5)	0	0
Oxygen saturation decreased	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (4.5)	1 (4.5)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Decreased appetite	1 (4.5)	0	0	0	1 (4.5)
Hyperglycaemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (18.2)	1 (4.5)	3 (13.6)	0	0
Pain in extremity	2 (9.1)	0	2 (9.1)	0	0
Growth retardation	1 (4.5)	0	1 (4.5)	0	0
Osteonecrosis	1 (4.5)	1 (4.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.5)	0	0	1 (4.5)	0
Bone giant cell tumour benign	1 (4.5)	0	0	1 (4.5)	0
Nervous system disorders					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	1 (4.5)	0	1 (4.5)	0	0
Headache	1 (4.5)	0	0	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (18.2)	3 (13.6)	0	0	1 (4.5)
Cough	2 (9.1)	2 (9.1)	0	0	0
Dyspnoea	1 (4.5)	0	0	0	1 (4.5)
Dyspnoea exertional	1 (4.5)	1 (4.5)	0	0	0
Epistaxis	1 (4.5)	1 (4.5)	0	0	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0	0	0
Pharyngeal erythema	1 (4.5)	1 (4.5)	0	0	0
Pleural effusion	1 (4.5)	0	1 (4.5)	0	0
Tachypnoea	1 (4.5)	0	0	0	1 (4.5)
Skin and subcutaneous tissue disorders					
-Total	4 (18.2)	2 (9.1)	0	2 (9.1)	0
Dermatitis atopic	1 (4.5)	0	0	1 (4.5)	0
Dry skin	1 (4.5)	1 (4.5)	0	0	0
Papule	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (4.5)	0	0	1 (4.5)	0
Vascular disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Hypertension	1 (4.5)	0	0	1 (4.5)	0

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Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (69.6)	1 (4.3)	7 (30.4)	6 (26.1)	2 (8.7)
Congenital, familial and genetic disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Cerebral cavernous malformation	1 (4.3)	1 (4.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Deafness unilateral	1 (4.3)	0	1 (4.3)	0	0
Endocrine disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Delayed puberty	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypothyroidism	1 (4.3)	0	1 (4.3)	0	0
Eye disorders					
-Total	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Dry eye	1 (4.3)	1 (4.3)	0	0	0
Mydriasis	1 (4.3)	0	1 (4.3)	0	0
Gastrointestinal disorders					
-Total	4 (17.4)	2 (8.7)	2 (8.7)	0	0
Diarrhoea	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Constipation	1 (4.3)	1 (4.3)	0	0	0
Irritable bowel syndrome	1 (4.3)	0	1 (4.3)	0	0
Nausea	1 (4.3)	1 (4.3)	0	0	0
Vomiting	1 (4.3)	1 (4.3)	0	0	0
General disorders and administration site conditions					
-Total	5 (21.7)	2 (8.7)	3 (13.0)	0	0
Fatigue	1 (4.3)	0	1 (4.3)	0	0
Non-cardiac chest pain	1 (4.3)	1 (4.3)	0	0	0
Pain	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (4.3)	0	1 (4.3)	0	0
Xerosis	1 (4.3)	1 (4.3)	0	0	0
Immune system disorders					
-Total	6 (26.1)	2 (8.7)	4 (17.4)	0	0
Hypogammaglobulinaemia	3 (13.0)	0	3 (13.0)	0	0
Seasonal allergy	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Infections and infestations					
-Total	10 (43.5)	0	4 (17.4)	5 (21.7)	1 (4.3)
Sinusitis	4 (17.4)	0	4 (17.4)	0	0
Upper respiratory tract infection	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Rhinovirus infection	2 (8.7)	0	2 (8.7)	0	0
Skin infection	2 (8.7)	0	2 (8.7)	0	0
Acute sinusitis	1 (4.3)	0	1 (4.3)	0	0
Bronchiolitis	1 (4.3)	0	0	1 (4.3)	0
Bronchitis	1 (4.3)	0	1 (4.3)	0	0
Clostridium difficile colitis	1 (4.3)	0	0	1 (4.3)	0
Conjunctivitis	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (4.3)	1 (4.3)	0	0	0
Ear infection	1 (4.3)	0	0	1 (4.3)	0
Folliculitis	1 (4.3)	0	1 (4.3)	0	0
Fungal infection	1 (4.3)	0	1 (4.3)	0	0
Fungal skin infection	1 (4.3)	0	1 (4.3)	0	0
Gastroenteritis escherichia coli	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis salmonella	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis viral	1 (4.3)	0	1 (4.3)	0	0
Herpes zoster	1 (4.3)	0	1 (4.3)	0	0
Influenza	1 (4.3)	0	1 (4.3)	0	0
Meningitis pneumococcal	1 (4.3)	0	0	1 (4.3)	0
Nail infection	1 (4.3)	0	1 (4.3)	0	0
Oral candidiasis	1 (4.3)	0	1 (4.3)	0	0
Oral herpes	1 (4.3)	1 (4.3)	0	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Otitis media acute	1 (4.3)	0	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	0	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (4.3)	0	0	1 (4.3)	0
Septic shock	1 (4.3)	0	0	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Syphilis	1 (4.3)	0	1 (4.3)	0	0
Urinary tract infection	1 (4.3)	0	1 (4.3)	0	0
Urinary tract infection pseudomonal	1 (4.3)	0	1 (4.3)	0	0
Varicella zoster virus infection	1 (4.3)	0	1 (4.3)	0	0
Injury, poisoning and procedural complications					
-Total	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Abdominal injury	1 (4.3)	1 (4.3)	0	0	0
Infusion related reaction	1 (4.3)	0	0	1 (4.3)	0
Investigations					
-Total	2 (8.7)	2 (8.7)	0	0	0
Neutrophil count decreased	2 (8.7)	2 (8.7)	0	0	0
Blood bilirubin increased	1 (4.3)	1 (4.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Hypercholesterolaemia	1 (4.3)	0	1 (4.3)	0	0
Hyperlipidaemia	1 (4.3)	0	1 (4.3)	0	0
Hypernatraemia	1 (4.3)	0	0	1 (4.3)	0
Hypertriglyceridaemia	1 (4.3)	0	1 (4.3)	0	0
Iron overload	1 (4.3)	0	1 (4.3)	0	0
Obesity	1 (4.3)	0	0	1 (4.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Arthralgia	1 (4.3)	0	1 (4.3)	0	0
Joint effusion	1 (4.3)	0	1 (4.3)	0	0
Osteopenia	1 (4.3)	1 (4.3)	0	0	0
Synovitis	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	2 (8.7)	0	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorder	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0
Psychiatric disorders					
-Total	2 (8.7)	0	2 (8.7)	0	0
Anxiety	1 (4.3)	0	1 (4.3)	0	0
Tic	1 (4.3)	0	1 (4.3)	0	0
Reproductive system and breast disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Endometriosis	1 (4.3)	0	0	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (26.1)	1 (4.3)	2 (8.7)	1 (4.3)	2 (8.7)
Rhinorrhoea	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Cough	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Dyspnoea	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Sleep apnoea syndrome	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Hypoxia	1 (4.3)	0	0	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (4.3)	0	0	0	1 (4.3)
Respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Wheezing	1 (4.3)	0	1 (4.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Rash	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Eczema	1 (4.3)	0	0	1 (4.3)	0
Rash erythematous	1 (4.3)	1 (4.3)	0	0	0
Rash maculo-papular	1 (4.3)	1 (4.3)	0	0	0
Vascular disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Hypertension	1 (4.3)	0	1 (4.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	0	1 (20.0)	1 (20.0)
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Pain	1 (20.0)	1 (20.0)	0	0	0
Pyrexia	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Otitis media	1 (20.0)	0	1 (20.0)	0	0
Rhinovirus infection	1 (20.0)	0	1 (20.0)	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Urinary tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Psychiatric disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Anxiety	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	1 (3.6)	1 (3.6)	8 (28.6)	18 (64.3)
Blood and lymphatic system disorders					
-Total	18 (64.3)	0	4 (14.3)	11 (39.3)	3 (10.7)
Anaemia	8 (28.6)	3 (10.7)	1 (3.6)	4 (14.3)	0
Febrile neutropenia	7 (25.0)	0	0	7 (25.0)	0
Neutropenia	5 (17.9)	0	1 (3.6)	2 (7.1)	2 (7.1)
Disseminated intravascular coagulation	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Thrombocytopenia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Coagulopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Lymphadenopathy	2 (7.1)	1 (3.6)	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (7.1)	0	0	2 (7.1)	0
Agranulocytosis	1 (3.6)	0	0	1 (3.6)	0
Eosinophilia	1 (3.6)	0	1 (3.6)	0	0
Hypercoagulation	1 (3.6)	0	1 (3.6)	0	0
Leukopenia	1 (3.6)	0	0	1 (3.6)	0
Splenomegaly	1 (3.6)	0	1 (3.6)	0	0
Cardiac disorders					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Left ventricular dysfunction	1 (3.6)	0	1 (3.6)	0	0
Pericardial effusion	1 (3.6)	1 (3.6)	0	0	0
Sinus tachycardia	1 (3.6)	0	1 (3.6)	0	0
Endocrine disorders					
-Total	2 (7.1)	0	2 (7.1)	0	0
Adrenal insufficiency	1 (3.6)	0	1 (3.6)	0	0
Hypothyroidism	1 (3.6)	0	1 (3.6)	0	0
Eye disorders					
-Total	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Eye pain	2 (7.1)	1 (3.6)	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eyelid oedema	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Eye oedema	1 (3.6)	1 (3.6)	0	0	0
Retinal haemorrhage	1 (3.6)	0	1 (3.6)	0	0
Visual field defect	1 (3.6)	0	1 (3.6)	0	0
Gastrointestinal disorders					
-Total	21 (75.0)	9 (32.1)	8 (28.6)	4 (14.3)	0
Diarrhoea	8 (28.6)	3 (10.7)	4 (14.3)	1 (3.6)	0
Vomiting	8 (28.6)	6 (21.4)	2 (7.1)	0	0
Abdominal pain	5 (17.9)	0	5 (17.9)	0	0
Constipation	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Nausea	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Abdominal pain upper	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Pancreatitis	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Abdominal rigidity	1 (3.6)	0	1 (3.6)	0	0
Ascites	1 (3.6)	0	1 (3.6)	0	0
Dyspepsia	1 (3.6)	1 (3.6)	0	0	0
Mouth haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Mouth swelling	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (3.6)	1 (3.6)	0	0	0
Peritoneal haematoma	1 (3.6)	1 (3.6)	0	0	0
Stomatitis	1 (3.6)	0	0	1 (3.6)	0
General disorders and administration site conditions					
-Total	15 (53.6)	8 (28.6)	4 (14.3)	2 (7.1)	1 (3.6)
Pyrexia	9 (32.1)	4 (14.3)	4 (14.3)	1 (3.6)	0
Asthenia	3 (10.7)	3 (10.7)	0	0	0
Face oedema	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Oedema peripheral	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Catheter site erythema	1 (3.6)	1 (3.6)	0	0	0
Fatigue	1 (3.6)	1 (3.6)	0	0	0
Generalised oedema	1 (3.6)	0	1 (3.6)	0	0
Influenza like illness	1 (3.6)	0	1 (3.6)	0	0
Localised oedema	1 (3.6)	1 (3.6)	0	0	0
Multiple organ dysfunction syndrome	1 (3.6)	0	0	0	1 (3.6)
Non-cardiac chest pain	1 (3.6)	1 (3.6)	0	0	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (17.9)	2 (7.1)	3 (10.7)	0	0
Cholelithiasis	1 (3.6)	0	1 (3.6)	0	0
Hepatic cytolysis	1 (3.6)	1 (3.6)	0	0	0
Hepatomegaly	1 (3.6)	1 (3.6)	0	0	0
Hyperbilirubinaemia	1 (3.6)	0	1 (3.6)	0	0
Liver disorder	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					
-Total	22 (78.6)	0	3 (10.7)	10 (35.7)	9 (32.1)
Cytokine release syndrome	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Hypogammaglobulinaemia	10 (35.7)	1 (3.6)	5 (17.9)	4 (14.3)	0
Immunodeficiency	4 (14.3)	0	0	4 (14.3)	0
Chronic graft versus host disease	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Haemophagocytic lymphohistiocytosis	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Allergy to immunoglobulin therapy	1 (3.6)	1 (3.6)	0	0	0
Drug hypersensitivity	1 (3.6)	0	0	1 (3.6)	0
Graft versus host disease	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (3.6)	1 (3.6)	0	0	0
Infections and infestations					
-Total	25 (89.3)	5 (17.9)	5 (17.9)	7 (25.0)	8 (28.6)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)	0	0
Conjunctivitis	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Gastroenteritis	4 (14.3)	2 (7.1)	0	2 (7.1)	0
Nail infection	3 (10.7)	3 (10.7)	0	0	0
Pneumonia	3 (10.7)	0	1 (3.6)	0	2 (7.1)
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Rhinitis	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Sepsis	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Upper respiratory tract infection	3 (10.7)	3 (10.7)	0	0	0
Bronchopulmonary aspergillosis	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Herpes zoster	2 (7.1)	0	0	2 (7.1)	0
Oral infection	2 (7.1)	0	2 (7.1)	0	0
Parainfluenzae virus infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Rhinovirus infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Adenovirus infection	1 (3.6)	0	0	1 (3.6)	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Bronchitis	1 (3.6)	0	1 (3.6)	0	0
Candida infection	1 (3.6)	0	1 (3.6)	0	0
Covid-19	1 (3.6)	0	0	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	0	0	1 (3.6)
Cystitis	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	0	1 (3.6)	0
Device related sepsis	1 (3.6)	0	0	1 (3.6)	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Ear, nose and throat infection	1 (3.6)	0	1 (3.6)	0	0
Encephalitis	1 (3.6)	0	0	0	1 (3.6)
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Fungal infection	1 (3.6)	0	1 (3.6)	0	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Herpes virus infection	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (3.6)	0	0	0	1 (3.6)
Molluscum contagiosum	1 (3.6)	1 (3.6)	0	0	0
Myringitis	1 (3.6)	1 (3.6)	0	0	0
Neutropenic infection	1 (3.6)	0	0	1 (3.6)	0
Ophthalmic herpes zoster	1 (3.6)	0	1 (3.6)	0	0
Oral candidiasis	1 (3.6)	0	1 (3.6)	0	0
Oral herpes	1 (3.6)	0	1 (3.6)	0	0
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Paronychia	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	0	1 (3.6)
Pneumonia fungal	1 (3.6)	0	0	1 (3.6)	0
Pneumonia viral	1 (3.6)	0	0	1 (3.6)	0
Respiratory tract infection viral	1 (3.6)	0	1 (3.6)	0	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	0	0	1 (3.6)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (3.6)	0	1 (3.6)	0	0
Streptococcal sepsis	1 (3.6)	0	1 (3.6)	0	0
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Viral infection	1 (3.6)	0	1 (3.6)	0	0
Viral skin infection	1 (3.6)	1 (3.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Fall	1 (3.6)	0	1 (3.6)	0	0
Infusion related reaction	1 (3.6)	0	1 (3.6)	0	0
Ligament sprain	1 (3.6)	1 (3.6)	0	0	0
Procedural pain	1 (3.6)	1 (3.6)	0	0	0
Investigations					
-Total	18 (64.3)	1 (3.6)	5 (17.9)	5 (17.9)	7 (25.0)
Lymphocyte count decreased	7 (25.0)	1 (3.6)	0	3 (10.7)	3 (10.7)
Neutrophil count decreased	6 (21.4)	0	0	0	6 (21.4)
Platelet count decreased	6 (21.4)	2 (7.1)	1 (3.6)	1 (3.6)	2 (7.1)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (21.4)	1 (3.6)	0	1 (3.6)	4 (14.3)
Alanine aminotransferase increased	2 (7.1)	0	0	2 (7.1)	0
Immunoglobulins decreased	2 (7.1)	0	2 (7.1)	0	0
Aspartate aminotransferase increased	1 (3.6)	0	0	1 (3.6)	0
Blood bilirubin increased	1 (3.6)	0	0	1 (3.6)	0
Blood fibrinogen decreased	1 (3.6)	0	0	0	1 (3.6)
Blood immunoglobulin g decreased	1 (3.6)	0	1 (3.6)	0	0
Blood lactate dehydrogenase increased	1 (3.6)	0	1 (3.6)	0	0
Blood uric acid increased	1 (3.6)	0	0	1 (3.6)	0
Bone density decreased	1 (3.6)	1 (3.6)	0	0	0
C-reactive protein increased	1 (3.6)	0	0	1 (3.6)	0
Gamma-glutamyltransferase increased	1 (3.6)	0	0	1 (3.6)	0
Hepatitis b virus test positive	1 (3.6)	0	1 (3.6)	0	0
Oxygen saturation decreased	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	1 (3.6)	0	1 (3.6)	0	0
Serum ferritin increased	1 (3.6)	1 (3.6)	0	0	0
Weight decreased	1 (3.6)	0	0	1 (3.6)	0
Metabolism and nutrition disorders					
-Total	11 (39.3)	2 (7.1)	2 (7.1)	5 (17.9)	2 (7.1)
Decreased appetite	5 (17.9)	2 (7.1)	1 (3.6)	1 (3.6)	1 (3.6)
Hypokalaemia	5 (17.9)	1 (3.6)	1 (3.6)	3 (10.7)	0
Hypophosphataemia	4 (14.3)	0	1 (3.6)	2 (7.1)	1 (3.6)
Hyperglycaemia	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Haemochromatosis	1 (3.6)	0	0	1 (3.6)	0
Hypernatraemia	1 (3.6)	1 (3.6)	0	0	0
Hyperuricaemia	1 (3.6)	0	1 (3.6)	0	0
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)	0	0
Hypocalcaemia	1 (3.6)	0	0	1 (3.6)	0
Malnutrition	1 (3.6)	0	0	1 (3.6)	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (46.4)	5 (17.9)	7 (25.0)	1 (3.6)	0
Pain in extremity	6 (21.4)	2 (7.1)	4 (14.3)	0	0
Back pain	5 (17.9)	1 (3.6)	3 (10.7)	1 (3.6)	0
Arthralgia	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Growth retardation	1 (3.6)	0	1 (3.6)	0	0
Muscular weakness	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal chest pain	1 (3.6)	1 (3.6)	0	0	0
Myalgia	1 (3.6)	1 (3.6)	0	0	0
Osteonecrosis	1 (3.6)	1 (3.6)	0	0	0
Pain in jaw	1 (3.6)	1 (3.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (14.3)	1 (3.6)	1 (3.6)	2 (7.1)	0
Skin papilloma	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Bone giant cell tumour benign	1 (3.6)	0	0	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	0	0	1 (3.6)	0
Nervous system disorders					
-Total	17 (60.7)	5 (17.9)	7 (25.0)	3 (10.7)	2 (7.1)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	10 (35.7)	6 (21.4)	3 (10.7)	1 (3.6)	0
Encephalopathy	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Seizure	2 (7.1)	0	0	2 (7.1)	0
Tremor	2 (7.1)	2 (7.1)	0	0	0
Amnesia	1 (3.6)	0	1 (3.6)	0	0
Autonomic neuropathy	1 (3.6)	0	0	1 (3.6)	0
Cerebral haemorrhage	1 (3.6)	0	0	0	1 (3.6)
Dysarthria	1 (3.6)	0	1 (3.6)	0	0
Dysgeusia	1 (3.6)	1 (3.6)	0	0	0
Hydrocephalus	1 (3.6)	0	0	0	1 (3.6)
Hyperaesthesia	1 (3.6)	1 (3.6)	0	0	0
Memory impairment	1 (3.6)	0	1 (3.6)	0	0
Neuralgia	1 (3.6)	0	1 (3.6)	0	0
Psychiatric disorders					
-Total	11 (39.3)	3 (10.7)	7 (25.0)	1 (3.6)	0
Anxiety	4 (14.3)	0	3 (10.7)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Hallucination	2 (7.1)	0	2 (7.1)	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Sleep disorder	2 (7.1)	0	2 (7.1)	0	0
Hallucination, visual	1 (3.6)	0	1 (3.6)	0	0
Renal and urinary disorders					
-Total	6 (21.4)	2 (7.1)	2 (7.1)	1 (3.6)	1 (3.6)
Dysuria	2 (7.1)	2 (7.1)	0	0	0
Anuria	1 (3.6)	0	0	0	1 (3.6)
Renal failure	1 (3.6)	0	1 (3.6)	0	0
Renal tubular disorder	1 (3.6)	0	0	1 (3.6)	0
Urinary tract disorder	1 (3.6)	0	1 (3.6)	0	0
Reproductive system and breast disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Female genital tract fistula	1 (3.6)	1 (3.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (60.7)	9 (32.1)	3 (10.7)	3 (10.7)	2 (7.1)
Cough	10 (35.7)	8 (28.6)	2 (7.1)	0	0
Pulmonary oedema	4 (14.3)	1 (3.6)	0	3 (10.7)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (10.7)	0	3 (10.7)	0	0
Oropharyngeal pain	3 (10.7)	3 (10.7)	0	0	0
Bronchial oedema	1 (3.6)	1 (3.6)	0	0	0
Bronchospasm	1 (3.6)	0	1 (3.6)	0	0
Dyspnoea	1 (3.6)	0	0	0	1 (3.6)
Dyspnoea exertional	1 (3.6)	1 (3.6)	0	0	0
Epistaxis	1 (3.6)	1 (3.6)	0	0	0
Lung disorder	1 (3.6)	1 (3.6)	0	0	0
Painful respiration	1 (3.6)	1 (3.6)	0	0	0
Pharyngeal erythema	1 (3.6)	1 (3.6)	0	0	0
Pleural effusion	1 (3.6)	0	1 (3.6)	0	0
Productive cough	1 (3.6)	1 (3.6)	0	0	0
Respiratory disorder	1 (3.6)	0	1 (3.6)	0	0
Respiratory failure	1 (3.6)	0	0	0	1 (3.6)
Tachypnoea	1 (3.6)	0	0	0	1 (3.6)
Skin and subcutaneous tissue disorders					
-Total	13 (46.4)	4 (14.3)	6 (21.4)	3 (10.7)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis atopic	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Dry skin	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Erythema	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Pruritus	2 (7.1)	0	2 (7.1)	0	0
Rash	2 (7.1)	0	2 (7.1)	0	0
Decubitus ulcer	1 (3.6)	0	0	1 (3.6)	0
Dermatitis allergic	1 (3.6)	1 (3.6)	0	0	0
Hangnail	1 (3.6)	1 (3.6)	0	0	0
Papule	1 (3.6)	1 (3.6)	0	0	0
Photosensitivity reaction	1 (3.6)	0	1 (3.6)	0	0
Pruritus allergic	1 (3.6)	0	1 (3.6)	0	0
Rash macular	1 (3.6)	0	0	1 (3.6)	0
Rash maculo-papular	1 (3.6)	0	1 (3.6)	0	0
Rash vesicular	1 (3.6)	1 (3.6)	0	0	0
Urticaria	1 (3.6)	0	1 (3.6)	0	0
Vascular disorders					
-Total	8 (28.6)	2 (7.1)	2 (7.1)	3 (10.7)	1 (3.6)
Hypotension	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Venoocclusive disease	1 (3.6)	0	0	0	1 (3.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (100)	0	5 (11.1)	10 (22.2)	30 (66.7)
Blood and lymphatic system disorders					
-Total	31 (68.9)	1 (2.2)	5 (11.1)	18 (40.0)	7 (15.6)
Febrile neutropenia	20 (44.4)	0	0	18 (40.0)	2 (4.4)
Anaemia	16 (35.6)	4 (8.9)	7 (15.6)	5 (11.1)	0
Thrombocytopenia	5 (11.1)	0	0	1 (2.2)	4 (8.9)
Coagulopathy	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Disseminated intravascular coagulation	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Neutropenia	3 (6.7)	0	1 (2.2)	0	2 (4.4)
Splenomegaly	3 (6.7)	3 (6.7)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (4.4)	0	0	2 (4.4)	0
Leukocytosis	1 (2.2)	0	1 (2.2)	0	0
Leukopenia	1 (2.2)	0	1 (2.2)	0	0
Lymphocytosis	1 (2.2)	0	1 (2.2)	0	0
Cardiac disorders					
-Total	22 (48.9)	7 (15.6)	5 (11.1)	5 (11.1)	5 (11.1)
Tachycardia	17 (37.8)	7 (15.6)	7 (15.6)	2 (4.4)	1 (2.2)
Bradycardia	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Cardiac arrest	3 (6.7)	0	0	0	3 (6.7)
Left ventricular dysfunction	3 (6.7)	0	0	3 (6.7)	0
Cardiac failure	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Sinus tachycardia	2 (4.4)	2 (4.4)	0	0	0
Atrioventricular block first degree	1 (2.2)	0	1 (2.2)	0	0
Cardiac failure congestive	1 (2.2)	0	1 (2.2)	0	0
Mitral valve incompetence	1 (2.2)	1 (2.2)	0	0	0
Right ventricular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Sinus bradycardia	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tricuspid valve incompetence	1 (2.2)	1 (2.2)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.2)	1 (2.2)	0	0	0
Cerebral cavernous malformation	1 (2.2)	1 (2.2)	0	0	0
Ear and labyrinth disorders					
-Total	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Deafness unilateral	1 (2.2)	0	1 (2.2)	0	0
Ear pain	1 (2.2)	1 (2.2)	0	0	0
Ear pruritus	1 (2.2)	1 (2.2)	0	0	0
Endocrine disorders					
-Total	5 (11.1)	0	5 (11.1)	0	0
Adrenal insufficiency	3 (6.7)	0	3 (6.7)	0	0
Hypothyroidism	2 (4.4)	0	2 (4.4)	0	0
Delayed puberty	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	11 (24.4)	9 (20.0)	2 (4.4)	0	0
Ocular hyperaemia	3 (6.7)	3 (6.7)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cataract	2 (4.4)	2 (4.4)	0	0	0
Conjunctival haemorrhage	2 (4.4)	2 (4.4)	0	0	0
Visual impairment	2 (4.4)	2 (4.4)	0	0	0
Dry eye	1 (2.2)	1 (2.2)	0	0	0
Eyelid oedema	1 (2.2)	1 (2.2)	0	0	0
Hypermetropia	1 (2.2)	1 (2.2)	0	0	0
Mydriasis	1 (2.2)	0	1 (2.2)	0	0
Periorbital oedema	1 (2.2)	1 (2.2)	0	0	0
Periorbital swelling	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	33 (73.3)	10 (22.2)	11 (24.4)	11 (24.4)	1 (2.2)
Vomiting	18 (40.0)	11 (24.4)	6 (13.3)	1 (2.2)	0
Diarrhoea	17 (37.8)	13 (28.9)	3 (6.7)	1 (2.2)	0
Nausea	16 (35.6)	9 (20.0)	6 (13.3)	1 (2.2)	0
Constipation	7 (15.6)	4 (8.9)	3 (6.7)	0	0
Abdominal pain	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Mouth haemorrhage	4 (8.9)	1 (2.2)	1 (2.2)	2 (4.4)	0
Abdominal distension	3 (6.7)	1 (2.2)	2 (4.4)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	2 (4.4)	2 (4.4)	0	0	0
Gastrointestinal sounds abnormal	2 (4.4)	2 (4.4)	0	0	0
Pancreatitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Proctalgia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Abdominal compartment syndrome	1 (2.2)	0	0	0	1 (2.2)
Abdominal pain upper	1 (2.2)	1 (2.2)	0	0	0
Anal fissure	1 (2.2)	0	1 (2.2)	0	0
Anal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Dry mouth	1 (2.2)	0	1 (2.2)	0	0
Dysphagia	1 (2.2)	0	0	1 (2.2)	0
Gastrointestinal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal inflammation	1 (2.2)	0	1 (2.2)	0	0
Gastrooesophageal reflux disease	1 (2.2)	0	1 (2.2)	0	0
Gingival bleeding	1 (2.2)	0	1 (2.2)	0	0
Gingival erythema	1 (2.2)	1 (2.2)	0	0	0
Gingivitis ulcerative	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (2.2)	1 (2.2)	0	0	0
Ileus	1 (2.2)	0	1 (2.2)	0	0
Irritable bowel syndrome	1 (2.2)	0	1 (2.2)	0	0
Lip dry	1 (2.2)	0	1 (2.2)	0	0
Lip oedema	1 (2.2)	1 (2.2)	0	0	0
Melaena	1 (2.2)	0	0	1 (2.2)	0
Neutropenic colitis	1 (2.2)	0	0	1 (2.2)	0
Stomatitis	1 (2.2)	0	1 (2.2)	0	0
Trichoglossia	1 (2.2)	0	1 (2.2)	0	0
Upper gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	37 (82.2)	16 (35.6)	9 (20.0)	8 (17.8)	4 (8.9)
Pyrexia	25 (55.6)	9 (20.0)	6 (13.3)	8 (17.8)	2 (4.4)
Fatigue	16 (35.6)	13 (28.9)	3 (6.7)	0	0
Chills	7 (15.6)	5 (11.1)	2 (4.4)	0	0
Oedema peripheral	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Face oedema	4 (8.9)	3 (6.7)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	4 (8.9)	2 (4.4)	2 (4.4)	0	0
Pain	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Catheter site pain	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Drug withdrawal syndrome	2 (4.4)	0	2 (4.4)	0	0
Malaise	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Multiple organ dysfunction syndrome	2 (4.4)	0	0	0	2 (4.4)
Catheter site haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Chest discomfort	1 (2.2)	0	0	1 (2.2)	0
Crying	1 (2.2)	0	1 (2.2)	0	0
Facial pain	1 (2.2)	0	1 (2.2)	0	0
Localised oedema	1 (2.2)	1 (2.2)	0	0	0
Non-cardiac chest pain	1 (2.2)	1 (2.2)	0	0	0
Oedema due to hepatic disease	1 (2.2)	0	1 (2.2)	0	0
Sluggishness	1 (2.2)	0	1 (2.2)	0	0
Swelling face	1 (2.2)	1 (2.2)	0	0	0
Systemic inflammatory response syndrome	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device occlusion	1 (2.2)	1 (2.2)	0	0	0
Xerosis	1 (2.2)	1 (2.2)	0	0	0
Hepatobiliary disorders					
-Total	10 (22.2)	4 (8.9)	3 (6.7)	1 (2.2)	2 (4.4)
Hyperbilirubinaemia	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Gallbladder enlargement	2 (4.4)	2 (4.4)	0	0	0
Hepatomegaly	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Hypertransaminasaemia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Biliary tract disorder	1 (2.2)	1 (2.2)	0	0	0
Cholelithiasis	1 (2.2)	1 (2.2)	0	0	0
Cholestasis	1 (2.2)	0	0	0	1 (2.2)
Hepatic function abnormal	1 (2.2)	0	1 (2.2)	0	0
Ocular icterus	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	42 (93.3)	2 (4.4)	18 (40.0)	12 (26.7)	10 (22.2)
Cytokine release syndrome	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Hypogammaglobulinaemia	19 (42.2)	1 (2.2)	15 (33.3)	3 (6.7)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)
Seasonal allergy	4 (8.9)	2 (4.4)	2 (4.4)	0	0
Allergy to immunoglobulin therapy	1 (2.2)	0	0	1 (2.2)	0
Drug hypersensitivity	1 (2.2)	0	1 (2.2)	0	0
Engraftment syndrome	1 (2.2)	0	0	1 (2.2)	0
Graft versus host disease	1 (2.2)	0	0	1 (2.2)	0
Selective igg subclass deficiency	1 (2.2)	0	1 (2.2)	0	0
Infections and infestations					
-Total	29 (64.4)	1 (2.2)	8 (17.8)	15 (33.3)	5 (11.1)
Upper respiratory tract infection	8 (17.8)	2 (4.4)	5 (11.1)	1 (2.2)	0
Rhinovirus infection	6 (13.3)	0	6 (13.3)	0	0
Sinusitis	5 (11.1)	0	4 (8.9)	1 (2.2)	0
Clostridium difficile infection	4 (8.9)	1 (2.2)	0	3 (6.7)	0
Staphylococcal bacteraemia	4 (8.9)	0	0	4 (8.9)	0
Candida infection	3 (6.7)	0	2 (4.4)	0	1 (2.2)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Metapneumovirus infection	3 (6.7)	0	0	3 (6.7)	0
Oral herpes	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Otitis media	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Staphylococcal infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Acute sinusitis	2 (4.4)	0	2 (4.4)	0	0
Ear infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Gastroenteritis	2 (4.4)	2 (4.4)	0	0	0
Gastroenteritis viral	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Herpes simplex	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Human herpesvirus 6 infection	2 (4.4)	0	0	2 (4.4)	0
Influenza	2 (4.4)	0	2 (4.4)	0	0
Oral candidiasis	2 (4.4)	0	2 (4.4)	0	0
Otitis externa	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Parainfluenzae virus infection	2 (4.4)	0	1 (2.2)	0	1 (2.2)
Pneumonia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Respiratory syncytial virus infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	2 (4.4)	0	0	0	2 (4.4)
Skin infection	2 (4.4)	0	2 (4.4)	0	0
Varicella zoster virus infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Adenovirus infection	1 (2.2)	0	0	1 (2.2)	0
Anal abscess	1 (2.2)	0	0	1 (2.2)	0
Atypical pneumonia	1 (2.2)	1 (2.2)	0	0	0
Bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Bk virus infection	1 (2.2)	0	0	1 (2.2)	0
Bronchiolitis	1 (2.2)	0	0	1 (2.2)	0
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Cellulitis	1 (2.2)	0	1 (2.2)	0	0
Cholecystitis infective	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Coronavirus infection	1 (2.2)	0	0	1 (2.2)	0
Covid-19	1 (2.2)	1 (2.2)	0	0	0
Cytomegalovirus infection reactivation	1 (2.2)	0	0	1 (2.2)	0
Encephalitis	1 (2.2)	0	0	0	1 (2.2)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (2.2)	0	0	1 (2.2)	0
Folliculitis	1 (2.2)	0	1 (2.2)	0	0
Fungal infection	1 (2.2)	0	1 (2.2)	0	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis clostridial	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis norovirus	1 (2.2)	1 (2.2)	0	0	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Gastrointestinal infection	1 (2.2)	1 (2.2)	0	0	0
Gingivitis	1 (2.2)	1 (2.2)	0	0	0
Granulicatella infection	1 (2.2)	0	0	1 (2.2)	0
Herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Klebsiella bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Localised infection	1 (2.2)	1 (2.2)	0	0	0
Mastoiditis	1 (2.2)	0	0	1 (2.2)	0
Meningitis pneumococcal	1 (2.2)	0	0	1 (2.2)	0
Nail infection	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Pharyngitis streptococcal	1 (2.2)	0	0	1 (2.2)	0
Pneumocystis jirovecii pneumonia	1 (2.2)	0	0	1 (2.2)	0
Pneumonia respiratory syncytial viral	1 (2.2)	0	0	1 (2.2)	0
Salmonellosis	1 (2.2)	0	1 (2.2)	0	0
Sinusitis fungal	1 (2.2)	0	0	1 (2.2)	0
Soft tissue infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Stomatococcal infection	1 (2.2)	0	1 (2.2)	0	0
Syphilis	1 (2.2)	0	1 (2.2)	0	0
Systemic candida	1 (2.2)	0	0	1 (2.2)	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection pseudomonal	1 (2.2)	0	1 (2.2)	0	0
Viral infection	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (2.2)	0	0	1 (2.2)	0
Injury, poisoning and procedural complications					
-Total	17 (37.8)	7 (15.6)	7 (15.6)	1 (2.2)	2 (4.4)
Infusion related reaction	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Contusion	2 (4.4)	2 (4.4)	0	0	0
Skin abrasion	2 (4.4)	2 (4.4)	0	0	0
Transfusion reaction	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Wound	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Abdominal injury	1 (2.2)	1 (2.2)	0	0	0
Fall	1 (2.2)	0	1 (2.2)	0	0
Fibula fracture	1 (2.2)	0	1 (2.2)	0	0
Ligament sprain	1 (2.2)	1 (2.2)	0	0	0
Limb injury	1 (2.2)	0	1 (2.2)	0	0
Post-traumatic neck syndrome	1 (2.2)	0	1 (2.2)	0	0
Procedural pain	1 (2.2)	0	1 (2.2)	0	0
Scratch	1 (2.2)	1 (2.2)	0	0	0
Skin injury	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin wound	1 (2.2)	1 (2.2)	0	0	0
Transplant failure	1 (2.2)	0	0	0	1 (2.2)
Vasoplegia syndrome	1 (2.2)	0	0	0	1 (2.2)
Investigations					
-Total	37 (82.2)	2 (4.4)	4 (8.9)	14 (31.1)	17 (37.8)
Aspartate aminotransferase increased	18 (40.0)	2 (4.4)	6 (13.3)	7 (15.6)	3 (6.7)
Alanine aminotransferase increased	16 (35.6)	3 (6.7)	8 (17.8)	5 (11.1)	0
Platelet count decreased	16 (35.6)	4 (8.9)	2 (4.4)	5 (11.1)	5 (11.1)
Neutrophil count decreased	15 (33.3)	1 (2.2)	2 (4.4)	4 (8.9)	8 (17.8)
White blood cell count decreased	15 (33.3)	2 (4.4)	4 (8.9)	1 (2.2)	8 (17.8)
Blood bilirubin increased	12 (26.7)	1 (2.2)	3 (6.7)	8 (17.8)	0
Lymphocyte count decreased	10 (22.2)	0	1 (2.2)	7 (15.6)	2 (4.4)
International normalised ratio increased	9 (20.0)	6 (13.3)	3 (6.7)	0	0
Blood immunoglobulin a decreased	7 (15.6)	5 (11.1)	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	7 (15.6)	4 (8.9)	1 (2.2)	2 (4.4)	0
Activated partial thromboplastin time prolonged	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Blood creatinine increased	5 (11.1)	1 (2.2)	1 (2.2)	2 (4.4)	1 (2.2)
Electrocardiogram qt prolonged	5 (11.1)	1 (2.2)	2 (4.4)	1 (2.2)	1 (2.2)
Blood fibrinogen decreased	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Blood lactate dehydrogenase increased	4 (8.9)	3 (6.7)	0	1 (2.2)	0
C-reactive protein increased	4 (8.9)	2 (4.4)	0	2 (4.4)	0
Serum ferritin increased	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Weight increased	4 (8.9)	1 (2.2)	1 (2.2)	2 (4.4)	0
Blood immunoglobulin g decreased	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Blood uric acid increased	3 (6.7)	2 (4.4)	0	0	1 (2.2)
Fibrin d dimer increased	3 (6.7)	2 (4.4)	0	1 (2.2)	0
Lipase increased	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Oxygen saturation decreased	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Urine output decreased	2 (4.4)	0	0	1 (2.2)	1 (2.2)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amylase increased	1 (2.2)	1 (2.2)	0	0	0
Bacterial test positive	1 (2.2)	0	0	1 (2.2)	0
Blood alkaline phosphatase increased	1 (2.2)	1 (2.2)	0	0	0
Blood bicarbonate decreased	1 (2.2)	0	1 (2.2)	0	0
Blood creatine phosphokinase increased	1 (2.2)	0	0	0	1 (2.2)
Blood glucose increased	1 (2.2)	0	0	0	1 (2.2)
Blood phosphorus increased	1 (2.2)	0	1 (2.2)	0	0
Blood testosterone decreased	1 (2.2)	1 (2.2)	0	0	0
Blood thyroid stimulating hormone increased	1 (2.2)	1 (2.2)	0	0	0
Blood urea increased	1 (2.2)	0	0	1 (2.2)	0
Breath sounds abnormal	1 (2.2)	0	1 (2.2)	0	0
Cardiac murmur	1 (2.2)	1 (2.2)	0	0	0
Coagulation test abnormal	1 (2.2)	1 (2.2)	0	0	0
Ejection fraction decreased	1 (2.2)	0	1 (2.2)	0	0
Electrocardiogram t wave abnormal	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus test positive	1 (2.2)	0	1 (2.2)	0	0
Gamma-glutamyltransferase increased	1 (2.2)	0	0	1 (2.2)	0
Haemoglobin decreased	1 (2.2)	0	0	1 (2.2)	0
Haptoglobin decreased	1 (2.2)	1 (2.2)	0	0	0
Heart sounds abnormal	1 (2.2)	1 (2.2)	0	0	0
Staphylococcus test positive	1 (2.2)	1 (2.2)	0	0	0
Troponin increased	1 (2.2)	0	0	1 (2.2)	0
Weight decreased	1 (2.2)	0	1 (2.2)	0	0
Metabolism and nutrition disorders					
-Total	39 (86.7)	7 (15.6)	8 (17.8)	16 (35.6)	8 (17.8)
Decreased appetite	25 (55.6)	9 (20.0)	6 (13.3)	9 (20.0)	1 (2.2)
Hypocalcaemia	15 (33.3)	2 (4.4)	9 (20.0)	4 (8.9)	0
Hypokalaemia	15 (33.3)	2 (4.4)	5 (11.1)	6 (13.3)	2 (4.4)
Hypophosphataemia	14 (31.1)	3 (6.7)	5 (11.1)	6 (13.3)	0
Hypoalbuminaemia	9 (20.0)	0	8 (17.8)	1 (2.2)	0
Hyperuricaemia	8 (17.8)	7 (15.6)	0	1 (2.2)	0
Hypervolaemia	7 (15.6)	0	2 (4.4)	5 (11.1)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	6 (13.3)	0	3 (6.7)	3 (6.7)	0
Hyperphosphataemia	5 (11.1)	4 (8.9)	0	0	1 (2.2)
Hypercalcaemia	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Hyperkalaemia	3 (6.7)	0	1 (2.2)	1 (2.2)	1 (2.2)
Hypertriglyceridaemia	3 (6.7)	0	1 (2.2)	1 (2.2)	1 (2.2)
Hypomagnesaemia	3 (6.7)	3 (6.7)	0	0	0
Hyponatraemia	3 (6.7)	3 (6.7)	0	0	0
Metabolic acidosis	3 (6.7)	1 (2.2)	0	0	2 (4.4)
Tumour lysis syndrome	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Acidosis	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Hyperchloraemia	2 (4.4)	2 (4.4)	0	0	0
Hypermagnesaemia	2 (4.4)	2 (4.4)	0	0	0
Hypernatraemia	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Iron overload	2 (4.4)	0	2 (4.4)	0	0
Calcium deficiency	1 (2.2)	1 (2.2)	0	0	0
Dehydration	1 (2.2)	0	1 (2.2)	0	0
Haemosiderosis	1 (2.2)	0	1 (2.2)	0	0
Hypercholesterolaemia	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlactacidaemia	1 (2.2)	1 (2.2)	0	0	0
Hyperlipidaemia	1 (2.2)	0	1 (2.2)	0	0
Hypoglycaemia	1 (2.2)	0	1 (2.2)	0	0
Hypophagia	1 (2.2)	0	1 (2.2)	0	0
Malnutrition	1 (2.2)	0	0	1 (2.2)	0
Metabolic syndrome	1 (2.2)	0	1 (2.2)	0	0
Obesity	1 (2.2)	0	0	1 (2.2)	0
Polydipsia	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	30 (66.7)	12 (26.7)	11 (24.4)	6 (13.3)	1 (2.2)
Pain in extremity	10 (22.2)	6 (13.3)	3 (6.7)	1 (2.2)	0
Myalgia	9 (20.0)	5 (11.1)	4 (8.9)	0	0
Arthralgia	8 (17.8)	3 (6.7)	4 (8.9)	1 (2.2)	0
Back pain	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Bone pain	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Neck pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Growth retardation	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (2.2)	0	0	1 (2.2)	0
Joint effusion	1 (2.2)	0	1 (2.2)	0	0
Muscle rigidity	1 (2.2)	1 (2.2)	0	0	0
Muscle spasms	1 (2.2)	0	1 (2.2)	0	0
Muscular weakness	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal chest pain	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal pain	1 (2.2)	0	1 (2.2)	0	0
Myositis	1 (2.2)	0	1 (2.2)	0	0
Osteopenia	1 (2.2)	1 (2.2)	0	0	0
Pain in jaw	1 (2.2)	0	0	1 (2.2)	0
Rhabdomyolysis	1 (2.2)	0	0	0	1 (2.2)
Synovitis	1 (2.2)	0	1 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.2)	0	1 (2.2)	0	0
Cancer pain	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorders					
-Total	28 (62.2)	9 (20.0)	10 (22.2)	7 (15.6)	2 (4.4)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	16 (35.6)	6 (13.3)	8 (17.8)	2 (4.4)	0
Encephalopathy	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0
Somnolence	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Dizziness	4 (8.9)	4 (8.9)	0	0	0
Tremor	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Cognitive disorder	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Lethargy	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Dysgeusia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Aphasia	1 (2.2)	1 (2.2)	0	0	0
Cerebral haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Depressed level of consciousness	1 (2.2)	0	0	1 (2.2)	0
Disturbance in attention	1 (2.2)	1 (2.2)	0	0	0
Dysarthria	1 (2.2)	0	0	1 (2.2)	0
Extrapyramidal disorder	1 (2.2)	0	1 (2.2)	0	0
Generalised tonic-clonic seizure	1 (2.2)	0	1 (2.2)	0	0
Hypoaesthesia	1 (2.2)	1 (2.2)	0	0	0
Migraine	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Monoparesis	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorder	1 (2.2)	0	0	1 (2.2)	0
Neurological decompensation	1 (2.2)	0	0	0	1 (2.2)
Paraesthesia	1 (2.2)	1 (2.2)	0	0	0
Seizure	1 (2.2)	0	0	1 (2.2)	0
Psychiatric disorders					
-Total	27 (60.0)	9 (20.0)	12 (26.7)	6 (13.3)	0
Anxiety	9 (20.0)	2 (4.4)	6 (13.3)	1 (2.2)	0
Delirium	8 (17.8)	2 (4.4)	3 (6.7)	3 (6.7)	0
Agitation	6 (13.3)	3 (6.7)	3 (6.7)	0	0
Confusional state	5 (11.1)	5 (11.1)	0	0	0
Mental status changes	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Irritability	3 (6.7)	3 (6.7)	0	0	0
Insomnia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Affect lability	1 (2.2)	0	1 (2.2)	0	0
Automatism	1 (2.2)	1 (2.2)	0	0	0
Hallucination	1 (2.2)	1 (2.2)	0	0	0
Mood altered	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nightmare	1 (2.2)	1 (2.2)	0	0	0
Persistent depressive disorder	1 (2.2)	0	1 (2.2)	0	0
Restlessness	1 (2.2)	0	1 (2.2)	0	0
Sleep disorder	1 (2.2)	0	1 (2.2)	0	0
Social avoidant behaviour	1 (2.2)	0	1 (2.2)	0	0
Tearfulness	1 (2.2)	1 (2.2)	0	0	0
Tic	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	15 (33.3)	3 (6.7)	4 (8.9)	4 (8.9)	4 (8.9)
Acute kidney injury	10 (22.2)	2 (4.4)	2 (4.4)	3 (6.7)	3 (6.7)
Dysuria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Haematuria	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Pollakiuria	2 (4.4)	0	2 (4.4)	0	0
Urinary retention	2 (4.4)	0	2 (4.4)	0	0
Anuria	1 (2.2)	1 (2.2)	0	0	0
Azotaemia	1 (2.2)	0	1 (2.2)	0	0
Bladder dilatation	1 (2.2)	0	1 (2.2)	0	0
Incontinence	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Kidney enlargement	1 (2.2)	0	1 (2.2)	0	0
Micturition urgency	1 (2.2)	0	1 (2.2)	0	0
Renal failure	1 (2.2)	0	0	0	1 (2.2)
Renal mass	1 (2.2)	0	1 (2.2)	0	0
Renal tubular dysfunction	1 (2.2)	1 (2.2)	0	0	0
Renal tubular necrosis	1 (2.2)	0	0	0	1 (2.2)
Urinary incontinence	1 (2.2)	0	1 (2.2)	0	0
Reproductive system and breast disorders					
-Total	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Dysmenorrhoea	1 (2.2)	0	1 (2.2)	0	0
Endometriosis	1 (2.2)	0	0	1 (2.2)	0
Perineal rash	1 (2.2)	0	1 (2.2)	0	0
Vaginal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Vaginal ulceration	1 (2.2)	0	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	32 (71.1)	8 (17.8)	3 (6.7)	9 (20.0)	12 (26.7)
Hypoxia	14 (31.1)	0	1 (2.2)	10 (22.2)	3 (6.7)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	13 (28.9)	10 (22.2)	3 (6.7)	0	0
Nasal congestion	9 (20.0)	7 (15.6)	2 (4.4)	0	0
Pulmonary oedema	8 (17.8)	1 (2.2)	3 (6.7)	3 (6.7)	1 (2.2)
Tachypnoea	8 (17.8)	3 (6.7)	1 (2.2)	4 (8.9)	0
Dyspnoea	6 (13.3)	1 (2.2)	2 (4.4)	2 (4.4)	1 (2.2)
Pleural effusion	6 (13.3)	3 (6.7)	0	2 (4.4)	1 (2.2)
Rhinorrhoea	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Epistaxis	5 (11.1)	2 (4.4)	2 (4.4)	1 (2.2)	0
Respiratory failure	5 (11.1)	0	0	0	5 (11.1)
Oropharyngeal pain	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Respiratory distress	4 (8.9)	0	2 (4.4)	0	2 (4.4)
Acute respiratory distress syndrome	3 (6.7)	0	0	0	3 (6.7)
Atelectasis	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Rhinitis allergic	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Sleep apnoea syndrome	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Wheezing	2 (4.4)	0	2 (4.4)	0	0
Acute respiratory failure	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradypnoea	1 (2.2)	0	0	1 (2.2)	0
Haemoptysis	1 (2.2)	0	1 (2.2)	0	0
Laryngeal oedema	1 (2.2)	0	0	0	1 (2.2)
Lung infiltration	1 (2.2)	0	0	1 (2.2)	0
Nasal discomfort	1 (2.2)	0	1 (2.2)	0	0
Nasal dryness	1 (2.2)	1 (2.2)	0	0	0
Oropharyngeal plaque	1 (2.2)	0	1 (2.2)	0	0
Paranasal sinus discomfort	1 (2.2)	0	1 (2.2)	0	0
Paranasal sinus inflammation	1 (2.2)	1 (2.2)	0	0	0
Pharyngeal erythema	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal exudate	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Pharyngeal oedema	1 (2.2)	0	1 (2.2)	0	0
Pulmonary mass	1 (2.2)	0	1 (2.2)	0	0
Respiratory acidosis	1 (2.2)	0	0	1 (2.2)	0
Skin and subcutaneous tissue disorders					
-Total	23 (51.1)	10 (22.2)	9 (20.0)	4 (8.9)	0

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Dry skin	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Pruritus	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Blister	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Eczema	3 (6.7)	2 (4.4)	0	1 (2.2)	0
Erythema	3 (6.7)	3 (6.7)	0	0	0
Hyperhidrosis	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Rash papular	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Ingrowing nail	2 (4.4)	0	2 (4.4)	0	0
Petechiae	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Rash maculo-papular	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Skin discolouration	2 (4.4)	2 (4.4)	0	0	0
Decubitus ulcer	1 (2.2)	0	1 (2.2)	0	0
Dermatitis	1 (2.2)	1 (2.2)	0	0	0
Dermatitis diaper	1 (2.2)	0	1 (2.2)	0	0
Miliaria	1 (2.2)	1 (2.2)	0	0	0
Night sweats	1 (2.2)	1 (2.2)	0	0	0
Purpura	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	1 (2.2)	1 (2.2)	0	0	0
Rash pruritic	1 (2.2)	1 (2.2)	0	0	0
Scab	1 (2.2)	1 (2.2)	0	0	0
Skin hypopigmentation	1 (2.2)	1 (2.2)	0	0	0
Skin lesion	1 (2.2)	0	1 (2.2)	0	0
Skin necrosis	1 (2.2)	0	0	1 (2.2)	0
Skin ulcer	1 (2.2)	1 (2.2)	0	0	0
Vancomycin infusion reaction	1 (2.2)	0	0	1 (2.2)	0
Social circumstances					
-Total	1 (2.2)	0	1 (2.2)	0	0
Patient uncooperative	1 (2.2)	0	1 (2.2)	0	0
Surgical and medical procedures					
-Total	1 (2.2)	0	0	1 (2.2)	0
Thrombolysis	1 (2.2)	0	0	1 (2.2)	0
Vascular disorders					
-Total	24 (53.3)	3 (6.7)	5 (11.1)	9 (20.0)	7 (15.6)
Hypotension	19 (42.2)	1 (2.2)	4 (8.9)	7 (15.6)	7 (15.6)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	12 (26.7)	3 (6.7)	6 (13.3)	3 (6.7)	0
Capillary leak syndrome	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Flushing	1 (2.2)	1 (2.2)	0	0	0
Hot flush	1 (2.2)	1 (2.2)	0	0	0
Peripheral ischaemia	1 (2.2)	0	1 (2.2)	0	0
Thrombosis	1 (2.2)	0	1 (2.2)	0	0
Venoocclusive disease	1 (2.2)	0	0	1 (2.2)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders					
-Total	6 (85.7)	0	2 (28.6)	0	4 (57.1)
Neutropenia	3 (42.9)	0	0	0	3 (42.9)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)	0	0
Anaemia	1 (14.3)	0	1 (14.3)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Hypofibrinogenaemia	1 (14.3)	0	1 (14.3)	0	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	0	1 (14.3)
Cardiac dysfunction	2 (28.6)	2 (28.6)	0	0	0
Cardiac failure	1 (14.3)	0	0	0	1 (14.3)
Gastrointestinal disorders					
-Total	6 (85.7)	2 (28.6)	4 (57.1)	0	0
Constipation	2 (28.6)	2 (28.6)	0	0	0
Nausea	2 (28.6)	2 (28.6)	0	0	0
Pancreatitis	2 (28.6)	0	2 (28.6)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Enteritis	1 (14.3)	0	1 (14.3)	0	0
Enterocolitis	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	1 (14.3)	0	0	0
Trichoglossia	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Face oedema	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza like illness	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)
Hepatic function abnormal	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)
Immune system disorders					
-Total	7 (100)	0	2 (28.6)	2 (28.6)	3 (42.9)
Cytokine release syndrome	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Infections and infestations					
-Total	6 (85.7)	2 (28.6)	0	3 (42.9)	1 (14.3)
Upper respiratory tract infection	2 (28.6)	0	0	2 (28.6)	0
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bk virus infection	1 (14.3)	1 (14.3)	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	1 (14.3)	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0
Sinusitis	1 (14.3)	0	1 (14.3)	0	0
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Urinary tract infection viral	1 (14.3)	1 (14.3)	0	0	0
Investigations					
-Total	5 (71.4)	0	0	0	5 (71.4)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Serum ferritin increased	3 (42.9)	0	3 (42.9)	0	0
Blood fibrinogen decreased	2 (28.6)	0	2 (28.6)	0	0
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Blood creatine phosphokinase increased	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Metabolic acidosis	1 (14.3)	0	0	0	1 (14.3)
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Psychiatric disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Anxiety	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	4 (57.1)	1 (14.3)	1 (14.3)	0	2 (28.6)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (28.6)	0	0	0	2 (28.6)
Cystitis haemorrhagic	1 (14.3)	0	1 (14.3)	0	0
Haematuria	1 (14.3)	1 (14.3)	0	0	0
Proteinuria	1 (14.3)	1 (14.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Heavy menstrual bleeding	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	1 (14.3)	2 (28.6)	0	3 (42.9)
Hypoxia	3 (42.9)	0	0	0	3 (42.9)
Pleural effusion	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Epistaxis	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0	0	0
Upper respiratory tract inflammation	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Erythema nodosum	1 (14.3)	1 (14.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Skin swelling	1 (14.3)	1 (14.3)	0	0	0
Skin ulcer	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Hypertension	1 (14.3)	0	1 (14.3)	0	0
Hypotension	1 (14.3)	0	0	0	1 (14.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (100)	2 (4.2)	4 (8.3)	16 (33.3)	26 (54.2)
Blood and lymphatic system disorders					
-Total	29 (60.4)	2 (4.2)	5 (10.4)	17 (35.4)	5 (10.4)
Febrile neutropenia	14 (29.2)	0	0	14 (29.2)	0
Anaemia	13 (27.1)	2 (4.2)	4 (8.3)	7 (14.6)	0
Neutropenia	5 (10.4)	0	1 (2.1)	1 (2.1)	3 (6.3)
Thrombocytopenia	4 (8.3)	0	0	1 (2.1)	3 (6.3)
Disseminated intravascular coagulation	3 (6.3)	0	3 (6.3)	0	0
Leukopenia	3 (6.3)	0	1 (2.1)	1 (2.1)	1 (2.1)
Coagulopathy	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Pancytopenia	2 (4.2)	0	0	2 (4.2)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	2 (4.2)	1 (2.1)	1 (2.1)	0	0
B-cell aplasia	1 (2.1)	0	1 (2.1)	0	0
Eosinophilia	1 (2.1)	0	1 (2.1)	0	0
Lymphopenia	1 (2.1)	0	0	1 (2.1)	0
Cardiac disorders					
-Total	10 (20.8)	5 (10.4)	2 (4.2)	3 (6.3)	0
Tachycardia	7 (14.6)	4 (8.3)	2 (4.2)	1 (2.1)	0
Left ventricular dysfunction	2 (4.2)	0	0	2 (4.2)	0
Bradycardia	1 (2.1)	1 (2.1)	0	0	0
Cardiac dysfunction	1 (2.1)	1 (2.1)	0	0	0
Cardiac failure congestive	1 (2.1)	0	1 (2.1)	0	0
Mitral valve incompetence	1 (2.1)	1 (2.1)	0	0	0
Pericardial effusion	1 (2.1)	1 (2.1)	0	0	0
Right ventricular dysfunction	1 (2.1)	1 (2.1)	0	0	0
Sinus tachycardia	1 (2.1)	0	1 (2.1)	0	0
Ear and labyrinth disorders					
-Total	1 (2.1)	1 (2.1)	0	0	0
Ear pain	1 (2.1)	1 (2.1)	0	0	0
Endocrine disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.2)	0	2 (4.2)	0	0
Adrenal insufficiency	1 (2.1)	0	1 (2.1)	0	0
Hypothyroidism	1 (2.1)	0	1 (2.1)	0	0
Eye disorders					
-Total	5 (10.4)	2 (4.2)	3 (6.3)	0	0
Eye oedema	1 (2.1)	1 (2.1)	0	0	0
Eye pain	1 (2.1)	1 (2.1)	0	0	0
Eyelid oedema	1 (2.1)	0	1 (2.1)	0	0
Periorbital swelling	1 (2.1)	0	1 (2.1)	0	0
Retinal haemorrhage	1 (2.1)	0	1 (2.1)	0	0
Visual field defect	1 (2.1)	0	1 (2.1)	0	0
Visual impairment	1 (2.1)	1 (2.1)	0	0	0
Gastrointestinal disorders					
-Total	32 (66.7)	13 (27.1)	12 (25.0)	7 (14.6)	0
Vomiting	14 (29.2)	7 (14.6)	7 (14.6)	0	0
Diarrhoea	12 (25.0)	6 (12.5)	5 (10.4)	1 (2.1)	0
Nausea	12 (25.0)	8 (16.7)	3 (6.3)	1 (2.1)	0
Abdominal pain	9 (18.8)	2 (4.2)	5 (10.4)	2 (4.2)	0
Constipation	5 (10.4)	3 (6.3)	2 (4.2)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Abdominal distension	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Ascites	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Gastrointestinal sounds abnormal	2 (4.2)	2 (4.2)	0	0	0
Mouth haemorrhage	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Stomatitis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Anal haemorrhage	1 (2.1)	1 (2.1)	0	0	0
Enterocolitis	1 (2.1)	0	1 (2.1)	0	0
Gastrooesophageal reflux disease	1 (2.1)	0	1 (2.1)	0	0
Gingival bleeding	1 (2.1)	0	1 (2.1)	0	0
Gingivitis ulcerative	1 (2.1)	0	0	1 (2.1)	0
Haematemesis	1 (2.1)	1 (2.1)	0	0	0
Lip dry	1 (2.1)	0	1 (2.1)	0	0
Lip oedema	1 (2.1)	1 (2.1)	0	0	0
Mouth swelling	1 (2.1)	1 (2.1)	0	0	0
Neutropenic colitis	1 (2.1)	0	0	1 (2.1)	0
Odynophagia	1 (2.1)	1 (2.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (2.1)	0	1 (2.1)	0	0
Proctalgia	1 (2.1)	0	0	1 (2.1)	0
Trichoglossia	1 (2.1)	0	1 (2.1)	0	0
Upper gastrointestinal haemorrhage	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	20 (41.7)	12 (25.0)	5 (10.4)	2 (4.2)	1 (2.1)
Pyrexia	11 (22.9)	5 (10.4)	3 (6.3)	2 (4.2)	1 (2.1)
Fatigue	6 (12.5)	6 (12.5)	0	0	0
Chills	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Face oedema	4 (8.3)	3 (6.3)	1 (2.1)	0	0
Asthenia	2 (4.2)	2 (4.2)	0	0	0
Generalised oedema	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Influenza like illness	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Oedema peripheral	2 (4.2)	2 (4.2)	0	0	0
Catheter site erythema	1 (2.1)	1 (2.1)	0	0	0
Catheter site pain	1 (2.1)	0	0	1 (2.1)	0
Chest discomfort	1 (2.1)	0	0	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Crying	1 (2.1)	0	1 (2.1)	0	0
Facial pain	1 (2.1)	0	1 (2.1)	0	0
Localised oedema	1 (2.1)	1 (2.1)	0	0	0
Malaise	1 (2.1)	0	1 (2.1)	0	0
Oedema due to hepatic disease	1 (2.1)	0	1 (2.1)	0	0
Pain	1 (2.1)	0	0	1 (2.1)	0
Sluggishness	1 (2.1)	0	1 (2.1)	0	0
Swelling face	1 (2.1)	1 (2.1)	0	0	0
Vascular device occlusion	1 (2.1)	1 (2.1)	0	0	0
Hepatobiliary disorders					
-Total	7 (14.6)	3 (6.3)	2 (4.2)	1 (2.1)	1 (2.1)
Hepatic function abnormal	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Hepatomegaly	2 (4.2)	2 (4.2)	0	0	0
Hyperbilirubinaemia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Cholelithiasis	1 (2.1)	0	1 (2.1)	0	0
Immune system disorders					
-Total	41 (85.4)	2 (4.2)	12 (25.0)	16 (33.3)	11 (22.9)
Cytokine release syndrome	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	14 (29.2)	0	9 (18.8)	5 (10.4)	0
Haemophagocytic lymphohistiocytosis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Immunodeficiency	2 (4.2)	0	0	2 (4.2)	0
Hypersensitivity	1 (2.1)	1 (2.1)	0	0	0
Infections and infestations					
-Total	23 (47.9)	4 (8.3)	6 (12.5)	12 (25.0)	1 (2.1)
Conjunctivitis	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Candida infection	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Nail infection	2 (4.2)	2 (4.2)	0	0	0
Oral herpes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Oral infection	2 (4.2)	0	2 (4.2)	0	0
Staphylococcal infection	2 (4.2)	0	0	2 (4.2)	0
Adenovirus infection	1 (2.1)	0	0	1 (2.1)	0
Anal abscess	1 (2.1)	0	0	1 (2.1)	0
Bk virus infection	1 (2.1)	1 (2.1)	0	0	0
Bronchopulmonary aspergillosis	1 (2.1)	0	0	1 (2.1)	0
Cholecystitis infective	1 (2.1)	0	1 (2.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (2.1)	0	0	1 (2.1)	0
Encephalitis viral	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis norovirus	1 (2.1)	1 (2.1)	0	0	0
Gingivitis	1 (2.1)	1 (2.1)	0	0	0
Granulicatella infection	1 (2.1)	0	0	1 (2.1)	0
Herpes simplex	1 (2.1)	0	0	1 (2.1)	0
Human herpesvirus 6 infection	1 (2.1)	0	0	1 (2.1)	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Myringitis	1 (2.1)	1 (2.1)	0	0	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Otitis externa	1 (2.1)	0	1 (2.1)	0	0
Paronychia	1 (2.1)	0	1 (2.1)	0	0
Pneumonia	1 (2.1)	0	0	1 (2.1)	0
Pneumonia fungal	1 (2.1)	0	0	1 (2.1)	0
Pneumonia viral	1 (2.1)	0	0	1 (2.1)	0
Rhinovirus infection	1 (2.1)	0	1 (2.1)	0	0
Sinusitis	1 (2.1)	0	0	1 (2.1)	0
Soft tissue infection	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (2.1)	0	1 (2.1)	0	0
Systemic candida	1 (2.1)	0	0	1 (2.1)	0
Varicella zoster virus infection	1 (2.1)	0	0	1 (2.1)	0
Injury, poisoning and procedural complications					
-Total	5 (10.4)	2 (4.2)	2 (4.2)	0	1 (2.1)
Fall	2 (4.2)	0	2 (4.2)	0	0
Infusion related reaction	1 (2.1)	0	1 (2.1)	0	0
Procedural pain	1 (2.1)	1 (2.1)	0	0	0
Transfusion reaction	1 (2.1)	1 (2.1)	0	0	0
Transplant failure	1 (2.1)	0	0	0	1 (2.1)
Investigations					
-Total	36 (75.0)	4 (8.3)	8 (16.7)	8 (16.7)	16 (33.3)
Alanine aminotransferase increased	13 (27.1)	3 (6.3)	6 (12.5)	4 (8.3)	0
Neutrophil count decreased	13 (27.1)	0	2 (4.2)	1 (2.1)	10 (20.8)
Platelet count decreased	13 (27.1)	2 (4.2)	1 (2.1)	5 (10.4)	5 (10.4)
White blood cell count decreased	13 (27.1)	3 (6.3)	0	1 (2.1)	9 (18.8)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	10 (20.8)	2 (4.2)	4 (8.3)	2 (4.2)	2 (4.2)
Lymphocyte count decreased	10 (20.8)	1 (2.1)	0	4 (8.3)	5 (10.4)
Blood bilirubin increased	5 (10.4)	0	1 (2.1)	4 (8.3)	0
Blood fibrinogen decreased	4 (8.3)	2 (4.2)	1 (2.1)	0	1 (2.1)
Blood immunoglobulin a decreased	4 (8.3)	4 (8.3)	0	0	0
Blood immunoglobulin m decreased	4 (8.3)	4 (8.3)	0	0	0
Serum ferritin increased	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Activated partial thromboplastin time prolonged	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Blood lactate dehydrogenase increased	3 (6.3)	2 (4.2)	1 (2.1)	0	0
C-reactive protein increased	3 (6.3)	1 (2.1)	0	2 (4.2)	0
International normalised ratio increased	3 (6.3)	3 (6.3)	0	0	0
Immunoglobulins decreased	2 (4.2)	0	2 (4.2)	0	0
Weight increased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood creatine phosphokinase increased	1 (2.1)	0	0	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (2.1)	0	0	1 (2.1)	0
Blood glucose increased	1 (2.1)	0	0	0	1 (2.1)
Blood testosterone decreased	1 (2.1)	1 (2.1)	0	0	0
Blood uric acid increased	1 (2.1)	1 (2.1)	0	0	0
Breath sounds abnormal	1 (2.1)	0	1 (2.1)	0	0
Coagulation test abnormal	1 (2.1)	1 (2.1)	0	0	0
Electrocardiogram qt prolonged	1 (2.1)	0	0	1 (2.1)	0
Enterovirus test positive	1 (2.1)	0	1 (2.1)	0	0
Fibrin d dimer increased	1 (2.1)	1 (2.1)	0	0	0
Gamma-glutamyltransferase increased	1 (2.1)	0	0	1 (2.1)	0
Haemoglobin decreased	1 (2.1)	0	0	1 (2.1)	0
Prothrombin time prolonged	1 (2.1)	0	1 (2.1)	0	0
Weight decreased	1 (2.1)	0	1 (2.1)	0	0
Metabolism and nutrition disorders					
-Total	25 (52.1)	5 (10.4)	4 (8.3)	13 (27.1)	3 (6.3)
Decreased appetite	14 (29.2)	6 (12.5)	1 (2.1)	6 (12.5)	1 (2.1)
Hypokalaemia	11 (22.9)	2 (4.2)	2 (4.2)	6 (12.5)	1 (2.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	10 (20.8)	3 (6.3)	2 (4.2)	4 (8.3)	1 (2.1)
Hypocalcaemia	6 (12.5)	2 (4.2)	2 (4.2)	2 (4.2)	0
Hypoalbuminaemia	5 (10.4)	0	5 (10.4)	0	0
Hyperglycaemia	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Hypomagnesaemia	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Tumour lysis syndrome	2 (4.2)	0	0	2 (4.2)	0
Hypermagnesaemia	1 (2.1)	1 (2.1)	0	0	0
Hypernatraemia	1 (2.1)	1 (2.1)	0	0	0
Hypertriglyceridaemia	1 (2.1)	0	0	1 (2.1)	0
Hyperuricaemia	1 (2.1)	0	1 (2.1)	0	0
Hypervolaemia	1 (2.1)	0	1 (2.1)	0	0
Hyponatraemia	1 (2.1)	1 (2.1)	0	0	0
Malnutrition	1 (2.1)	0	0	1 (2.1)	0
Polydipsia	1 (2.1)	0	0	1 (2.1)	0
Musculoskeletal and connective tissue disorders					
-Total	20 (41.7)	8 (16.7)	10 (20.8)	2 (4.2)	0
Pain in extremity	9 (18.8)	5 (10.4)	4 (8.3)	0	0
Arthralgia	8 (16.7)	4 (8.3)	4 (8.3)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	5 (10.4)	1 (2.1)	3 (6.3)	1 (2.1)	0
Myalgia	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Pain in jaw	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Bone pain	1 (2.1)	0	1 (2.1)	0	0
Musculoskeletal chest pain	1 (2.1)	1 (2.1)	0	0	0
Neck pain	1 (2.1)	0	1 (2.1)	0	0
Nervous system disorders					
-Total	21 (43.8)	9 (18.8)	8 (16.7)	4 (8.3)	0
Headache	12 (25.0)	8 (16.7)	2 (4.2)	2 (4.2)	0
Encephalopathy	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Dizziness	3 (6.3)	3 (6.3)	0	0	0
Tremor	3 (6.3)	3 (6.3)	0	0	0
Dysgeusia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Lethargy	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Somnolence	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Amnesia	1 (2.1)	0	1 (2.1)	0	0
Aphasia	1 (2.1)	1 (2.1)	0	0	0
Cognitive disorder	1 (2.1)	0	1 (2.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (2.1)	0	0	1 (2.1)	0
Disturbance in attention	1 (2.1)	1 (2.1)	0	0	0
Hyperaesthesia	1 (2.1)	1 (2.1)	0	0	0
Hypoaesthesia	1 (2.1)	1 (2.1)	0	0	0
Neuralgia	1 (2.1)	0	1 (2.1)	0	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Psychiatric disorders					
-Total	17 (35.4)	7 (14.6)	9 (18.8)	1 (2.1)	0
Anxiety	5 (10.4)	1 (2.1)	3 (6.3)	1 (2.1)	0
Confusional state	4 (8.3)	4 (8.3)	0	0	0
Hallucination	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Insomnia	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Agitation	2 (4.2)	2 (4.2)	0	0	0
Delirium	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Irritability	2 (4.2)	2 (4.2)	0	0	0
Affect lability	1 (2.1)	0	1 (2.1)	0	0
Hallucination, visual	1 (2.1)	0	1 (2.1)	0	0
Restlessness	1 (2.1)	0	1 (2.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (2.1)	0	1 (2.1)	0	0
Social avoidant behaviour	1 (2.1)	0	1 (2.1)	0	0
Renal and urinary disorders					
-Total	10 (20.8)	4 (8.3)	4 (8.3)	0	2 (4.2)
Acute kidney injury	3 (6.3)	1 (2.1)	1 (2.1)	0	1 (2.1)
Dysuria	2 (4.2)	2 (4.2)	0	0	0
Haematuria	2 (4.2)	2 (4.2)	0	0	0
Anuria	1 (2.1)	0	0	0	1 (2.1)
Incontinence	1 (2.1)	0	1 (2.1)	0	0
Pollakiuria	1 (2.1)	0	1 (2.1)	0	0
Proteinuria	1 (2.1)	1 (2.1)	0	0	0
Renal failure	1 (2.1)	0	1 (2.1)	0	0
Renal tubular dysfunction	1 (2.1)	1 (2.1)	0	0	0
Urinary incontinence	1 (2.1)	0	1 (2.1)	0	0
Urinary tract disorder	1 (2.1)	0	1 (2.1)	0	0
Reproductive system and breast disorders					
-Total	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Female genital tract fistula	1 (2.1)	1 (2.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heavy menstrual bleeding	1 (2.1)	1 (2.1)	0	0	0
Vaginal haemorrhage	1 (2.1)	0	1 (2.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	24 (50.0)	10 (20.8)	4 (8.3)	6 (12.5)	4 (8.3)
Hypoxia	8 (16.7)	0	3 (6.3)	2 (4.2)	3 (6.3)
Cough	7 (14.6)	6 (12.5)	1 (2.1)	0	0
Pulmonary oedema	6 (12.5)	2 (4.2)	0	4 (8.3)	0
Tachypnoea	5 (10.4)	3 (6.3)	1 (2.1)	1 (2.1)	0
Pleural effusion	4 (8.3)	3 (6.3)	0	0	1 (2.1)
Epistaxis	3 (6.3)	2 (4.2)	0	1 (2.1)	0
Oropharyngeal pain	3 (6.3)	3 (6.3)	0	0	0
Atelectasis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Dyspnoea	2 (4.2)	0	0	2 (4.2)	0
Nasal congestion	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Rhinorrhoea	2 (4.2)	2 (4.2)	0	0	0
Bradypnoea	1 (2.1)	0	0	1 (2.1)	0
Lung infiltration	1 (2.1)	0	0	1 (2.1)	0
Nasal dryness	1 (2.1)	1 (2.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (2.1)	0	1 (2.1)	0	0
Painful respiration	1 (2.1)	1 (2.1)	0	0	0
Paranasal sinus discomfort	1 (2.1)	0	1 (2.1)	0	0
Pharyngeal erythema	1 (2.1)	0	1 (2.1)	0	0
Pharyngeal exudate	1 (2.1)	0	1 (2.1)	0	0
Pharyngeal oedema	1 (2.1)	0	1 (2.1)	0	0
Productive cough	1 (2.1)	1 (2.1)	0	0	0
Pulmonary mass	1 (2.1)	0	1 (2.1)	0	0
Respiratory disorder	1 (2.1)	0	1 (2.1)	0	0
Respiratory distress	1 (2.1)	0	1 (2.1)	0	0
Wheezing	1 (2.1)	0	1 (2.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (35.4)	8 (16.7)	7 (14.6)	2 (4.2)	0
Pruritus	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rash	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rash papular	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Dermatitis atopic	2 (4.2)	2 (4.2)	0	0	0
Erythema	2 (4.2)	2 (4.2)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Blister	1 (2.1)	1 (2.1)	0	0	0
Dry skin	1 (2.1)	1 (2.1)	0	0	0
Eczema	1 (2.1)	1 (2.1)	0	0	0
Erythema nodosum	1 (2.1)	1 (2.1)	0	0	0
Hyperhidrosis	1 (2.1)	0	1 (2.1)	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.1)	1 (2.1)	0	0	0
Pruritus allergic	1 (2.1)	0	1 (2.1)	0	0
Purpura	1 (2.1)	1 (2.1)	0	0	0
Rash pruritic	1 (2.1)	1 (2.1)	0	0	0
Rash vesicular	1 (2.1)	1 (2.1)	0	0	0
Skin lesion	1 (2.1)	0	1 (2.1)	0	0
Skin ulcer	1 (2.1)	0	1 (2.1)	0	0
Urticaria	1 (2.1)	0	1 (2.1)	0	0
Vancomycin infusion reaction	1 (2.1)	0	0	1 (2.1)	0
Social circumstances					
-Total	1 (2.1)	0	1 (2.1)	0	0
Patient uncooperative	1 (2.1)	0	1 (2.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=48 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	15 (31.3)	4 (8.3)	4 (8.3)	5 (10.4)	2 (4.2)
Hypotension	9 (18.8)	1 (2.1)	3 (6.3)	3 (6.3)	2 (4.2)
Hypertension	6 (12.5)	3 (6.3)	2 (4.2)	1 (2.1)	0
Capillary leak syndrome	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Flushing	1 (2.1)	1 (2.1)	0	0	0
Hot flush	1 (2.1)	1 (2.1)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	2 (6.3)	4 (12.5)	5 (15.6)	20 (62.5)
Blood and lymphatic system disorders					
-Total	21 (65.6)	1 (3.1)	3 (9.4)	9 (28.1)	8 (25.0)
Febrile neutropenia	12 (37.5)	0	0	10 (31.3)	2 (6.3)
Anaemia	8 (25.0)	3 (9.4)	4 (12.5)	1 (3.1)	0
Disseminated intravascular coagulation	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Neutropenia	4 (12.5)	0	1 (3.1)	0	3 (9.4)
Thrombocytopenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Coagulopathy	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Splenomegaly	2 (6.3)	2 (6.3)	0	0	0
Hypofibrinogenaemia	1 (3.1)	0	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	14 (43.8)	5 (15.6)	4 (12.5)	2 (6.3)	3 (9.4)
Tachycardia	10 (31.3)	3 (9.4)	5 (15.6)	1 (3.1)	1 (3.1)
Bradycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sinus tachycardia	2 (6.3)	2 (6.3)	0	0	0
Atrioventricular block first degree	1 (3.1)	0	1 (3.1)	0	0
Cardiac arrest	1 (3.1)	0	0	0	1 (3.1)
Cardiac dysfunction	1 (3.1)	1 (3.1)	0	0	0
Cardiac failure	1 (3.1)	0	0	0	1 (3.1)
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Sinus bradycardia	1 (3.1)	0	0	1 (3.1)	0
Ear and labyrinth disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Ear pruritus	1 (3.1)	1 (3.1)	0	0	0
Endocrine disorders					
-Total	3 (9.4)	0	3 (9.4)	0	0
Adrenal insufficiency	3 (9.4)	0	3 (9.4)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.5)	4 (12.5)	0	0	0
Conjunctival haemorrhage	2 (6.3)	2 (6.3)	0	0	0
Ocular hyperaemia	2 (6.3)	2 (6.3)	0	0	0
Eyelid oedema	1 (3.1)	1 (3.1)	0	0	0
Periorbital oedema	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	19 (59.4)	6 (18.8)	6 (18.8)	6 (18.8)	1 (3.1)
Vomiting	7 (21.9)	5 (15.6)	1 (3.1)	1 (3.1)	0
Constipation	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Nausea	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Diarrhoea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Pancreatitis	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Abdominal pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Mouth haemorrhage	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Abdominal compartment syndrome	1 (3.1)	0	0	0	1 (3.1)
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Anal fissure	1 (3.1)	0	1 (3.1)	0	0
Ascites	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (3.1)	0	1 (3.1)	0	0
Dysphagia	1 (3.1)	0	0	1 (3.1)	0
Gingival erythema	1 (3.1)	1 (3.1)	0	0	0
Ileus	1 (3.1)	0	1 (3.1)	0	0
Melaena	1 (3.1)	0	0	1 (3.1)	0
General disorders and administration site conditions					
-Total	20 (62.5)	8 (25.0)	4 (12.5)	5 (15.6)	3 (9.4)
Pyrexia	13 (40.6)	6 (18.8)	2 (6.3)	4 (12.5)	1 (3.1)
Fatigue	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Face oedema	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Oedema peripheral	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Generalised oedema	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Chills	2 (6.3)	2 (6.3)	0	0	0
Drug withdrawal syndrome	2 (6.3)	0	2 (6.3)	0	0
Multiple organ dysfunction syndrome	2 (6.3)	0	0	0	2 (6.3)
Catheter site haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Catheter site pain	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised oedema	1 (3.1)	1 (3.1)	0	0	0
Systemic inflammatory response syndrome	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	10 (31.3)	2 (6.3)	4 (12.5)	2 (6.3)	2 (6.3)
Hepatic function abnormal	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Hyperbilirubinaemia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Gallbladder enlargement	2 (6.3)	2 (6.3)	0	0	0
Hypertransaminasaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Biliary tract disorder	1 (3.1)	1 (3.1)	0	0	0
Cholelithiasis	1 (3.1)	1 (3.1)	0	0	0
Cholestasis	1 (3.1)	0	0	0	1 (3.1)
Hepatomegaly	1 (3.1)	0	0	0	1 (3.1)
Ocular icterus	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	26 (81.3)	1 (3.1)	9 (28.1)	6 (18.8)	10 (31.3)
Cytokine release syndrome	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)
Hypogammaglobulinaemia	9 (28.1)	2 (6.3)	5 (15.6)	2 (6.3)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Immunodeficiency	1 (3.1)	0	0	1 (3.1)	0
Seasonal allergy	1 (3.1)	0	1 (3.1)	0	0
Selective igg subclass deficiency	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	12 (37.5)	2 (6.3)	4 (12.5)	4 (12.5)	2 (6.3)
Clostridium difficile infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Staphylococcal infection	3 (9.4)	0	3 (9.4)	0	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Atypical pneumonia	1 (3.1)	1 (3.1)	0	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	0	1 (3.1)
Klebsiella bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Localised infection	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection viral	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	6 (18.8)	1 (3.1)	4 (12.5)	0	1 (3.1)
Wound	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Contusion	1 (3.1)	1 (3.1)	0	0	0
Infusion related reaction	1 (3.1)	0	1 (3.1)	0	0
Procedural pain	1 (3.1)	0	1 (3.1)	0	0
Scratch	1 (3.1)	1 (3.1)	0	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Skin injury	1 (3.1)	0	1 (3.1)	0	0
Skin wound	1 (3.1)	1 (3.1)	0	0	0
Transfusion reaction	1 (3.1)	0	1 (3.1)	0	0
Vasoplegia syndrome	1 (3.1)	0	0	0	1 (3.1)
Investigations					
-Total	21 (65.6)	0	0	9 (28.1)	12 (37.5)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	11 (34.4)	0	3 (9.4)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	9 (28.1)	0	2 (6.3)	6 (18.8)	1 (3.1)
Platelet count decreased	8 (25.0)	2 (6.3)	2 (6.3)	1 (3.1)	3 (9.4)
Blood bilirubin increased	7 (21.9)	1 (3.1)	1 (3.1)	5 (15.6)	0
Neutrophil count decreased	7 (21.9)	0	1 (3.1)	1 (3.1)	5 (15.6)
International normalised ratio increased	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Alanine aminotransferase increased	5 (15.6)	1 (3.1)	2 (6.3)	2 (6.3)	0
Lymphocyte count decreased	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Electrocardiogram qt prolonged	4 (12.5)	1 (3.1)	2 (6.3)	0	1 (3.1)
Serum ferritin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Activated partial thromboplastin time prolonged	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blood creatinine increased	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)
Blood fibrinogen decreased	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Blood immunoglobulin g decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Fibrin d dimer increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Lipase increased	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Urine output decreased	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Weight increased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Amylase increased	1 (3.1)	1 (3.1)	0	0	0
Bacterial test positive	1 (3.1)	0	0	1 (3.1)	0
Blood alkaline phosphatase increased	1 (3.1)	1 (3.1)	0	0	0
Blood bicarbonate decreased	1 (3.1)	0	1 (3.1)	0	0
Blood creatine phosphokinase increased	1 (3.1)	0	0	0	1 (3.1)
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)	0	0
Blood lactate dehydrogenase increased	1 (3.1)	0	0	1 (3.1)	0
Blood phosphorus increased	1 (3.1)	0	1 (3.1)	0	0
Blood uric acid increased	1 (3.1)	1 (3.1)	0	0	0
C-reactive protein increased	1 (3.1)	0	0	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac murmur	1 (3.1)	1 (3.1)	0	0	0
Electrocardiogram t wave abnormal	1 (3.1)	0	1 (3.1)	0	0
Gamma-glutamyltransferase increased	1 (3.1)	0	0	1 (3.1)	0
Haptoglobin decreased	1 (3.1)	1 (3.1)	0	0	0
Oxygen saturation decreased	1 (3.1)	1 (3.1)	0	0	0
Staphylococcus test positive	1 (3.1)	1 (3.1)	0	0	0
Troponin increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	21 (65.6)	3 (9.4)	5 (15.6)	8 (25.0)	5 (15.6)
Decreased appetite	10 (31.3)	3 (9.4)	3 (9.4)	4 (12.5)	0
Hypocalcaemia	10 (31.3)	0	7 (21.9)	3 (9.4)	0
Hypokalaemia	8 (25.0)	1 (3.1)	3 (9.4)	3 (9.4)	1 (3.1)
Hypophosphataemia	7 (21.9)	0	3 (9.4)	4 (12.5)	0
Hyperuricaemia	6 (18.8)	5 (15.6)	0	1 (3.1)	0
Hypoalbuminaemia	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Hyperglycaemia	5 (15.6)	0	3 (9.4)	2 (6.3)	0
Hyperphosphataemia	5 (15.6)	4 (12.5)	0	0	1 (3.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	5 (15.6)	0	1 (3.1)	4 (12.5)	0
Hypercalcaemia	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Hypomagnesaemia	3 (9.4)	3 (9.4)	0	0	0
Metabolic acidosis	3 (9.4)	1 (3.1)	0	0	2 (6.3)
Acidosis	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hyperkalaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hyponatraemia	2 (6.3)	2 (6.3)	0	0	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0
Calcium deficiency	1 (3.1)	1 (3.1)	0	0	0
Dehydration	1 (3.1)	0	1 (3.1)	0	0
Haemosiderosis	1 (3.1)	0	1 (3.1)	0	0
Hyperchloraemia	1 (3.1)	1 (3.1)	0	0	0
Hyperlactacidaemia	1 (3.1)	1 (3.1)	0	0	0
Hypermagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)
Hypertriglyceridaemia	1 (3.1)	0	0	0	1 (3.1)
Hypoglycaemia	1 (3.1)	0	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (40.6)	7 (21.9)	3 (9.4)	2 (6.3)	1 (3.1)
Myalgia	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Arthralgia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Muscular weakness	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Pain in extremity	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Back pain	1 (3.1)	1 (3.1)	0	0	0
Bone pain	1 (3.1)	0	1 (3.1)	0	0
Haemarthrosis	1 (3.1)	0	0	1 (3.1)	0
Muscle rigidity	1 (3.1)	1 (3.1)	0	0	0
Muscle spasms	1 (3.1)	0	1 (3.1)	0	0
Myositis	1 (3.1)	0	1 (3.1)	0	0
Rhabdomyolysis	1 (3.1)	0	0	0	1 (3.1)
Nervous system disorders					
-Total	19 (59.4)	5 (15.6)	8 (25.0)	4 (12.5)	2 (6.3)
Headache	11 (34.4)	4 (12.5)	7 (21.9)	0	0
Encephalopathy	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Somnolence	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Tremor	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Cognitive disorder	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (3.1)	0	0	0	1 (3.1)
Dysarthria	1 (3.1)	0	0	1 (3.1)	0
Dysgeusia	1 (3.1)	1 (3.1)	0	0	0
Generalised tonic-clonic seizure	1 (3.1)	0	1 (3.1)	0	0
Lethargy	1 (3.1)	1 (3.1)	0	0	0
Monoparesis	1 (3.1)	0	1 (3.1)	0	0
Neurological decompensation	1 (3.1)	0	0	0	1 (3.1)
Paraesthesia	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Psychiatric disorders					
-Total	11 (34.4)	5 (15.6)	1 (3.1)	5 (15.6)	0
Delirium	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Agitation	3 (9.4)	0	3 (9.4)	0	0
Confusional state	3 (9.4)	3 (9.4)	0	0	0
Mental status changes	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Anxiety	1 (3.1)	0	0	1 (3.1)	0
Automatism	1 (3.1)	1 (3.1)	0	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (3.1)	1 (3.1)	0	0	0
Sleep disorder	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	10 (31.3)	1 (3.1)	2 (6.3)	3 (9.4)	4 (12.5)
Acute kidney injury	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Urinary retention	2 (6.3)	0	2 (6.3)	0	0
Anuria	1 (3.1)	1 (3.1)	0	0	0
Azotaemia	1 (3.1)	0	1 (3.1)	0	0
Bladder dilatation	1 (3.1)	0	1 (3.1)	0	0
Dysuria	1 (3.1)	1 (3.1)	0	0	0
Micturition urgency	1 (3.1)	0	1 (3.1)	0	0
Pollakiuria	1 (3.1)	0	1 (3.1)	0	0
Renal failure	1 (3.1)	0	0	0	1 (3.1)
Renal tubular necrosis	1 (3.1)	0	0	0	1 (3.1)
Reproductive system and breast disorders					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Perineal rash	1 (3.1)	0	1 (3.1)	0	0
Vaginal ulceration	1 (3.1)	0	0	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	17 (53.1)	4 (12.5)	0	5 (15.6)	8 (25.0)
Hypoxia	9 (28.1)	0	2 (6.3)	4 (12.5)	3 (9.4)
Pulmonary oedema	6 (18.8)	0	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory failure	4 (12.5)	0	0	0	4 (12.5)
Cough	3 (9.4)	3 (9.4)	0	0	0
Pleural effusion	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Tachypnoea	3 (9.4)	0	0	3 (9.4)	0
Acute respiratory distress syndrome	2 (6.3)	0	0	0	2 (6.3)
Oropharyngeal pain	2 (6.3)	2 (6.3)	0	0	0
Respiratory distress	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Acute respiratory failure	1 (3.1)	0	0	1 (3.1)	0
Atelectasis	1 (3.1)	0	0	1 (3.1)	0
Dyspnoea	1 (3.1)	0	0	0	1 (3.1)
Epistaxis	1 (3.1)	0	1 (3.1)	0	0
Haemoptysis	1 (3.1)	0	1 (3.1)	0	0
Nasal congestion	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal discomfort	1 (3.1)	0	1 (3.1)	0	0
Pharyngeal haemorrhage	1 (3.1)	0	1 (3.1)	0	0
Respiratory acidosis	1 (3.1)	0	0	1 (3.1)	0
Skin and subcutaneous tissue disorders					
-Total	10 (31.3)	5 (15.6)	4 (12.5)	1 (3.1)	0
Pruritus	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Blister	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Erythema	2 (6.3)	2 (6.3)	0	0	0
Hyperhidrosis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Petechiae	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Rash	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Decubitus ulcer	1 (3.1)	0	1 (3.1)	0	0
Dermatitis	1 (3.1)	1 (3.1)	0	0	0
Dermatitis diaper	1 (3.1)	0	1 (3.1)	0	0
Scab	1 (3.1)	1 (3.1)	0	0	0
Skin discolouration	1 (3.1)	1 (3.1)	0	0	0
Skin necrosis	1 (3.1)	0	0	1 (3.1)	0
Skin ulcer	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Surgical and medical procedures					
-Total	1 (3.1)	0	0	1 (3.1)	0
Thrombolysis	1 (3.1)	0	0	1 (3.1)	0
Vascular disorders					
-Total	13 (40.6)	0	3 (9.4)	6 (18.8)	4 (12.5)
Hypotension	12 (37.5)	0	3 (9.4)	5 (15.6)	4 (12.5)
Hypertension	7 (21.9)	1 (3.1)	3 (9.4)	3 (9.4)	0
Peripheral ischaemia	1 (3.1)	0	1 (3.1)	0	0
Thrombosis	1 (3.1)	0	1 (3.1)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (95.8)	6 (12.5)	16 (33.3)	8 (16.7)	16 (33.3)
Blood and lymphatic system disorders					
-Total	12 (25.0)	2 (4.2)	3 (6.3)	4 (8.3)	3 (6.3)
Anaemia	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Febrile neutropenia	3 (6.3)	0	0	3 (6.3)	0
Neutropenia	3 (6.3)	0	0	1 (2.1)	2 (4.2)
Thrombocytopenia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
B-cell aplasia	1 (2.1)	0	1 (2.1)	0	0
Disseminated intravascular coagulation	1 (2.1)	0	0	1 (2.1)	0
Eosinophilia	1 (2.1)	0	1 (2.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (2.1)	0	1 (2.1)	0	0
Leukopenia	1 (2.1)	0	1 (2.1)	0	0
Lymphopenia	1 (2.1)	0	0	1 (2.1)	0
Cardiac disorders					
-Total	5 (10.4)	3 (6.3)	1 (2.1)	0	1 (2.1)
Tachycardia	2 (4.2)	2 (4.2)	0	0	0
Cardiac arrest	1 (2.1)	0	0	0	1 (2.1)
Left ventricular dysfunction	1 (2.1)	0	1 (2.1)	0	0
Tricuspid valve incompetence	1 (2.1)	1 (2.1)	0	0	0
Eye disorders					
-Total	3 (6.3)	3 (6.3)	0	0	0
Cataract	2 (4.2)	2 (4.2)	0	0	0
Hypermetropia	1 (2.1)	1 (2.1)	0	0	0
Ocular hyperaemia	1 (2.1)	1 (2.1)	0	0	0
Gastrointestinal disorders					
-Total	13 (27.1)	9 (18.8)	3 (6.3)	1 (2.1)	0
Nausea	4 (8.3)	3 (6.3)	1 (2.1)	0	0
Vomiting	4 (8.3)	4 (8.3)	0	0	0
Constipation	3 (6.3)	1 (2.1)	2 (4.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (6.3)	3 (6.3)	0	0	0
Pancreatitis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Abdominal pain	1 (2.1)	1 (2.1)	0	0	0
Abdominal pain upper	1 (2.1)	1 (2.1)	0	0	0
Abdominal rigidity	1 (2.1)	0	1 (2.1)	0	0
Dyspepsia	1 (2.1)	1 (2.1)	0	0	0
Enteritis	1 (2.1)	0	1 (2.1)	0	0
Mouth haemorrhage	1 (2.1)	1 (2.1)	0	0	0
Peritoneal haematoma	1 (2.1)	1 (2.1)	0	0	0
Proctalgia	1 (2.1)	1 (2.1)	0	0	0
Trichoglossia	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	15 (31.3)	10 (20.8)	2 (4.2)	3 (6.3)	0
Pyrexia	10 (20.8)	5 (10.4)	3 (6.3)	2 (4.2)	0
Fatigue	4 (8.3)	4 (8.3)	0	0	0
Asthenia	1 (2.1)	1 (2.1)	0	0	0
Chills	1 (2.1)	1 (2.1)	0	0	0
Non-cardiac chest pain	1 (2.1)	1 (2.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (2.1)	0	0	1 (2.1)	0
Hepatobiliary disorders					
-Total	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Hepatic cytolysis	1 (2.1)	1 (2.1)	0	0	0
Liver disorder	1 (2.1)	0	1 (2.1)	0	0
Immune system disorders					
-Total	13 (27.1)	1 (2.1)	10 (20.8)	2 (4.2)	0
Hypogammaglobulinaemia	9 (18.8)	0	9 (18.8)	0	0
Graft versus host disease	2 (4.2)	0	0	2 (4.2)	0
Allergy to immunoglobulin therapy	1 (2.1)	1 (2.1)	0	0	0
Drug hypersensitivity	1 (2.1)	0	1 (2.1)	0	0
Engraftment syndrome	1 (2.1)	0	0	1 (2.1)	0
Infections and infestations					
-Total	28 (58.3)	3 (6.3)	9 (18.8)	9 (18.8)	7 (14.6)
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Gastroenteritis	4 (8.3)	2 (4.2)	0	2 (4.2)	0
Rhinovirus infection	4 (8.3)	0	3 (6.3)	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (8.3)	1 (2.1)	1 (2.1)	2 (4.2)	0
Metapneumovirus infection	3 (6.3)	0	0	3 (6.3)	0
Respiratory syncytial virus infection	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Otitis media	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Parainfluenzae virus infection	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Pneumocystis jirovecii pneumonia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Pneumonia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Respiratory tract infection	2 (4.2)	0	2 (4.2)	0	0
Rhinitis	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Sinusitis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Viral infection	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Bacteraemia	1 (2.1)	0	0	0	1 (2.1)
Bronchopulmonary aspergillosis	1 (2.1)	0	0	0	1 (2.1)
Coronavirus infection	1 (2.1)	0	0	1 (2.1)	0
Cystitis	1 (2.1)	0	1 (2.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (2.1)	0	0	1 (2.1)	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Ear, nose and throat infection	1 (2.1)	0	1 (2.1)	0	0
Encephalitis	1 (2.1)	0	0	0	1 (2.1)
Enterobacter infection	1 (2.1)	0	0	1 (2.1)	0
Gastroenteritis viral	1 (2.1)	1 (2.1)	0	0	0
Gingivitis	1 (2.1)	1 (2.1)	0	0	0
Human herpesvirus 6 infection	1 (2.1)	0	0	1 (2.1)	0
Influenza	1 (2.1)	0	1 (2.1)	0	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Mastoiditis	1 (2.1)	0	0	1 (2.1)	0
Oral candidiasis	1 (2.1)	0	1 (2.1)	0	0
Oral herpes	1 (2.1)	0	1 (2.1)	0	0
Otitis externa	1 (2.1)	0	0	1 (2.1)	0
Paronychia	1 (2.1)	0	1 (2.1)	0	0
Respiratory tract infection viral	1 (2.1)	0	1 (2.1)	0	0
Salmonellosis	1 (2.1)	0	1 (2.1)	0	0
Septic shock	1 (2.1)	0	0	0	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal skin infection	1 (2.1)	0	1 (2.1)	0	0
Tinea pedis	1 (2.1)	1 (2.1)	0	0	0
Urinary tract infection	1 (2.1)	0	0	1 (2.1)	0
Viral haemorrhagic cystitis	1 (2.1)	0	0	1 (2.1)	0
Injury, poisoning and procedural complications					
-Total	7 (14.6)	5 (10.4)	2 (4.2)	0	0
Infusion related reaction	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Contusion	1 (2.1)	1 (2.1)	0	0	0
Ligament sprain	1 (2.1)	1 (2.1)	0	0	0
Limb injury	1 (2.1)	0	1 (2.1)	0	0
Skin abrasion	1 (2.1)	1 (2.1)	0	0	0
Investigations					
-Total	19 (39.6)	4 (8.3)	4 (8.3)	6 (12.5)	5 (10.4)
Neutrophil count decreased	7 (14.6)	1 (2.1)	1 (2.1)	1 (2.1)	4 (8.3)
White blood cell count decreased	6 (12.5)	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)
Platelet count decreased	4 (8.3)	2 (4.2)	0	1 (2.1)	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood bilirubin increased	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Blood immunoglobulin a decreased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood uric acid increased	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Lymphocyte count decreased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood creatinine increased	1 (2.1)	0	1 (2.1)	0	0
Blood immunoglobulin m decreased	1 (2.1)	0	0	1 (2.1)	0
Blood urea increased	1 (2.1)	0	0	1 (2.1)	0
Bone density decreased	1 (2.1)	1 (2.1)	0	0	0
Hepatitis b virus test positive	1 (2.1)	0	1 (2.1)	0	0
Immunoglobulins decreased	1 (2.1)	0	1 (2.1)	0	0
Oxygen saturation decreased	1 (2.1)	0	1 (2.1)	0	0
Weight decreased	1 (2.1)	0	0	1 (2.1)	0
Metabolism and nutrition disorders					
-Total	10 (20.8)	3 (6.3)	1 (2.1)	4 (8.3)	2 (4.2)
Decreased appetite	4 (8.3)	2 (4.2)	1 (2.1)	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	3 (6.3)	0	1 (2.1)	1 (2.1)	1 (2.1)
Hyperuricaemia	2 (4.2)	2 (4.2)	0	0	0
Haemochromatosis	1 (2.1)	0	0	1 (2.1)	0
Hyperchloraemia	1 (2.1)	1 (2.1)	0	0	0
Hyperkalaemia	1 (2.1)	0	1 (2.1)	0	0
Hypervolaemia	1 (2.1)	0	0	1 (2.1)	0
Hypophagia	1 (2.1)	0	1 (2.1)	0	0
Hypophosphataemia	1 (2.1)	0	1 (2.1)	0	0
Iron overload	1 (2.1)	0	1 (2.1)	0	0
Malnutrition	1 (2.1)	0	0	1 (2.1)	0
Tumour lysis syndrome	1 (2.1)	0	0	0	1 (2.1)
Musculoskeletal and connective tissue disorders					
-Total	10 (20.8)	4 (8.3)	4 (8.3)	2 (4.2)	0
Back pain	4 (8.3)	2 (4.2)	1 (2.1)	1 (2.1)	0
Pain in extremity	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Arthralgia	2 (4.2)	2 (4.2)	0	0	0
Bone pain	1 (2.1)	1 (2.1)	0	0	0
Growth retardation	1 (2.1)	0	1 (2.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (2.1)	1 (2.1)	0	0	0
Musculoskeletal pain	1 (2.1)	0	1 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Skin papilloma	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Myelodysplastic syndrome	1 (2.1)	0	0	1 (2.1)	0
Nervous system disorders					
-Total	9 (18.8)	4 (8.3)	3 (6.3)	0	2 (4.2)
Headache	6 (12.5)	3 (6.3)	3 (6.3)	0	0
Autonomic neuropathy	1 (2.1)	0	0	1 (2.1)	0
Cerebral haemorrhage	1 (2.1)	0	0	0	1 (2.1)
Dizziness	1 (2.1)	1 (2.1)	0	0	0
Hydrocephalus	1 (2.1)	0	0	0	1 (2.1)
Memory impairment	1 (2.1)	0	1 (2.1)	0	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Psychiatric disorders					
-Total	6 (12.5)	1 (2.1)	4 (8.3)	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Mental status changes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Agitation	1 (2.1)	1 (2.1)	0	0	0
Delirium	1 (2.1)	0	1 (2.1)	0	0
Mood altered	1 (2.1)	1 (2.1)	0	0	0
Nightmare	1 (2.1)	1 (2.1)	0	0	0
Sleep disorder	1 (2.1)	0	1 (2.1)	0	0
Tearfulness	1 (2.1)	1 (2.1)	0	0	0
Renal and urinary disorders					
-Total	4 (8.3)	1 (2.1)	1 (2.1)	1 (2.1)	1 (2.1)
Acute kidney injury	2 (4.2)	1 (2.1)	0	0	1 (2.1)
Cystitis haemorrhagic	1 (2.1)	0	1 (2.1)	0	0
Renal tubular disorder	1 (2.1)	0	0	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (35.4)	10 (20.8)	3 (6.3)	2 (4.2)	2 (4.2)
Cough	9 (18.8)	7 (14.6)	2 (4.2)	0	0
Nasal congestion	4 (8.3)	4 (8.3)	0	0	0
Rhinorrhoea	3 (6.3)	3 (6.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Hypoxia	2 (4.2)	0	0	2 (4.2)	0
Pleural effusion	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Acute respiratory distress syndrome	1 (2.1)	0	0	0	1 (2.1)
Bronchial oedema	1 (2.1)	1 (2.1)	0	0	0
Dyspnoea	1 (2.1)	0	1 (2.1)	0	0
Lung disorder	1 (2.1)	1 (2.1)	0	0	0
Paranasal sinus inflammation	1 (2.1)	1 (2.1)	0	0	0
Respiratory distress	1 (2.1)	0	0	0	1 (2.1)
Rhinitis allergic	1 (2.1)	1 (2.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (22.9)	7 (14.6)	3 (6.3)	1 (2.1)	0
Dry skin	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rash	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Decubitus ulcer	1 (2.1)	0	0	1 (2.1)	0
Dermatitis allergic	1 (2.1)	1 (2.1)	0	0	0
Dermatitis atopic	1 (2.1)	1 (2.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hangnail	1 (2.1)	1 (2.1)	0	0	0
Ingrowing nail	1 (2.1)	0	1 (2.1)	0	0
Night sweats	1 (2.1)	1 (2.1)	0	0	0
Skin discolouration	1 (2.1)	1 (2.1)	0	0	0
Skin swelling	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					
-Total	3 (6.3)	1 (2.1)	0	1 (2.1)	1 (2.1)
Hypotension	2 (4.2)	1 (2.1)	0	0	1 (2.1)
Hypertension	1 (2.1)	0	1 (2.1)	0	0
Venoocclusive disease	1 (2.1)	0	0	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (85.2)	3 (11.1)	8 (29.6)	7 (25.9)	5 (18.5)
Blood and lymphatic system disorders					
-Total	5 (18.5)	1 (3.7)	1 (3.7)	2 (7.4)	1 (3.7)
Neutropenia	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Anaemia	1 (3.7)	0	0	1 (3.7)	0
Lymphadenopathy	1 (3.7)	1 (3.7)	0	0	0
Lymphocytosis	1 (3.7)	0	1 (3.7)	0	0
Cardiac disorders					
-Total	2 (7.4)	0	0	0	2 (7.4)
Cardiac failure	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Cardiac arrest	1 (3.7)	0	0	0	1 (3.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Hypothyroidism	1 (3.7)	0	1 (3.7)	0	0
Eye disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Visual impairment	1 (3.7)	1 (3.7)	0	0	0
Gastrointestinal disorders					
-Total	7 (25.9)	4 (14.8)	3 (11.1)	0	0
Diarrhoea	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Vomiting	2 (7.4)	2 (7.4)	0	0	0
Abdominal pain	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal haemorrhage	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal inflammation	1 (3.7)	0	1 (3.7)	0	0
Nausea	1 (3.7)	0	1 (3.7)	0	0
Stomatitis	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	9 (33.3)	5 (18.5)	4 (14.8)	0	0
Pyrexia	5 (18.5)	2 (7.4)	3 (11.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	2 (7.4)	2 (7.4)	0	0	0
Malaise	1 (3.7)	1 (3.7)	0	0	0
Oedema peripheral	1 (3.7)	1 (3.7)	0	0	0
Pain	1 (3.7)	0	1 (3.7)	0	0
Hepatobiliary disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Hypertransaminasaemia	1 (3.7)	1 (3.7)	0	0	0
Immune system disorders					
-Total	3 (11.1)	0	1 (3.7)	2 (7.4)	0
Allergy to immunoglobulin therapy	1 (3.7)	0	0	1 (3.7)	0
Hypogammaglobulinaemia	1 (3.7)	0	1 (3.7)	0	0
Immunodeficiency	1 (3.7)	0	0	1 (3.7)	0
Infections and infestations					
-Total	11 (40.7)	2 (7.4)	5 (18.5)	3 (11.1)	1 (3.7)
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Ear infection	2 (7.4)	0	2 (7.4)	0	0
Nasopharyngitis	2 (7.4)	1 (3.7)	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Acute sinusitis	1 (3.7)	0	1 (3.7)	0	0
Adenovirus infection	1 (3.7)	0	0	1 (3.7)	0
Bacteraemia	1 (3.7)	0	1 (3.7)	0	0
Bk virus infection	1 (3.7)	0	0	1 (3.7)	0
Cellulitis	1 (3.7)	0	1 (3.7)	0	0
Conjunctivitis	1 (3.7)	0	1 (3.7)	0	0
Gastroenteritis	1 (3.7)	1 (3.7)	0	0	0
Gastroenteritis clostridial	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal infection	1 (3.7)	1 (3.7)	0	0	0
Herpes simplex	1 (3.7)	0	1 (3.7)	0	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0
Molluscum contagiosum	1 (3.7)	1 (3.7)	0	0	0
Nail infection	1 (3.7)	1 (3.7)	0	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Pharyngitis streptococcal	1 (3.7)	0	0	1 (3.7)	0
Pneumonia	1 (3.7)	0	0	0	1 (3.7)
Respiratory tract infection	1 (3.7)	1 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.7)	0	1 (3.7)	0	0
Sinusitis	1 (3.7)	0	1 (3.7)	0	0
Sinusitis fungal	1 (3.7)	0	0	1 (3.7)	0
Staphylococcal bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Viral upper respiratory tract infection	1 (3.7)	0	0	1 (3.7)	0
Injury, poisoning and procedural complications					
-Total	2 (7.4)	0	2 (7.4)	0	0
Fibula fracture	1 (3.7)	0	1 (3.7)	0	0
Post-traumatic neck syndrome	1 (3.7)	0	1 (3.7)	0	0
Investigations					
-Total	11 (40.7)	3 (11.1)	3 (11.1)	5 (18.5)	0
White blood cell count decreased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Neutrophil count decreased	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Lymphocyte count decreased	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (3.7)	1 (3.7)	0	0	0
Blood thyroid stimulating hormone increased	1 (3.7)	1 (3.7)	0	0	0
C-reactive protein increased	1 (3.7)	1 (3.7)	0	0	0
Ejection fraction decreased	1 (3.7)	0	1 (3.7)	0	0
Heart sounds abnormal	1 (3.7)	1 (3.7)	0	0	0
Platelet count decreased	1 (3.7)	1 (3.7)	0	0	0
Weight increased	1 (3.7)	0	0	1 (3.7)	0
Metabolism and nutrition disorders					
-Total	5 (18.5)	1 (3.7)	3 (11.1)	0	1 (3.7)
Decreased appetite	2 (7.4)	0	2 (7.4)	0	0
Hyperuricaemia	1 (3.7)	1 (3.7)	0	0	0
Metabolic acidosis	1 (3.7)	0	0	0	1 (3.7)
Metabolic syndrome	1 (3.7)	0	1 (3.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (18.5)	1 (3.7)	3 (11.1)	1 (3.7)	0
Back pain	2 (7.4)	0	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Arthralgia	1 (3.7)	0	1 (3.7)	0	0
Bone pain	1 (3.7)	0	1 (3.7)	0	0
Myalgia	1 (3.7)	0	1 (3.7)	0	0
Neck pain	1 (3.7)	1 (3.7)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.7)	0	1 (3.7)	0	0
Cancer pain	1 (3.7)	0	1 (3.7)	0	0
Nervous system disorders					
-Total	5 (18.5)	3 (11.1)	2 (7.4)	0	0
Headache	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Extrapyramidal disorder	1 (3.7)	0	1 (3.7)	0	0
Migraine	1 (3.7)	0	1 (3.7)	0	0
Psychiatric disorders					
-Total	4 (14.8)	0	4 (14.8)	0	0
Anxiety	3 (11.1)	0	3 (11.1)	0	0
Persistent depressive disorder	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (3.7)	0	0	1 (3.7)	0
Acute kidney injury	1 (3.7)	0	1 (3.7)	0	0
Dysuria	1 (3.7)	0	1 (3.7)	0	0
Haematuria	1 (3.7)	0	0	1 (3.7)	0
Kidney enlargement	1 (3.7)	0	1 (3.7)	0	0
Renal mass	1 (3.7)	0	1 (3.7)	0	0
Reproductive system and breast disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Dysmenorrhoea	1 (3.7)	0	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (25.9)	1 (3.7)	4 (14.8)	1 (3.7)	1 (3.7)
Cough	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Nasal congestion	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Oropharyngeal pain	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Bronchospasm	1 (3.7)	0	1 (3.7)	0	0
Epistaxis	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (3.7)	0	0	1 (3.7)	0
Respiratory failure	1 (3.7)	0	0	0	1 (3.7)
Rhinitis allergic	1 (3.7)	0	1 (3.7)	0	0
Upper respiratory tract inflammation	1 (3.7)	0	1 (3.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (33.3)	5 (18.5)	4 (14.8)	0	0
Dry skin	3 (11.1)	3 (11.1)	0	0	0
Eczema	1 (3.7)	1 (3.7)	0	0	0
Erythema	1 (3.7)	0	1 (3.7)	0	0
Ingrowing nail	1 (3.7)	0	1 (3.7)	0	0
Miliaria	1 (3.7)	1 (3.7)	0	0	0
Photosensitivity reaction	1 (3.7)	0	1 (3.7)	0	0
Pruritus	1 (3.7)	0	1 (3.7)	0	0
Rash	1 (3.7)	1 (3.7)	0	0	0
Skin hypopigmentation	1 (3.7)	1 (3.7)	0	0	0
Vascular disorders					
-Total	3 (11.1)	0	0	1 (3.7)	2 (7.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Venoocclusive disease	1 (3.7)	0	0	0	1 (3.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (72.7)	3 (9.1)	7 (21.2)	8 (24.2)	6 (18.2)
Blood and lymphatic system disorders					
-Total	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Agranulocytosis	1 (3.0)	0	0	1 (3.0)	0
Anaemia	1 (3.0)	0	1 (3.0)	0	0
Lymphadenopathy	1 (3.0)	0	1 (3.0)	0	0
Neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	0	1 (3.0)	0	0
Congenital, familial and genetic disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral cavernous malformation	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Deafness unilateral	1 (3.0)	0	1 (3.0)	0	0
Endocrine disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Delayed puberty	1 (3.0)	0	1 (3.0)	0	0
Hypothyroidism	1 (3.0)	0	1 (3.0)	0	0
Eye disorders					
-Total	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Dry eye	1 (3.0)	1 (3.0)	0	0	0
Eye pain	1 (3.0)	0	0	1 (3.0)	0
Eyelid oedema	1 (3.0)	1 (3.0)	0	0	0
Mydriasis	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Diarrhoea	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Nausea	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (3.0)	1 (3.0)	0	0	0
General disorders and administration site conditions					
-Total	7 (21.2)	4 (12.1)	2 (6.1)	1 (3.0)	0
Pyrexia	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Pain	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Fatigue	1 (3.0)	0	1 (3.0)	0	0
Non-cardiac chest pain	1 (3.0)	1 (3.0)	0	0	0
Xerosis	1 (3.0)	1 (3.0)	0	0	0
Immune system disorders					
-Total	5 (15.2)	1 (3.0)	3 (9.1)	1 (3.0)	0
Hypogammaglobulinaemia	2 (6.1)	0	2 (6.1)	0	0
Chronic graft versus host disease	1 (3.0)	0	1 (3.0)	0	0
Drug hypersensitivity	1 (3.0)	0	0	1 (3.0)	0
Seasonal allergy	1 (3.0)	1 (3.0)	0	0	0
Infections and infestations					
-Total	17 (51.5)	2 (6.1)	5 (15.2)	7 (21.2)	3 (9.1)
Sinusitis	4 (12.1)	0	4 (12.1)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Sepsis	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Upper respiratory tract infection	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Fungal infection	2 (6.1)	0	2 (6.1)	0	0
Herpes zoster	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Oral herpes	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Skin infection	2 (6.1)	0	2 (6.1)	0	0
Urinary tract infection	2 (6.1)	0	2 (6.1)	0	0
Acute sinusitis	1 (3.0)	0	1 (3.0)	0	0
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Covid-19	1 (3.0)	0	0	1 (3.0)	0
Device related sepsis	1 (3.0)	0	0	1 (3.0)	0
Ear infection	1 (3.0)	0	0	1 (3.0)	0
Fungal skin infection	1 (3.0)	0	1 (3.0)	0	0
Gastroenteritis	1 (3.0)	1 (3.0)	0	0	0
Herpes virus infection	1 (3.0)	0	1 (3.0)	0	0
Influenza	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (3.0)	0	0	1 (3.0)	0
Neutropenic infection	1 (3.0)	0	0	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	1 (3.0)	0	0
Oral candidiasis	1 (3.0)	0	1 (3.0)	0	0
Otitis media	1 (3.0)	0	1 (3.0)	0	0
Otitis media acute	1 (3.0)	0	1 (3.0)	0	0
Rhinitis	1 (3.0)	1 (3.0)	0	0	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Septic shock	1 (3.0)	0	0	0	1 (3.0)
Staphylococcal abscess	1 (3.0)	0	0	1 (3.0)	0
Streptococcal sepsis	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection pseudomonal	1 (3.0)	0	1 (3.0)	0	0
Varicella zoster virus infection	1 (3.0)	0	1 (3.0)	0	0
Viral skin infection	1 (3.0)	1 (3.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.0)	1 (3.0)	0	0	0
Ligament sprain	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	4 (12.1)	3 (9.1)	0	0	1 (3.0)
Neutrophil count decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Platelet count decreased	2 (6.1)	2 (6.1)	0	0	0
Blood bilirubin increased	1 (3.0)	1 (3.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Decreased appetite	1 (3.0)	0	0	0	1 (3.0)
Hypercholesterolaemia	1 (3.0)	0	1 (3.0)	0	0
Hypernatraemia	1 (3.0)	0	0	1 (3.0)	0
Hypertriglyceridaemia	1 (3.0)	0	1 (3.0)	0	0
Iron overload	1 (3.0)	0	1 (3.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (18.2)	2 (6.1)	4 (12.1)	0	0
Pain in extremity	2 (6.1)	0	2 (6.1)	0	0
Growth retardation	1 (3.0)	0	1 (3.0)	0	0
Joint effusion	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (3.0)	1 (3.0)	0	0	0
Osteopenia	1 (3.0)	1 (3.0)	0	0	0
Synovitis	1 (3.0)	0	1 (3.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.0)	0	0	1 (3.0)	0
Bone giant cell tumour benign	1 (3.0)	0	0	1 (3.0)	0
Nervous system disorders					
-Total	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Dysarthria	1 (3.0)	0	1 (3.0)	0	0
Headache	1 (3.0)	0	0	1 (3.0)	0
Nervous system disorder	1 (3.0)	0	0	1 (3.0)	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Psychiatric disorders					
-Total	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Anxiety	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Tic	1 (3.0)	0	1 (3.0)	0	0
Reproductive system and breast disorders					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.0)	0	0	1 (3.0)	0
Endometriosis	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (21.2)	4 (12.1)	1 (3.0)	0	2 (6.1)
Cough	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Rhinorrhoea	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Dyspnoea	1 (3.0)	1 (3.0)	0	0	0
Dyspnoea exertional	1 (3.0)	1 (3.0)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0
Laryngeal oedema	1 (3.0)	0	0	0	1 (3.0)
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Pharyngeal erythema	1 (3.0)	1 (3.0)	0	0	0
Respiratory failure	1 (3.0)	0	0	0	1 (3.0)
Sleep apnoea syndrome	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.2)	2 (6.1)	0	3 (9.1)	0
Dermatitis atopic	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (3.0)	1 (3.0)	0	0	0
Eczema	1 (3.0)	0	0	1 (3.0)	0
Papule	1 (3.0)	1 (3.0)	0	0	0
Rash macular	1 (3.0)	0	0	1 (3.0)	0
Vascular disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Hypertension	1 (3.0)	0	1 (3.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (47.1)	0	3 (17.6)	4 (23.5)	1 (5.9)
Blood and lymphatic system disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Hypercoagulation	1 (5.9)	0	1 (5.9)	0	0
Gastrointestinal disorders					
-Total	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Constipation	1 (5.9)	1 (5.9)	0	0	0
Diarrhoea	1 (5.9)	1 (5.9)	0	0	0
Irritable bowel syndrome	1 (5.9)	0	1 (5.9)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Pyrexia	2 (11.8)	0	2 (11.8)	0	0
Multiple organ dysfunction syndrome	1 (5.9)	0	0	0	1 (5.9)
Immune system disorders					
-Total	4 (23.5)	1 (5.9)	2 (11.8)	0	1 (5.9)
Seasonal allergy	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Chronic graft versus host disease	1 (5.9)	0	0	1 (5.9)	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	0	0	1 (5.9)
Hypogammaglobulinaemia	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	6 (35.3)	0	2 (11.8)	3 (17.6)	1 (5.9)
Rhinovirus infection	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Pneumonia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Sinusitis	2 (11.8)	0	2 (11.8)	0	0
Upper respiratory tract infection	2 (11.8)	0	2 (11.8)	0	0
Bronchiolitis	1 (5.9)	0	0	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (5.9)	0	1 (5.9)	0	0
Clostridium difficile colitis	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Covid-19	1 (5.9)	1 (5.9)	0	0	0
Covid-19 pneumonia	1 (5.9)	0	0	0	1 (5.9)
Enterovirus infection	1 (5.9)	0	0	1 (5.9)	0
Folliculitis	1 (5.9)	0	1 (5.9)	0	0
Gastroenteritis escherichia coli	1 (5.9)	0	0	1 (5.9)	0
Gastroenteritis salmonella	1 (5.9)	0	0	1 (5.9)	0
Gastroenteritis viral	1 (5.9)	0	1 (5.9)	0	0
Influenza	1 (5.9)	0	0	0	1 (5.9)
Nail infection	1 (5.9)	0	1 (5.9)	0	0
Otitis media	1 (5.9)	0	1 (5.9)	0	0
Parainfluenzae virus infection	1 (5.9)	0	0	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	0	0	1 (5.9)	0
Skin infection	1 (5.9)	0	1 (5.9)	0	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Syphilis	1 (5.9)	0	1 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Abdominal injury	1 (5.9)	1 (5.9)	0	0	0
Infusion related reaction	1 (5.9)	0	0	1 (5.9)	0
Investigations					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Blood immunoglobulin g decreased	1 (5.9)	0	1 (5.9)	0	0
Oxygen saturation decreased	1 (5.9)	0	0	1 (5.9)	0
Metabolism and nutrition disorders					
-Total	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Hyperglycaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperlipidaemia	1 (5.9)	0	1 (5.9)	0	0
Obesity	1 (5.9)	0	0	1 (5.9)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Arthralgia	1 (5.9)	0	1 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Headache	1 (5.9)	0	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (17.6)	0	1 (5.9)	1 (5.9)	1 (5.9)
Dyspnoea	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Cough	1 (5.9)	1 (5.9)	0	0	0
Hypoxia	1 (5.9)	0	0	1 (5.9)	0
Pleural effusion	1 (5.9)	0	1 (5.9)	0	0
Rhinorrhoea	1 (5.9)	0	1 (5.9)	0	0
Sleep apnoea syndrome	1 (5.9)	0	1 (5.9)	0	0
Tachypnoea	1 (5.9)	0	0	0	1 (5.9)
Wheezing	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Rash	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Rash erythematous	1 (5.9)	1 (5.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (5.9)	1 (5.9)	0	0	0
Vascular disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Hypertension	1 (5.9)	0	0	1 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (100)	1 (2.1)	3 (6.3)	13 (27.1)	31 (64.6)
Blood and lymphatic system disorders					
-Total	32 (66.7)	1 (2.1)	6 (12.5)	19 (39.6)	6 (12.5)
Anaemia	16 (33.3)	4 (8.3)	5 (10.4)	7 (14.6)	0
Febrile neutropenia	15 (31.3)	0	0	15 (31.3)	0
Neutropenia	7 (14.6)	0	1 (2.1)	2 (4.2)	4 (8.3)
Thrombocytopenia	5 (10.4)	0	0	2 (4.2)	3 (6.3)
Disseminated intravascular coagulation	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Leukopenia	3 (6.3)	0	1 (2.1)	1 (2.1)	1 (2.1)
Coagulopathy	2 (4.2)	1 (2.1)	0	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (4.2)	0	0	2 (4.2)	0
Pancytopenia	2 (4.2)	0	0	2 (4.2)	0
Splenomegaly	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Agranulocytosis	1 (2.1)	0	0	1 (2.1)	0
B-cell aplasia	1 (2.1)	0	1 (2.1)	0	0
Eosinophilia	1 (2.1)	0	1 (2.1)	0	0
Leukocytosis	1 (2.1)	0	1 (2.1)	0	0
Lymphadenopathy	1 (2.1)	0	1 (2.1)	0	0
Cardiac disorders					
-Total	12 (25.0)	5 (10.4)	3 (6.3)	3 (6.3)	1 (2.1)
Tachycardia	7 (14.6)	4 (8.3)	2 (4.2)	1 (2.1)	0
Left ventricular dysfunction	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Bradycardia	1 (2.1)	1 (2.1)	0	0	0
Cardiac arrest	1 (2.1)	0	0	0	1 (2.1)
Cardiac dysfunction	1 (2.1)	1 (2.1)	0	0	0
Cardiac failure congestive	1 (2.1)	0	1 (2.1)	0	0
Mitral valve incompetence	1 (2.1)	1 (2.1)	0	0	0
Pericardial effusion	1 (2.1)	1 (2.1)	0	0	0
Right ventricular dysfunction	1 (2.1)	1 (2.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (2.1)	0	1 (2.1)	0	0
Tricuspid valve incompetence	1 (2.1)	1 (2.1)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.1)	1 (2.1)	0	0	0
Cerebral cavernous malformation	1 (2.1)	1 (2.1)	0	0	0
Ear and labyrinth disorders					
-Total	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Deafness unilateral	1 (2.1)	0	1 (2.1)	0	0
Ear pain	1 (2.1)	1 (2.1)	0	0	0
Endocrine disorders					
-Total	3 (6.3)	0	3 (6.3)	0	0
Hypothyroidism	2 (4.2)	0	2 (4.2)	0	0
Adrenal insufficiency	1 (2.1)	0	1 (2.1)	0	0
Delayed puberty	1 (2.1)	0	1 (2.1)	0	0
Eye disorders					
-Total	10 (20.8)	5 (10.4)	4 (8.3)	1 (2.1)	0
Cataract	2 (4.2)	2 (4.2)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Eyelid oedema	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Dry eye	1 (2.1)	1 (2.1)	0	0	0
Eye oedema	1 (2.1)	1 (2.1)	0	0	0
Hypermetropia	1 (2.1)	1 (2.1)	0	0	0
Mydriasis	1 (2.1)	0	1 (2.1)	0	0
Ocular hyperaemia	1 (2.1)	1 (2.1)	0	0	0
Periorbital swelling	1 (2.1)	0	1 (2.1)	0	0
Retinal haemorrhage	1 (2.1)	0	1 (2.1)	0	0
Visual field defect	1 (2.1)	0	1 (2.1)	0	0
Visual impairment	1 (2.1)	1 (2.1)	0	0	0
Gastrointestinal disorders					
-Total	39 (81.3)	15 (31.3)	15 (31.3)	9 (18.8)	0
Diarrhoea	19 (39.6)	11 (22.9)	6 (12.5)	2 (4.2)	0
Vomiting	17 (35.4)	10 (20.8)	7 (14.6)	0	0
Nausea	15 (31.3)	10 (20.8)	4 (8.3)	1 (2.1)	0
Abdominal pain	9 (18.8)	2 (4.2)	5 (10.4)	2 (4.2)	0
Constipation	8 (16.7)	4 (8.3)	4 (8.3)	0	0
Abdominal pain upper	4 (8.3)	3 (6.3)	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	3 (6.3)	2 (4.2)	0	1 (2.1)	0
Pancreatitis	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Abdominal distension	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Ascites	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Gastrointestinal sounds abnormal	2 (4.2)	2 (4.2)	0	0	0
Proctalgia	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Stomatitis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Trichoglossia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Abdominal rigidity	1 (2.1)	0	1 (2.1)	0	0
Anal haemorrhage	1 (2.1)	1 (2.1)	0	0	0
Dyspepsia	1 (2.1)	1 (2.1)	0	0	0
Enteritis	1 (2.1)	0	1 (2.1)	0	0
Enterocolitis	1 (2.1)	0	1 (2.1)	0	0
Gastrooesophageal reflux disease	1 (2.1)	0	1 (2.1)	0	0
Gingival bleeding	1 (2.1)	0	1 (2.1)	0	0
Gingivitis ulcerative	1 (2.1)	0	0	1 (2.1)	0
Haematemesis	1 (2.1)	1 (2.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip dry	1 (2.1)	0	1 (2.1)	0	0
Lip oedema	1 (2.1)	1 (2.1)	0	0	0
Mouth swelling	1 (2.1)	1 (2.1)	0	0	0
Neutropenic colitis	1 (2.1)	0	0	1 (2.1)	0
Odynophagia	1 (2.1)	1 (2.1)	0	0	0
Peritoneal haematoma	1 (2.1)	1 (2.1)	0	0	0
Upper gastrointestinal haemorrhage	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	29 (60.4)	18 (37.5)	5 (10.4)	5 (10.4)	1 (2.1)
Pyrexia	18 (37.5)	9 (18.8)	3 (6.3)	5 (10.4)	1 (2.1)
Fatigue	10 (20.8)	9 (18.8)	1 (2.1)	0	0
Chills	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Face oedema	4 (8.3)	3 (6.3)	1 (2.1)	0	0
Pain	4 (8.3)	1 (2.1)	1 (2.1)	2 (4.2)	0
Asthenia	3 (6.3)	3 (6.3)	0	0	0
Generalised oedema	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Influenza like illness	2 (4.2)	1 (2.1)	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	2 (4.2)	2 (4.2)	0	0	0
Oedema peripheral	2 (4.2)	2 (4.2)	0	0	0
Catheter site erythema	1 (2.1)	1 (2.1)	0	0	0
Catheter site pain	1 (2.1)	0	0	1 (2.1)	0
Chest discomfort	1 (2.1)	0	0	1 (2.1)	0
Crying	1 (2.1)	0	1 (2.1)	0	0
Facial pain	1 (2.1)	0	1 (2.1)	0	0
Localised oedema	1 (2.1)	1 (2.1)	0	0	0
Malaise	1 (2.1)	0	1 (2.1)	0	0
Oedema due to hepatic disease	1 (2.1)	0	1 (2.1)	0	0
Sluggishness	1 (2.1)	0	1 (2.1)	0	0
Swelling face	1 (2.1)	1 (2.1)	0	0	0
Vascular device occlusion	1 (2.1)	1 (2.1)	0	0	0
Xerosis	1 (2.1)	1 (2.1)	0	0	0
Hepatobiliary disorders					
-Total	9 (18.8)	4 (8.3)	3 (6.3)	1 (2.1)	1 (2.1)
Hepatic function abnormal	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Hepatomegaly	2 (4.2)	2 (4.2)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Cholelithiasis	1 (2.1)	0	1 (2.1)	0	0
Hepatic cytolysis	1 (2.1)	1 (2.1)	0	0	0
Liver disorder	1 (2.1)	0	1 (2.1)	0	0
Immune system disorders					
-Total	44 (91.7)	1 (2.1)	15 (31.3)	17 (35.4)	11 (22.9)
Cytokine release syndrome	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)
Hypogammaglobulinaemia	22 (45.8)	0	17 (35.4)	5 (10.4)	0
Drug hypersensitivity	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Graft versus host disease	2 (4.2)	0	0	2 (4.2)	0
Haemophagocytic lymphohistiocytosis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Immunodeficiency	2 (4.2)	0	0	2 (4.2)	0
Allergy to immunoglobulin therapy	1 (2.1)	1 (2.1)	0	0	0
Chronic graft versus host disease	1 (2.1)	0	1 (2.1)	0	0
Engraftment syndrome	1 (2.1)	0	0	1 (2.1)	0
Hypersensitivity	1 (2.1)	1 (2.1)	0	0	0
Seasonal allergy	1 (2.1)	1 (2.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	39 (81.3)	4 (8.3)	7 (14.6)	18 (37.5)	10 (20.8)
Upper respiratory tract infection	7 (14.6)	3 (6.3)	1 (2.1)	3 (6.3)	0
Conjunctivitis	6 (12.5)	2 (4.2)	4 (8.3)	0	0
Gastroenteritis	5 (10.4)	3 (6.3)	0	2 (4.2)	0
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Rhinovirus infection	5 (10.4)	0	4 (8.3)	1 (2.1)	0
Sinusitis	5 (10.4)	0	3 (6.3)	2 (4.2)	0
Oral herpes	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Candida infection	3 (6.3)	0	2 (4.2)	0	1 (2.1)
Metapneumovirus infection	3 (6.3)	0	0	3 (6.3)	0
Oral candidiasis	3 (6.3)	0	3 (6.3)	0	0
Otitis media	3 (6.3)	0	2 (4.2)	1 (2.1)	0
Pneumonia	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Respiratory syncytial virus infection	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Rhinitis	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Sepsis	3 (6.3)	0	0	1 (2.1)	2 (4.2)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	3 (6.3)	0	2 (4.2)	1 (2.1)	0
Bronchopulmonary aspergillosis	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Fungal infection	2 (4.2)	0	2 (4.2)	0	0
Gingivitis	2 (4.2)	2 (4.2)	0	0	0
Herpes zoster	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Human herpesvirus 6 infection	2 (4.2)	0	0	2 (4.2)	0
Influenza	2 (4.2)	0	2 (4.2)	0	0
Nail infection	2 (4.2)	2 (4.2)	0	0	0
Oral infection	2 (4.2)	0	2 (4.2)	0	0
Otitis externa	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Parainfluenzae virus infection	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Paronychia	2 (4.2)	0	2 (4.2)	0	0
Pneumocystis jirovecii pneumonia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Respiratory tract infection	2 (4.2)	0	2 (4.2)	0	0
Septic shock	2 (4.2)	0	0	0	2 (4.2)
Skin infection	2 (4.2)	0	2 (4.2)	0	0
Staphylococcal infection	2 (4.2)	0	0	2 (4.2)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Viral infection	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Acute sinusitis	1 (2.1)	0	1 (2.1)	0	0
Adenovirus infection	1 (2.1)	0	0	1 (2.1)	0
Anal abscess	1 (2.1)	0	0	1 (2.1)	0
Bacteraemia	1 (2.1)	0	0	0	1 (2.1)
Bk virus infection	1 (2.1)	1 (2.1)	0	0	0
Bronchitis	1 (2.1)	0	1 (2.1)	0	0
Cholecystitis infective	1 (2.1)	0	1 (2.1)	0	0
Clostridium difficile infection	1 (2.1)	0	0	1 (2.1)	0
Coronavirus infection	1 (2.1)	0	0	1 (2.1)	0
Covid-19	1 (2.1)	0	0	1 (2.1)	0
Cystitis	1 (2.1)	0	1 (2.1)	0	0
Cytomegalovirus infection reactivation	1 (2.1)	0	0	1 (2.1)	0
Device related infection	1 (2.1)	0	0	1 (2.1)	0
Device related sepsis	1 (2.1)	0	0	1 (2.1)	0
Ear infection	1 (2.1)	0	0	1 (2.1)	0
Ear, nose and throat infection	1 (2.1)	0	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.1)	0	0	0	1 (2.1)
Encephalitis viral	1 (2.1)	0	0	1 (2.1)	0
Enterobacter infection	1 (2.1)	0	0	1 (2.1)	0
Fungal skin infection	1 (2.1)	0	1 (2.1)	0	0
Gastroenteritis norovirus	1 (2.1)	1 (2.1)	0	0	0
Gastroenteritis viral	1 (2.1)	1 (2.1)	0	0	0
Granulicatella infection	1 (2.1)	0	0	1 (2.1)	0
Herpes simplex	1 (2.1)	0	0	1 (2.1)	0
Herpes virus infection	1 (2.1)	0	1 (2.1)	0	0
Klebsiella infection	1 (2.1)	0	0	1 (2.1)	0
Mastoiditis	1 (2.1)	0	0	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	0	0	1 (2.1)	0
Myringitis	1 (2.1)	1 (2.1)	0	0	0
Neutropenic infection	1 (2.1)	0	0	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	1 (2.1)	0	0
Otitis media acute	1 (2.1)	0	1 (2.1)	0	0
Pneumonia fungal	1 (2.1)	0	0	1 (2.1)	0
Pneumonia viral	1 (2.1)	0	0	1 (2.1)	0
Respiratory tract infection viral	1 (2.1)	0	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (2.1)	0	1 (2.1)	0	0
Soft tissue infection	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal abscess	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal sepsis	1 (2.1)	0	0	0	1 (2.1)
Staphylococcal skin infection	1 (2.1)	0	1 (2.1)	0	0
Stomatococcal infection	1 (2.1)	0	1 (2.1)	0	0
Streptococcal sepsis	1 (2.1)	0	1 (2.1)	0	0
Systemic candida	1 (2.1)	0	0	1 (2.1)	0
Tinea pedis	1 (2.1)	1 (2.1)	0	0	0
Urinary tract infection pseudomonal	1 (2.1)	0	1 (2.1)	0	0
Viral haemorrhagic cystitis	1 (2.1)	0	0	1 (2.1)	0
Viral skin infection	1 (2.1)	1 (2.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	11 (22.9)	7 (14.6)	3 (6.3)	0	1 (2.1)
Infusion related reaction	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Fall	2 (4.2)	0	2 (4.2)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ligament sprain	2 (4.2)	2 (4.2)	0	0	0
Contusion	1 (2.1)	1 (2.1)	0	0	0
Limb injury	1 (2.1)	0	1 (2.1)	0	0
Procedural pain	1 (2.1)	1 (2.1)	0	0	0
Skin abrasion	1 (2.1)	1 (2.1)	0	0	0
Transfusion reaction	1 (2.1)	1 (2.1)	0	0	0
Transplant failure	1 (2.1)	0	0	0	1 (2.1)
Investigations					
-Total	37 (77.1)	3 (6.3)	7 (14.6)	10 (20.8)	17 (35.4)
Neutrophil count decreased	16 (33.3)	1 (2.1)	1 (2.1)	2 (4.2)	12 (25.0)
Platelet count decreased	16 (33.3)	4 (8.3)	1 (2.1)	6 (12.5)	5 (10.4)
White blood cell count decreased	14 (29.2)	3 (6.3)	1 (2.1)	1 (2.1)	9 (18.8)
Alanine aminotransferase increased	13 (27.1)	2 (4.2)	6 (12.5)	5 (10.4)	0
Lymphocyte count decreased	11 (22.9)	1 (2.1)	0	5 (10.4)	5 (10.4)
Aspartate aminotransferase increased	10 (20.8)	2 (4.2)	4 (8.3)	2 (4.2)	2 (4.2)
Blood bilirubin increased	6 (12.5)	0	2 (4.2)	4 (8.3)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	6 (12.5)	5 (10.4)	0	1 (2.1)	0
Blood immunoglobulin m decreased	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Blood fibrinogen decreased	4 (8.3)	2 (4.2)	1 (2.1)	0	1 (2.1)
Serum ferritin increased	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Activated partial thromboplastin time prolonged	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Blood lactate dehydrogenase increased	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Blood uric acid increased	3 (6.3)	1 (2.1)	0	1 (2.1)	1 (2.1)
C-reactive protein increased	3 (6.3)	1 (2.1)	0	2 (4.2)	0
International normalised ratio increased	3 (6.3)	3 (6.3)	0	0	0
Blood creatinine increased	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Immunoglobulins decreased	2 (4.2)	0	2 (4.2)	0	0
Weight decreased	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Weight increased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood creatine phosphokinase increased	1 (2.1)	0	0	1 (2.1)	0
Blood glucose increased	1 (2.1)	0	0	0	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood testosterone decreased	1 (2.1)	1 (2.1)	0	0	0
Blood urea increased	1 (2.1)	0	0	1 (2.1)	0
Bone density decreased	1 (2.1)	1 (2.1)	0	0	0
Breath sounds abnormal	1 (2.1)	0	1 (2.1)	0	0
Coagulation test abnormal	1 (2.1)	1 (2.1)	0	0	0
Electrocardiogram qt prolonged	1 (2.1)	0	0	1 (2.1)	0
Enterovirus test positive	1 (2.1)	0	1 (2.1)	0	0
Fibrin d dimer increased	1 (2.1)	1 (2.1)	0	0	0
Gamma-glutamyltransferase increased	1 (2.1)	0	0	1 (2.1)	0
Haemoglobin decreased	1 (2.1)	0	0	1 (2.1)	0
Hepatitis b virus test positive	1 (2.1)	0	1 (2.1)	0	0
Oxygen saturation decreased	1 (2.1)	0	1 (2.1)	0	0
Prothrombin time prolonged	1 (2.1)	0	1 (2.1)	0	0
Metabolism and nutrition disorders					
-Total	30 (62.5)	7 (14.6)	5 (10.4)	13 (27.1)	5 (10.4)
Decreased appetite	18 (37.5)	8 (16.7)	2 (4.2)	6 (12.5)	2 (4.2)
Hypokalaemia	12 (25.0)	2 (4.2)	3 (6.3)	6 (12.5)	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	11 (22.9)	3 (6.3)	3 (6.3)	4 (8.3)	1 (2.1)
Hypocalcaemia	6 (12.5)	2 (4.2)	2 (4.2)	2 (4.2)	0
Hypoalbuminaemia	5 (10.4)	0	5 (10.4)	0	0
Hyperglycaemia	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Hyperuricaemia	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Hypomagnesaemia	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Tumour lysis syndrome	3 (6.3)	0	0	2 (4.2)	1 (2.1)
Hypernatraemia	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Hypertriglyceridaemia	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Hypervolaemia	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Iron overload	2 (4.2)	0	2 (4.2)	0	0
Malnutrition	2 (4.2)	0	0	2 (4.2)	0
Haemochromatosis	1 (2.1)	0	0	1 (2.1)	0
Hyperchloraemia	1 (2.1)	1 (2.1)	0	0	0
Hypercholesterolaemia	1 (2.1)	0	1 (2.1)	0	0
Hyperkalaemia	1 (2.1)	0	1 (2.1)	0	0
Hypermagnesaemia	1 (2.1)	1 (2.1)	0	0	0
Hyponatraemia	1 (2.1)	1 (2.1)	0	0	0
Hypophagia	1 (2.1)	0	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Polydipsia	1 (2.1)	0	0	1 (2.1)	0
Musculoskeletal and connective tissue disorders					
-Total	28 (58.3)	11 (22.9)	13 (27.1)	4 (8.3)	0
Pain in extremity	13 (27.1)	6 (12.5)	6 (12.5)	1 (2.1)	0
Arthralgia	9 (18.8)	5 (10.4)	4 (8.3)	0	0
Back pain	8 (16.7)	2 (4.2)	4 (8.3)	2 (4.2)	0
Myalgia	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Bone pain	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Growth retardation	2 (4.2)	0	2 (4.2)	0	0
Musculoskeletal chest pain	2 (4.2)	2 (4.2)	0	0	0
Pain in jaw	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Joint effusion	1 (2.1)	0	1 (2.1)	0	0
Musculoskeletal pain	1 (2.1)	0	1 (2.1)	0	0
Neck pain	1 (2.1)	0	1 (2.1)	0	0
Osteonecrosis	1 (2.1)	1 (2.1)	0	0	0
Osteopenia	1 (2.1)	1 (2.1)	0	0	0
Synovitis	1 (2.1)	0	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (8.3)	1 (2.1)	1 (2.1)	2 (4.2)	0
Skin papilloma	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Bone giant cell tumour benign	1 (2.1)	0	0	1 (2.1)	0
Myelodysplastic syndrome	1 (2.1)	0	0	1 (2.1)	0
Nervous system disorders					
-Total	26 (54.2)	9 (18.8)	9 (18.8)	6 (12.5)	2 (4.2)
Headache	15 (31.3)	8 (16.7)	4 (8.3)	3 (6.3)	0
Dizziness	4 (8.3)	4 (8.3)	0	0	0
Encephalopathy	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Seizure	3 (6.3)	0	0	3 (6.3)	0
Tremor	3 (6.3)	3 (6.3)	0	0	0
Dysgeusia	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Lethargy	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Somnolence	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Amnesia	1 (2.1)	0	1 (2.1)	0	0
Aphasia	1 (2.1)	1 (2.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Autonomic neuropathy	1 (2.1)	0	0	1 (2.1)	0
Cerebral haemorrhage	1 (2.1)	0	0	0	1 (2.1)
Cognitive disorder	1 (2.1)	0	1 (2.1)	0	0
Depressed level of consciousness	1 (2.1)	0	0	1 (2.1)	0
Disturbance in attention	1 (2.1)	1 (2.1)	0	0	0
Dysarthria	1 (2.1)	0	1 (2.1)	0	0
Hydrocephalus	1 (2.1)	0	0	0	1 (2.1)
Hyperaesthesia	1 (2.1)	1 (2.1)	0	0	0
Hypoaesthesia	1 (2.1)	1 (2.1)	0	0	0
Memory impairment	1 (2.1)	0	1 (2.1)	0	0
Nervous system disorder	1 (2.1)	0	0	1 (2.1)	0
Neuralgia	1 (2.1)	0	1 (2.1)	0	0
Psychiatric disorders					
-Total	24 (50.0)	8 (16.7)	14 (29.2)	2 (4.2)	0
Anxiety	10 (20.8)	3 (6.3)	6 (12.5)	1 (2.1)	0
Confusional state	4 (8.3)	4 (8.3)	0	0	0
Agitation	3 (6.3)	3 (6.3)	0	0	0
Delirium	3 (6.3)	1 (2.1)	2 (4.2)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Insomnia	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Irritability	2 (4.2)	2 (4.2)	0	0	0
Mental status changes	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Sleep disorder	2 (4.2)	0	2 (4.2)	0	0
Affect lability	1 (2.1)	0	1 (2.1)	0	0
Hallucination, visual	1 (2.1)	0	1 (2.1)	0	0
Mood altered	1 (2.1)	1 (2.1)	0	0	0
Nightmare	1 (2.1)	1 (2.1)	0	0	0
Restlessness	1 (2.1)	0	1 (2.1)	0	0
Social avoidant behaviour	1 (2.1)	0	1 (2.1)	0	0
Tearfulness	1 (2.1)	1 (2.1)	0	0	0
Tic	1 (2.1)	0	1 (2.1)	0	0
Renal and urinary disorders					
-Total	14 (29.2)	5 (10.4)	5 (10.4)	1 (2.1)	3 (6.3)
Acute kidney injury	5 (10.4)	2 (4.2)	1 (2.1)	0	2 (4.2)
Dysuria	2 (4.2)	2 (4.2)	0	0	0
Haematuria	2 (4.2)	2 (4.2)	0	0	0
Anuria	1 (2.1)	0	0	0	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (2.1)	0	1 (2.1)	0	0
Incontinence	1 (2.1)	0	1 (2.1)	0	0
Pollakiuria	1 (2.1)	0	1 (2.1)	0	0
Proteinuria	1 (2.1)	1 (2.1)	0	0	0
Renal failure	1 (2.1)	0	1 (2.1)	0	0
Renal tubular disorder	1 (2.1)	0	0	1 (2.1)	0
Renal tubular dysfunction	1 (2.1)	1 (2.1)	0	0	0
Urinary incontinence	1 (2.1)	0	1 (2.1)	0	0
Urinary tract disorder	1 (2.1)	0	1 (2.1)	0	0
Reproductive system and breast disorders					
-Total	4 (8.3)	2 (4.2)	1 (2.1)	1 (2.1)	0
Endometriosis	1 (2.1)	0	0	1 (2.1)	0
Female genital tract fistula	1 (2.1)	1 (2.1)	0	0	0
Heavy menstrual bleeding	1 (2.1)	1 (2.1)	0	0	0
Vaginal haemorrhage	1 (2.1)	0	1 (2.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (75.0)	16 (33.3)	6 (12.5)	7 (14.6)	7 (14.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	17 (35.4)	13 (27.1)	4 (8.3)	0	0
Hypoxia	10 (20.8)	0	3 (6.3)	4 (8.3)	3 (6.3)
Nasal congestion	6 (12.5)	5 (10.4)	1 (2.1)	0	0
Pulmonary oedema	6 (12.5)	2 (4.2)	0	4 (8.3)	0
Epistaxis	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Pleural effusion	5 (10.4)	3 (6.3)	1 (2.1)	0	1 (2.1)
Rhinorrhoea	5 (10.4)	4 (8.3)	1 (2.1)	0	0
Tachypnoea	5 (10.4)	3 (6.3)	1 (2.1)	1 (2.1)	0
Dyspnoea	4 (8.3)	1 (2.1)	1 (2.1)	2 (4.2)	0
Oropharyngeal pain	4 (8.3)	4 (8.3)	0	0	0
Atelectasis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Pharyngeal erythema	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Respiratory distress	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Acute respiratory distress syndrome	1 (2.1)	0	0	0	1 (2.1)
Bradypnoea	1 (2.1)	0	0	1 (2.1)	0
Bronchial oedema	1 (2.1)	1 (2.1)	0	0	0
Dyspnoea exertional	1 (2.1)	1 (2.1)	0	0	0
Laryngeal oedema	1 (2.1)	0	0	0	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lung disorder	1 (2.1)	1 (2.1)	0	0	0
Lung infiltration	1 (2.1)	0	0	1 (2.1)	0
Nasal dryness	1 (2.1)	1 (2.1)	0	0	0
Oropharyngeal plaque	1 (2.1)	0	1 (2.1)	0	0
Painful respiration	1 (2.1)	1 (2.1)	0	0	0
Paranasal sinus discomfort	1 (2.1)	0	1 (2.1)	0	0
Paranasal sinus inflammation	1 (2.1)	1 (2.1)	0	0	0
Pharyngeal exudate	1 (2.1)	0	1 (2.1)	0	0
Pharyngeal oedema	1 (2.1)	0	1 (2.1)	0	0
Productive cough	1 (2.1)	1 (2.1)	0	0	0
Pulmonary mass	1 (2.1)	0	1 (2.1)	0	0
Respiratory disorder	1 (2.1)	0	1 (2.1)	0	0
Respiratory failure	1 (2.1)	0	0	0	1 (2.1)
Rhinitis allergic	1 (2.1)	1 (2.1)	0	0	0
Sleep apnoea syndrome	1 (2.1)	1 (2.1)	0	0	0
Wheezing	1 (2.1)	0	1 (2.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	24 (50.0)	10 (20.8)	8 (16.7)	6 (12.5)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Rash	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Dermatitis atopic	3 (6.3)	2 (4.2)	0	1 (2.1)	0
Pruritus	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rash papular	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Eczema	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Erythema	2 (4.2)	2 (4.2)	0	0	0
Rash maculo-papular	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Blister	1 (2.1)	1 (2.1)	0	0	0
Decubitus ulcer	1 (2.1)	0	0	1 (2.1)	0
Dermatitis allergic	1 (2.1)	1 (2.1)	0	0	0
Erythema nodosum	1 (2.1)	1 (2.1)	0	0	0
Hangnail	1 (2.1)	1 (2.1)	0	0	0
Hyperhidrosis	1 (2.1)	0	1 (2.1)	0	0
Ingrowing nail	1 (2.1)	0	1 (2.1)	0	0
Night sweats	1 (2.1)	1 (2.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.1)	1 (2.1)	0	0	0
Papule	1 (2.1)	1 (2.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus allergic	1 (2.1)	0	1 (2.1)	0	0
Purpura	1 (2.1)	1 (2.1)	0	0	0
Rash macular	1 (2.1)	0	0	1 (2.1)	0
Rash pruritic	1 (2.1)	1 (2.1)	0	0	0
Rash vesicular	1 (2.1)	1 (2.1)	0	0	0
Skin discolouration	1 (2.1)	1 (2.1)	0	0	0
Skin lesion	1 (2.1)	0	1 (2.1)	0	0
Skin swelling	1 (2.1)	1 (2.1)	0	0	0
Skin ulcer	1 (2.1)	0	1 (2.1)	0	0
Urticaria	1 (2.1)	0	1 (2.1)	0	0
Vancomycin infusion reaction	1 (2.1)	0	0	1 (2.1)	0
Social circumstances					
-Total	1 (2.1)	0	1 (2.1)	0	0
Patient uncooperative	1 (2.1)	0	1 (2.1)	0	0
Vascular disorders					
-Total	17 (35.4)	5 (10.4)	5 (10.4)	4 (8.3)	3 (6.3)
Hypotension	10 (20.8)	2 (4.2)	3 (6.3)	2 (4.2)	3 (6.3)
Hypertension	8 (16.7)	3 (6.3)	4 (8.3)	1 (2.1)	0
Capillary leak syndrome	2 (4.2)	0	1 (2.1)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flushing	1 (2.1)	1 (2.1)	0	0	0
Hot flush	1 (2.1)	1 (2.1)	0	0	0
Venoocclusive disease	1 (2.1)	0	0	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	3 (9.4)	6 (18.8)	23 (71.9)
Blood and lymphatic system disorders					
-Total	23 (71.9)	0	5 (15.6)	10 (31.3)	8 (25.0)
Febrile neutropenia	12 (37.5)	0	0	10 (31.3)	2 (6.3)
Anaemia	9 (28.1)	3 (9.4)	4 (12.5)	2 (6.3)	0
Disseminated intravascular coagulation	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Neutropenia	4 (12.5)	0	1 (3.1)	0	3 (9.4)
Thrombocytopenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Coagulopathy	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Splenomegaly	2 (6.3)	2 (6.3)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercoagulation	1 (3.1)	0	1 (3.1)	0	0
Hypofibrinogenaemia	1 (3.1)	0	1 (3.1)	0	0
Lymphadenopathy	1 (3.1)	1 (3.1)	0	0	0
Lymphocytosis	1 (3.1)	0	1 (3.1)	0	0
Cardiac disorders					
-Total	16 (50.0)	5 (15.6)	4 (12.5)	2 (6.3)	5 (15.6)
Tachycardia	10 (31.3)	3 (9.4)	5 (15.6)	1 (3.1)	1 (3.1)
Cardiac failure	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Bradycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Cardiac arrest	2 (6.3)	0	0	0	2 (6.3)
Sinus tachycardia	2 (6.3)	2 (6.3)	0	0	0
Atrioventricular block first degree	1 (3.1)	0	1 (3.1)	0	0
Cardiac dysfunction	1 (3.1)	1 (3.1)	0	0	0
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Sinus bradycardia	1 (3.1)	0	0	1 (3.1)	0
Ear and labyrinth disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Ear pruritus	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	4 (12.5)	0	4 (12.5)	0	0
Adrenal insufficiency	3 (9.4)	0	3 (9.4)	0	0
Hypothyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	5 (15.6)	5 (15.6)	0	0	0
Conjunctival haemorrhage	2 (6.3)	2 (6.3)	0	0	0
Ocular hyperaemia	2 (6.3)	2 (6.3)	0	0	0
Eyelid oedema	1 (3.1)	1 (3.1)	0	0	0
Periorbital oedema	1 (3.1)	1 (3.1)	0	0	0
Visual impairment	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	21 (65.6)	6 (18.8)	8 (25.0)	6 (18.8)	1 (3.1)
Vomiting	9 (28.1)	7 (21.9)	1 (3.1)	1 (3.1)	0
Diarrhoea	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Nausea	7 (21.9)	2 (6.3)	4 (12.5)	1 (3.1)	0
Constipation	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Pancreatitis	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Abdominal pain	2 (6.3)	0	2 (6.3)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Abdominal compartment syndrome	1 (3.1)	0	0	0	1 (3.1)
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Anal fissure	1 (3.1)	0	1 (3.1)	0	0
Ascites	1 (3.1)	1 (3.1)	0	0	0
Dry mouth	1 (3.1)	0	1 (3.1)	0	0
Dysphagia	1 (3.1)	0	0	1 (3.1)	0
Gastrointestinal haemorrhage	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal inflammation	1 (3.1)	0	1 (3.1)	0	0
Gingival erythema	1 (3.1)	1 (3.1)	0	0	0
Ileus	1 (3.1)	0	1 (3.1)	0	0
Irritable bowel syndrome	1 (3.1)	0	1 (3.1)	0	0
Melaena	1 (3.1)	0	0	1 (3.1)	0
Stomatitis	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	24 (75.0)	7 (21.9)	8 (25.0)	5 (15.6)	4 (12.5)
Pyrexia	17 (53.1)	5 (15.6)	7 (21.9)	4 (12.5)	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Oedema peripheral	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Face oedema	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Generalised oedema	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Multiple organ dysfunction syndrome	3 (9.4)	0	0	0	3 (9.4)
Chills	2 (6.3)	2 (6.3)	0	0	0
Drug withdrawal syndrome	2 (6.3)	0	2 (6.3)	0	0
Catheter site haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Catheter site pain	1 (3.1)	1 (3.1)	0	0	0
Localised oedema	1 (3.1)	1 (3.1)	0	0	0
Malaise	1 (3.1)	1 (3.1)	0	0	0
Pain	1 (3.1)	0	1 (3.1)	0	0
Systemic inflammatory response syndrome	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	10 (31.3)	2 (6.3)	4 (12.5)	2 (6.3)	2 (6.3)
Hepatic function abnormal	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Hyperbilirubinaemia	3 (9.4)	0	2 (6.3)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gallbladder enlargement	2 (6.3)	2 (6.3)	0	0	0
Hypertransaminasaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Biliary tract disorder	1 (3.1)	1 (3.1)	0	0	0
Cholelithiasis	1 (3.1)	1 (3.1)	0	0	0
Cholestasis	1 (3.1)	0	0	0	1 (3.1)
Hepatomegaly	1 (3.1)	0	0	0	1 (3.1)
Ocular icterus	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	27 (84.4)	1 (3.1)	8 (25.0)	7 (21.9)	11 (34.4)
Cytokine release syndrome	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)
Hypogammaglobulinaemia	11 (34.4)	2 (6.3)	7 (21.9)	2 (6.3)	0
Haemophagocytic lymphohistiocytosis	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
Seasonal allergy	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Immunodeficiency	2 (6.3)	0	0	2 (6.3)	0
Allergy to immunoglobulin therapy	1 (3.1)	0	0	1 (3.1)	0
Chronic graft versus host disease	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Selective igg subclass deficiency	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	21 (65.6)	4 (12.5)	6 (18.8)	7 (21.9)	4 (12.5)
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Rhinovirus infection	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Staphylococcal bacteraemia	4 (12.5)	0	0	4 (12.5)	0
Clostridium difficile infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Parainfluenzae virus infection	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Pneumonia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Staphylococcal infection	3 (9.4)	0	3 (9.4)	0	0
Bacteraemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Ear infection	2 (6.3)	0	2 (6.3)	0	0
Nail infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Otitis media	2 (6.3)	0	2 (6.3)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Adenovirus infection	1 (3.1)	0	0	1 (3.1)	0
Atypical pneumonia	1 (3.1)	1 (3.1)	0	0	0
Bk virus infection	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Cellulitis	1 (3.1)	0	1 (3.1)	0	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Covid-19	1 (3.1)	1 (3.1)	0	0	0
Covid-19 pneumonia	1 (3.1)	0	0	0	1 (3.1)
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	0	1 (3.1)
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis clostridial	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis escherichia coli	1 (3.1)	0	0	1 (3.1)	0
Gastroenteritis salmonella	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal infection	1 (3.1)	1 (3.1)	0	0	0
Herpes simplex	1 (3.1)	0	1 (3.1)	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Influenza	1 (3.1)	0	0	0	1 (3.1)
Klebsiella bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Localised infection	1 (3.1)	1 (3.1)	0	0	0
Meningitis bacterial	1 (3.1)	0	0	1 (3.1)	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Otitis externa	1 (3.1)	0	1 (3.1)	0	0
Pharyngitis streptococcal	1 (3.1)	0	0	1 (3.1)	0
Pneumonia respiratory syncytial viral	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection	1 (3.1)	1 (3.1)	0	0	0
Sinusitis fungal	1 (3.1)	0	0	1 (3.1)	0
Skin infection	1 (3.1)	0	1 (3.1)	0	0
Syphilis	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection viral	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (3.1)	0	0	1 (3.1)	0
Injury, poisoning and procedural complications					
-Total	10 (31.3)	2 (6.3)	6 (18.8)	1 (3.1)	1 (3.1)
Infusion related reaction	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Wound	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Abdominal injury	1 (3.1)	1 (3.1)	0	0	0
Contusion	1 (3.1)	1 (3.1)	0	0	0
Fibula fracture	1 (3.1)	0	1 (3.1)	0	0
Post-traumatic neck syndrome	1 (3.1)	0	1 (3.1)	0	0
Procedural pain	1 (3.1)	0	1 (3.1)	0	0
Scratch	1 (3.1)	1 (3.1)	0	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Skin injury	1 (3.1)	0	1 (3.1)	0	0
Skin wound	1 (3.1)	1 (3.1)	0	0	0
Transfusion reaction	1 (3.1)	0	1 (3.1)	0	0
Vasoplegia syndrome	1 (3.1)	0	0	0	1 (3.1)
Investigations					

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (71.9)	0	2 (6.3)	9 (28.1)	12 (37.5)
White blood cell count decreased	11 (34.4)	0	3 (9.4)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	9 (28.1)	0	2 (6.3)	6 (18.8)	1 (3.1)
Neutrophil count decreased	8 (25.0)	0	1 (3.1)	2 (6.3)	5 (15.6)
Platelet count decreased	8 (25.0)	2 (6.3)	2 (6.3)	1 (3.1)	3 (9.4)
Blood bilirubin increased	7 (21.9)	1 (3.1)	1 (3.1)	5 (15.6)	0
International normalised ratio increased	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Lymphocyte count decreased	6 (18.8)	0	1 (3.1)	5 (15.6)	0
Alanine aminotransferase increased	5 (15.6)	1 (3.1)	2 (6.3)	2 (6.3)	0
Blood immunoglobulin g decreased	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Electrocardiogram qt prolonged	4 (12.5)	1 (3.1)	2 (6.3)	0	1 (3.1)
Serum ferritin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Activated partial thromboplastin time prolonged	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blood creatinine increased	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Blood immunoglobulin m decreased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Blood lactate dehydrogenase increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
C-reactive protein increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Fibrin d dimer increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Lipase increased	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Oxygen saturation decreased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Urine output decreased	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Weight increased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Amylase increased	1 (3.1)	1 (3.1)	0	0	0
Bacterial test positive	1 (3.1)	0	0	1 (3.1)	0
Blood alkaline phosphatase increased	1 (3.1)	1 (3.1)	0	0	0
Blood bicarbonate decreased	1 (3.1)	0	1 (3.1)	0	0
Blood creatine phosphokinase increased	1 (3.1)	0	0	0	1 (3.1)
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood phosphorus increased	1 (3.1)	0	1 (3.1)	0	0
Blood thyroid stimulating hormone increased	1 (3.1)	1 (3.1)	0	0	0
Blood uric acid increased	1 (3.1)	1 (3.1)	0	0	0
Cardiac murmur	1 (3.1)	1 (3.1)	0	0	0
Ejection fraction decreased	1 (3.1)	0	1 (3.1)	0	0
Electrocardiogram t wave abnormal	1 (3.1)	0	1 (3.1)	0	0
Gamma-glutamyltransferase increased	1 (3.1)	0	0	1 (3.1)	0
Haptoglobin decreased	1 (3.1)	1 (3.1)	0	0	0
Heart sounds abnormal	1 (3.1)	1 (3.1)	0	0	0
Staphylococcus test positive	1 (3.1)	1 (3.1)	0	0	0
Troponin increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	22 (68.8)	2 (6.3)	5 (15.6)	9 (28.1)	6 (18.8)
Decreased appetite	12 (37.5)	3 (9.4)	5 (15.6)	4 (12.5)	0
Hypocalcaemia	10 (31.3)	0	7 (21.9)	3 (9.4)	0
Hypokalaemia	8 (25.0)	1 (3.1)	3 (9.4)	3 (9.4)	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	7 (21.9)	0	3 (9.4)	4 (12.5)	0
Hyperglycaemia	6 (18.8)	0	3 (9.4)	3 (9.4)	0
Hyperuricaemia	6 (18.8)	5 (15.6)	0	1 (3.1)	0
Hypoalbuminaemia	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Hyperphosphataemia	5 (15.6)	4 (12.5)	0	0	1 (3.1)
Hypervolaemia	5 (15.6)	0	1 (3.1)	4 (12.5)	0
Metabolic acidosis	4 (12.5)	1 (3.1)	0	0	3 (9.4)
Hypercalcaemia	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Hypomagnesaemia	3 (9.4)	3 (9.4)	0	0	0
Acidosis	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hyperkalaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hyponatraemia	2 (6.3)	2 (6.3)	0	0	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0
Calcium deficiency	1 (3.1)	1 (3.1)	0	0	0
Dehydration	1 (3.1)	0	1 (3.1)	0	0
Haemosiderosis	1 (3.1)	0	1 (3.1)	0	0
Hyperchloraemia	1 (3.1)	1 (3.1)	0	0	0
Hyperlactacidaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperlipidaemia	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)
Hypertriglyceridaemia	1 (3.1)	0	0	0	1 (3.1)
Hypoglycaemia	1 (3.1)	0	1 (3.1)	0	0
Metabolic syndrome	1 (3.1)	0	1 (3.1)	0	0
Obesity	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	16 (50.0)	6 (18.8)	6 (18.8)	3 (9.4)	1 (3.1)
Myalgia	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Pain in extremity	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Arthralgia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Back pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Bone pain	2 (6.3)	0	2 (6.3)	0	0
Muscular weakness	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Haemarthrosis	1 (3.1)	0	0	1 (3.1)	0
Muscle rigidity	1 (3.1)	1 (3.1)	0	0	0
Muscle spasms	1 (3.1)	0	1 (3.1)	0	0
Myositis	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (3.1)	1 (3.1)	0	0	0
Rhabdomyolysis	1 (3.1)	0	0	0	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.1)	0	1 (3.1)	0	0
Cancer pain	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	21 (65.6)	6 (18.8)	9 (28.1)	4 (12.5)	2 (6.3)
Headache	12 (37.5)	5 (15.6)	7 (21.9)	0	0
Encephalopathy	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Somnolence	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Tremor	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Cognitive disorder	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Cerebral haemorrhage	1 (3.1)	0	0	0	1 (3.1)
Dysarthria	1 (3.1)	0	0	1 (3.1)	0
Dysgeusia	1 (3.1)	1 (3.1)	0	0	0
Extrapyramidal disorder	1 (3.1)	0	1 (3.1)	0	0
Generalised tonic-clonic seizure	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	1 (3.1)	1 (3.1)	0	0	0
Migraine	1 (3.1)	0	1 (3.1)	0	0
Monoparesis	1 (3.1)	0	1 (3.1)	0	0
Neurological decompensation	1 (3.1)	0	0	0	1 (3.1)
Paraesthesia	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Psychiatric disorders					
-Total	15 (46.9)	5 (15.6)	5 (15.6)	5 (15.6)	0
Delirium	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Anxiety	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Agitation	3 (9.4)	0	3 (9.4)	0	0
Confusional state	3 (9.4)	3 (9.4)	0	0	0
Mental status changes	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Automatism	1 (3.1)	1 (3.1)	0	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Persistent depressive disorder	1 (3.1)	0	1 (3.1)	0	0
Sleep disorder	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (34.4)	1 (3.1)	2 (6.3)	4 (12.5)	4 (12.5)
Acute kidney injury	7 (21.9)	0	1 (3.1)	3 (9.4)	3 (9.4)
Dysuria	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Urinary retention	2 (6.3)	0	2 (6.3)	0	0
Anuria	1 (3.1)	1 (3.1)	0	0	0
Azotaemia	1 (3.1)	0	1 (3.1)	0	0
Bladder dilatation	1 (3.1)	0	1 (3.1)	0	0
Haematuria	1 (3.1)	0	0	1 (3.1)	0
Kidney enlargement	1 (3.1)	0	1 (3.1)	0	0
Micturition urgency	1 (3.1)	0	1 (3.1)	0	0
Pollakiuria	1 (3.1)	0	1 (3.1)	0	0
Renal failure	1 (3.1)	0	0	0	1 (3.1)
Renal mass	1 (3.1)	0	1 (3.1)	0	0
Renal tubular necrosis	1 (3.1)	0	0	0	1 (3.1)
Reproductive system and breast disorders					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Dysmenorrhoea	1 (3.1)	0	1 (3.1)	0	0
Perineal rash	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal ulceration	1 (3.1)	0	0	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	2 (6.3)	2 (6.3)	5 (15.6)	10 (31.3)
Hypoxia	10 (31.3)	0	1 (3.1)	6 (18.8)	3 (9.4)
Cough	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Pulmonary oedema	6 (18.8)	0	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory failure	5 (15.6)	0	0	0	5 (15.6)
Oropharyngeal pain	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Pleural effusion	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Tachypnoea	4 (12.5)	0	0	3 (9.4)	1 (3.1)
Dyspnoea	3 (9.4)	0	1 (3.1)	0	2 (6.3)
Nasal congestion	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Acute respiratory distress syndrome	2 (6.3)	0	0	0	2 (6.3)
Epistaxis	2 (6.3)	0	2 (6.3)	0	0
Respiratory distress	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Acute respiratory failure	1 (3.1)	0	0	1 (3.1)	0
Atelectasis	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchospasm	1 (3.1)	0	1 (3.1)	0	0
Haemoptysis	1 (3.1)	0	1 (3.1)	0	0
Nasal discomfort	1 (3.1)	0	1 (3.1)	0	0
Pharyngeal haemorrhage	1 (3.1)	0	1 (3.1)	0	0
Respiratory acidosis	1 (3.1)	0	0	1 (3.1)	0
Rhinitis allergic	1 (3.1)	0	1 (3.1)	0	0
Rhinorrhoea	1 (3.1)	0	1 (3.1)	0	0
Sleep apnoea syndrome	1 (3.1)	0	1 (3.1)	0	0
Upper respiratory tract inflammation	1 (3.1)	0	1 (3.1)	0	0
Wheezing	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (50.0)	7 (21.9)	8 (25.0)	1 (3.1)	0
Pruritus	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Rash	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Dry skin	3 (9.4)	3 (9.4)	0	0	0
Erythema	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blister	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperhidrosis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Petechiae	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Decubitus ulcer	1 (3.1)	0	1 (3.1)	0	0
Dermatitis	1 (3.1)	1 (3.1)	0	0	0
Dermatitis diaper	1 (3.1)	0	1 (3.1)	0	0
Eczema	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Miliaria	1 (3.1)	1 (3.1)	0	0	0
Photosensitivity reaction	1 (3.1)	0	1 (3.1)	0	0
Rash erythematous	1 (3.1)	1 (3.1)	0	0	0
Rash maculo-papular	1 (3.1)	1 (3.1)	0	0	0
Scab	1 (3.1)	1 (3.1)	0	0	0
Skin discolouration	1 (3.1)	1 (3.1)	0	0	0
Skin hypopigmentation	1 (3.1)	1 (3.1)	0	0	0
Skin necrosis	1 (3.1)	0	0	1 (3.1)	0
Skin ulcer	1 (3.1)	1 (3.1)	0	0	0
Surgical and medical procedures					
-Total	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombolysis	1 (3.1)	0	0	1 (3.1)	0
Vascular disorders					
-Total	17 (53.1)	0	3 (9.4)	8 (25.0)	6 (18.8)
Hypotension	14 (43.8)	0	3 (9.4)	6 (18.8)	5 (15.6)
Hypertension	8 (25.0)	1 (3.1)	3 (9.4)	4 (12.5)	0
Peripheral ischaemia	1 (3.1)	0	1 (3.1)	0	0
Thrombosis	1 (3.1)	0	1 (3.1)	0	0
Venoocclusive disease	1 (3.1)	0	0	0	1 (3.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	1 (7.7)	0	5 (38.5)	7 (53.8)
Blood and lymphatic system disorders					
-Total	11 (84.6)	1 (7.7)	2 (15.4)	6 (46.2)	2 (15.4)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)	0	0
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Disseminated intravascular coagulation	1 (7.7)	0	1 (7.7)	0	0
Hypofibrinogenaemia	1 (7.7)	0	1 (7.7)	0	0
Leukopenia	1 (7.7)	0	0	0	1 (7.7)
Splenomegaly	1 (7.7)	1 (7.7)	0	0	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (53.8)	6 (46.2)	0	1 (7.7)	0
Tachycardia	6 (46.2)	6 (46.2)	0	0	0
Cardiac dysfunction	1 (7.7)	1 (7.7)	0	0	0
Left ventricular dysfunction	1 (7.7)	0	0	1 (7.7)	0
Ear and labyrinth disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Ear pain	1 (7.7)	1 (7.7)	0	0	0
Eye disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Ocular hyperaemia	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	10 (76.9)	5 (38.5)	3 (23.1)	2 (15.4)	0
Nausea	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Vomiting	5 (38.5)	2 (15.4)	3 (23.1)	0	0
Diarrhoea	4 (30.8)	4 (30.8)	0	0	0
Abdominal pain	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Constipation	2 (15.4)	2 (15.4)	0	0	0
Anal haemorrhage	1 (7.7)	1 (7.7)	0	0	0
Enterocolitis	1 (7.7)	0	1 (7.7)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	1 (7.7)	1 (7.7)	0	0	0
Gastrooesophageal reflux disease	1 (7.7)	0	1 (7.7)	0	0
Haematemesis	1 (7.7)	1 (7.7)	0	0	0
Lip oedema	1 (7.7)	1 (7.7)	0	0	0
Neutropenic colitis	1 (7.7)	0	0	1 (7.7)	0
Proctalgia	1 (7.7)	0	0	1 (7.7)	0
General disorders and administration site conditions					
-Total	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Fatigue	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Pyrexia	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Catheter site haemorrhage	1 (7.7)	1 (7.7)	0	0	0
Chills	1 (7.7)	1 (7.7)	0	0	0
Generalised oedema	1 (7.7)	1 (7.7)	0	0	0
Vascular device occlusion	1 (7.7)	1 (7.7)	0	0	0
Hepatobiliary disorders					
-Total	4 (30.8)	2 (15.4)	1 (7.7)	0	1 (7.7)
Hepatic function abnormal	2 (15.4)	0	1 (7.7)	0	1 (7.7)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (7.7)	1 (7.7)	0	0	0
Ocular icterus	1 (7.7)	1 (7.7)	0	0	0
Immune system disorders					
-Total	12 (92.3)	0	6 (46.2)	5 (38.5)	1 (7.7)
Cytokine release syndrome	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Hypogammaglobulinaemia	2 (15.4)	0	2 (15.4)	0	0
Infections and infestations					
-Total	5 (38.5)	1 (7.7)	1 (7.7)	3 (23.1)	0
Anal abscess	1 (7.7)	0	0	1 (7.7)	0
Otitis externa	1 (7.7)	0	1 (7.7)	0	0
Paronychia	1 (7.7)	0	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	0	1 (7.7)	0
Urinary tract infection viral	1 (7.7)	1 (7.7)	0	0	0
Varicella zoster virus infection	1 (7.7)	0	0	1 (7.7)	0
Injury, poisoning and procedural complications					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Procedural pain	1 (7.7)	0	1 (7.7)	0	0
Transfusion reaction	1 (7.7)	1 (7.7)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	11 (84.6)	2 (15.4)	0	3 (23.1)	6 (46.2)
Platelet count decreased	8 (61.5)	3 (23.1)	1 (7.7)	4 (30.8)	0
White blood cell count decreased	8 (61.5)	1 (7.7)	2 (15.4)	0	5 (38.5)
Lymphocyte count decreased	7 (53.8)	1 (7.7)	0	4 (30.8)	2 (15.4)
Neutrophil count decreased	7 (53.8)	0	2 (15.4)	0	5 (38.5)
International normalised ratio increased	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Alanine aminotransferase increased	4 (30.8)	0	2 (15.4)	2 (15.4)	0
Aspartate aminotransferase increased	4 (30.8)	0	1 (7.7)	3 (23.1)	0
Blood immunoglobulin a decreased	4 (30.8)	4 (30.8)	0	0	0
Blood immunoglobulin m decreased	4 (30.8)	4 (30.8)	0	0	0
Activated partial thromboplastin time prolonged	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Blood bilirubin increased	3 (23.1)	1 (7.7)	0	2 (15.4)	0
Blood fibrinogen decreased	3 (23.1)	2 (15.4)	1 (7.7)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	2 (15.4)	0	2 (15.4)	0	0
Blood creatine phosphokinase increased	1 (7.7)	0	0	1 (7.7)	0
Blood lactate dehydrogenase increased	1 (7.7)	1 (7.7)	0	0	0
Blood uric acid increased	1 (7.7)	1 (7.7)	0	0	0
C-reactive protein increased	1 (7.7)	1 (7.7)	0	0	0
Electrocardiogram qt prolonged	1 (7.7)	1 (7.7)	0	0	0
Haemoglobin decreased	1 (7.7)	0	0	1 (7.7)	0
Weight increased	1 (7.7)	0	0	1 (7.7)	0
Metabolism and nutrition disorders					
-Total	9 (69.2)	2 (15.4)	2 (15.4)	5 (38.5)	0
Decreased appetite	7 (53.8)	4 (30.8)	1 (7.7)	2 (15.4)	0
Hypokalaemia	3 (23.1)	0	1 (7.7)	2 (15.4)	0
Hyperphosphataemia	2 (15.4)	2 (15.4)	0	0	0
Hypophosphataemia	2 (15.4)	0	0	2 (15.4)	0
Dehydration	1 (7.7)	0	1 (7.7)	0	0
Hypertriglyceridaemia	1 (7.7)	0	0	1 (7.7)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (7.7)	1 (7.7)	0	0	0
Hypoalbuminaemia	1 (7.7)	0	1 (7.7)	0	0
Hypomagnesaemia	1 (7.7)	1 (7.7)	0	0	0
Metabolic acidosis	1 (7.7)	1 (7.7)	0	0	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (61.5)	6 (46.2)	2 (15.4)	0	0
Pain in extremity	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Myalgia	4 (30.8)	2 (15.4)	2 (15.4)	0	0
Arthralgia	2 (15.4)	2 (15.4)	0	0	0
Nervous system disorders					
-Total	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Headache	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Dizziness	1 (7.7)	1 (7.7)	0	0	0
Hypoaesthesia	1 (7.7)	1 (7.7)	0	0	0
Lethargy	1 (7.7)	1 (7.7)	0	0	0
Tremor	1 (7.7)	1 (7.7)	0	0	0
Psychiatric disorders					

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Anxiety	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Agitation	1 (7.7)	1 (7.7)	0	0	0
Irritability	1 (7.7)	1 (7.7)	0	0	0
Mental status changes	1 (7.7)	1 (7.7)	0	0	0
Renal and urinary disorders					
-Total	4 (30.8)	2 (15.4)	1 (7.7)	0	1 (7.7)
Acute kidney injury	1 (7.7)	0	0	0	1 (7.7)
Dysuria	1 (7.7)	1 (7.7)	0	0	0
Micturition urgency	1 (7.7)	0	1 (7.7)	0	0
Pollakiuria	1 (7.7)	0	1 (7.7)	0	0
Renal tubular dysfunction	1 (7.7)	1 (7.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (61.5)	5 (38.5)	1 (7.7)	1 (7.7)	1 (7.7)
Oropharyngeal pain	3 (23.1)	3 (23.1)	0	0	0
Cough	2 (15.4)	2 (15.4)	0	0	0
Hypoxia	2 (15.4)	0	0	1 (7.7)	1 (7.7)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (15.4)	2 (15.4)	0	0	0
Tachypnoea	2 (15.4)	2 (15.4)	0	0	0
Pleural effusion	1 (7.7)	1 (7.7)	0	0	0
Respiratory distress	1 (7.7)	0	1 (7.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (53.8)	6 (46.2)	1 (7.7)	0	0
Pruritus	2 (15.4)	2 (15.4)	0	0	0
Rash papular	2 (15.4)	2 (15.4)	0	0	0
Blister	1 (7.7)	1 (7.7)	0	0	0
Dermatitis	1 (7.7)	1 (7.7)	0	0	0
Dry skin	1 (7.7)	1 (7.7)	0	0	0
Eczema	1 (7.7)	1 (7.7)	0	0	0
Erythema nodosum	1 (7.7)	1 (7.7)	0	0	0
Rash pruritic	1 (7.7)	1 (7.7)	0	0	0
Skin ulcer	1 (7.7)	0	1 (7.7)	0	0
Vascular disorders					
-Total	4 (30.8)	2 (15.4)	0	1 (7.7)	1 (7.7)
Hypotension	3 (23.1)	1 (7.7)	0	1 (7.7)	1 (7.7)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	1 (7.7)	1 (7.7)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	66 (98.5)	3 (4.5)	8 (11.9)	16 (23.9)	39 (58.2)
Blood and lymphatic system disorders					
-Total	39 (58.2)	2 (3.0)	6 (9.0)	20 (29.9)	11 (16.4)
Febrile neutropenia	20 (29.9)	0	0	18 (26.9)	2 (3.0)
Anaemia	13 (19.4)	2 (3.0)	3 (4.5)	8 (11.9)	0
Thrombocytopenia	8 (11.9)	0	0	2 (3.0)	6 (9.0)
Neutropenia	7 (10.4)	0	2 (3.0)	1 (1.5)	4 (6.0)
Disseminated intravascular coagulation	6 (9.0)	0	4 (6.0)	2 (3.0)	0
Coagulopathy	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Splenomegaly	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Leukopenia	2 (3.0)	0	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (3.0)	0	0	2 (3.0)	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Eosinophilia	1 (1.5)	0	1 (1.5)	0	0
Lymphopenia	1 (1.5)	0	0	1 (1.5)	0
Cardiac disorders					
-Total	17 (25.4)	4 (6.0)	6 (9.0)	4 (6.0)	3 (4.5)
Tachycardia	11 (16.4)	1 (1.5)	7 (10.4)	2 (3.0)	1 (1.5)
Bradycardia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Sinus tachycardia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Left ventricular dysfunction	2 (3.0)	0	0	2 (3.0)	0
Atrioventricular block first degree	1 (1.5)	0	1 (1.5)	0	0
Cardiac arrest	1 (1.5)	0	0	0	1 (1.5)
Cardiac dysfunction	1 (1.5)	1 (1.5)	0	0	0
Cardiac failure	1 (1.5)	0	0	0	1 (1.5)
Cardiac failure congestive	1 (1.5)	0	1 (1.5)	0	0
Mitral valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Pericardial effusion	1 (1.5)	1 (1.5)	0	0	0
Right ventricular dysfunction	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (1.5)	0	0	1 (1.5)	0
Ear and labyrinth disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Ear pruritus	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					
-Total	5 (7.5)	0	5 (7.5)	0	0
Adrenal insufficiency	4 (6.0)	0	4 (6.0)	0	0
Hypothyroidism	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	8 (11.9)	5 (7.5)	3 (4.5)	0	0
Conjunctival haemorrhage	2 (3.0)	2 (3.0)	0	0	0
Eyelid oedema	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Eye oedema	1 (1.5)	1 (1.5)	0	0	0
Eye pain	1 (1.5)	1 (1.5)	0	0	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0	0	0
Periorbital oedema	1 (1.5)	1 (1.5)	0	0	0
Periorbital swelling	1 (1.5)	0	1 (1.5)	0	0
Retinal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual impairment	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	41 (61.2)	14 (20.9)	15 (22.4)	11 (16.4)	1 (1.5)
Vomiting	16 (23.9)	10 (14.9)	5 (7.5)	1 (1.5)	0
Nausea	12 (17.9)	5 (7.5)	5 (7.5)	2 (3.0)	0
Diarrhoea	11 (16.4)	4 (6.0)	6 (9.0)	1 (1.5)	0
Constipation	9 (13.4)	4 (6.0)	5 (7.5)	0	0
Abdominal pain	8 (11.9)	2 (3.0)	5 (7.5)	1 (1.5)	0
Mouth haemorrhage	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Pancreatitis	4 (6.0)	0	3 (4.5)	1 (1.5)	0
Abdominal distension	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Abdominal pain upper	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Ascites	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Stomatitis	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Abdominal compartment syndrome	1 (1.5)	0	0	0	1 (1.5)
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Dry mouth	1 (1.5)	0	1 (1.5)	0	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	1 (1.5)	1 (1.5)	0	0	0
Gingival bleeding	1 (1.5)	0	1 (1.5)	0	0
Gingival erythema	1 (1.5)	1 (1.5)	0	0	0
Gingivitis ulcerative	1 (1.5)	0	0	1 (1.5)	0
Ileus	1 (1.5)	0	1 (1.5)	0	0
Lip dry	1 (1.5)	0	1 (1.5)	0	0
Melaena	1 (1.5)	0	0	1 (1.5)	0
Mouth swelling	1 (1.5)	1 (1.5)	0	0	0
Odynophagia	1 (1.5)	1 (1.5)	0	0	0
Trichoglossia	1 (1.5)	0	1 (1.5)	0	0
Upper gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	34 (50.7)	15 (22.4)	8 (11.9)	7 (10.4)	4 (6.0)
Pyrexia	21 (31.3)	9 (13.4)	4 (6.0)	6 (9.0)	2 (3.0)
Face oedema	8 (11.9)	5 (7.5)	2 (3.0)	1 (1.5)	0
Fatigue	6 (9.0)	5 (7.5)	1 (1.5)	0	0
Oedema peripheral	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	5 (7.5)	3 (4.5)	2 (3.0)	0	0
Generalised oedema	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Asthenia	2 (3.0)	2 (3.0)	0	0	0
Catheter site pain	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Drug withdrawal syndrome	2 (3.0)	0	2 (3.0)	0	0
Influenza like illness	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Localised oedema	2 (3.0)	2 (3.0)	0	0	0
Multiple organ dysfunction syndrome	2 (3.0)	0	0	0	2 (3.0)
Catheter site erythema	1 (1.5)	1 (1.5)	0	0	0
Chest discomfort	1 (1.5)	0	0	1 (1.5)	0
Crying	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Malaise	1 (1.5)	0	1 (1.5)	0	0
Oedema due to hepatic disease	1 (1.5)	0	1 (1.5)	0	0
Pain	1 (1.5)	0	0	1 (1.5)	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Swelling face	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (1.5)	0	0	1 (1.5)	0
Hepatobiliary disorders					
-Total	13 (19.4)	3 (4.5)	5 (7.5)	3 (4.5)	2 (3.0)
Hyperbilirubinaemia	5 (7.5)	1 (1.5)	3 (4.5)	1 (1.5)	0
Hepatic function abnormal	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Cholelithiasis	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Gallbladder enlargement	2 (3.0)	2 (3.0)	0	0	0
Hepatomegaly	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Hypertransaminasaemia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Biliary tract disorder	1 (1.5)	1 (1.5)	0	0	0
Cholestasis	1 (1.5)	0	0	0	1 (1.5)
Immune system disorders					
-Total	55 (82.1)	3 (4.5)	15 (22.4)	17 (25.4)	20 (29.9)
Cytokine release syndrome	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)
Hypogammaglobulinaemia	21 (31.3)	2 (3.0)	12 (17.9)	7 (10.4)	0
Haemophagocytic lymphohistiocytosis	5 (7.5)	1 (1.5)	1 (1.5)	2 (3.0)	1 (1.5)
Immunodeficiency	3 (4.5)	0	0	3 (4.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (1.5)	1 (1.5)	0	0	0
Seasonal allergy	1 (1.5)	0	1 (1.5)	0	0
Selective igg subclass deficiency	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	30 (44.8)	5 (7.5)	9 (13.4)	13 (19.4)	3 (4.5)
Conjunctivitis	5 (7.5)	1 (1.5)	4 (6.0)	0	0
Staphylococcal infection	5 (7.5)	0	3 (4.5)	2 (3.0)	0
Clostridium difficile infection	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Candida infection	3 (4.5)	0	2 (3.0)	0	1 (1.5)
Staphylococcal bacteraemia	3 (4.5)	0	0	3 (4.5)	0
Encephalitis viral	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Nail infection	2 (3.0)	2 (3.0)	0	0	0
Oral herpes	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Oral infection	2 (3.0)	0	2 (3.0)	0	0
Rhinovirus infection	2 (3.0)	0	2 (3.0)	0	0
Adenovirus infection	1 (1.5)	0	0	1 (1.5)	0
Atypical pneumonia	1 (1.5)	1 (1.5)	0	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	1 (1.5)	1 (1.5)	0	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis norovirus	1 (1.5)	1 (1.5)	0	0	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes simplex	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0
Oral candidiasis	1 (1.5)	0	1 (1.5)	0	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	9 (13.4)	2 (3.0)	5 (7.5)	0	2 (3.0)
Fall	2 (3.0)	0	2 (3.0)	0	0
Infusion related reaction	2 (3.0)	0	2 (3.0)	0	0
Wound	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Contusion	1 (1.5)	1 (1.5)	0	0	0
Procedural pain	1 (1.5)	1 (1.5)	0	0	0
Scratch	1 (1.5)	1 (1.5)	0	0	0
Skin abrasion	1 (1.5)	1 (1.5)	0	0	0
Skin injury	1 (1.5)	0	1 (1.5)	0	0
Skin wound	1 (1.5)	1 (1.5)	0	0	0
Transfusion reaction	1 (1.5)	0	1 (1.5)	0	0
Transplant failure	1 (1.5)	0	0	0	1 (1.5)
Vasoplegia syndrome	1 (1.5)	0	0	0	1 (1.5)
Investigations					

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	46 (68.7)	2 (3.0)	8 (11.9)	14 (20.9)	22 (32.8)
White blood cell count decreased	16 (23.9)	2 (3.0)	1 (1.5)	2 (3.0)	11 (16.4)
Aspartate aminotransferase increased	15 (22.4)	2 (3.0)	5 (7.5)	5 (7.5)	3 (4.5)
Alanine aminotransferase increased	14 (20.9)	4 (6.0)	6 (9.0)	4 (6.0)	0
Neutrophil count decreased	13 (19.4)	0	1 (1.5)	2 (3.0)	10 (14.9)
Platelet count decreased	13 (19.4)	1 (1.5)	2 (3.0)	2 (3.0)	8 (11.9)
Blood bilirubin increased	9 (13.4)	0	2 (3.0)	7 (10.4)	0
Lymphocyte count decreased	8 (11.9)	1 (1.5)	0	4 (6.0)	3 (4.5)
Serum ferritin increased	6 (9.0)	1 (1.5)	3 (4.5)	2 (3.0)	0
Blood creatinine increased	4 (6.0)	1 (1.5)	0	2 (3.0)	1 (1.5)
Blood fibrinogen decreased	4 (6.0)	0	2 (3.0)	1 (1.5)	1 (1.5)
Electrocardiogram qt prolonged	4 (6.0)	0	2 (3.0)	1 (1.5)	1 (1.5)
Activated partial thromboplastin time prolonged	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Blood lactate dehydrogenase increased	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
C-reactive protein increased	3 (4.5)	0	0	3 (4.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	3 (4.5)	2 (3.0)	0	1 (1.5)	0
International normalised ratio increased	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Weight increased	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Blood immunoglobulin g decreased	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Blood immunoglobulin m decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Gamma-glutamyltransferase increased	2 (3.0)	0	0	2 (3.0)	0
Immunoglobulins decreased	2 (3.0)	0	2 (3.0)	0	0
Lipase increased	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Urine output decreased	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Amylase increased	1 (1.5)	1 (1.5)	0	0	0
Bacterial test positive	1 (1.5)	0	0	1 (1.5)	0
Blood alkaline phosphatase increased	1 (1.5)	1 (1.5)	0	0	0
Blood bicarbonate decreased	1 (1.5)	0	1 (1.5)	0	0
Blood creatine phosphokinase increased	1 (1.5)	0	0	0	1 (1.5)
Blood glucose increased	1 (1.5)	0	0	0	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)	0	0
Blood phosphorus increased	1 (1.5)	0	1 (1.5)	0	0
Blood testosterone decreased	1 (1.5)	1 (1.5)	0	0	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Breath sounds abnormal	1 (1.5)	0	1 (1.5)	0	0
Cardiac murmur	1 (1.5)	1 (1.5)	0	0	0
Coagulation test abnormal	1 (1.5)	1 (1.5)	0	0	0
Electrocardiogram t wave abnormal	1 (1.5)	0	1 (1.5)	0	0
Enterovirus test positive	1 (1.5)	0	1 (1.5)	0	0
Haptoglobin decreased	1 (1.5)	1 (1.5)	0	0	0
Oxygen saturation decreased	1 (1.5)	1 (1.5)	0	0	0
Prothrombin time prolonged	1 (1.5)	0	1 (1.5)	0	0
Staphylococcus test positive	1 (1.5)	1 (1.5)	0	0	0
Troponin increased	1 (1.5)	0	0	1 (1.5)	0
Weight decreased	1 (1.5)	0	1 (1.5)	0	0
Metabolism and nutrition disorders					
-Total	37 (55.2)	6 (9.0)	7 (10.4)	16 (23.9)	8 (11.9)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	17 (25.4)	5 (7.5)	3 (4.5)	8 (11.9)	1 (1.5)
Hypocalcaemia	16 (23.9)	2 (3.0)	9 (13.4)	5 (7.5)	0
Hypokalaemia	16 (23.9)	3 (4.5)	4 (6.0)	7 (10.4)	2 (3.0)
Hypophosphataemia	15 (22.4)	3 (4.5)	5 (7.5)	6 (9.0)	1 (1.5)
Hypoalbuminaemia	10 (14.9)	0	9 (13.4)	1 (1.5)	0
Hyperglycaemia	8 (11.9)	0	4 (6.0)	4 (6.0)	0
Hyperuricaemia	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Hypervolaemia	6 (9.0)	0	2 (3.0)	4 (6.0)	0
Hypomagnesaemia	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Hypercalcaemia	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Hyperphosphataemia	3 (4.5)	2 (3.0)	0	0	1 (1.5)
Hyponatraemia	3 (4.5)	3 (4.5)	0	0	0
Tumour lysis syndrome	3 (4.5)	0	0	3 (4.5)	0
Acidosis	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Hyperkalaemia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Hypermagnesaemia	2 (3.0)	2 (3.0)	0	0	0
Hypernatraemia	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Metabolic acidosis	2 (3.0)	0	0	0	2 (3.0)
Calcium deficiency	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemosiderosis	1 (1.5)	0	1 (1.5)	0	0
Hyperchloraemia	1 (1.5)	1 (1.5)	0	0	0
Hyperlactacidaemia	1 (1.5)	1 (1.5)	0	0	0
Hypertriglyceridaemia	1 (1.5)	0	0	0	1 (1.5)
Hypoglycaemia	1 (1.5)	0	1 (1.5)	0	0
Malnutrition	1 (1.5)	0	0	1 (1.5)	0
Polydipsia	1 (1.5)	0	0	1 (1.5)	0
Musculoskeletal and connective tissue disorders					
-Total	25 (37.3)	9 (13.4)	11 (16.4)	4 (6.0)	1 (1.5)
Arthralgia	8 (11.9)	2 (3.0)	5 (7.5)	1 (1.5)	0
Back pain	6 (9.0)	2 (3.0)	3 (4.5)	1 (1.5)	0
Pain in extremity	6 (9.0)	2 (3.0)	4 (6.0)	0	0
Myalgia	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Bone pain	2 (3.0)	0	2 (3.0)	0	0
Muscular weakness	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Pain in jaw	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Haemarthrosis	1 (1.5)	0	0	1 (1.5)	0
Muscle rigidity	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (1.5)	0	1 (1.5)	0	0
Musculoskeletal chest pain	1 (1.5)	1 (1.5)	0	0	0
Myositis	1 (1.5)	0	1 (1.5)	0	0
Neck pain	1 (1.5)	0	1 (1.5)	0	0
Rhabdomyolysis	1 (1.5)	0	0	0	1 (1.5)
Nervous system disorders					
-Total	35 (52.2)	10 (14.9)	15 (22.4)	8 (11.9)	2 (3.0)
Headache	20 (29.9)	10 (14.9)	8 (11.9)	2 (3.0)	0
Encephalopathy	8 (11.9)	1 (1.5)	3 (4.5)	4 (6.0)	0
Somnolence	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Tremor	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Cognitive disorder	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Dysgeusia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Dizziness	2 (3.0)	2 (3.0)	0	0	0
Lethargy	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Seizure	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Amnesia	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Cerebral haemorrhage	1 (1.5)	0	0	0	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysarthria	1 (1.5)	0	0	1 (1.5)	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Hyperaesthesia	1 (1.5)	1 (1.5)	0	0	0
Monoparesis	1 (1.5)	0	1 (1.5)	0	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Neurological decompensation	1 (1.5)	0	0	0	1 (1.5)
Paraesthesia	1 (1.5)	1 (1.5)	0	0	0
Psychiatric disorders					
-Total	23 (34.3)	8 (11.9)	9 (13.4)	6 (9.0)	0
Delirium	7 (10.4)	2 (3.0)	2 (3.0)	3 (4.5)	0
Confusional state	5 (7.5)	5 (7.5)	0	0	0
Agitation	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Anxiety	4 (6.0)	0	2 (3.0)	2 (3.0)	0
Insomnia	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Hallucination	3 (4.5)	1 (1.5)	2 (3.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (3.0)	2 (3.0)	0	0	0
Mental status changes	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Sleep disorder	2 (3.0)	0	2 (3.0)	0	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Automatism	1 (1.5)	1 (1.5)	0	0	0
Hallucination, visual	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Renal and urinary disorders					
-Total	16 (23.9)	3 (4.5)	5 (7.5)	3 (4.5)	5 (7.5)
Acute kidney injury	8 (11.9)	1 (1.5)	1 (1.5)	3 (4.5)	3 (4.5)
Anuria	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Dysuria	2 (3.0)	2 (3.0)	0	0	0
Haematuria	2 (3.0)	2 (3.0)	0	0	0
Renal failure	2 (3.0)	0	1 (1.5)	0	1 (1.5)
Urinary retention	2 (3.0)	0	2 (3.0)	0	0
Azotaemia	1 (1.5)	0	1 (1.5)	0	0
Bladder dilatation	1 (1.5)	0	1 (1.5)	0	0
Incontinence	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pollakiuria	1 (1.5)	0	1 (1.5)	0	0
Proteinuria	1 (1.5)	1 (1.5)	0	0	0
Renal tubular necrosis	1 (1.5)	0	0	0	1 (1.5)
Urinary incontinence	1 (1.5)	0	1 (1.5)	0	0
Urinary tract disorder	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					
-Total	5 (7.5)	2 (3.0)	2 (3.0)	1 (1.5)	0
Female genital tract fistula	1 (1.5)	1 (1.5)	0	0	0
Heavy menstrual bleeding	1 (1.5)	1 (1.5)	0	0	0
Perineal rash	1 (1.5)	0	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Vaginal ulceration	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	33 (49.3)	9 (13.4)	3 (4.5)	10 (14.9)	11 (16.4)
Hypoxia	15 (22.4)	0	5 (7.5)	5 (7.5)	5 (7.5)
Pulmonary oedema	12 (17.9)	2 (3.0)	3 (4.5)	6 (9.0)	1 (1.5)
Cough	8 (11.9)	7 (10.4)	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	6 (9.0)	3 (4.5)	0	2 (3.0)	1 (1.5)
Tachypnoea	6 (9.0)	1 (1.5)	1 (1.5)	4 (6.0)	0
Epistaxis	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Respiratory failure	4 (6.0)	0	0	0	4 (6.0)
Atelectasis	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Dyspnoea	3 (4.5)	0	0	2 (3.0)	1 (1.5)
Nasal congestion	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Acute respiratory distress syndrome	2 (3.0)	0	0	0	2 (3.0)
Oropharyngeal pain	2 (3.0)	2 (3.0)	0	0	0
Respiratory distress	2 (3.0)	0	1 (1.5)	0	1 (1.5)
Acute respiratory failure	1 (1.5)	0	0	1 (1.5)	0
Bradypnoea	1 (1.5)	0	0	1 (1.5)	0
Haemoptysis	1 (1.5)	0	1 (1.5)	0	0
Lung infiltration	1 (1.5)	0	0	1 (1.5)	0
Nasal discomfort	1 (1.5)	0	1 (1.5)	0	0
Nasal dryness	1 (1.5)	1 (1.5)	0	0	0
Oropharyngeal plaque	1 (1.5)	0	1 (1.5)	0	0
Painful respiration	1 (1.5)	1 (1.5)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paranasal sinus discomfort	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal erythema	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal exudate	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal oedema	1 (1.5)	0	1 (1.5)	0	0
Productive cough	1 (1.5)	1 (1.5)	0	0	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory acidosis	1 (1.5)	0	0	1 (1.5)	0
Respiratory disorder	1 (1.5)	0	1 (1.5)	0	0
Wheezing	1 (1.5)	0	1 (1.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (29.9)	7 (10.4)	10 (14.9)	3 (4.5)	0
Rash	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Erythema	4 (6.0)	4 (6.0)	0	0	0
Pruritus	4 (6.0)	0	4 (6.0)	0	0
Hyperhidrosis	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Blister	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Dermatitis atopic	2 (3.0)	2 (3.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Petechiae	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Rash maculo-papular	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Decubitus ulcer	1 (1.5)	0	1 (1.5)	0	0
Dermatitis diaper	1 (1.5)	0	1 (1.5)	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.5)	1 (1.5)	0	0	0
Pruritus allergic	1 (1.5)	0	1 (1.5)	0	0
Purpura	1 (1.5)	1 (1.5)	0	0	0
Rash papular	1 (1.5)	0	1 (1.5)	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Scab	1 (1.5)	1 (1.5)	0	0	0
Skin discolouration	1 (1.5)	1 (1.5)	0	0	0
Skin lesion	1 (1.5)	0	1 (1.5)	0	0
Skin necrosis	1 (1.5)	0	0	1 (1.5)	0
Skin ulcer	1 (1.5)	1 (1.5)	0	0	0
Urticaria	1 (1.5)	0	1 (1.5)	0	0
Vancomycin infusion reaction	1 (1.5)	0	0	1 (1.5)	0
Social circumstances					
-Total	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Patient uncooperative	1 (1.5)	0	1 (1.5)	0	0
Surgical and medical procedures					
-Total	1 (1.5)	0	0	1 (1.5)	0
Thrombolysis	1 (1.5)	0	0	1 (1.5)	0
Vascular disorders					
-Total	24 (35.8)	2 (3.0)	7 (10.4)	10 (14.9)	5 (7.5)
Hypotension	18 (26.9)	0	6 (9.0)	7 (10.4)	5 (7.5)
Hypertension	12 (17.9)	3 (4.5)	5 (7.5)	4 (6.0)	0
Capillary leak syndrome	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Flushing	1 (1.5)	1 (1.5)	0	0	0
Hot flush	1 (1.5)	1 (1.5)	0	0	0
Peripheral ischaemia	1 (1.5)	0	1 (1.5)	0	0
Thrombosis	1 (1.5)	0	1 (1.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	3 (23.1)	5 (38.5)	2 (15.4)	3 (23.1)
Blood and lymphatic system disorders					
-Total	3 (23.1)	1 (7.7)	0	0	2 (15.4)
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Anaemia	1 (7.7)	1 (7.7)	0	0	0
Eye disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Cataract	1 (7.7)	1 (7.7)	0	0	0
Ocular hyperaemia	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	5 (38.5)	4 (30.8)	1 (7.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (15.4)	2 (15.4)	0	0	0
Abdominal pain	1 (7.7)	1 (7.7)	0	0	0
Constipation	1 (7.7)	1 (7.7)	0	0	0
Diarrhoea	1 (7.7)	1 (7.7)	0	0	0
Enteritis	1 (7.7)	0	1 (7.7)	0	0
Nausea	1 (7.7)	1 (7.7)	0	0	0
Proctalgia	1 (7.7)	1 (7.7)	0	0	0
Stomatitis	1 (7.7)	1 (7.7)	0	0	0
Trichoglossia	1 (7.7)	1 (7.7)	0	0	0
General disorders and administration site conditions					
-Total	3 (23.1)	3 (23.1)	0	0	0
Fatigue	2 (15.4)	2 (15.4)	0	0	0
Oedema peripheral	1 (7.7)	1 (7.7)	0	0	0
Immune system disorders					
-Total	3 (23.1)	0	3 (23.1)	0	0
Hypogammaglobulinaemia	3 (23.1)	0	3 (23.1)	0	0
Infections and infestations					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Nasopharyngitis	1 (7.7)	1 (7.7)	0	0	0
Sinusitis	1 (7.7)	0	1 (7.7)	0	0
Tinea pedis	1 (7.7)	1 (7.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (15.4)	2 (15.4)	0	0	0
Contusion	1 (7.7)	1 (7.7)	0	0	0
Infusion related reaction	1 (7.7)	1 (7.7)	0	0	0
Investigations					
-Total	10 (76.9)	3 (23.1)	3 (23.1)	3 (23.1)	1 (7.7)
Neutrophil count decreased	4 (30.8)	1 (7.7)	1 (7.7)	1 (7.7)	1 (7.7)
White blood cell count decreased	3 (23.1)	2 (15.4)	0	1 (7.7)	0
Blood immunoglobulin a decreased	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Lymphocyte count decreased	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Alanine aminotransferase increased	1 (7.7)	1 (7.7)	0	0	0
Blood bilirubin increased	1 (7.7)	0	1 (7.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (7.7)	0	0	1 (7.7)	0
Platelet count decreased	1 (7.7)	1 (7.7)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Decreased appetite	1 (7.7)	1 (7.7)	0	0	0
Hyperuricaemia	1 (7.7)	1 (7.7)	0	0	0
Nervous system disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Headache	2 (15.4)	2 (15.4)	0	0	0
Renal and urinary disorders					
-Total	1 (7.7)	0	1 (7.7)	0	0
Cystitis haemorrhagic	1 (7.7)	0	1 (7.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (46.2)	4 (30.8)	2 (15.4)	0	0
Cough	3 (23.1)	3 (23.1)	0	0	0
Rhinorrhoea	3 (23.1)	3 (23.1)	0	0	0
Nasal congestion	2 (15.4)	2 (15.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (7.7)	1 (7.7)	0	0	0
Paranasal sinus inflammation	1 (7.7)	1 (7.7)	0	0	0
Pleural effusion	1 (7.7)	0	1 (7.7)	0	0
Upper respiratory tract inflammation	1 (7.7)	0	1 (7.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Dry skin	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Skin swelling	1 (7.7)	1 (7.7)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (90.3)	6 (9.7)	19 (30.6)	13 (21.0)	18 (29.0)
Blood and lymphatic system disorders					
-Total	14 (22.6)	2 (3.2)	4 (6.5)	6 (9.7)	2 (3.2)
Anaemia	5 (8.1)	3 (4.8)	0	2 (3.2)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Neutropenia	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Thrombocytopenia	2 (3.2)	0	0	1 (1.6)	1 (1.6)
B-cell aplasia	1 (1.6)	0	1 (1.6)	0	0
Disseminated intravascular coagulation	1 (1.6)	0	0	1 (1.6)	0
Eosinophilia	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (1.6)	0	1 (1.6)	0	0
Leukopenia	1 (1.6)	0	1 (1.6)	0	0
Lymphadenopathy	1 (1.6)	1 (1.6)	0	0	0
Lymphocytosis	1 (1.6)	0	1 (1.6)	0	0
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Cardiac disorders					
-Total	7 (11.3)	3 (4.8)	1 (1.6)	0	3 (4.8)
Cardiac arrest	2 (3.2)	0	0	0	2 (3.2)
Cardiac failure	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Tachycardia	2 (3.2)	2 (3.2)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	1 (1.6)	0	0
Tricuspid valve incompetence	1 (1.6)	1 (1.6)	0	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Hypothyroidism	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					
-Total	2 (3.2)	2 (3.2)	0	0	0
Cataract	1 (1.6)	1 (1.6)	0	0	0
Hypermetropia	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual impairment	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal disorders					
-Total	15 (24.2)	9 (14.5)	5 (8.1)	1 (1.6)	0
Diarrhoea	6 (9.7)	5 (8.1)	1 (1.6)	0	0
Nausea	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Vomiting	4 (6.5)	4 (6.5)	0	0	0
Constipation	2 (3.2)	0	2 (3.2)	0	0
Pancreatitis	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Abdominal pain	1 (1.6)	0	1 (1.6)	0	0
Abdominal pain upper	1 (1.6)	1 (1.6)	0	0	0
Abdominal rigidity	1 (1.6)	0	1 (1.6)	0	0
Dyspepsia	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal inflammation	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Peritoneal haematoma	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	21 (33.9)	12 (19.4)	6 (9.7)	3 (4.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	15 (24.2)	7 (11.3)	6 (9.7)	2 (3.2)	0
Fatigue	4 (6.5)	4 (6.5)	0	0	0
Pain	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Chills	1 (1.6)	1 (1.6)	0	0	0
Malaise	1 (1.6)	1 (1.6)	0	0	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Hepatobiliary disorders					
-Total	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Hepatic cytolysis	1 (1.6)	1 (1.6)	0	0	0
Hypertransaminasaemia	1 (1.6)	1 (1.6)	0	0	0
Liver disorder	1 (1.6)	0	1 (1.6)	0	0
Immune system disorders					
-Total	13 (21.0)	1 (1.6)	8 (12.9)	4 (6.5)	0
Hypogammaglobulinaemia	7 (11.3)	0	7 (11.3)	0	0
Allergy to immunoglobulin therapy	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Graft versus host disease	2 (3.2)	0	0	2 (3.2)	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Engraftment syndrome	1 (1.6)	0	0	1 (1.6)	0
Immunodeficiency	1 (1.6)	0	0	1 (1.6)	0
Infections and infestations					
-Total	37 (59.7)	4 (6.5)	13 (21.0)	12 (19.4)	8 (12.9)
Upper respiratory tract infection	8 (12.9)	3 (4.8)	3 (4.8)	2 (3.2)	0
Nasopharyngitis	6 (9.7)	3 (4.8)	3 (4.8)	0	0
Rhinovirus infection	5 (8.1)	0	4 (6.5)	1 (1.6)	0
Gastroenteritis	4 (6.5)	2 (3.2)	0	2 (3.2)	0
Parainfluenzae virus infection	4 (6.5)	1 (1.6)	1 (1.6)	1 (1.6)	1 (1.6)
Metapneumovirus infection	3 (4.8)	0	0	3 (4.8)	0
Otitis media	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Pneumonia	3 (4.8)	1 (1.6)	1 (1.6)	0	1 (1.6)
Respiratory syncytial virus infection	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Respiratory tract infection	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Bacteraemia	2 (3.2)	0	1 (1.6)	0	1 (1.6)
Ear infection	2 (3.2)	0	2 (3.2)	0	0
Otitis externa	2 (3.2)	0	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Rhinitis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Sinusitis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Viral infection	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Adenovirus infection	1 (1.6)	0	0	1 (1.6)	0
Bk virus infection	1 (1.6)	0	0	1 (1.6)	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis	1 (1.6)	0	1 (1.6)	0	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Coronavirus infection	1 (1.6)	0	0	1 (1.6)	0
Cystitis	1 (1.6)	0	1 (1.6)	0	0
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Ear, nose and throat infection	1 (1.6)	0	1 (1.6)	0	0
Encephalitis	1 (1.6)	0	0	0	1 (1.6)
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal infection	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Herpes simplex	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Influenza	1 (1.6)	0	1 (1.6)	0	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Nail infection	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	0	1 (1.6)	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	0	1 (1.6)	0	0
Pharyngitis streptococcal	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection viral	1 (1.6)	0	1 (1.6)	0	0
Salmonellosis	1 (1.6)	0	1 (1.6)	0	0
Septic shock	1 (1.6)	0	0	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis fungal	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal skin infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral haemorrhagic cystitis	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Injury, poisoning and procedural complications					
-Total	7 (11.3)	3 (4.8)	4 (6.5)	0	0
Infusion related reaction	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Fibula fracture	1 (1.6)	0	1 (1.6)	0	0
Ligament sprain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	0	1 (1.6)	0	0
Post-traumatic neck syndrome	1 (1.6)	0	1 (1.6)	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Investigations					
-Total	20 (32.3)	4 (6.5)	4 (6.5)	8 (12.9)	4 (6.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	7 (11.3)	2 (3.2)	2 (3.2)	2 (3.2)	1 (1.6)
Neutrophil count decreased	6 (9.7)	1 (1.6)	0	2 (3.2)	3 (4.8)
Platelet count decreased	4 (6.5)	2 (3.2)	0	1 (1.6)	1 (1.6)
Blood uric acid increased	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Lymphocyte count decreased	2 (3.2)	0	0	2 (3.2)	0
Alanine aminotransferase increased	1 (1.6)	0	0	1 (1.6)	0
Blood bilirubin increased	1 (1.6)	0	0	1 (1.6)	0
Blood creatinine increased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.6)	1 (1.6)	0	0	0
Blood urea increased	1 (1.6)	0	0	1 (1.6)	0
Bone density decreased	1 (1.6)	1 (1.6)	0	0	0
C-reactive protein increased	1 (1.6)	1 (1.6)	0	0	0
Ejection fraction decreased	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heart sounds abnormal	1 (1.6)	1 (1.6)	0	0	0
Hepatitis b virus test positive	1 (1.6)	0	1 (1.6)	0	0
Immunoglobulins decreased	1 (1.6)	0	1 (1.6)	0	0
Oxygen saturation decreased	1 (1.6)	0	1 (1.6)	0	0
Weight decreased	1 (1.6)	0	0	1 (1.6)	0
Weight increased	1 (1.6)	0	0	1 (1.6)	0
Metabolism and nutrition disorders					
-Total	13 (21.0)	2 (3.2)	4 (6.5)	4 (6.5)	3 (4.8)
Decreased appetite	5 (8.1)	1 (1.6)	3 (4.8)	1 (1.6)	0
Hypokalaemia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Hyperuricaemia	2 (3.2)	2 (3.2)	0	0	0
Haemochromatosis	1 (1.6)	0	0	1 (1.6)	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hyperkalaemia	1 (1.6)	0	1 (1.6)	0	0
Hypervolaemia	1 (1.6)	0	0	1 (1.6)	0
Hypophagia	1 (1.6)	0	1 (1.6)	0	0
Hypophosphataemia	1 (1.6)	0	1 (1.6)	0	0
Iron overload	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	0	0	1 (1.6)
Metabolic syndrome	1 (1.6)	0	1 (1.6)	0	0
Tumour lysis syndrome	1 (1.6)	0	0	0	1 (1.6)
Musculoskeletal and connective tissue disorders					
-Total	15 (24.2)	5 (8.1)	7 (11.3)	3 (4.8)	0
Back pain	6 (9.7)	2 (3.2)	2 (3.2)	2 (3.2)	0
Pain in extremity	5 (8.1)	2 (3.2)	2 (3.2)	1 (1.6)	0
Arthralgia	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Bone pain	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Growth retardation	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal pain	1 (1.6)	0	1 (1.6)	0	0
Myalgia	1 (1.6)	0	1 (1.6)	0	0
Neck pain	1 (1.6)	1 (1.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (6.5)	1 (1.6)	2 (3.2)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Cancer pain	1 (1.6)	0	1 (1.6)	0	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Nervous system disorders					
-Total	12 (19.4)	5 (8.1)	5 (8.1)	0	2 (3.2)
Headache	8 (12.9)	4 (6.5)	4 (6.5)	0	0
Autonomic neuropathy	1 (1.6)	0	0	1 (1.6)	0
Cerebral haemorrhage	1 (1.6)	0	0	0	1 (1.6)
Dizziness	1 (1.6)	1 (1.6)	0	0	0
Extrapyramidal disorder	1 (1.6)	0	1 (1.6)	0	0
Hydrocephalus	1 (1.6)	0	0	0	1 (1.6)
Memory impairment	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Seizure	1 (1.6)	0	0	1 (1.6)	0
Psychiatric disorders					
-Total	10 (16.1)	1 (1.6)	8 (12.9)	1 (1.6)	0
Anxiety	6 (9.7)	1 (1.6)	5 (8.1)	0	0
Mental status changes	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Agitation	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (1.6)	0	1 (1.6)	0	0
Mood altered	1 (1.6)	1 (1.6)	0	0	0
Nightmare	1 (1.6)	1 (1.6)	0	0	0
Persistent depressive disorder	1 (1.6)	0	1 (1.6)	0	0
Sleep disorder	1 (1.6)	0	1 (1.6)	0	0
Tearfulness	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	4 (6.5)	1 (1.6)	0	2 (3.2)	1 (1.6)
Acute kidney injury	3 (4.8)	1 (1.6)	1 (1.6)	0	1 (1.6)
Dysuria	1 (1.6)	0	1 (1.6)	0	0
Haematuria	1 (1.6)	0	0	1 (1.6)	0
Kidney enlargement	1 (1.6)	0	1 (1.6)	0	0
Renal mass	1 (1.6)	0	1 (1.6)	0	0
Renal tubular disorder	1 (1.6)	0	0	1 (1.6)	0
Reproductive system and breast disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Dysmenorrhoea	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	18 (29.0)	7 (11.3)	5 (8.1)	3 (4.8)	3 (4.8)
Cough	8 (12.9)	5 (8.1)	3 (4.8)	0	0
Nasal congestion	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Hypoxia	3 (4.8)	0	0	3 (4.8)	0
Epistaxis	2 (3.2)	0	2 (3.2)	0	0
Oropharyngeal pain	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Rhinitis allergic	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Acute respiratory distress syndrome	1 (1.6)	0	0	0	1 (1.6)
Bronchial oedema	1 (1.6)	1 (1.6)	0	0	0
Bronchospasm	1 (1.6)	0	1 (1.6)	0	0
Dyspnoea	1 (1.6)	0	1 (1.6)	0	0
Lung disorder	1 (1.6)	1 (1.6)	0	0	0
Pleural effusion	1 (1.6)	1 (1.6)	0	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Skin and subcutaneous tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (27.4)	10 (16.1)	6 (9.7)	1 (1.6)	0
Dry skin	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Rash	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Ingrowing nail	2 (3.2)	0	2 (3.2)	0	0
Decubitus ulcer	1 (1.6)	0	0	1 (1.6)	0
Dermatitis allergic	1 (1.6)	1 (1.6)	0	0	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Erythema	1 (1.6)	0	1 (1.6)	0	0
Hangnail	1 (1.6)	1 (1.6)	0	0	0
Miliaria	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	1 (1.6)	0	0	0
Photosensitivity reaction	1 (1.6)	0	1 (1.6)	0	0
Pruritus	1 (1.6)	0	1 (1.6)	0	0
Skin discolouration	1 (1.6)	1 (1.6)	0	0	0
Skin hypopigmentation	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	6 (9.7)	1 (1.6)	0	2 (3.2)	3 (4.8)
Hypotension	4 (6.5)	1 (1.6)	0	1 (1.6)	2 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

			All patients N=8		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	1 (12.5)	2 (25.0)	2 (25.0)	1 (12.5)
Congenital, familial and genetic disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Cerebral cavernous malformation	1 (12.5)	1 (12.5)	0	0	0
Ear and labyrinth disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Deafness unilateral	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	2 (25.0)	2 (25.0)	0	0	0
Non-cardiac chest pain	1 (12.5)	1 (12.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Xerosis	1 (12.5)	1 (12.5)	0	0	0
Immune system disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Hypogammaglobulinaemia	2 (25.0)	0	2 (25.0)	0	0
Infections and infestations					
-Total	3 (37.5)	0	0	3 (37.5)	0
Upper respiratory tract infection	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Acute sinusitis	1 (12.5)	0	1 (12.5)	0	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Ear infection	1 (12.5)	0	0	1 (12.5)	0
Herpes zoster	1 (12.5)	0	1 (12.5)	0	0
Influenza	1 (12.5)	0	1 (12.5)	0	0
Oral herpes	1 (12.5)	1 (12.5)	0	0	0
Otitis media	1 (12.5)	0	1 (12.5)	0	0
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal abscess	1 (12.5)	0	0	1 (12.5)	0
Investigations					

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	2 (25.0)	0	0	0
Neutrophil count decreased	2 (25.0)	2 (25.0)	0	0	0
Blood bilirubin increased	1 (12.5)	1 (12.5)	0	0	0
Platelet count decreased	1 (12.5)	1 (12.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	1 (12.5)	0	0	0
Laryngeal oedema	1 (12.5)	0	0	0	1 (12.5)
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Sleep apnoea syndrome	1 (12.5)	1 (12.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Eczema	1 (12.5)	0	0	1 (12.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

			All patients N=42		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (61.9)	2 (4.8)	8 (19.0)	10 (23.8)	6 (14.3)
Blood and lymphatic system disorders					
-Total	4 (9.5)	0	2 (4.8)	1 (2.4)	1 (2.4)
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Hypercoagulation	1 (2.4)	0	1 (2.4)	0	0
Lymphadenopathy	1 (2.4)	0	1 (2.4)	0	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Endocrine disorders					
-Total	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delayed puberty	1 (2.4)	0	1 (2.4)	0	0
Hypothyroidism	1 (2.4)	0	1 (2.4)	0	0
Eye disorders					
-Total	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Dry eye	1 (2.4)	1 (2.4)	0	0	0
Eye pain	1 (2.4)	0	0	1 (2.4)	0
Eyelid oedema	1 (2.4)	1 (2.4)	0	0	0
Mydriasis	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	7 (16.7)	4 (9.5)	2 (4.8)	1 (2.4)	0
Diarrhoea	5 (11.9)	3 (7.1)	1 (2.4)	1 (2.4)	0
Constipation	1 (2.4)	1 (2.4)	0	0	0
Irritable bowel syndrome	1 (2.4)	0	1 (2.4)	0	0
Nausea	1 (2.4)	1 (2.4)	0	0	0
Vomiting	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					
-Total	7 (16.7)	2 (4.8)	3 (7.1)	1 (2.4)	1 (2.4)
Pyrexia	5 (11.9)	2 (4.8)	2 (4.8)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Fatigue	1 (2.4)	0	1 (2.4)	0	0
Multiple organ dysfunction syndrome	1 (2.4)	0	0	0	1 (2.4)
Immune system disorders					
-Total	7 (16.7)	2 (4.8)	3 (7.1)	1 (2.4)	1 (2.4)
Seasonal allergy	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Chronic graft versus host disease	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Drug hypersensitivity	1 (2.4)	0	0	1 (2.4)	0
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	0	0	1 (2.4)
Hypogammaglobulinaemia	1 (2.4)	0	1 (2.4)	0	0
Infections and infestations					
-Total	20 (47.6)	2 (4.8)	7 (16.7)	7 (16.7)	4 (9.5)
Sinusitis	5 (11.9)	0	5 (11.9)	0	0
Rhinovirus infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Conjunctivitis	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Sepsis	3 (7.1)	0	0	1 (2.4)	2 (4.8)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Bronchitis	2 (4.8)	0	2 (4.8)	0	0
Covid-19	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Fungal infection	2 (4.8)	0	2 (4.8)	0	0
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Skin infection	2 (4.8)	0	2 (4.8)	0	0
Urinary tract infection	2 (4.8)	0	2 (4.8)	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Candida infection	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	0	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Device related sepsis	1 (2.4)	0	0	1 (2.4)	0
Enterovirus infection	1 (2.4)	0	0	1 (2.4)	0
Folliculitis	1 (2.4)	0	1 (2.4)	0	0
Fungal skin infection	1 (2.4)	0	1 (2.4)	0	0
Gastroenteritis	1 (2.4)	1 (2.4)	0	0	0
Gastroenteritis escherichia coli	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (2.4)	0	1 (2.4)	0	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Influenza	1 (2.4)	0	0	0	1 (2.4)
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Nail infection	1 (2.4)	0	1 (2.4)	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Oral candidiasis	1 (2.4)	0	1 (2.4)	0	0
Oral herpes	1 (2.4)	0	1 (2.4)	0	0
Otitis media	1 (2.4)	0	1 (2.4)	0	0
Otitis media acute	1 (2.4)	0	1 (2.4)	0	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	0	0	1 (2.4)	0
Rhinitis	1 (2.4)	1 (2.4)	0	0	0
Septic shock	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Syphilis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection pseudomonal	1 (2.4)	0	1 (2.4)	0	0
Varicella zoster virus infection	1 (2.4)	0	1 (2.4)	0	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (7.1)	2 (4.8)	0	1 (2.4)	0
Abdominal injury	1 (2.4)	1 (2.4)	0	0	0
Infusion related reaction	1 (2.4)	0	0	1 (2.4)	0
Ligament sprain	1 (2.4)	1 (2.4)	0	0	0
Investigations					
-Total	4 (9.5)	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.4)
Blood immunoglobulin g decreased	1 (2.4)	0	1 (2.4)	0	0
Neutrophil count decreased	1 (2.4)	0	0	0	1 (2.4)
Oxygen saturation decreased	1 (2.4)	0	0	1 (2.4)	0
Platelet count decreased	1 (2.4)	1 (2.4)	0	0	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (14.3)	0	2 (4.8)	3 (7.1)	1 (2.4)
Decreased appetite	1 (2.4)	0	0	0	1 (2.4)
Hypercholesterolaemia	1 (2.4)	0	1 (2.4)	0	0
Hyperglycaemia	1 (2.4)	0	0	1 (2.4)	0
Hyperlipidaemia	1 (2.4)	0	1 (2.4)	0	0
Hypernatraemia	1 (2.4)	0	0	1 (2.4)	0
Hypertriglyceridaemia	1 (2.4)	0	1 (2.4)	0	0
Iron overload	1 (2.4)	0	1 (2.4)	0	0
Obesity	1 (2.4)	0	0	1 (2.4)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (16.7)	2 (4.8)	5 (11.9)	0	0
Pain in extremity	2 (4.8)	0	2 (4.8)	0	0
Arthralgia	1 (2.4)	0	1 (2.4)	0	0
Growth retardation	1 (2.4)	0	1 (2.4)	0	0
Joint effusion	1 (2.4)	0	1 (2.4)	0	0
Osteonecrosis	1 (2.4)	1 (2.4)	0	0	0
Osteopenia	1 (2.4)	1 (2.4)	0	0	0
Synovitis	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.4)	0	0	1 (2.4)	0
Bone giant cell tumour benign	1 (2.4)	0	0	1 (2.4)	0
Nervous system disorders					
-Total	4 (9.5)	0	2 (4.8)	2 (4.8)	0
Headache	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Dysarthria	1 (2.4)	0	1 (2.4)	0	0
Nervous system disorder	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	0	1 (2.4)	0
Psychiatric disorders					
-Total	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Anxiety	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Tic	1 (2.4)	0	1 (2.4)	0	0
Reproductive system and breast disorders					
-Total	1 (2.4)	0	0	1 (2.4)	0
Endometriosis	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	8 (19.0)	3 (7.1)	2 (4.8)	1 (2.4)	2 (4.8)
Cough	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Dyspnoea	2 (4.8)	0	1 (2.4)	0	1 (2.4)
Rhinorrhoea	2 (4.8)	0	2 (4.8)	0	0
Dyspnoea exertional	1 (2.4)	1 (2.4)	0	0	0
Epistaxis	1 (2.4)	1 (2.4)	0	0	0
Hypoxia	1 (2.4)	0	0	1 (2.4)	0
Oropharyngeal pain	1 (2.4)	1 (2.4)	0	0	0
Pharyngeal erythema	1 (2.4)	1 (2.4)	0	0	0
Pleural effusion	1 (2.4)	0	1 (2.4)	0	0
Respiratory failure	1 (2.4)	0	0	0	1 (2.4)
Sleep apnoea syndrome	1 (2.4)	0	1 (2.4)	0	0
Tachypnoea	1 (2.4)	0	0	0	1 (2.4)
Wheezing	1 (2.4)	0	1 (2.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (14.3)	3 (7.1)	1 (2.4)	2 (4.8)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Dermatitis atopic	1 (2.4)	0	0	1 (2.4)	0
Dry skin	1 (2.4)	1 (2.4)	0	0	0
Papule	1 (2.4)	1 (2.4)	0	0	0
Rash erythematous	1 (2.4)	1 (2.4)	0	0	0
Rash macular	1 (2.4)	0	0	1 (2.4)	0
Rash maculo-papular	1 (2.4)	1 (2.4)	0	0	0
Vascular disorders					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Hypertension	2 (4.8)	0	1 (2.4)	1 (2.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	1 (7.7)	4 (30.8)	8 (61.5)
Blood and lymphatic system disorders					
-Total	11 (84.6)	1 (7.7)	2 (15.4)	6 (46.2)	2 (15.4)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)	0	0
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Disseminated intravascular coagulation	1 (7.7)	0	1 (7.7)	0	0
Hypofibrinogenaemia	1 (7.7)	0	1 (7.7)	0	0
Leukopenia	1 (7.7)	0	0	0	1 (7.7)
Splenomegaly	1 (7.7)	1 (7.7)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	7 (53.8)	6 (46.2)	0	1 (7.7)	0
Tachycardia	6 (46.2)	6 (46.2)	0	0	0
Cardiac dysfunction	1 (7.7)	1 (7.7)	0	0	0
Left ventricular dysfunction	1 (7.7)	0	0	1 (7.7)	0
Congenital, familial and genetic disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Cerebral cavernous malformation	1 (7.7)	1 (7.7)	0	0	0
Ear and labyrinth disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Deafness unilateral	1 (7.7)	0	1 (7.7)	0	0
Ear pain	1 (7.7)	1 (7.7)	0	0	0
Eye disorders					
-Total	3 (23.1)	3 (23.1)	0	0	0
Ocular hyperaemia	2 (15.4)	2 (15.4)	0	0	0
Cataract	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (76.9)	4 (30.8)	4 (30.8)	2 (15.4)	0
Nausea	7 (53.8)	6 (46.2)	1 (7.7)	0	0
Vomiting	6 (46.2)	3 (23.1)	3 (23.1)	0	0
Diarrhoea	5 (38.5)	5 (38.5)	0	0	0
Abdominal pain	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Constipation	3 (23.1)	3 (23.1)	0	0	0
Proctalgia	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Anal haemorrhage	1 (7.7)	1 (7.7)	0	0	0
Enteritis	1 (7.7)	0	1 (7.7)	0	0
Enterocolitis	1 (7.7)	0	1 (7.7)	0	0
Gastrointestinal sounds abnormal	1 (7.7)	1 (7.7)	0	0	0
Gastrooesophageal reflux disease	1 (7.7)	0	1 (7.7)	0	0
Haematemesis	1 (7.7)	1 (7.7)	0	0	0
Lip oedema	1 (7.7)	1 (7.7)	0	0	0
Neutropenic colitis	1 (7.7)	0	0	1 (7.7)	0
Stomatitis	1 (7.7)	1 (7.7)	0	0	0
Trichoglossia	1 (7.7)	1 (7.7)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	8 (61.5)	7 (53.8)	1 (7.7)	0	0
Fatigue	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Pyrexia	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Catheter site haemorrhage	1 (7.7)	1 (7.7)	0	0	0
Chills	1 (7.7)	1 (7.7)	0	0	0
Generalised oedema	1 (7.7)	1 (7.7)	0	0	0
Non-cardiac chest pain	1 (7.7)	1 (7.7)	0	0	0
Oedema peripheral	1 (7.7)	1 (7.7)	0	0	0
Vascular device occlusion	1 (7.7)	1 (7.7)	0	0	0
Xerosis	1 (7.7)	1 (7.7)	0	0	0
Hepatobiliary disorders					
-Total	4 (30.8)	2 (15.4)	1 (7.7)	0	1 (7.7)
Hepatic function abnormal	2 (15.4)	0	1 (7.7)	0	1 (7.7)
Hepatomegaly	1 (7.7)	1 (7.7)	0	0	0
Ocular icterus	1 (7.7)	1 (7.7)	0	0	0
Immune system disorders					
-Total	13 (100)	0	7 (53.8)	5 (38.5)	1 (7.7)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Hypogammaglobulinaemia	6 (46.2)	0	6 (46.2)	0	0
Infections and infestations					
-Total	5 (38.5)	1 (7.7)	0	4 (30.8)	0
Upper respiratory tract infection	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Acute sinusitis	1 (7.7)	0	1 (7.7)	0	0
Anal abscess	1 (7.7)	0	0	1 (7.7)	0
Conjunctivitis	1 (7.7)	0	1 (7.7)	0	0
Ear infection	1 (7.7)	0	0	1 (7.7)	0
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Herpes zoster	1 (7.7)	0	1 (7.7)	0	0
Influenza	1 (7.7)	0	1 (7.7)	0	0
Nasopharyngitis	1 (7.7)	1 (7.7)	0	0	0
Oral herpes	1 (7.7)	1 (7.7)	0	0	0
Otitis externa	1 (7.7)	0	1 (7.7)	0	0
Otitis media	1 (7.7)	0	1 (7.7)	0	0
Paronychia	1 (7.7)	0	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	0	1 (7.7)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (7.7)	0	1 (7.7)	0	0
Skin infection	1 (7.7)	0	1 (7.7)	0	0
Staphylococcal abscess	1 (7.7)	0	0	1 (7.7)	0
Tinea pedis	1 (7.7)	1 (7.7)	0	0	0
Urinary tract infection viral	1 (7.7)	1 (7.7)	0	0	0
Varicella zoster virus infection	1 (7.7)	0	0	1 (7.7)	0
Injury, poisoning and procedural complications					
-Total	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Contusion	1 (7.7)	1 (7.7)	0	0	0
Infusion related reaction	1 (7.7)	1 (7.7)	0	0	0
Procedural pain	1 (7.7)	0	1 (7.7)	0	0
Transfusion reaction	1 (7.7)	1 (7.7)	0	0	0
Investigations					
-Total	11 (84.6)	1 (7.7)	1 (7.7)	3 (23.1)	6 (46.2)
Neutrophil count decreased	9 (69.2)	1 (7.7)	2 (15.4)	1 (7.7)	5 (38.5)
Platelet count decreased	9 (69.2)	4 (30.8)	1 (7.7)	4 (30.8)	0
White blood cell count decreased	9 (69.2)	2 (15.4)	2 (15.4)	0	5 (38.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (53.8)	0	1 (7.7)	4 (30.8)	2 (15.4)
Blood immunoglobulin a decreased	6 (46.2)	5 (38.5)	0	1 (7.7)	0
International normalised ratio increased	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Blood immunoglobulin m decreased	5 (38.5)	4 (30.8)	0	1 (7.7)	0
Alanine aminotransferase increased	4 (30.8)	0	2 (15.4)	2 (15.4)	0
Aspartate aminotransferase increased	4 (30.8)	0	1 (7.7)	3 (23.1)	0
Blood bilirubin increased	4 (30.8)	1 (7.7)	1 (7.7)	2 (15.4)	0
Activated partial thromboplastin time prolonged	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Blood fibrinogen decreased	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Serum ferritin increased	2 (15.4)	0	2 (15.4)	0	0
Blood creatine phosphokinase increased	1 (7.7)	0	0	1 (7.7)	0
Blood lactate dehydrogenase increased	1 (7.7)	1 (7.7)	0	0	0
Blood uric acid increased	1 (7.7)	1 (7.7)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (7.7)	1 (7.7)	0	0	0
Electrocardiogram qt prolonged	1 (7.7)	1 (7.7)	0	0	0
Haemoglobin decreased	1 (7.7)	0	0	1 (7.7)	0
Weight increased	1 (7.7)	0	0	1 (7.7)	0
Metabolism and nutrition disorders					
-Total	10 (76.9)	3 (23.1)	2 (15.4)	5 (38.5)	0
Decreased appetite	8 (61.5)	5 (38.5)	1 (7.7)	2 (15.4)	0
Hypokalaemia	3 (23.1)	0	1 (7.7)	2 (15.4)	0
Hyperphosphataemia	2 (15.4)	2 (15.4)	0	0	0
Hyperuricaemia	2 (15.4)	2 (15.4)	0	0	0
Hypophosphataemia	2 (15.4)	0	0	2 (15.4)	0
Dehydration	1 (7.7)	0	1 (7.7)	0	0
Hypertriglyceridaemia	1 (7.7)	0	0	1 (7.7)	0
Hypoalbuminaemia	1 (7.7)	0	1 (7.7)	0	0
Hypomagnesaemia	1 (7.7)	1 (7.7)	0	0	0
Metabolic acidosis	1 (7.7)	1 (7.7)	0	0	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	8 (61.5)	6 (46.2)	2 (15.4)	0	0
Pain in extremity	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Myalgia	4 (30.8)	2 (15.4)	2 (15.4)	0	0
Arthralgia	2 (15.4)	2 (15.4)	0	0	0
Nervous system disorders					
-Total	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Headache	4 (30.8)	3 (23.1)	1 (7.7)	0	0
Dizziness	1 (7.7)	1 (7.7)	0	0	0
Hypoaesthesia	1 (7.7)	1 (7.7)	0	0	0
Lethargy	1 (7.7)	1 (7.7)	0	0	0
Tremor	1 (7.7)	1 (7.7)	0	0	0
Psychiatric disorders					
-Total	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Anxiety	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Agitation	1 (7.7)	1 (7.7)	0	0	0
Irritability	1 (7.7)	1 (7.7)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (7.7)	1 (7.7)	0	0	0
Renal and urinary disorders					
-Total	5 (38.5)	2 (15.4)	2 (15.4)	0	1 (7.7)
Acute kidney injury	1 (7.7)	0	0	0	1 (7.7)
Cystitis haemorrhagic	1 (7.7)	0	1 (7.7)	0	0
Dysuria	1 (7.7)	1 (7.7)	0	0	0
Micturition urgency	1 (7.7)	0	1 (7.7)	0	0
Pollakiuria	1 (7.7)	0	1 (7.7)	0	0
Renal tubular dysfunction	1 (7.7)	1 (7.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (76.9)	4 (30.8)	3 (23.1)	1 (7.7)	2 (15.4)
Cough	4 (30.8)	4 (30.8)	0	0	0
Rhinorrhoea	4 (30.8)	4 (30.8)	0	0	0
Oropharyngeal pain	3 (23.1)	3 (23.1)	0	0	0
Hypoxia	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Nasal congestion	2 (15.4)	2 (15.4)	0	0	0
Pleural effusion	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Tachypnoea	2 (15.4)	2 (15.4)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (7.7)	1 (7.7)	0	0	0
Epistaxis	1 (7.7)	1 (7.7)	0	0	0
Laryngeal oedema	1 (7.7)	0	0	0	1 (7.7)
Paranasal sinus inflammation	1 (7.7)	1 (7.7)	0	0	0
Respiratory distress	1 (7.7)	0	1 (7.7)	0	0
Sleep apnoea syndrome	1 (7.7)	1 (7.7)	0	0	0
Upper respiratory tract inflammation	1 (7.7)	0	1 (7.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (61.5)	5 (38.5)	2 (15.4)	1 (7.7)	0
Dry skin	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Eczema	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Pruritus	2 (15.4)	2 (15.4)	0	0	0
Rash papular	2 (15.4)	2 (15.4)	0	0	0
Blister	1 (7.7)	1 (7.7)	0	0	0
Dermatitis	1 (7.7)	1 (7.7)	0	0	0
Erythema nodosum	1 (7.7)	1 (7.7)	0	0	0
Rash pruritic	1 (7.7)	1 (7.7)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin swelling	1 (7.7)	1 (7.7)	0	0	0
Skin ulcer	1 (7.7)	0	1 (7.7)	0	0
Vascular disorders					
-Total	4 (30.8)	2 (15.4)	0	1 (7.7)	1 (7.7)
Hypotension	3 (23.1)	1 (7.7)	0	1 (7.7)	1 (7.7)
Hypertension	1 (7.7)	1 (7.7)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (100)	1 (1.5)	5 (7.5)	15 (22.4)	46 (68.7)
Blood and lymphatic system disorders					
-Total	44 (65.7)	0	9 (13.4)	23 (34.3)	12 (17.9)
Febrile neutropenia	21 (31.3)	0	0	19 (28.4)	2 (3.0)
Anaemia	17 (25.4)	4 (6.0)	4 (6.0)	9 (13.4)	0
Neutropenia	9 (13.4)	0	2 (3.0)	2 (3.0)	5 (7.5)
Thrombocytopenia	9 (13.4)	0	0	3 (4.5)	6 (9.0)
Disseminated intravascular coagulation	7 (10.4)	0	4 (6.0)	3 (4.5)	0
Coagulopathy	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Splenomegaly	3 (4.5)	2 (3.0)	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Lymphadenopathy	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Lymphopenia	2 (3.0)	0	0	2 (3.0)	0
Pancytopenia	2 (3.0)	0	0	2 (3.0)	0
Agranulocytosis	1 (1.5)	0	0	1 (1.5)	0
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Eosinophilia	1 (1.5)	0	1 (1.5)	0	0
Hypercoagulation	1 (1.5)	0	1 (1.5)	0	0
Leukocytosis	1 (1.5)	0	1 (1.5)	0	0
Lymphocytosis	1 (1.5)	0	1 (1.5)	0	0
Cardiac disorders					
-Total	21 (31.3)	4 (6.0)	7 (10.4)	4 (6.0)	6 (9.0)
Tachycardia	11 (16.4)	1 (1.5)	7 (10.4)	2 (3.0)	1 (1.5)
Bradycardia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Cardiac arrest	3 (4.5)	0	0	0	3 (4.5)
Cardiac failure	3 (4.5)	0	0	1 (1.5)	2 (3.0)
Left ventricular dysfunction	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Sinus tachycardia	3 (4.5)	2 (3.0)	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.5)	0	1 (1.5)	0	0
Cardiac dysfunction	1 (1.5)	1 (1.5)	0	0	0
Cardiac failure congestive	1 (1.5)	0	1 (1.5)	0	0
Mitral valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Pericardial effusion	1 (1.5)	1 (1.5)	0	0	0
Right ventricular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Sinus bradycardia	1 (1.5)	0	0	1 (1.5)	0
Tricuspid valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Ear and labyrinth disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Ear pruritus	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					
-Total	7 (10.4)	0	7 (10.4)	0	0
Adrenal insufficiency	4 (6.0)	0	4 (6.0)	0	0
Hypothyroidism	3 (4.5)	0	3 (4.5)	0	0
Delayed puberty	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	12 (17.9)	7 (10.4)	4 (6.0)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eyelid oedema	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Conjunctival haemorrhage	2 (3.0)	2 (3.0)	0	0	0
Eye pain	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Visual impairment	2 (3.0)	2 (3.0)	0	0	0
Cataract	1 (1.5)	1 (1.5)	0	0	0
Dry eye	1 (1.5)	1 (1.5)	0	0	0
Eye oedema	1 (1.5)	1 (1.5)	0	0	0
Hypermetropia	1 (1.5)	1 (1.5)	0	0	0
Mydriasis	1 (1.5)	0	1 (1.5)	0	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0	0	0
Periorbital oedema	1 (1.5)	1 (1.5)	0	0	0
Periorbital swelling	1 (1.5)	0	1 (1.5)	0	0
Retinal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	50 (74.6)	17 (25.4)	19 (28.4)	13 (19.4)	1 (1.5)
Diarrhoea	21 (31.3)	11 (16.4)	8 (11.9)	2 (3.0)	0
Vomiting	20 (29.9)	14 (20.9)	5 (7.5)	1 (1.5)	0
Nausea	15 (22.4)	6 (9.0)	7 (10.4)	2 (3.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	11 (16.4)	4 (6.0)	7 (10.4)	0	0
Abdominal pain	8 (11.9)	1 (1.5)	6 (9.0)	1 (1.5)	0
Pancreatitis	6 (9.0)	1 (1.5)	3 (4.5)	2 (3.0)	0
Mouth haemorrhage	5 (7.5)	2 (3.0)	1 (1.5)	2 (3.0)	0
Abdominal pain upper	4 (6.0)	3 (4.5)	1 (1.5)	0	0
Abdominal distension	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Ascites	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Stomatitis	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Abdominal compartment syndrome	1 (1.5)	0	0	0	1 (1.5)
Abdominal rigidity	1 (1.5)	0	1 (1.5)	0	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Dry mouth	1 (1.5)	0	1 (1.5)	0	0
Dyspepsia	1 (1.5)	1 (1.5)	0	0	0
Dysphagia	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal inflammation	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal sounds abnormal	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival bleeding	1 (1.5)	0	1 (1.5)	0	0
Gingival erythema	1 (1.5)	1 (1.5)	0	0	0
Gingivitis ulcerative	1 (1.5)	0	0	1 (1.5)	0
Ileus	1 (1.5)	0	1 (1.5)	0	0
Irritable bowel syndrome	1 (1.5)	0	1 (1.5)	0	0
Lip dry	1 (1.5)	0	1 (1.5)	0	0
Melaena	1 (1.5)	0	0	1 (1.5)	0
Mouth swelling	1 (1.5)	1 (1.5)	0	0	0
Odynophagia	1 (1.5)	1 (1.5)	0	0	0
Peritoneal haematoma	1 (1.5)	1 (1.5)	0	0	0
Trichoglossia	1 (1.5)	0	1 (1.5)	0	0
Upper gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	45 (67.2)	18 (26.9)	12 (17.9)	10 (14.9)	5 (7.5)
Pyrexia	32 (47.8)	12 (17.9)	9 (13.4)	9 (13.4)	2 (3.0)
Fatigue	11 (16.4)	9 (13.4)	2 (3.0)	0	0
Face oedema	8 (11.9)	5 (7.5)	2 (3.0)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	6 (9.0)	4 (6.0)	2 (3.0)	0	0
Oedema peripheral	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Pain	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Generalised oedema	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Asthenia	3 (4.5)	3 (4.5)	0	0	0
Multiple organ dysfunction syndrome	3 (4.5)	0	0	0	3 (4.5)
Catheter site pain	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Drug withdrawal syndrome	2 (3.0)	0	2 (3.0)	0	0
Influenza like illness	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Localised oedema	2 (3.0)	2 (3.0)	0	0	0
Malaise	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Catheter site erythema	1 (1.5)	1 (1.5)	0	0	0
Chest discomfort	1 (1.5)	0	0	1 (1.5)	0
Crying	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Non-cardiac chest pain	1 (1.5)	1 (1.5)	0	0	0
Oedema due to hepatic disease	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Swelling face	1 (1.5)	1 (1.5)	0	0	0
Systemic inflammatory response syndrome	1 (1.5)	0	0	1 (1.5)	0
Hepatobiliary disorders					
-Total	15 (22.4)	4 (6.0)	6 (9.0)	3 (4.5)	2 (3.0)
Hyperbilirubinaemia	5 (7.5)	1 (1.5)	3 (4.5)	1 (1.5)	0
Hepatic function abnormal	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Cholelithiasis	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Gallbladder enlargement	2 (3.0)	2 (3.0)	0	0	0
Hepatomegaly	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Hypertransaminasaemia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Biliary tract disorder	1 (1.5)	1 (1.5)	0	0	0
Cholestasis	1 (1.5)	0	0	0	1 (1.5)
Hepatic cytolysis	1 (1.5)	1 (1.5)	0	0	0
Liver disorder	1 (1.5)	0	1 (1.5)	0	0
Immune system disorders					
-Total	58 (86.6)	2 (3.0)	16 (23.9)	19 (28.4)	21 (31.3)
Cytokine release syndrome	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	27 (40.3)	2 (3.0)	18 (26.9)	7 (10.4)	0
Haemophagocytic lymphohistiocytosis	6 (9.0)	1 (1.5)	1 (1.5)	2 (3.0)	2 (3.0)
Immunodeficiency	4 (6.0)	0	0	4 (6.0)	0
Seasonal allergy	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Allergy to immunoglobulin therapy	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Chronic graft versus host disease	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Drug hypersensitivity	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Graft versus host disease	2 (3.0)	0	0	2 (3.0)	0
Engraftment syndrome	1 (1.5)	0	0	1 (1.5)	0
Hypersensitivity	1 (1.5)	1 (1.5)	0	0	0
Selective igg subclass deficiency	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	55 (82.1)	7 (10.4)	13 (19.4)	21 (31.3)	14 (20.9)
Upper respiratory tract infection	11 (16.4)	4 (6.0)	5 (7.5)	2 (3.0)	0
Rhinovirus infection	9 (13.4)	0	7 (10.4)	2 (3.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	7 (10.4)	2 (3.0)	5 (7.5)	0	0
Nasopharyngitis	6 (9.0)	3 (4.5)	3 (4.5)	0	0
Sinusitis	6 (9.0)	0	4 (6.0)	2 (3.0)	0
Gastroenteritis	5 (7.5)	3 (4.5)	0	2 (3.0)	0
Parainfluenzae virus infection	5 (7.5)	1 (1.5)	1 (1.5)	2 (3.0)	1 (1.5)
Pneumonia	5 (7.5)	1 (1.5)	1 (1.5)	1 (1.5)	2 (3.0)
Staphylococcal bacteraemia	5 (7.5)	0	0	5 (7.5)	0
Staphylococcal infection	5 (7.5)	0	3 (4.5)	2 (3.0)	0
Candida infection	4 (6.0)	0	3 (4.5)	0	1 (1.5)
Clostridium difficile infection	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Nail infection	4 (6.0)	3 (4.5)	1 (1.5)	0	0
Otitis media	4 (6.0)	0	3 (4.5)	1 (1.5)	0
Bacteraemia	3 (4.5)	0	1 (1.5)	1 (1.5)	1 (1.5)
Metapneumovirus infection	3 (4.5)	0	0	3 (4.5)	0
Oral candidiasis	3 (4.5)	0	3 (4.5)	0	0
Oral herpes	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Respiratory syncytial virus infection	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Respiratory tract infection	3 (4.5)	1 (1.5)	2 (3.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Sepsis	3 (4.5)	0	0	1 (1.5)	2 (3.0)
Urinary tract infection	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Adenovirus infection	2 (3.0)	0	0	2 (3.0)	0
Bk virus infection	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Bronchitis	2 (3.0)	0	2 (3.0)	0	0
Bronchopulmonary aspergillosis	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Covid-19	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Ear infection	2 (3.0)	0	2 (3.0)	0	0
Encephalitis	2 (3.0)	0	0	0	2 (3.0)
Encephalitis viral	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Fungal infection	2 (3.0)	0	2 (3.0)	0	0
Gastroenteritis viral	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Gingivitis	2 (3.0)	2 (3.0)	0	0	0
Herpes simplex	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Herpes zoster	2 (3.0)	0	0	2 (3.0)	0
Human herpesvirus 6 infection	2 (3.0)	0	0	2 (3.0)	0
Influenza	2 (3.0)	0	1 (1.5)	0	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (3.0)	0	2 (3.0)	0	0
Otitis externa	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Pneumocystis jirovecii pneumonia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Septic shock	2 (3.0)	0	0	0	2 (3.0)
Skin infection	2 (3.0)	0	2 (3.0)	0	0
Viral infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Acute sinusitis	1 (1.5)	0	1 (1.5)	0	0
Atypical pneumonia	1 (1.5)	1 (1.5)	0	0	0
Bronchiolitis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	1 (1.5)	0	0
Cholecystitis infective	1 (1.5)	0	1 (1.5)	0	0
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0
Coronavirus infection	1 (1.5)	0	0	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cystitis	1 (1.5)	0	1 (1.5)	0	0
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related infection	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Ear, nose and throat infection	1 (1.5)	0	1 (1.5)	0	0
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis clostridial	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis norovirus	1 (1.5)	1 (1.5)	0	0	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal infection	1 (1.5)	1 (1.5)	0	0	0
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Herpes virus infection	1 (1.5)	0	1 (1.5)	0	0
Klebsiella bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0	0	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis bacterial	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Myringitis	1 (1.5)	1 (1.5)	0	0	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	1 (1.5)	0	0
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	0	1 (1.5)	0	0
Pharyngitis streptococcal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection viral	1 (1.5)	0	1 (1.5)	0	0
Salmonellosis	1 (1.5)	0	1 (1.5)	0	0
Sinusitis fungal	1 (1.5)	0	0	1 (1.5)	0
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Staphylococcal skin infection	1 (1.5)	0	1 (1.5)	0	0
Stomatococcal infection	1 (1.5)	0	1 (1.5)	0	0
Streptococcal sepsis	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Syphilis	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Urinary tract infection pseudomonal	1 (1.5)	0	1 (1.5)	0	0
Varicella zoster virus infection	1 (1.5)	0	1 (1.5)	0	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral skin infection	1 (1.5)	1 (1.5)	0	0	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	18 (26.9)	7 (10.4)	8 (11.9)	1 (1.5)	2 (3.0)
Infusion related reaction	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Fall	2 (3.0)	0	2 (3.0)	0	0
Ligament sprain	2 (3.0)	2 (3.0)	0	0	0
Skin abrasion	2 (3.0)	2 (3.0)	0	0	0
Wound	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Abdominal injury	1 (1.5)	1 (1.5)	0	0	0
Contusion	1 (1.5)	1 (1.5)	0	0	0
Fibula fracture	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (1.5)	0	1 (1.5)	0	0
Post-traumatic neck syndrome	1 (1.5)	0	1 (1.5)	0	0
Procedural pain	1 (1.5)	1 (1.5)	0	0	0
Scratch	1 (1.5)	1 (1.5)	0	0	0
Skin injury	1 (1.5)	0	1 (1.5)	0	0
Skin wound	1 (1.5)	1 (1.5)	0	0	0
Transfusion reaction	1 (1.5)	0	1 (1.5)	0	0
Transplant failure	1 (1.5)	0	0	0	1 (1.5)
Vasoplegia syndrome	1 (1.5)	0	0	0	1 (1.5)
Investigations					
-Total	49 (73.1)	2 (3.0)	8 (11.9)	16 (23.9)	23 (34.3)
White blood cell count decreased	16 (23.9)	1 (1.5)	2 (3.0)	2 (3.0)	11 (16.4)
Aspartate aminotransferase increased	15 (22.4)	2 (3.0)	5 (7.5)	5 (7.5)	3 (4.5)
Neutrophil count decreased	15 (22.4)	0	0	3 (4.5)	12 (17.9)
Platelet count decreased	15 (22.4)	2 (3.0)	2 (3.0)	3 (4.5)	8 (11.9)
Alanine aminotransferase increased	14 (20.9)	3 (4.5)	6 (9.0)	5 (7.5)	0
Lymphocyte count decreased	10 (14.9)	1 (1.5)	0	6 (9.0)	3 (4.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	9 (13.4)	0	2 (3.0)	7 (10.4)	0
Serum ferritin increased	6 (9.0)	1 (1.5)	3 (4.5)	2 (3.0)	0
Blood creatinine increased	5 (7.5)	1 (1.5)	1 (1.5)	2 (3.0)	1 (1.5)
Blood fibrinogen decreased	4 (6.0)	0	2 (3.0)	1 (1.5)	1 (1.5)
Blood immunoglobulin g decreased	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Blood lactate dehydrogenase increased	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
C-reactive protein increased	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Electrocardiogram qt prolonged	4 (6.0)	0	2 (3.0)	1 (1.5)	1 (1.5)
Activated partial thromboplastin time prolonged	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Blood uric acid increased	3 (4.5)	1 (1.5)	0	1 (1.5)	1 (1.5)
Fibrin d dimer increased	3 (4.5)	2 (3.0)	0	1 (1.5)	0
International normalised ratio increased	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Oxygen saturation decreased	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Weight increased	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Blood immunoglobulin m decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gamma-glutamyltransferase increased	2 (3.0)	0	0	2 (3.0)	0
Immunoglobulins decreased	2 (3.0)	0	2 (3.0)	0	0
Lipase increased	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Urine output decreased	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Weight decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Amylase increased	1 (1.5)	1 (1.5)	0	0	0
Bacterial test positive	1 (1.5)	0	0	1 (1.5)	0
Blood alkaline phosphatase increased	1 (1.5)	1 (1.5)	0	0	0
Blood bicarbonate decreased	1 (1.5)	0	1 (1.5)	0	0
Blood creatine phosphokinase increased	1 (1.5)	0	0	0	1 (1.5)
Blood glucose increased	1 (1.5)	0	0	0	1 (1.5)
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)	0	0
Blood phosphorus increased	1 (1.5)	0	1 (1.5)	0	0
Blood testosterone decreased	1 (1.5)	1 (1.5)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (1.5)	0	0	1 (1.5)	0
Bone density decreased	1 (1.5)	1 (1.5)	0	0	0
Breath sounds abnormal	1 (1.5)	0	1 (1.5)	0	0
Cardiac murmur	1 (1.5)	1 (1.5)	0	0	0
Coagulation test abnormal	1 (1.5)	1 (1.5)	0	0	0
Ejection fraction decreased	1 (1.5)	0	1 (1.5)	0	0
Electrocardiogram t wave abnormal	1 (1.5)	0	1 (1.5)	0	0
Enterovirus test positive	1 (1.5)	0	1 (1.5)	0	0
Haptoglobin decreased	1 (1.5)	1 (1.5)	0	0	0
Heart sounds abnormal	1 (1.5)	1 (1.5)	0	0	0
Hepatitis b virus test positive	1 (1.5)	0	1 (1.5)	0	0
Prothrombin time prolonged	1 (1.5)	0	1 (1.5)	0	0
Staphylococcus test positive	1 (1.5)	1 (1.5)	0	0	0
Troponin increased	1 (1.5)	0	0	1 (1.5)	0
Metabolism and nutrition disorders					
-Total	42 (62.7)	6 (9.0)	8 (11.9)	17 (25.4)	11 (16.4)
Decreased appetite	22 (32.8)	6 (9.0)	6 (9.0)	8 (11.9)	2 (3.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	17 (25.4)	3 (4.5)	5 (7.5)	7 (10.4)	2 (3.0)
Hypocalcaemia	16 (23.9)	2 (3.0)	9 (13.4)	5 (7.5)	0
Hypophosphataemia	16 (23.9)	3 (4.5)	6 (9.0)	6 (9.0)	1 (1.5)
Hypoalbuminaemia	10 (14.9)	0	9 (13.4)	1 (1.5)	0
Hyperglycaemia	9 (13.4)	0	4 (6.0)	5 (7.5)	0
Hyperuricaemia	7 (10.4)	5 (7.5)	1 (1.5)	1 (1.5)	0
Hypervolaemia	7 (10.4)	0	2 (3.0)	5 (7.5)	0
Hypomagnesaemia	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Tumour lysis syndrome	4 (6.0)	0	0	3 (4.5)	1 (1.5)
Hypercalcaemia	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Hyperkalaemia	3 (4.5)	0	1 (1.5)	1 (1.5)	1 (1.5)
Hypernatraemia	3 (4.5)	1 (1.5)	0	1 (1.5)	1 (1.5)
Hyperphosphataemia	3 (4.5)	2 (3.0)	0	0	1 (1.5)
Hyponatraemia	3 (4.5)	3 (4.5)	0	0	0
Metabolic acidosis	3 (4.5)	0	0	0	3 (4.5)
Acidosis	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Hyperchloraemia	2 (3.0)	2 (3.0)	0	0	0
Hypermagnesaemia	2 (3.0)	2 (3.0)	0	0	0
Hypertriglyceridaemia	2 (3.0)	0	1 (1.5)	0	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	2 (3.0)	0	2 (3.0)	0	0
Malnutrition	2 (3.0)	0	0	2 (3.0)	0
Calcium deficiency	1 (1.5)	1 (1.5)	0	0	0
Haemochromatosis	1 (1.5)	0	0	1 (1.5)	0
Haemosiderosis	1 (1.5)	0	1 (1.5)	0	0
Hypercholesterolaemia	1 (1.5)	0	1 (1.5)	0	0
Hyperlactacidaemia	1 (1.5)	1 (1.5)	0	0	0
Hyperlipidaemia	1 (1.5)	0	1 (1.5)	0	0
Hypoglycaemia	1 (1.5)	0	1 (1.5)	0	0
Hypophagia	1 (1.5)	0	1 (1.5)	0	0
Metabolic syndrome	1 (1.5)	0	1 (1.5)	0	0
Obesity	1 (1.5)	0	0	1 (1.5)	0
Polydipsia	1 (1.5)	0	0	1 (1.5)	0
Musculoskeletal and connective tissue disorders					
-Total	36 (53.7)	11 (16.4)	17 (25.4)	7 (10.4)	1 (1.5)
Pain in extremity	12 (17.9)	4 (6.0)	7 (10.4)	1 (1.5)	0
Arthralgia	10 (14.9)	3 (4.5)	6 (9.0)	1 (1.5)	0
Back pain	10 (14.9)	2 (3.0)	5 (7.5)	3 (4.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	6 (9.0)	4 (6.0)	2 (3.0)	0	0
Bone pain	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Growth retardation	2 (3.0)	0	2 (3.0)	0	0
Muscular weakness	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Musculoskeletal chest pain	2 (3.0)	2 (3.0)	0	0	0
Neck pain	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Pain in jaw	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Haemarthrosis	1 (1.5)	0	0	1 (1.5)	0
Joint effusion	1 (1.5)	0	1 (1.5)	0	0
Muscle rigidity	1 (1.5)	1 (1.5)	0	0	0
Muscle spasms	1 (1.5)	0	1 (1.5)	0	0
Musculoskeletal pain	1 (1.5)	0	1 (1.5)	0	0
Myositis	1 (1.5)	0	1 (1.5)	0	0
Osteonecrosis	1 (1.5)	1 (1.5)	0	0	0
Osteopenia	1 (1.5)	1 (1.5)	0	0	0
Rhabdomyolysis	1 (1.5)	0	0	0	1 (1.5)
Synovitis	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Skin papilloma	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Bone giant cell tumour benign	1 (1.5)	0	0	1 (1.5)	0
Cancer pain	1 (1.5)	0	1 (1.5)	0	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Nervous system disorders					
-Total	41 (61.2)	10 (14.9)	17 (25.4)	10 (14.9)	4 (6.0)
Headache	23 (34.3)	10 (14.9)	10 (14.9)	3 (4.5)	0
Encephalopathy	8 (11.9)	1 (1.5)	3 (4.5)	4 (6.0)	0
Somnolence	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0
Tremor	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Seizure	4 (6.0)	0	1 (1.5)	3 (4.5)	0
Cognitive disorder	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Dizziness	3 (4.5)	3 (4.5)	0	0	0
Dysgeusia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Cerebral haemorrhage	2 (3.0)	0	0	0	2 (3.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Lethargy	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Amnesia	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Autonomic neuropathy	1 (1.5)	0	0	1 (1.5)	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Extrapyramidal disorder	1 (1.5)	0	1 (1.5)	0	0
Generalised tonic-clonic seizure	1 (1.5)	0	1 (1.5)	0	0
Hydrocephalus	1 (1.5)	0	0	0	1 (1.5)
Hyperaesthesia	1 (1.5)	1 (1.5)	0	0	0
Memory impairment	1 (1.5)	0	1 (1.5)	0	0
Migraine	1 (1.5)	0	1 (1.5)	0	0
Monoparesis	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorder	1 (1.5)	0	0	1 (1.5)	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Neurological decompensation	1 (1.5)	0	0	0	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	1 (1.5)	1 (1.5)	0	0	0
Psychiatric disorders					
-Total	34 (50.7)	9 (13.4)	18 (26.9)	7 (10.4)	0
Anxiety	12 (17.9)	2 (3.0)	8 (11.9)	2 (3.0)	0
Delirium	8 (11.9)	2 (3.0)	3 (4.5)	3 (4.5)	0
Agitation	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Confusional state	5 (7.5)	5 (7.5)	0	0	0
Insomnia	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Mental status changes	4 (6.0)	0	2 (3.0)	2 (3.0)	0
Hallucination	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Sleep disorder	3 (4.5)	0	3 (4.5)	0	0
Irritability	2 (3.0)	2 (3.0)	0	0	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Automatism	1 (1.5)	1 (1.5)	0	0	0
Hallucination, visual	1 (1.5)	0	1 (1.5)	0	0
Mood altered	1 (1.5)	1 (1.5)	0	0	0
Nightmare	1 (1.5)	1 (1.5)	0	0	0
Persistent depressive disorder	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tearfulness	1 (1.5)	1 (1.5)	0	0	0
Tic	1 (1.5)	0	1 (1.5)	0	0
Renal and urinary disorders					
-Total	20 (29.9)	4 (6.0)	5 (7.5)	5 (7.5)	6 (9.0)
Acute kidney injury	11 (16.4)	2 (3.0)	2 (3.0)	3 (4.5)	4 (6.0)
Dysuria	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Haematuria	3 (4.5)	2 (3.0)	0	1 (1.5)	0
Anuria	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Renal failure	2 (3.0)	0	1 (1.5)	0	1 (1.5)
Urinary retention	2 (3.0)	0	2 (3.0)	0	0
Azotaemia	1 (1.5)	0	1 (1.5)	0	0
Bladder dilatation	1 (1.5)	0	1 (1.5)	0	0
Incontinence	1 (1.5)	0	1 (1.5)	0	0
Kidney enlargement	1 (1.5)	0	1 (1.5)	0	0
Pollakiuria	1 (1.5)	0	1 (1.5)	0	0
Proteinuria	1 (1.5)	1 (1.5)	0	0	0
Renal mass	1 (1.5)	0	1 (1.5)	0	0
Renal tubular disorder	1 (1.5)	0	0	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (1.5)	0	0	0	1 (1.5)
Urinary incontinence	1 (1.5)	0	1 (1.5)	0	0
Urinary tract disorder	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					
-Total	6 (9.0)	2 (3.0)	2 (3.0)	2 (3.0)	0
Dysmenorrhoea	1 (1.5)	0	1 (1.5)	0	0
Endometriosis	1 (1.5)	0	0	1 (1.5)	0
Female genital tract fistula	1 (1.5)	1 (1.5)	0	0	0
Heavy menstrual bleeding	1 (1.5)	1 (1.5)	0	0	0
Perineal rash	1 (1.5)	0	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Vaginal ulceration	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	45 (67.2)	14 (20.9)	5 (7.5)	11 (16.4)	15 (22.4)
Cough	19 (28.4)	14 (20.9)	5 (7.5)	0	0
Hypoxia	18 (26.9)	0	4 (6.0)	9 (13.4)	5 (7.5)
Pulmonary oedema	12 (17.9)	2 (3.0)	3 (4.5)	6 (9.0)	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	7 (10.4)	5 (7.5)	2 (3.0)	0	0
Pleural effusion	7 (10.4)	3 (4.5)	1 (1.5)	2 (3.0)	1 (1.5)
Tachypnoea	7 (10.4)	1 (1.5)	1 (1.5)	4 (6.0)	1 (1.5)
Dyspnoea	6 (9.0)	0	2 (3.0)	2 (3.0)	2 (3.0)
Epistaxis	6 (9.0)	3 (4.5)	2 (3.0)	1 (1.5)	0
Respiratory failure	6 (9.0)	0	0	0	6 (9.0)
Oropharyngeal pain	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Acute respiratory distress syndrome	3 (4.5)	0	0	0	3 (4.5)
Atelectasis	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Respiratory distress	3 (4.5)	0	1 (1.5)	0	2 (3.0)
Pharyngeal erythema	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Rhinitis allergic	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Rhinorrhoea	2 (3.0)	0	2 (3.0)	0	0
Wheezing	2 (3.0)	0	2 (3.0)	0	0
Acute respiratory failure	1 (1.5)	0	0	1 (1.5)	0
Bradypnoea	1 (1.5)	0	0	1 (1.5)	0
Bronchial oedema	1 (1.5)	1 (1.5)	0	0	0
Bronchospasm	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (1.5)	1 (1.5)	0	0	0
Haemoptysis	1 (1.5)	0	1 (1.5)	0	0
Lung disorder	1 (1.5)	1 (1.5)	0	0	0
Lung infiltration	1 (1.5)	0	0	1 (1.5)	0
Nasal discomfort	1 (1.5)	0	1 (1.5)	0	0
Nasal dryness	1 (1.5)	1 (1.5)	0	0	0
Oropharyngeal plaque	1 (1.5)	0	1 (1.5)	0	0
Painful respiration	1 (1.5)	1 (1.5)	0	0	0
Paranasal sinus discomfort	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal exudate	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal oedema	1 (1.5)	0	1 (1.5)	0	0
Productive cough	1 (1.5)	1 (1.5)	0	0	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory acidosis	1 (1.5)	0	0	1 (1.5)	0
Respiratory disorder	1 (1.5)	0	1 (1.5)	0	0
Sleep apnoea syndrome	1 (1.5)	0	1 (1.5)	0	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (47.8)	12 (17.9)	14 (20.9)	6 (9.0)	0
Rash	8 (11.9)	4 (6.0)	4 (6.0)	0	0
Dry skin	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Erythema	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Pruritus	5 (7.5)	0	5 (7.5)	0	0
Dermatitis atopic	3 (4.5)	2 (3.0)	0	1 (1.5)	0
Hyperhidrosis	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Rash maculo-papular	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Blister	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Decubitus ulcer	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Ingrowing nail	2 (3.0)	0	2 (3.0)	0	0
Petechiae	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Skin discolouration	2 (3.0)	2 (3.0)	0	0	0
Dermatitis allergic	1 (1.5)	1 (1.5)	0	0	0
Dermatitis diaper	1 (1.5)	0	1 (1.5)	0	0
Eczema	1 (1.5)	1 (1.5)	0	0	0
Hangnail	1 (1.5)	1 (1.5)	0	0	0
Miliaria	1 (1.5)	1 (1.5)	0	0	0
Night sweats	1 (1.5)	1 (1.5)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=67		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palmar-plantar erythrodysaesthesia syndrome	1 (1.5)	1 (1.5)	0	0	0
Papule	1 (1.5)	1 (1.5)	0	0	0
Photosensitivity reaction	1 (1.5)	0	1 (1.5)	0	0
Pruritus allergic	1 (1.5)	0	1 (1.5)	0	0
Purpura	1 (1.5)	1 (1.5)	0	0	0
Rash erythematous	1 (1.5)	1 (1.5)	0	0	0
Rash macular	1 (1.5)	0	0	1 (1.5)	0
Rash papular	1 (1.5)	0	1 (1.5)	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Scab	1 (1.5)	1 (1.5)	0	0	0
Skin hypopigmentation	1 (1.5)	1 (1.5)	0	0	0
Skin lesion	1 (1.5)	0	1 (1.5)	0	0
Skin necrosis	1 (1.5)	0	0	1 (1.5)	0
Skin ulcer	1 (1.5)	1 (1.5)	0	0	0
Urticaria	1 (1.5)	0	1 (1.5)	0	0
Vancomycin infusion reaction	1 (1.5)	0	0	1 (1.5)	0
Social circumstances					
-Total	1 (1.5)	0	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Patient uncooperative	1 (1.5)	0	1 (1.5)	0	0
Surgical and medical procedures					
-Total	1 (1.5)	0	0	1 (1.5)	0
Thrombolysis	1 (1.5)	0	0	1 (1.5)	0
Vascular disorders					
-Total	30 (44.8)	3 (4.5)	8 (11.9)	11 (16.4)	8 (11.9)
Hypotension	21 (31.3)	1 (1.5)	6 (9.0)	7 (10.4)	7 (10.4)
Hypertension	15 (22.4)	3 (4.5)	7 (10.4)	5 (7.5)	0
Capillary leak syndrome	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Venoocclusive disease	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Flushing	1 (1.5)	1 (1.5)	0	0	0
Hot flush	1 (1.5)	1 (1.5)	0	0	0
Peripheral ischaemia	1 (1.5)	0	1 (1.5)	0	0
Thrombosis	1 (1.5)	0	1 (1.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=26			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (100)	1 (3.8)	3 (11.5)	10 (38.5)	12 (46.2)
Blood and lymphatic system disorders					
-Total	19 (73.1)	1 (3.8)	3 (11.5)	10 (38.5)	5 (19.2)
Febrile neutropenia	10 (38.5)	0	0	9 (34.6)	1 (3.8)
Anaemia	8 (30.8)	3 (11.5)	2 (7.7)	3 (11.5)	0
Neutropenia	4 (15.4)	0	1 (3.8)	1 (3.8)	2 (7.7)
Thrombocytopenia	4 (15.4)	0	0	2 (7.7)	2 (7.7)
Leukopenia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Disseminated intravascular coagulation	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Pancytopenia	2 (7.7)	0	0	2 (7.7)	0
B-cell aplasia	1 (3.8)	0	1 (3.8)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coagulopathy	1 (3.8)	0	0	1 (3.8)	0
Cardiac disorders					
-Total	7 (26.9)	3 (11.5)	1 (3.8)	2 (7.7)	1 (3.8)
Tachycardia	6 (23.1)	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)
Left ventricular dysfunction	1 (3.8)	0	0	1 (3.8)	0
Sinus bradycardia	1 (3.8)	0	0	1 (3.8)	0
Endocrine disorders					
-Total	2 (7.7)	0	2 (7.7)	0	0
Adrenal insufficiency	1 (3.8)	0	1 (3.8)	0	0
Hypothyroidism	1 (3.8)	0	1 (3.8)	0	0
Eye disorders					
-Total	3 (11.5)	3 (11.5)	0	0	0
Ocular hyperaemia	2 (7.7)	2 (7.7)	0	0	0
Conjunctival haemorrhage	1 (3.8)	1 (3.8)	0	0	0
Eyelid oedema	1 (3.8)	1 (3.8)	0	0	0
Gastrointestinal disorders					
-Total	14 (53.8)	5 (19.2)	4 (15.4)	5 (19.2)	0
Constipation	5 (19.2)	5 (19.2)	0	0	0
Nausea	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0
Diarrhoea	4 (15.4)	2 (7.7)	2 (7.7)	0	0
Abdominal pain	3 (11.5)	1 (3.8)	2 (7.7)	0	0
Ascites	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Abdominal distension	1 (3.8)	0	1 (3.8)	0	0
Anal fissure	1 (3.8)	0	1 (3.8)	0	0
Melaena	1 (3.8)	0	0	1 (3.8)	0
Mouth haemorrhage	1 (3.8)	0	1 (3.8)	0	0
Pancreatitis	1 (3.8)	0	0	1 (3.8)	0
Stomatitis	1 (3.8)	0	0	1 (3.8)	0
Trichoglossia	1 (3.8)	0	1 (3.8)	0	0
General disorders and administration site conditions					
-Total	13 (50.0)	5 (19.2)	5 (19.2)	1 (3.8)	2 (7.7)
Pyrexia	9 (34.6)	4 (15.4)	4 (15.4)	0	1 (3.8)
Face oedema	4 (15.4)	1 (3.8)	2 (7.7)	1 (3.8)	0
Fatigue	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Influenza like illness	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Catheter site pain	1 (3.8)	1 (3.8)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	1 (3.8)	0	1 (3.8)	0	0
Generalised oedema	1 (3.8)	0	1 (3.8)	0	0
Multiple organ dysfunction syndrome	1 (3.8)	0	0	0	1 (3.8)
Oedema peripheral	1 (3.8)	0	0	1 (3.8)	0
Systemic inflammatory response syndrome	1 (3.8)	0	0	1 (3.8)	0
Hepatobiliary disorders					
-Total	3 (11.5)	1 (3.8)	1 (3.8)	0	1 (3.8)
Cholelithiasis	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Cholestasis	1 (3.8)	0	0	0	1 (3.8)
Gallbladder enlargement	1 (3.8)	1 (3.8)	0	0	0
Ocular icterus	1 (3.8)	1 (3.8)	0	0	0
Immune system disorders					
-Total	22 (84.6)	2 (7.7)	10 (38.5)	6 (23.1)	4 (15.4)
Cytokine release syndrome	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Hypogammaglobulinaemia	9 (34.6)	1 (3.8)	6 (23.1)	2 (7.7)	0
Immunodeficiency	2 (7.7)	0	0	2 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (3.8)	0	0	0	1 (3.8)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	7 (26.9)	2 (7.7)	2 (7.7)	2 (7.7)	1 (3.8)
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)	0	0
Clostridium difficile infection	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Encephalitis	1 (3.8)	0	0	0	1 (3.8)
Localised infection	1 (3.8)	1 (3.8)	0	0	0
Nail infection	1 (3.8)	1 (3.8)	0	0	0
Staphylococcal bacteraemia	1 (3.8)	0	0	1 (3.8)	0
Injury, poisoning and procedural complications					
-Total	3 (11.5)	1 (3.8)	1 (3.8)	0	1 (3.8)
Infusion related reaction	1 (3.8)	0	1 (3.8)	0	0
Scratch	1 (3.8)	1 (3.8)	0	0	0
Skin injury	1 (3.8)	0	1 (3.8)	0	0
Skin wound	1 (3.8)	1 (3.8)	0	0	0
Vasoplegia syndrome	1 (3.8)	0	0	0	1 (3.8)
Wound	1 (3.8)	0	0	1 (3.8)	0
Investigations					
-Total	16 (61.5)	0	1 (3.8)	6 (23.1)	9 (34.6)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	8 (30.8)	1 (3.8)	2 (7.7)	1 (3.8)	4 (15.4)
Platelet count decreased	7 (26.9)	2 (7.7)	1 (3.8)	0	4 (15.4)
Alanine aminotransferase increased	6 (23.1)	2 (7.7)	3 (11.5)	1 (3.8)	0
Neutrophil count decreased	6 (23.1)	0	1 (3.8)	1 (3.8)	4 (15.4)
Aspartate aminotransferase increased	5 (19.2)	1 (3.8)	2 (7.7)	1 (3.8)	1 (3.8)
Lymphocyte count decreased	4 (15.4)	0	0	4 (15.4)	0
Serum ferritin increased	4 (15.4)	1 (3.8)	1 (3.8)	2 (7.7)	0
Blood bilirubin increased	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Blood immunoglobulin m decreased	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
C-reactive protein increased	3 (11.5)	0	0	3 (11.5)	0
International normalised ratio increased	3 (11.5)	3 (11.5)	0	0	0
Activated partial thromboplastin time prolonged	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Blood immunoglobulin a decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Electrocardiogram qt prolonged	2 (7.7)	0	1 (3.8)	0	1 (3.8)
Fibrin d dimer increased	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Lipase increased	2 (7.7)	1 (3.8)	0	0	1 (3.8)
Amylase increased	1 (3.8)	1 (3.8)	0	0	0
Bacterial test positive	1 (3.8)	0	0	1 (3.8)	0
Blood creatine phosphokinase increased	1 (3.8)	0	0	0	1 (3.8)
Blood creatinine increased	1 (3.8)	0	0	1 (3.8)	0
Blood fibrinogen decreased	1 (3.8)	0	1 (3.8)	0	0
Blood lactate dehydrogenase increased	1 (3.8)	0	0	1 (3.8)	0
Blood phosphorus increased	1 (3.8)	0	1 (3.8)	0	0
Blood testosterone decreased	1 (3.8)	1 (3.8)	0	0	0
Electrocardiogram t wave abnormal	1 (3.8)	0	1 (3.8)	0	0
Oxygen saturation decreased	1 (3.8)	1 (3.8)	0	0	0
Troponin increased	1 (3.8)	0	0	1 (3.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	12 (46.2)	3 (11.5)	3 (11.5)	3 (11.5)	3 (11.5)
Hypocalcaemia	6 (23.1)	0	4 (15.4)	2 (7.7)	0
Hypokalaemia	5 (19.2)	1 (3.8)	0	2 (7.7)	2 (7.7)
Decreased appetite	4 (15.4)	2 (7.7)	1 (3.8)	1 (3.8)	0
Hypophosphataemia	4 (15.4)	0	2 (7.7)	2 (7.7)	0
Hyperuricaemia	3 (11.5)	3 (11.5)	0	0	0
Hypoalbuminaemia	2 (7.7)	0	2 (7.7)	0	0
Calcium deficiency	1 (3.8)	1 (3.8)	0	0	0
Dehydration	1 (3.8)	0	1 (3.8)	0	0
Haemosiderosis	1 (3.8)	0	1 (3.8)	0	0
Hypercalcaemia	1 (3.8)	0	1 (3.8)	0	0
Hyperglycaemia	1 (3.8)	0	0	1 (3.8)	0
Hyperlactacidaemia	1 (3.8)	1 (3.8)	0	0	0
Hypernatraemia	1 (3.8)	0	0	0	1 (3.8)
Hyperphosphataemia	1 (3.8)	1 (3.8)	0	0	0
Hypertriglyceridaemia	1 (3.8)	0	0	0	1 (3.8)
Hypervolaemia	1 (3.8)	0	0	1 (3.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (3.8)	1 (3.8)	0	0	0
Malnutrition	1 (3.8)	0	0	1 (3.8)	0
Metabolic acidosis	1 (3.8)	1 (3.8)	0	0	0
Tumour lysis syndrome	1 (3.8)	0	0	1 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (30.8)	3 (11.5)	2 (7.7)	2 (7.7)	1 (3.8)
Arthralgia	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Back pain	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Myalgia	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Pain in extremity	2 (7.7)	2 (7.7)	0	0	0
Haemarthrosis	1 (3.8)	0	0	1 (3.8)	0
Myositis	1 (3.8)	0	1 (3.8)	0	0
Rhabdomyolysis	1 (3.8)	0	0	0	1 (3.8)
Nervous system disorders					
-Total	11 (42.3)	4 (15.4)	3 (11.5)	4 (15.4)	0
Headache	5 (19.2)	3 (11.5)	1 (3.8)	1 (3.8)	0
Cognitive disorder	2 (7.7)	0	2 (7.7)	0	0
Encephalopathy	2 (7.7)	0	0	2 (7.7)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysgeusia	1 (3.8)	1 (3.8)	0	0	0
Lethargy	1 (3.8)	1 (3.8)	0	0	0
Monoparesis	1 (3.8)	0	1 (3.8)	0	0
Seizure	1 (3.8)	0	0	1 (3.8)	0
Tremor	1 (3.8)	1 (3.8)	0	0	0
Psychiatric disorders					
-Total	8 (30.8)	5 (19.2)	2 (7.7)	1 (3.8)	0
Anxiety	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Confusional state	2 (7.7)	2 (7.7)	0	0	0
Insomnia	1 (3.8)	1 (3.8)	0	0	0
Irritability	1 (3.8)	1 (3.8)	0	0	0
Sleep disorder	1 (3.8)	0	1 (3.8)	0	0
Renal and urinary disorders					
-Total	4 (15.4)	2 (7.7)	0	0	2 (7.7)
Dysuria	2 (7.7)	2 (7.7)	0	0	0
Acute kidney injury	1 (3.8)	0	0	0	1 (3.8)
Anuria	1 (3.8)	0	0	0	1 (3.8)
Bladder dilatation	1 (3.8)	0	1 (3.8)	0	0
Renal tubular necrosis	1 (3.8)	0	0	0	1 (3.8)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary retention	1 (3.8)	0	1 (3.8)	0	0
Reproductive system and breast disorders					
-Total	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Heavy menstrual bleeding	1 (3.8)	1 (3.8)	0	0	0
Vaginal ulceration	1 (3.8)	0	0	1 (3.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (42.3)	5 (19.2)	1 (3.8)	2 (7.7)	3 (11.5)
Cough	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Acute respiratory distress syndrome	2 (7.7)	0	0	0	2 (7.7)
Hypoxia	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Nasal congestion	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Pleural effusion	2 (7.7)	0	0	1 (3.8)	1 (3.8)
Pulmonary oedema	2 (7.7)	0	0	2 (7.7)	0
Atelectasis	1 (3.8)	0	0	1 (3.8)	0
Dyspnoea	1 (3.8)	0	0	0	1 (3.8)
Epistaxis	1 (3.8)	1 (3.8)	0	0	0
Nasal dryness	1 (3.8)	1 (3.8)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory acidosis	1 (3.8)	0	0	1 (3.8)	0
Rhinorrhoea	1 (3.8)	1 (3.8)	0	0	0
Tachypnoea	1 (3.8)	0	0	1 (3.8)	0
Wheezing	1 (3.8)	0	1 (3.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (30.8)	6 (23.1)	1 (3.8)	1 (3.8)	0
Rash	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Erythema	2 (7.7)	2 (7.7)	0	0	0
Decubitus ulcer	1 (3.8)	0	1 (3.8)	0	0
Dermatitis	1 (3.8)	1 (3.8)	0	0	0
Eczema	1 (3.8)	1 (3.8)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (3.8)	1 (3.8)	0	0	0
Petechiae	1 (3.8)	0	0	1 (3.8)	0
Pruritus	1 (3.8)	0	1 (3.8)	0	0
Rash maculo-papular	1 (3.8)	0	1 (3.8)	0	0
Rash papular	1 (3.8)	1 (3.8)	0	0	0
Skin discolouration	1 (3.8)	1 (3.8)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin necrosis	1 (3.8)	0	0	1 (3.8)	0
Skin ulcer	1 (3.8)	1 (3.8)	0	0	0
Vascular disorders					
-Total	7 (26.9)	1 (3.8)	2 (7.7)	3 (11.5)	1 (3.8)
Hypotension	6 (23.1)	1 (3.8)	2 (7.7)	2 (7.7)	1 (3.8)
Capillary leak syndrome	1 (3.8)	0	0	1 (3.8)	0
Hypertension	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (98.1)	3 (5.6)	5 (9.3)	11 (20.4)	34 (63.0)
Blood and lymphatic system disorders					
-Total	31 (57.4)	2 (3.7)	5 (9.3)	16 (29.6)	8 (14.8)
Febrile neutropenia	16 (29.6)	0	0	15 (27.8)	1 (1.9)
Anaemia	13 (24.1)	2 (3.7)	6 (11.1)	5 (9.3)	0
Disseminated intravascular coagulation	5 (9.3)	0	4 (7.4)	1 (1.9)	0
Neutropenia	5 (9.3)	0	1 (1.9)	0	4 (7.4)
Coagulopathy	4 (7.4)	1 (1.9)	2 (3.7)	1 (1.9)	0
Splenomegaly	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Thrombocytopenia	4 (7.4)	0	0	0	4 (7.4)
Eosinophilia	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypofibrinogenaemia	1 (1.9)	0	1 (1.9)	0	0
Lymphopenia	1 (1.9)	0	0	1 (1.9)	0
Cardiac disorders					
-Total	17 (31.5)	7 (13.0)	5 (9.3)	3 (5.6)	2 (3.7)
Tachycardia	11 (20.4)	4 (7.4)	6 (11.1)	1 (1.9)	0
Bradycardia	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Sinus tachycardia	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Cardiac dysfunction	2 (3.7)	2 (3.7)	0	0	0
Left ventricular dysfunction	2 (3.7)	0	0	2 (3.7)	0
Atrioventricular block first degree	1 (1.9)	0	1 (1.9)	0	0
Cardiac arrest	1 (1.9)	0	0	0	1 (1.9)
Cardiac failure	1 (1.9)	0	0	0	1 (1.9)
Cardiac failure congestive	1 (1.9)	0	1 (1.9)	0	0
Mitral valve incompetence	1 (1.9)	1 (1.9)	0	0	0
Pericardial effusion	1 (1.9)	1 (1.9)	0	0	0
Right ventricular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	2 (3.7)	2 (3.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear pain	1 (1.9)	1 (1.9)	0	0	0
Ear pruritus	1 (1.9)	1 (1.9)	0	0	0
Endocrine disorders					
-Total	3 (5.6)	0	3 (5.6)	0	0
Adrenal insufficiency	3 (5.6)	0	3 (5.6)	0	0
Eye disorders					
-Total	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Conjunctival haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Eye oedema	1 (1.9)	1 (1.9)	0	0	0
Eye pain	1 (1.9)	1 (1.9)	0	0	0
Eyelid oedema	1 (1.9)	0	1 (1.9)	0	0
Periorbital oedema	1 (1.9)	1 (1.9)	0	0	0
Periorbital swelling	1 (1.9)	0	1 (1.9)	0	0
Retinal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Visual impairment	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	37 (68.5)	14 (25.9)	14 (25.9)	8 (14.8)	1 (1.9)
Vomiting	16 (29.6)	10 (18.5)	6 (11.1)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	13 (24.1)	8 (14.8)	4 (7.4)	1 (1.9)	0
Diarrhoea	11 (20.4)	6 (11.1)	4 (7.4)	1 (1.9)	0
Abdominal pain	8 (14.8)	2 (3.7)	4 (7.4)	2 (3.7)	0
Constipation	6 (11.1)	1 (1.9)	5 (9.3)	0	0
Abdominal pain upper	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Mouth haemorrhage	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Pancreatitis	3 (5.6)	0	3 (5.6)	0	0
Abdominal distension	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Gastrointestinal sounds abnormal	2 (3.7)	2 (3.7)	0	0	0
Abdominal compartment syndrome	1 (1.9)	0	0	0	1 (1.9)
Anal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Ascites	1 (1.9)	1 (1.9)	0	0	0
Dry mouth	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Enterocolitis	1 (1.9)	0	1 (1.9)	0	0
Gastrooesophageal reflux disease	1 (1.9)	0	1 (1.9)	0	0
Gingival bleeding	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival erythema	1 (1.9)	1 (1.9)	0	0	0
Gingivitis ulcerative	1 (1.9)	0	0	1 (1.9)	0
Haematemesis	1 (1.9)	1 (1.9)	0	0	0
Ileus	1 (1.9)	0	1 (1.9)	0	0
Lip dry	1 (1.9)	0	1 (1.9)	0	0
Lip oedema	1 (1.9)	1 (1.9)	0	0	0
Mouth swelling	1 (1.9)	1 (1.9)	0	0	0
Neutropenic colitis	1 (1.9)	0	0	1 (1.9)	0
Odynophagia	1 (1.9)	1 (1.9)	0	0	0
Proctalgia	1 (1.9)	0	0	1 (1.9)	0
Stomatitis	1 (1.9)	0	1 (1.9)	0	0
Upper gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	27 (50.0)	15 (27.8)	4 (7.4)	6 (11.1)	2 (3.7)
Pyrexia	15 (27.8)	7 (13.0)	1 (1.9)	6 (11.1)	1 (1.9)
Fatigue	8 (14.8)	7 (13.0)	1 (1.9)	0	0
Chills	6 (11.1)	4 (7.4)	2 (3.7)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Face oedema	4 (7.4)	4 (7.4)	0	0	0
Generalised oedema	4 (7.4)	2 (3.7)	2 (3.7)	0	0
Asthenia	2 (3.7)	2 (3.7)	0	0	0
Localised oedema	2 (3.7)	2 (3.7)	0	0	0
Catheter site erythema	1 (1.9)	1 (1.9)	0	0	0
Catheter site haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Catheter site pain	1 (1.9)	0	0	1 (1.9)	0
Chest discomfort	1 (1.9)	0	0	1 (1.9)	0
Crying	1 (1.9)	0	1 (1.9)	0	0
Drug withdrawal syndrome	1 (1.9)	0	1 (1.9)	0	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Malaise	1 (1.9)	0	1 (1.9)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	0	0	1 (1.9)
Oedema due to hepatic disease	1 (1.9)	0	1 (1.9)	0	0
Pain	1 (1.9)	0	0	1 (1.9)	0
Sluggishness	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Swelling face	1 (1.9)	1 (1.9)	0	0	0
Vascular device occlusion	1 (1.9)	1 (1.9)	0	0	0
Hepatobiliary disorders					
-Total	14 (25.9)	4 (7.4)	5 (9.3)	3 (5.6)	2 (3.7)
Hepatic function abnormal	5 (9.3)	0	2 (3.7)	2 (3.7)	1 (1.9)
Hyperbilirubinaemia	5 (9.3)	1 (1.9)	3 (5.6)	1 (1.9)	0
Hepatomegaly	3 (5.6)	2 (3.7)	0	0	1 (1.9)
Hypertransaminasaemia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Biliary tract disorder	1 (1.9)	1 (1.9)	0	0	0
Gallbladder enlargement	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	45 (83.3)	1 (1.9)	11 (20.4)	16 (29.6)	17 (31.5)
Cytokine release syndrome	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)
Hypogammaglobulinaemia	14 (25.9)	1 (1.9)	8 (14.8)	5 (9.3)	0
Haemophagocytic lymphohistiocytosis	4 (7.4)	1 (1.9)	1 (1.9)	2 (3.7)	0
Hypersensitivity	1 (1.9)	1 (1.9)	0	0	0
Immunodeficiency	1 (1.9)	0	0	1 (1.9)	0
Seasonal allergy	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	28 (51.9)	4 (7.4)	8 (14.8)	14 (25.9)	2 (3.7)
Staphylococcal infection	5 (9.3)	0	3 (5.6)	2 (3.7)	0
Candida infection	3 (5.6)	0	2 (3.7)	0	1 (1.9)
Clostridium difficile infection	2 (3.7)	0	0	2 (3.7)	0
Encephalitis viral	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Oral herpes	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Oral infection	2 (3.7)	0	2 (3.7)	0	0
Rhinovirus infection	2 (3.7)	0	2 (3.7)	0	0
Staphylococcal bacteraemia	2 (3.7)	0	0	2 (3.7)	0
Adenovirus infection	1 (1.9)	0	0	1 (1.9)	0
Anal abscess	1 (1.9)	0	0	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bk virus infection	1 (1.9)	1 (1.9)	0	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.9)	0	1 (1.9)	0	0
Conjunctivitis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	1 (1.9)	0	0	0
Gingivitis	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes simplex	1 (1.9)	0	0	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	0	0	1 (1.9)	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Meningitis bacterial	1 (1.9)	0	0	1 (1.9)	0
Myringitis	1 (1.9)	1 (1.9)	0	0	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Oral candidiasis	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	0	1 (1.9)	0	0
Pneumonia	1 (1.9)	0	0	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	8 (14.8)	2 (3.7)	5 (9.3)	0	1 (1.9)
Fall	2 (3.7)	0	2 (3.7)	0	0
Procedural pain	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Transfusion reaction	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Contusion	1 (1.9)	1 (1.9)	0	0	0
Infusion related reaction	1 (1.9)	0	1 (1.9)	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Transplant failure	1 (1.9)	0	0	0	1 (1.9)
Wound	1 (1.9)	0	1 (1.9)	0	0
Investigations					
-Total	41 (75.9)	4 (7.4)	7 (13.0)	11 (20.4)	19 (35.2)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	16 (29.6)	2 (3.7)	1 (1.9)	1 (1.9)	12 (22.2)
Aspartate aminotransferase increased	14 (25.9)	1 (1.9)	4 (7.4)	7 (13.0)	2 (3.7)
Neutrophil count decreased	14 (25.9)	0	2 (3.7)	1 (1.9)	11 (20.4)
Platelet count decreased	14 (25.9)	2 (3.7)	2 (3.7)	6 (11.1)	4 (7.4)
Alanine aminotransferase increased	12 (22.2)	2 (3.7)	5 (9.3)	5 (9.3)	0
Lymphocyte count decreased	11 (20.4)	2 (3.7)	0	4 (7.4)	5 (9.3)
Blood bilirubin increased	9 (16.7)	1 (1.9)	1 (1.9)	7 (13.0)	0
Blood fibrinogen decreased	6 (11.1)	2 (3.7)	2 (3.7)	1 (1.9)	1 (1.9)
International normalised ratio increased	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Activated partial thromboplastin time prolonged	4 (7.4)	2 (3.7)	2 (3.7)	0	0
Serum ferritin increased	4 (7.4)	0	4 (7.4)	0	0
Weight increased	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Blood creatinine increased	3 (5.6)	1 (1.9)	0	1 (1.9)	1 (1.9)
Blood immunoglobulin a decreased	3 (5.6)	3 (5.6)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	3 (5.6)	3 (5.6)	0	0	0
Blood lactate dehydrogenase increased	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Electrocardiogram qt prolonged	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Blood uric acid increased	2 (3.7)	2 (3.7)	0	0	0
Gamma-glutamyltransferase increased	2 (3.7)	0	0	2 (3.7)	0
Immunoglobulins decreased	2 (3.7)	0	2 (3.7)	0	0
Urine output decreased	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Blood alkaline phosphatase increased	1 (1.9)	1 (1.9)	0	0	0
Blood bicarbonate decreased	1 (1.9)	0	1 (1.9)	0	0
Blood creatine phosphokinase increased	1 (1.9)	0	0	1 (1.9)	0
Blood glucose increased	1 (1.9)	0	0	0	1 (1.9)
Breath sounds abnormal	1 (1.9)	0	1 (1.9)	0	0
C-reactive protein increased	1 (1.9)	1 (1.9)	0	0	0
Cardiac murmur	1 (1.9)	1 (1.9)	0	0	0
Coagulation test abnormal	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus test positive	1 (1.9)	0	1 (1.9)	0	0
Fibrin d dimer increased	1 (1.9)	1 (1.9)	0	0	0
Haemoglobin decreased	1 (1.9)	0	0	1 (1.9)	0
Haptoglobin decreased	1 (1.9)	1 (1.9)	0	0	0
Prothrombin time prolonged	1 (1.9)	0	1 (1.9)	0	0
Staphylococcus test positive	1 (1.9)	1 (1.9)	0	0	0
Weight decreased	1 (1.9)	0	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	34 (63.0)	5 (9.3)	6 (11.1)	18 (33.3)	5 (9.3)
Decreased appetite	20 (37.0)	7 (13.0)	3 (5.6)	9 (16.7)	1 (1.9)
Hypokalaemia	14 (25.9)	2 (3.7)	5 (9.3)	7 (13.0)	0
Hypophosphataemia	13 (24.1)	3 (5.6)	3 (5.6)	6 (11.1)	1 (1.9)
Hypocalcaemia	10 (18.5)	2 (3.7)	5 (9.3)	3 (5.6)	0
Hypoalbuminaemia	9 (16.7)	0	8 (14.8)	1 (1.9)	0
Hyperglycaemia	7 (13.0)	0	4 (7.4)	3 (5.6)	0
Hypervolaemia	5 (9.3)	0	2 (3.7)	3 (5.6)	0
Hypomagnesaemia	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Hyperphosphataemia	4 (7.4)	3 (5.6)	0	0	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Hyponatraemia	3 (5.6)	3 (5.6)	0	0	0
Tumour lysis syndrome	3 (5.6)	0	0	3 (5.6)	0
Acidosis	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Hypercalcaemia	2 (3.7)	0	0	2 (3.7)	0
Hyperkalaemia	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Hypermagnesaemia	2 (3.7)	2 (3.7)	0	0	0
Metabolic acidosis	2 (3.7)	0	0	0	2 (3.7)
Hyperchloraemia	1 (1.9)	1 (1.9)	0	0	0
Hypernatraemia	1 (1.9)	1 (1.9)	0	0	0
Hypertriglyceridaemia	1 (1.9)	0	0	1 (1.9)	0
Hypoglycaemia	1 (1.9)	0	1 (1.9)	0	0
Polydipsia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	25 (46.3)	12 (22.2)	11 (20.4)	2 (3.7)	0
Pain in extremity	9 (16.7)	4 (7.4)	5 (9.3)	0	0
Arthralgia	8 (14.8)	4 (7.4)	4 (7.4)	0	0
Myalgia	7 (13.0)	5 (9.3)	2 (3.7)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Bone pain	2 (3.7)	0	2 (3.7)	0	0
Muscular weakness	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Pain in jaw	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Muscle rigidity	1 (1.9)	1 (1.9)	0	0	0
Muscle spasms	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Neck pain	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	29 (53.7)	10 (18.5)	13 (24.1)	4 (7.4)	2 (3.7)
Headache	18 (33.3)	9 (16.7)	8 (14.8)	1 (1.9)	0
Encephalopathy	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Somnolence	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Tremor	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Dizziness	3 (5.6)	3 (5.6)	0	0	0
Dysgeusia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Lethargy	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (1.9)	0	0	0	1 (1.9)
Cognitive disorder	1 (1.9)	0	0	1 (1.9)	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Generalised tonic-clonic seizure	1 (1.9)	0	1 (1.9)	0	0
Hyperaesthesia	1 (1.9)	1 (1.9)	0	0	0
Hypoaesthesia	1 (1.9)	1 (1.9)	0	0	0
Neuralgia	1 (1.9)	0	1 (1.9)	0	0
Neurological decompensation	1 (1.9)	0	0	0	1 (1.9)
Paraesthesia	1 (1.9)	1 (1.9)	0	0	0
Seizure	1 (1.9)	0	1 (1.9)	0	0
Psychiatric disorders					
-Total	20 (37.0)	7 (13.0)	8 (14.8)	5 (9.3)	0
Delirium	7 (13.0)	2 (3.7)	2 (3.7)	3 (5.6)	0
Agitation	5 (9.3)	2 (3.7)	3 (5.6)	0	0
Confusional state	5 (9.3)	5 (9.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Hallucination	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Insomnia	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Mental status changes	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Irritability	2 (3.7)	2 (3.7)	0	0	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Automatism	1 (1.9)	1 (1.9)	0	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	16 (29.6)	3 (5.6)	6 (11.1)	3 (5.6)	4 (7.4)
Acute kidney injury	8 (14.8)	1 (1.9)	1 (1.9)	3 (5.6)	3 (5.6)
Haematuria	2 (3.7)	2 (3.7)	0	0	0
Pollakiuria	2 (3.7)	0	2 (3.7)	0	0
Renal failure	2 (3.7)	0	1 (1.9)	0	1 (1.9)
Anuria	1 (1.9)	1 (1.9)	0	0	0
Azotaemia	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	1 (1.9)	1 (1.9)	0	0	0
Incontinence	1 (1.9)	0	1 (1.9)	0	0
Micturition urgency	1 (1.9)	0	1 (1.9)	0	0
Proteinuria	1 (1.9)	1 (1.9)	0	0	0
Renal tubular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Urinary incontinence	1 (1.9)	0	1 (1.9)	0	0
Urinary retention	1 (1.9)	0	1 (1.9)	0	0
Urinary tract disorder	1 (1.9)	0	1 (1.9)	0	0
Reproductive system and breast disorders					
-Total	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Female genital tract fistula	1 (1.9)	1 (1.9)	0	0	0
Perineal rash	1 (1.9)	0	1 (1.9)	0	0
Vaginal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	30 (55.6)	9 (16.7)	3 (5.6)	9 (16.7)	9 (16.7)
Hypoxia	15 (27.8)	0	4 (7.4)	5 (9.3)	6 (11.1)
Pulmonary oedema	10 (18.5)	2 (3.7)	3 (5.6)	4 (7.4)	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	7 (13.0)	7 (13.0)	0	0	0
Tachypnoea	7 (13.0)	3 (5.6)	1 (1.9)	3 (5.6)	0
Oropharyngeal pain	5 (9.3)	5 (9.3)	0	0	0
Pleural effusion	5 (9.3)	4 (7.4)	0	1 (1.9)	0
Respiratory failure	4 (7.4)	0	0	0	4 (7.4)
Epistaxis	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Respiratory distress	3 (5.6)	0	2 (3.7)	0	1 (1.9)
Atelectasis	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Dyspnoea	2 (3.7)	0	0	2 (3.7)	0
Acute respiratory failure	1 (1.9)	0	0	1 (1.9)	0
Bradypnoea	1 (1.9)	0	0	1 (1.9)	0
Haemoptysis	1 (1.9)	0	1 (1.9)	0	0
Lung infiltration	1 (1.9)	0	0	1 (1.9)	0
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Nasal discomfort	1 (1.9)	0	1 (1.9)	0	0
Oropharyngeal plaque	1 (1.9)	0	1 (1.9)	0	0
Painful respiration	1 (1.9)	1 (1.9)	0	0	0
Paranasal sinus discomfort	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal erythema	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal exudate	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal oedema	1 (1.9)	0	1 (1.9)	0	0
Productive cough	1 (1.9)	1 (1.9)	0	0	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Respiratory disorder	1 (1.9)	0	1 (1.9)	0	0
Rhinorrhoea	1 (1.9)	1 (1.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (35.2)	7 (13.0)	10 (18.5)	2 (3.7)	0
Pruritus	5 (9.3)	2 (3.7)	3 (5.6)	0	0
Blister	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Hyperhidrosis	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Dermatitis atopic	2 (3.7)	2 (3.7)	0	0	0
Erythema	2 (3.7)	2 (3.7)	0	0	0
Rash	2 (3.7)	0	2 (3.7)	0	0
Rash papular	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Dermatitis diaper	1 (1.9)	0	1 (1.9)	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema nodosum	1 (1.9)	1 (1.9)	0	0	0
Petechiae	1 (1.9)	0	1 (1.9)	0	0
Pruritus allergic	1 (1.9)	0	1 (1.9)	0	0
Purpura	1 (1.9)	1 (1.9)	0	0	0
Rash maculo-papular	1 (1.9)	0	0	1 (1.9)	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Rash vesicular	1 (1.9)	1 (1.9)	0	0	0
Scab	1 (1.9)	1 (1.9)	0	0	0
Skin lesion	1 (1.9)	0	1 (1.9)	0	0
Skin ulcer	1 (1.9)	0	1 (1.9)	0	0
Urticaria	1 (1.9)	0	1 (1.9)	0	0
Vancomycin infusion reaction	1 (1.9)	0	0	1 (1.9)	0
Social circumstances					
-Total	1 (1.9)	0	1 (1.9)	0	0
Patient uncooperative	1 (1.9)	0	1 (1.9)	0	0
Surgical and medical procedures					
-Total	1 (1.9)	0	0	1 (1.9)	0
Thrombolysis	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	21 (38.9)	3 (5.6)	5 (9.3)	8 (14.8)	5 (9.3)
Hypotension	15 (27.8)	0	4 (7.4)	6 (11.1)	5 (9.3)
Hypertension	12 (22.2)	4 (7.4)	5 (9.3)	3 (5.6)	0
Capillary leak syndrome	1 (1.9)	0	1 (1.9)	0	0
Flushing	1 (1.9)	1 (1.9)	0	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0
Peripheral ischaemia	1 (1.9)	0	1 (1.9)	0	0
Thrombosis	1 (1.9)	0	1 (1.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=25			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (88.0)	4 (16.0)	8 (32.0)	6 (24.0)	4 (16.0)
Blood and lymphatic system disorders					
-Total	8 (32.0)	2 (8.0)	3 (12.0)	2 (8.0)	1 (4.0)
Anaemia	3 (12.0)	2 (8.0)	0	1 (4.0)	0
B-cell aplasia	1 (4.0)	0	1 (4.0)	0	0
Disseminated intravascular coagulation	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Leukocytosis	1 (4.0)	0	1 (4.0)	0	0
Leukopenia	1 (4.0)	0	1 (4.0)	0	0
Lymphadenopathy	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocytosis	1 (4.0)	0	1 (4.0)	0	0
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Cardiac disorders					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Left ventricular dysfunction	1 (4.0)	0	1 (4.0)	0	0
Tachycardia	1 (4.0)	1 (4.0)	0	0	0
Eye disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Ocular hyperaemia	1 (4.0)	1 (4.0)	0	0	0
Gastrointestinal disorders					
-Total	7 (28.0)	7 (28.0)	0	0	0
Diarrhoea	4 (16.0)	4 (16.0)	0	0	0
Vomiting	3 (12.0)	3 (12.0)	0	0	0
Abdominal pain upper	1 (4.0)	1 (4.0)	0	0	0
Dyspepsia	1 (4.0)	1 (4.0)	0	0	0
Nausea	1 (4.0)	1 (4.0)	0	0	0
Pancreatitis	1 (4.0)	1 (4.0)	0	0	0
Peritoneal haematoma	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	7 (28.0)	5 (20.0)	1 (4.0)	1 (4.0)	0
Pyrexia	5 (20.0)	3 (12.0)	1 (4.0)	1 (4.0)	0
Fatigue	2 (8.0)	2 (8.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Hepatic cytolysis	1 (4.0)	1 (4.0)	0	0	0
Immune system disorders					
-Total	5 (20.0)	0	5 (20.0)	0	0
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)	0	0
Infections and infestations					
-Total	12 (48.0)	1 (4.0)	5 (20.0)	4 (16.0)	2 (8.0)
Upper respiratory tract infection	4 (16.0)	2 (8.0)	0	2 (8.0)	0
Respiratory syncytial virus infection	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Otitis media	2 (8.0)	0	2 (8.0)	0	0
Parainfluenzae virus infection	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Rhinovirus infection	2 (8.0)	0	1 (4.0)	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (4.0)	0	0	0	1 (4.0)
Cellulitis	1 (4.0)	0	1 (4.0)	0	0
Conjunctivitis	1 (4.0)	0	1 (4.0)	0	0
Ear infection	1 (4.0)	0	1 (4.0)	0	0
Ear, nose and throat infection	1 (4.0)	0	1 (4.0)	0	0
Encephalitis	1 (4.0)	0	0	0	1 (4.0)
Gastroenteritis	1 (4.0)	0	0	1 (4.0)	0
Gastrointestinal infection	1 (4.0)	1 (4.0)	0	0	0
Herpes zoster	1 (4.0)	0	0	1 (4.0)	0
Metapneumovirus infection	1 (4.0)	0	0	1 (4.0)	0
Molluscum contagiosum	1 (4.0)	1 (4.0)	0	0	0
Nasopharyngitis	1 (4.0)	0	1 (4.0)	0	0
Otitis externa	1 (4.0)	0	1 (4.0)	0	0
Paronychia	1 (4.0)	0	1 (4.0)	0	0
Pneumocystis jirovecii pneumonia	1 (4.0)	0	0	1 (4.0)	0
Pneumonia	1 (4.0)	0	1 (4.0)	0	0
Respiratory tract infection	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (4.0)	0	1 (4.0)	0	0
Rhinitis	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal bacteraemia	1 (4.0)	0	0	1 (4.0)	0
Viral haemorrhagic cystitis	1 (4.0)	0	0	1 (4.0)	0
Injury, poisoning and procedural complications					
-Total	4 (16.0)	2 (8.0)	2 (8.0)	0	0
Infusion related reaction	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Fibula fracture	1 (4.0)	0	1 (4.0)	0	0
Skin abrasion	1 (4.0)	1 (4.0)	0	0	0
Investigations					
-Total	7 (28.0)	2 (8.0)	1 (4.0)	3 (12.0)	1 (4.0)
Neutrophil count decreased	4 (16.0)	1 (4.0)	1 (4.0)	1 (4.0)	1 (4.0)
White blood cell count decreased	4 (16.0)	2 (8.0)	1 (4.0)	0	1 (4.0)
Lymphocyte count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Platelet count decreased	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Blood lactate dehydrogenase increased	1 (4.0)	1 (4.0)	0	0	0
C-reactive protein increased	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (4.0)	0	0	1 (4.0)	0
Metabolism and nutrition disorders					
-Total	4 (16.0)	1 (4.0)	1 (4.0)	1 (4.0)	1 (4.0)
Decreased appetite	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Haemochromatosis	1 (4.0)	0	0	1 (4.0)	0
Hyperkalaemia	1 (4.0)	0	1 (4.0)	0	0
Hypokalaemia	1 (4.0)	0	0	0	1 (4.0)
Hypophosphataemia	1 (4.0)	0	1 (4.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Back pain	1 (4.0)	1 (4.0)	0	0	0
Growth retardation	1 (4.0)	0	1 (4.0)	0	0
Pain in extremity	1 (4.0)	1 (4.0)	0	0	0
Nervous system disorders					
-Total	6 (24.0)	3 (12.0)	2 (8.0)	0	1 (4.0)
Headache	5 (20.0)	3 (12.0)	2 (8.0)	0	0
Autonomic neuropathy	1 (4.0)	0	0	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (4.0)	0	0	0	1 (4.0)
Memory impairment	1 (4.0)	0	1 (4.0)	0	0
Seizure	1 (4.0)	0	0	1 (4.0)	0
Psychiatric disorders					
-Total	2 (8.0)	0	2 (8.0)	0	0
Persistent depressive disorder	1 (4.0)	0	1 (4.0)	0	0
Sleep disorder	1 (4.0)	0	1 (4.0)	0	0
Renal and urinary disorders					
-Total	1 (4.0)	0	0	1 (4.0)	0
Renal tubular disorder	1 (4.0)	0	0	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (28.0)	3 (12.0)	3 (12.0)	1 (4.0)	0
Cough	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Epistaxis	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Nasal congestion	2 (8.0)	2 (8.0)	0	0	0
Rhinitis allergic	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Bronchospasm	1 (4.0)	0	1 (4.0)	0	0
Hypoxia	1 (4.0)	0	0	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lung disorder	1 (4.0)	1 (4.0)	0	0	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)	0	0
Rhinorrhoea	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (24.0)	3 (12.0)	3 (12.0)	0	0
Dermatitis allergic	1 (4.0)	1 (4.0)	0	0	0
Dry skin	1 (4.0)	0	1 (4.0)	0	0
Erythema	1 (4.0)	0	1 (4.0)	0	0
Ingrowing nail	1 (4.0)	0	1 (4.0)	0	0
Miliaria	1 (4.0)	1 (4.0)	0	0	0
Rash	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Hypotension	1 (4.0)	1 (4.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (94.0)	5 (10.0)	16 (32.0)	9 (18.0)	17 (34.0)
Blood and lymphatic system disorders					
-Total	9 (18.0)	1 (2.0)	1 (2.0)	4 (8.0)	3 (6.0)
Neutropenia	4 (8.0)	0	0	2 (4.0)	2 (4.0)
Anaemia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Thrombocytopenia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Eosinophilia	1 (2.0)	0	1 (2.0)	0	0
Lymphopenia	1 (2.0)	0	0	1 (2.0)	0
Cardiac disorders					
-Total	5 (10.0)	2 (4.0)	0	0	3 (6.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	2 (4.0)	0	0	0	2 (4.0)
Cardiac failure	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Tachycardia	1 (2.0)	1 (2.0)	0	0	0
Tricuspid valve incompetence	1 (2.0)	1 (2.0)	0	0	0
Endocrine disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Hypothyroidism	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	3 (6.0)	3 (6.0)	0	0	0
Cataract	2 (4.0)	2 (4.0)	0	0	0
Hypermetropia	1 (2.0)	1 (2.0)	0	0	0
Visual impairment	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					
-Total	13 (26.0)	6 (12.0)	6 (12.0)	1 (2.0)	0
Nausea	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Constipation	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Diarrhoea	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Vomiting	3 (6.0)	3 (6.0)	0	0	0
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (2.0)	0	1 (2.0)	0	0
Enteritis	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal haemorrhage	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal inflammation	1 (2.0)	0	1 (2.0)	0	0
Mouth haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Pancreatitis	1 (2.0)	0	0	1 (2.0)	0
Proctalgia	1 (2.0)	1 (2.0)	0	0	0
Stomatitis	1 (2.0)	1 (2.0)	0	0	0
Trichoglossia	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	17 (34.0)	10 (20.0)	5 (10.0)	2 (4.0)	0
Pyrexia	10 (20.0)	4 (8.0)	5 (10.0)	1 (2.0)	0
Fatigue	4 (8.0)	4 (8.0)	0	0	0
Pain	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Asthenia	1 (2.0)	1 (2.0)	0	0	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Malaise	1 (2.0)	1 (2.0)	0	0	0
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (2.0)	1 (2.0)	0	0	0
Hepatobiliary disorders					
-Total	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Hypertransaminasaemia	1 (2.0)	1 (2.0)	0	0	0
Liver disorder	1 (2.0)	0	1 (2.0)	0	0
Immune system disorders					
-Total	11 (22.0)	1 (2.0)	6 (12.0)	4 (8.0)	0
Hypogammaglobulinaemia	5 (10.0)	0	5 (10.0)	0	0
Allergy to immunoglobulin therapy	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Graft versus host disease	2 (4.0)	0	0	2 (4.0)	0
Drug hypersensitivity	1 (2.0)	0	1 (2.0)	0	0
Engraftment syndrome	1 (2.0)	0	0	1 (2.0)	0
Immunodeficiency	1 (2.0)	0	0	1 (2.0)	0
Infections and infestations					
-Total	27 (54.0)	4 (8.0)	9 (18.0)	8 (16.0)	6 (12.0)
Nasopharyngitis	6 (12.0)	4 (8.0)	2 (4.0)	0	0
Gastroenteritis	4 (8.0)	3 (6.0)	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (8.0)	1 (2.0)	3 (6.0)	0	0
Rhinovirus infection	3 (6.0)	0	3 (6.0)	0	0
Sinusitis	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Bacteraemia	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Metapneumovirus infection	2 (4.0)	0	0	2 (4.0)	0
Parainfluenzae virus infection	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Pneumonia	2 (4.0)	1 (2.0)	0	0	1 (2.0)
Respiratory tract infection	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Viral infection	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Adenovirus infection	1 (2.0)	0	0	1 (2.0)	0
Bk virus infection	1 (2.0)	0	0	1 (2.0)	0
Coronavirus infection	1 (2.0)	0	0	1 (2.0)	0
Cystitis	1 (2.0)	0	1 (2.0)	0	0
Cytomegalovirus infection reactivation	1 (2.0)	0	0	1 (2.0)	0
Device related infection	1 (2.0)	0	0	1 (2.0)	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=50			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis clostridial	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis viral	1 (2.0)	1 (2.0)	0	0	0
Gingivitis	1 (2.0)	1 (2.0)	0	0	0
Herpes simplex	1 (2.0)	0	1 (2.0)	0	0
Human herpesvirus 6 infection	1 (2.0)	0	0	1 (2.0)	0
Influenza	1 (2.0)	0	1 (2.0)	0	0
Klebsiella infection	1 (2.0)	0	0	1 (2.0)	0
Mastoiditis	1 (2.0)	0	0	1 (2.0)	0
Nail infection	1 (2.0)	1 (2.0)	0	0	0
Oral candidiasis	1 (2.0)	0	1 (2.0)	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Otitis externa	1 (2.0)	0	0	1 (2.0)	0
Otitis media	1 (2.0)	0	0	1 (2.0)	0
Pharyngitis streptococcal	1 (2.0)	0	0	1 (2.0)	0
Pneumocystis jirovecii pneumonia	1 (2.0)	0	0	0	1 (2.0)
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Salmonellosis	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (2.0)	0	0	0	1 (2.0)
Sinusitis fungal	1 (2.0)	0	0	1 (2.0)	0
Staphylococcal sepsis	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal skin infection	1 (2.0)	0	1 (2.0)	0	0
Tinea pedis	1 (2.0)	1 (2.0)	0	0	0
Urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	0	1 (2.0)	0
Injury, poisoning and procedural complications					
-Total	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Contusion	1 (2.0)	1 (2.0)	0	0	0
Infusion related reaction	1 (2.0)	1 (2.0)	0	0	0
Ligament sprain	1 (2.0)	1 (2.0)	0	0	0
Limb injury	1 (2.0)	0	1 (2.0)	0	0
Post-traumatic neck syndrome	1 (2.0)	0	1 (2.0)	0	0
Investigations					
-Total	23 (46.0)	5 (10.0)	6 (12.0)	8 (16.0)	4 (8.0)
Neutrophil count decreased	6 (12.0)	1 (2.0)	0	2 (4.0)	3 (6.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (12.0)	2 (4.0)	1 (2.0)	3 (6.0)	0
Platelet count decreased	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Alanine aminotransferase increased	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Blood bilirubin increased	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Blood immunoglobulin a decreased	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Blood uric acid increased	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Lymphocyte count decreased	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Blood creatinine increased	1 (2.0)	0	1 (2.0)	0	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Blood immunoglobulin m decreased	1 (2.0)	0	0	1 (2.0)	0
Blood thyroid stimulating hormone increased	1 (2.0)	1 (2.0)	0	0	0
Blood urea increased	1 (2.0)	0	0	1 (2.0)	0
Bone density decreased	1 (2.0)	1 (2.0)	0	0	0
Ejection fraction decreased	1 (2.0)	0	1 (2.0)	0	0
Heart sounds abnormal	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatitis b virus test positive	1 (2.0)	0	1 (2.0)	0	0
Immunoglobulins decreased	1 (2.0)	0	1 (2.0)	0	0
Oxygen saturation decreased	1 (2.0)	0	1 (2.0)	0	0
Weight increased	1 (2.0)	0	0	1 (2.0)	0
Metabolism and nutrition disorders					
-Total	11 (22.0)	3 (6.0)	3 (6.0)	3 (6.0)	2 (4.0)
Hyperuricaemia	3 (6.0)	3 (6.0)	0	0	0
Decreased appetite	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Hypokalaemia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hyperchloraemia	1 (2.0)	1 (2.0)	0	0	0
Hypervolaemia	1 (2.0)	0	0	1 (2.0)	0
Hypophagia	1 (2.0)	0	1 (2.0)	0	0
Iron overload	1 (2.0)	0	1 (2.0)	0	0
Malnutrition	1 (2.0)	0	0	1 (2.0)	0
Metabolic acidosis	1 (2.0)	0	0	0	1 (2.0)
Metabolic syndrome	1 (2.0)	0	1 (2.0)	0	0
Tumour lysis syndrome	1 (2.0)	0	0	0	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	12 (24.0)	3 (6.0)	6 (12.0)	3 (6.0)	0
Back pain	5 (10.0)	1 (2.0)	2 (4.0)	2 (4.0)	0
Pain in extremity	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Arthralgia	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Bone pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Musculoskeletal chest pain	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal pain	1 (2.0)	0	1 (2.0)	0	0
Myalgia	1 (2.0)	0	1 (2.0)	0	0
Neck pain	1 (2.0)	1 (2.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Skin papilloma	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Cancer pain	1 (2.0)	0	1 (2.0)	0	0
Myelodysplastic syndrome	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					
-Total	8 (16.0)	4 (8.0)	3 (6.0)	0	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Dizziness	1 (2.0)	1 (2.0)	0	0	0
Extrapyramidal disorder	1 (2.0)	0	1 (2.0)	0	0
Hydrocephalus	1 (2.0)	0	0	0	1 (2.0)
Migraine	1 (2.0)	0	1 (2.0)	0	0
Psychiatric disorders					
-Total	8 (16.0)	1 (2.0)	6 (12.0)	1 (2.0)	0
Anxiety	6 (12.0)	1 (2.0)	5 (10.0)	0	0
Mental status changes	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Agitation	1 (2.0)	1 (2.0)	0	0	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Mood altered	1 (2.0)	1 (2.0)	0	0	0
Nightmare	1 (2.0)	1 (2.0)	0	0	0
Tearfulness	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	4 (8.0)	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)
Acute kidney injury	3 (6.0)	1 (2.0)	1 (2.0)	0	1 (2.0)
Cystitis haemorrhagic	1 (2.0)	0	1 (2.0)	0	0
Dysuria	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (2.0)	0	0	1 (2.0)	0
Kidney enlargement	1 (2.0)	0	1 (2.0)	0	0
Renal mass	1 (2.0)	0	1 (2.0)	0	0
Reproductive system and breast disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Dysmenorrhoea	1 (2.0)	0	1 (2.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (34.0)	8 (16.0)	4 (8.0)	2 (4.0)	3 (6.0)
Cough	9 (18.0)	7 (14.0)	2 (4.0)	0	0
Nasal congestion	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Hypoxia	2 (4.0)	0	0	2 (4.0)	0
Pleural effusion	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Rhinorrhoea	2 (4.0)	2 (4.0)	0	0	0
Acute respiratory distress syndrome	1 (2.0)	0	0	0	1 (2.0)
Bronchial oedema	1 (2.0)	1 (2.0)	0	0	0
Dyspnoea	1 (2.0)	0	1 (2.0)	0	0
Epistaxis	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Paranasal sinus inflammation	1 (2.0)	1 (2.0)	0	0	0
Respiratory distress	1 (2.0)	0	0	0	1 (2.0)
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Upper respiratory tract inflammation	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (28.0)	9 (18.0)	4 (8.0)	1 (2.0)	0
Dry skin	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Rash	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Decubitus ulcer	1 (2.0)	0	0	1 (2.0)	0
Dermatitis atopic	1 (2.0)	1 (2.0)	0	0	0
Eczema	1 (2.0)	1 (2.0)	0	0	0
Hangnail	1 (2.0)	1 (2.0)	0	0	0
Ingrowing nail	1 (2.0)	0	1 (2.0)	0	0
Night sweats	1 (2.0)	1 (2.0)	0	0	0
Photosensitivity reaction	1 (2.0)	0	1 (2.0)	0	0
Pruritus	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin discolouration	1 (2.0)	1 (2.0)	0	0	0
Skin hypopigmentation	1 (2.0)	1 (2.0)	0	0	0
Skin swelling	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	5 (10.0)	0	0	2 (4.0)	3 (6.0)
Hypotension	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Venoocclusive disease	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Hypertension	1 (2.0)	0	1 (2.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (70.0)	0	5 (25.0)	6 (30.0)	3 (15.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypercoagulation	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Delayed puberty	1 (5.0)	0	1 (5.0)	0	0
Hypothyroidism	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Dry eye	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Diarrhoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Constipation	1 (5.0)	1 (5.0)	0	0	0
Irritable bowel syndrome	1 (5.0)	0	1 (5.0)	0	0
Nausea	1 (5.0)	1 (5.0)	0	0	0
Vomiting	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	5 (25.0)	1 (5.0)	3 (15.0)	0	1 (5.0)
Pyrexia	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Fatigue	1 (5.0)	0	1 (5.0)	0	0
Multiple organ dysfunction syndrome	1 (5.0)	0	0	0	1 (5.0)
Immune system disorders					
-Total	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Chronic graft versus host disease	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	0	0	1 (5.0)
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Seasonal allergy	1 (5.0)	1 (5.0)	0	0	0
Infections and infestations					
-Total	10 (50.0)	0	5 (25.0)	4 (20.0)	1 (5.0)
Rhinovirus infection	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Sinusitis	3 (15.0)	0	3 (15.0)	0	0
Pneumonia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Conjunctivitis	1 (5.0)	1 (5.0)	0	0	0
Covid-19 pneumonia	1 (5.0)	0	0	0	1 (5.0)
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Fungal infection	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis escherichia coli	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (5.0)	0	0	0	1 (5.0)
Neutropenic infection	1 (5.0)	0	0	1 (5.0)	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	1 (5.0)	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Urinary tract infection	1 (5.0)	0	1 (5.0)	0	0
Varicella zoster virus infection	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Abdominal injury	1 (5.0)	1 (5.0)	0	0	0
Infusion related reaction	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	3 (15.0)	0	1 (5.0)	1 (5.0)	1 (5.0)
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Neutrophil count decreased	1 (5.0)	0	0	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oxygen saturation decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	4 (20.0)	0	1 (5.0)	2 (10.0)	1 (5.0)
Decreased appetite	1 (5.0)	0	0	0	1 (5.0)
Hypercholesterolaemia	1 (5.0)	0	1 (5.0)	0	0
Hyperglycaemia	1 (5.0)	0	0	1 (5.0)	0
Hypertriglyceridaemia	1 (5.0)	0	1 (5.0)	0	0
Iron overload	1 (5.0)	0	1 (5.0)	0	0
Obesity	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (20.0)	1 (5.0)	3 (15.0)	0	0
Growth retardation	1 (5.0)	0	1 (5.0)	0	0
Joint effusion	1 (5.0)	0	1 (5.0)	0	0
Osteopenia	1 (5.0)	1 (5.0)	0	0	0
Pain in extremity	1 (5.0)	0	1 (5.0)	0	0
Synovitis	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.0)	0	0	1 (5.0)	0
Bone giant cell tumour benign	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Dysarthria	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Reproductive system and breast disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Endometriosis	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (20.0)	1 (5.0)	2 (10.0)	0	1 (5.0)
Cough	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Dyspnoea	1 (5.0)	0	0	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (5.0)	1 (5.0)	0	0	0
Pharyngeal erythema	1 (5.0)	1 (5.0)	0	0	0
Pleural effusion	1 (5.0)	0	1 (5.0)	0	0
Rhinorrhoea	1 (5.0)	0	1 (5.0)	0	0
Sleep apnoea syndrome	1 (5.0)	0	1 (5.0)	0	0
Tachypnoea	1 (5.0)	0	0	0	1 (5.0)
Skin and subcutaneous tissue disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Dry skin	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	1 (5.0)	0	0	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypertension	2 (10.0)	0	1 (5.0)	1 (5.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (60.0)	3 (10.0)	5 (16.7)	6 (20.0)	4 (13.3)
Blood and lymphatic system disorders					
-Total	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Agranulocytosis	1 (3.3)	0	0	1 (3.3)	0
Anaemia	1 (3.3)	0	1 (3.3)	0	0
Lymphadenopathy	1 (3.3)	0	1 (3.3)	0	0
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Thrombocytopenia	1 (3.3)	0	1 (3.3)	0	0
Congenital, familial and genetic disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral cavernous malformation	1 (3.3)	1 (3.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Deafness unilateral	1 (3.3)	0	1 (3.3)	0	0
Eye disorders					
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Eye pain	1 (3.3)	0	0	1 (3.3)	0
Eyelid oedema	1 (3.3)	1 (3.3)	0	0	0
Mydriasis	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					
-Total	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Diarrhoea	2 (6.7)	1 (3.3)	0	1 (3.3)	0
General disorders and administration site conditions					
-Total	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Pyrexia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Non-cardiac chest pain	1 (3.3)	1 (3.3)	0	0	0
Xerosis	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	6 (20.0)	1 (3.3)	4 (13.3)	1 (3.3)	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0
Seasonal allergy	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Chronic graft versus host disease	1 (3.3)	0	1 (3.3)	0	0
Drug hypersensitivity	1 (3.3)	0	0	1 (3.3)	0
Infections and infestations					
-Total	13 (43.3)	2 (6.7)	2 (6.7)	6 (20.0)	3 (10.0)
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Sinusitis	3 (10.0)	0	3 (10.0)	0	0
Upper respiratory tract infection	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Bronchitis	2 (6.7)	0	2 (6.7)	0	0
Covid-19	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Herpes zoster	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Oral herpes	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Otitis media	2 (6.7)	0	2 (6.7)	0	0
Sepsis	2 (6.7)	0	0	0	2 (6.7)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (6.7)	0	2 (6.7)	0	0
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Bronchiolitis	1 (3.3)	0	0	1 (3.3)	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	0	1 (3.3)	0
Folliculitis	1 (3.3)	0	1 (3.3)	0	0
Fungal infection	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis viral	1 (3.3)	0	1 (3.3)	0	0
Herpes virus infection	1 (3.3)	0	1 (3.3)	0	0
Influenza	1 (3.3)	0	1 (3.3)	0	0
Meningitis pneumococcal	1 (3.3)	0	0	1 (3.3)	0
Nail infection	1 (3.3)	0	1 (3.3)	0	0
Ophthalmic herpes zoster	1 (3.3)	0	1 (3.3)	0	0
Oral candidiasis	1 (3.3)	0	1 (3.3)	0	0
Pneumonia respiratory syncytial viral	1 (3.3)	0	0	1 (3.3)	0
Rhinitis	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.3)	0	1 (3.3)	0	0
Septic shock	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal abscess	1 (3.3)	0	0	1 (3.3)	0
Streptococcal sepsis	1 (3.3)	0	1 (3.3)	0	0
Syphilis	1 (3.3)	0	1 (3.3)	0	0
Urinary tract infection	1 (3.3)	0	1 (3.3)	0	0
Urinary tract infection pseudomonal	1 (3.3)	0	1 (3.3)	0	0
Viral skin infection	1 (3.3)	1 (3.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.3)	1 (3.3)	0	0	0
Ligament sprain	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	3 (10.0)	3 (10.0)	0	0	0
Neutrophil count decreased	2 (6.7)	2 (6.7)	0	0	0
Platelet count decreased	2 (6.7)	2 (6.7)	0	0	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Hyperlipidaemia	1 (3.3)	0	1 (3.3)	0	0
Hypernatraemia	1 (3.3)	0	0	1 (3.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Arthralgia	1 (3.3)	0	1 (3.3)	0	0
Osteonecrosis	1 (3.3)	1 (3.3)	0	0	0
Pain in extremity	1 (3.3)	0	1 (3.3)	0	0
Nervous system disorders					
-Total	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Headache	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Nervous system disorder	1 (3.3)	0	0	1 (3.3)	0
Seizure	1 (3.3)	0	0	1 (3.3)	0
Psychiatric disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Tic	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (20.0)	3 (10.0)	0	1 (3.3)	2 (6.7)
Cough	2 (6.7)	2 (6.7)	0	0	0
Dyspnoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Rhinorrhoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Epistaxis	1 (3.3)	1 (3.3)	0	0	0
Hypoxia	1 (3.3)	0	0	1 (3.3)	0
Laryngeal oedema	1 (3.3)	0	0	0	1 (3.3)
Oropharyngeal pain	1 (3.3)	1 (3.3)	0	0	0
Respiratory failure	1 (3.3)	0	0	0	1 (3.3)
Sleep apnoea syndrome	1 (3.3)	1 (3.3)	0	0	0
Wheezing	1 (3.3)	0	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Dermatitis atopic	1 (3.3)	0	0	1 (3.3)	0
Eczema	1 (3.3)	0	0	1 (3.3)	0
Papule	1 (3.3)	1 (3.3)	0	0	0
Rash	1 (3.3)	0	1 (3.3)	0	0
Rash erythematous	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (3.3)	0	0	1 (3.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (100)	0	3 (11.5)	10 (38.5)	13 (50.0)
Blood and lymphatic system disorders					
-Total	20 (76.9)	0	5 (19.2)	10 (38.5)	5 (19.2)
Febrile neutropenia	10 (38.5)	0	0	9 (34.6)	1 (3.8)
Anaemia	8 (30.8)	3 (11.5)	2 (7.7)	3 (11.5)	0
Neutropenia	4 (15.4)	0	1 (3.8)	1 (3.8)	2 (7.7)
Thrombocytopenia	4 (15.4)	0	0	2 (7.7)	2 (7.7)
Disseminated intravascular coagulation	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Leukopenia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Pancytopenia	2 (7.7)	0	0	2 (7.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (3.8)	0	1 (3.8)	0	0
Coagulopathy	1 (3.8)	0	0	1 (3.8)	0
Hypercoagulation	1 (3.8)	0	1 (3.8)	0	0
Leukocytosis	1 (3.8)	0	1 (3.8)	0	0
Lymphadenopathy	1 (3.8)	1 (3.8)	0	0	0
Lymphocytosis	1 (3.8)	0	1 (3.8)	0	0
Cardiac disorders					
-Total	8 (30.8)	3 (11.5)	2 (7.7)	2 (7.7)	1 (3.8)
Tachycardia	6 (23.1)	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)
Left ventricular dysfunction	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Sinus bradycardia	1 (3.8)	0	0	1 (3.8)	0
Endocrine disorders					
-Total	3 (11.5)	0	3 (11.5)	0	0
Hypothyroidism	2 (7.7)	0	2 (7.7)	0	0
Adrenal insufficiency	1 (3.8)	0	1 (3.8)	0	0
Delayed puberty	1 (3.8)	0	1 (3.8)	0	0
Eye disorders					
-Total	5 (19.2)	5 (19.2)	0	0	0
Ocular hyperaemia	3 (11.5)	3 (11.5)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (3.8)	1 (3.8)	0	0	0
Dry eye	1 (3.8)	1 (3.8)	0	0	0
Eyelid oedema	1 (3.8)	1 (3.8)	0	0	0
Gastrointestinal disorders					
-Total	19 (73.1)	8 (30.8)	6 (23.1)	5 (19.2)	0
Diarrhoea	10 (38.5)	7 (26.9)	3 (11.5)	0	0
Vomiting	8 (30.8)	5 (19.2)	2 (7.7)	1 (3.8)	0
Nausea	6 (23.1)	3 (11.5)	2 (7.7)	1 (3.8)	0
Constipation	5 (19.2)	5 (19.2)	0	0	0
Abdominal pain	3 (11.5)	1 (3.8)	2 (7.7)	0	0
Ascites	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Pancreatitis	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Abdominal distension	1 (3.8)	0	1 (3.8)	0	0
Abdominal pain upper	1 (3.8)	1 (3.8)	0	0	0
Anal fissure	1 (3.8)	0	1 (3.8)	0	0
Dyspepsia	1 (3.8)	1 (3.8)	0	0	0
Irritable bowel syndrome	1 (3.8)	0	1 (3.8)	0	0
Melaena	1 (3.8)	0	0	1 (3.8)	0
Mouth haemorrhage	1 (3.8)	0	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritoneal haematoma	1 (3.8)	1 (3.8)	0	0	0
Stomatitis	1 (3.8)	0	0	1 (3.8)	0
Trichoglossia	1 (3.8)	0	1 (3.8)	0	0
General disorders and administration site conditions					
-Total	18 (69.2)	6 (23.1)	7 (26.9)	2 (7.7)	3 (11.5)
Pyrexia	12 (46.2)	4 (15.4)	6 (23.1)	1 (3.8)	1 (3.8)
Fatigue	5 (19.2)	3 (11.5)	2 (7.7)	0	0
Face oedema	4 (15.4)	1 (3.8)	2 (7.7)	1 (3.8)	0
Influenza like illness	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Multiple organ dysfunction syndrome	2 (7.7)	0	0	0	2 (7.7)
Pain	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Catheter site pain	1 (3.8)	1 (3.8)	0	0	0
Drug withdrawal syndrome	1 (3.8)	0	1 (3.8)	0	0
Generalised oedema	1 (3.8)	0	1 (3.8)	0	0
Oedema peripheral	1 (3.8)	0	0	1 (3.8)	0
Systemic inflammatory response syndrome	1 (3.8)	0	0	1 (3.8)	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (15.4)	2 (7.7)	1 (3.8)	0	1 (3.8)
Cholelithiasis	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Cholestasis	1 (3.8)	0	0	0	1 (3.8)
Gallbladder enlargement	1 (3.8)	1 (3.8)	0	0	0
Hepatic cytolysis	1 (3.8)	1 (3.8)	0	0	0
Ocular icterus	1 (3.8)	1 (3.8)	0	0	0
Immune system disorders					
-Total	23 (88.5)	1 (3.8)	11 (42.3)	6 (23.1)	5 (19.2)
Cytokine release syndrome	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Hypogammaglobulinaemia	14 (53.8)	1 (3.8)	11 (42.3)	2 (7.7)	0
Haemophagocytic lymphohistiocytosis	2 (7.7)	0	0	0	2 (7.7)
Immunodeficiency	2 (7.7)	0	0	2 (7.7)	0
Chronic graft versus host disease	1 (3.8)	0	0	1 (3.8)	0
Seasonal allergy	1 (3.8)	1 (3.8)	0	0	0
Infections and infestations					
-Total	19 (73.1)	2 (7.7)	7 (26.9)	6 (23.1)	4 (15.4)
Upper respiratory tract infection	6 (23.1)	3 (11.5)	1 (3.8)	2 (7.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=26			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)	0	0
Rhinovirus infection	4 (15.4)	0	2 (7.7)	2 (7.7)	0
Parainfluenzae virus infection	3 (11.5)	1 (3.8)	0	2 (7.7)	0
Pneumonia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Respiratory syncytial virus infection	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Sinusitis	3 (11.5)	0	3 (11.5)	0	0
Staphylococcal bacteraemia	3 (11.5)	0	0	3 (11.5)	0
Clostridium difficile infection	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Encephalitis	2 (7.7)	0	0	0	2 (7.7)
Otitis media	2 (7.7)	0	2 (7.7)	0	0
Bronchopulmonary aspergillosis	1 (3.8)	0	0	0	1 (3.8)
Cellulitis	1 (3.8)	0	1 (3.8)	0	0
Clostridium difficile colitis	1 (3.8)	0	0	1 (3.8)	0
Covid-19 pneumonia	1 (3.8)	0	0	0	1 (3.8)
Ear infection	1 (3.8)	0	1 (3.8)	0	0
Ear, nose and throat infection	1 (3.8)	0	1 (3.8)	0	0
Enterovirus infection	1 (3.8)	0	0	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=26			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal infection	1 (3.8)	0	1 (3.8)	0	0
Fungal skin infection	1 (3.8)	0	1 (3.8)	0	0
Gastroenteritis	1 (3.8)	0	0	1 (3.8)	0
Gastroenteritis escherichia coli	1 (3.8)	0	0	1 (3.8)	0
Gastroenteritis salmonella	1 (3.8)	0	0	1 (3.8)	0
Gastrointestinal infection	1 (3.8)	1 (3.8)	0	0	0
Herpes zoster	1 (3.8)	0	0	1 (3.8)	0
Influenza	1 (3.8)	0	0	0	1 (3.8)
Localised infection	1 (3.8)	1 (3.8)	0	0	0
Metapneumovirus infection	1 (3.8)	0	0	1 (3.8)	0
Molluscum contagiosum	1 (3.8)	1 (3.8)	0	0	0
Nail infection	1 (3.8)	1 (3.8)	0	0	0
Nasopharyngitis	1 (3.8)	0	1 (3.8)	0	0
Neutropenic infection	1 (3.8)	0	0	1 (3.8)	0
Otitis externa	1 (3.8)	0	1 (3.8)	0	0
Otitis media acute	1 (3.8)	0	1 (3.8)	0	0
Paronychia	1 (3.8)	0	1 (3.8)	0	0
Pneumocystis jirovecii pneumonia	1 (3.8)	0	0	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (3.8)	0	1 (3.8)	0	0
Respiratory tract infection viral	1 (3.8)	0	1 (3.8)	0	0
Rhinitis	1 (3.8)	0	1 (3.8)	0	0
Sepsis	1 (3.8)	0	0	1 (3.8)	0
Skin infection	1 (3.8)	0	1 (3.8)	0	0
Urinary tract infection	1 (3.8)	0	1 (3.8)	0	0
Varicella zoster virus infection	1 (3.8)	0	1 (3.8)	0	0
Viral haemorrhagic cystitis	1 (3.8)	0	0	1 (3.8)	0
Injury, poisoning and procedural complications					
-Total	8 (30.8)	4 (15.4)	2 (7.7)	1 (3.8)	1 (3.8)
Infusion related reaction	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Abdominal injury	1 (3.8)	1 (3.8)	0	0	0
Fibula fracture	1 (3.8)	0	1 (3.8)	0	0
Scratch	1 (3.8)	1 (3.8)	0	0	0
Skin abrasion	1 (3.8)	1 (3.8)	0	0	0
Skin injury	1 (3.8)	0	1 (3.8)	0	0
Skin wound	1 (3.8)	1 (3.8)	0	0	0
Vasoplegia syndrome	1 (3.8)	0	0	0	1 (3.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (3.8)	0	0	1 (3.8)	0
Investigations					
-Total	18 (69.2)	0	2 (7.7)	7 (26.9)	9 (34.6)
Neutrophil count decreased	8 (30.8)	0	1 (3.8)	2 (7.7)	5 (19.2)
White blood cell count decreased	8 (30.8)	1 (3.8)	2 (7.7)	1 (3.8)	4 (15.4)
Platelet count decreased	7 (26.9)	2 (7.7)	1 (3.8)	0	4 (15.4)
Alanine aminotransferase increased	6 (23.1)	2 (7.7)	3 (11.5)	1 (3.8)	0
Aspartate aminotransferase increased	5 (19.2)	1 (3.8)	2 (7.7)	1 (3.8)	1 (3.8)
Lymphocyte count decreased	5 (19.2)	0	0	5 (19.2)	0
C-reactive protein increased	4 (15.4)	1 (3.8)	0	3 (11.5)	0
Serum ferritin increased	4 (15.4)	1 (3.8)	1 (3.8)	2 (7.7)	0
Blood bilirubin increased	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Blood immunoglobulin g decreased	3 (11.5)	1 (3.8)	2 (7.7)	0	0
Blood immunoglobulin m decreased	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
International normalised ratio increased	3 (11.5)	3 (11.5)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Blood immunoglobulin a decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Blood lactate dehydrogenase increased	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Electrocardiogram qt prolonged	2 (7.7)	0	1 (3.8)	0	1 (3.8)
Fibrin d dimer increased	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Lipase increased	2 (7.7)	1 (3.8)	0	0	1 (3.8)
Oxygen saturation decreased	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Amylase increased	1 (3.8)	1 (3.8)	0	0	0
Bacterial test positive	1 (3.8)	0	0	1 (3.8)	0
Blood creatine phosphokinase increased	1 (3.8)	0	0	0	1 (3.8)
Blood creatinine increased	1 (3.8)	0	0	1 (3.8)	0
Blood fibrinogen decreased	1 (3.8)	0	1 (3.8)	0	0
Blood phosphorus increased	1 (3.8)	0	1 (3.8)	0	0
Blood testosterone decreased	1 (3.8)	1 (3.8)	0	0	0
Electrocardiogram t wave abnormal	1 (3.8)	0	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Troponin increased	1 (3.8)	0	0	1 (3.8)	0
Weight decreased	1 (3.8)	0	0	1 (3.8)	0
Metabolism and nutrition disorders					
-Total	15 (57.7)	3 (11.5)	3 (11.5)	5 (19.2)	4 (15.4)
Decreased appetite	8 (30.8)	3 (11.5)	3 (11.5)	1 (3.8)	1 (3.8)
Hypocalcaemia	6 (23.1)	0	4 (15.4)	2 (7.7)	0
Hypokalaemia	5 (19.2)	1 (3.8)	0	2 (7.7)	2 (7.7)
Hypophosphataemia	5 (19.2)	0	3 (11.5)	2 (7.7)	0
Hyperuricaemia	3 (11.5)	3 (11.5)	0	0	0
Hyperglycaemia	2 (7.7)	0	0	2 (7.7)	0
Hypertriglyceridaemia	2 (7.7)	0	1 (3.8)	0	1 (3.8)
Hypoalbuminaemia	2 (7.7)	0	2 (7.7)	0	0
Calcium deficiency	1 (3.8)	1 (3.8)	0	0	0
Dehydration	1 (3.8)	0	1 (3.8)	0	0
Haemochromatosis	1 (3.8)	0	0	1 (3.8)	0
Haemosiderosis	1 (3.8)	0	1 (3.8)	0	0
Hypercalcaemia	1 (3.8)	0	1 (3.8)	0	0
Hypercholesterolaemia	1 (3.8)	0	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (3.8)	0	1 (3.8)	0	0
Hyperlactacidaemia	1 (3.8)	1 (3.8)	0	0	0
Hypernatraemia	1 (3.8)	0	0	0	1 (3.8)
Hyperphosphataemia	1 (3.8)	1 (3.8)	0	0	0
Hypervolaemia	1 (3.8)	0	0	1 (3.8)	0
Hypomagnesaemia	1 (3.8)	1 (3.8)	0	0	0
Iron overload	1 (3.8)	0	1 (3.8)	0	0
Malnutrition	1 (3.8)	0	0	1 (3.8)	0
Metabolic acidosis	1 (3.8)	1 (3.8)	0	0	0
Obesity	1 (3.8)	0	0	1 (3.8)	0
Tumour lysis syndrome	1 (3.8)	0	0	1 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (42.3)	4 (15.4)	4 (15.4)	2 (7.7)	1 (3.8)
Pain in extremity	4 (15.4)	3 (11.5)	1 (3.8)	0	0
Back pain	3 (11.5)	2 (7.7)	0	1 (3.8)	0
Arthralgia	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Growth retardation	2 (7.7)	0	2 (7.7)	0	0
Myalgia	2 (7.7)	1 (3.8)	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (3.8)	0	0	1 (3.8)	0
Joint effusion	1 (3.8)	0	1 (3.8)	0	0
Myositis	1 (3.8)	0	1 (3.8)	0	0
Osteopenia	1 (3.8)	1 (3.8)	0	0	0
Rhabdomyolysis	1 (3.8)	0	0	0	1 (3.8)
Synovitis	1 (3.8)	0	1 (3.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.8)	0	0	1 (3.8)	0
Bone giant cell tumour benign	1 (3.8)	0	0	1 (3.8)	0
Nervous system disorders					
-Total	15 (57.7)	6 (23.1)	4 (15.4)	4 (15.4)	1 (3.8)
Headache	8 (30.8)	5 (19.2)	2 (7.7)	1 (3.8)	0
Cognitive disorder	2 (7.7)	0	2 (7.7)	0	0
Encephalopathy	2 (7.7)	0	0	2 (7.7)	0
Seizure	2 (7.7)	0	0	2 (7.7)	0
Autonomic neuropathy	1 (3.8)	0	0	1 (3.8)	0
Cerebral haemorrhage	1 (3.8)	0	0	0	1 (3.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	1 (3.8)	0	1 (3.8)	0	0
Dysgeusia	1 (3.8)	1 (3.8)	0	0	0
Lethargy	1 (3.8)	1 (3.8)	0	0	0
Memory impairment	1 (3.8)	0	1 (3.8)	0	0
Monoparesis	1 (3.8)	0	1 (3.8)	0	0
Tremor	1 (3.8)	1 (3.8)	0	0	0
Psychiatric disorders					
-Total	12 (46.2)	6 (23.1)	5 (19.2)	1 (3.8)	0
Anxiety	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0
Confusional state	2 (7.7)	2 (7.7)	0	0	0
Sleep disorder	2 (7.7)	0	2 (7.7)	0	0
Insomnia	1 (3.8)	1 (3.8)	0	0	0
Irritability	1 (3.8)	1 (3.8)	0	0	0
Persistent depressive disorder	1 (3.8)	0	1 (3.8)	0	0
Renal and urinary disorders					
-Total	5 (19.2)	2 (7.7)	0	1 (3.8)	2 (7.7)
Dysuria	2 (7.7)	2 (7.7)	0	0	0
Acute kidney injury	1 (3.8)	0	0	0	1 (3.8)
Anuria	1 (3.8)	0	0	0	1 (3.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bladder dilatation	1 (3.8)	0	1 (3.8)	0	0
Renal tubular disorder	1 (3.8)	0	0	1 (3.8)	0
Renal tubular necrosis	1 (3.8)	0	0	0	1 (3.8)
Urinary retention	1 (3.8)	0	1 (3.8)	0	0
Reproductive system and breast disorders					
-Total	3 (11.5)	1 (3.8)	0	2 (7.7)	0
Endometriosis	1 (3.8)	0	0	1 (3.8)	0
Heavy menstrual bleeding	1 (3.8)	1 (3.8)	0	0	0
Vaginal ulceration	1 (3.8)	0	0	1 (3.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (61.5)	7 (26.9)	3 (11.5)	2 (7.7)	4 (15.4)
Cough	6 (23.1)	3 (11.5)	3 (11.5)	0	0
Nasal congestion	4 (15.4)	3 (11.5)	1 (3.8)	0	0
Epistaxis	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Hypoxia	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Pleural effusion	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Acute respiratory distress syndrome	2 (7.7)	0	0	0	2 (7.7)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (7.7)	0	0	0	2 (7.7)
Pulmonary oedema	2 (7.7)	0	0	2 (7.7)	0
Rhinitis allergic	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Rhinorrhoea	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Tachypnoea	2 (7.7)	0	0	1 (3.8)	1 (3.8)
Atelectasis	1 (3.8)	0	0	1 (3.8)	0
Bronchospasm	1 (3.8)	0	1 (3.8)	0	0
Dyspnoea exertional	1 (3.8)	1 (3.8)	0	0	0
Lung disorder	1 (3.8)	1 (3.8)	0	0	0
Nasal dryness	1 (3.8)	1 (3.8)	0	0	0
Oropharyngeal pain	1 (3.8)	0	1 (3.8)	0	0
Pharyngeal erythema	1 (3.8)	1 (3.8)	0	0	0
Respiratory acidosis	1 (3.8)	0	0	1 (3.8)	0
Sleep apnoea syndrome	1 (3.8)	0	1 (3.8)	0	0
Wheezing	1 (3.8)	0	1 (3.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (46.2)	7 (26.9)	4 (15.4)	1 (3.8)	0
Rash	4 (15.4)	3 (11.5)	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Dry skin	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Rash maculo-papular	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Decubitus ulcer	1 (3.8)	0	1 (3.8)	0	0
Dermatitis	1 (3.8)	1 (3.8)	0	0	0
Dermatitis allergic	1 (3.8)	1 (3.8)	0	0	0
Eczema	1 (3.8)	1 (3.8)	0	0	0
Ingrowing nail	1 (3.8)	0	1 (3.8)	0	0
Miliaria	1 (3.8)	1 (3.8)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (3.8)	1 (3.8)	0	0	0
Petechiae	1 (3.8)	0	0	1 (3.8)	0
Pruritus	1 (3.8)	0	1 (3.8)	0	0
Rash papular	1 (3.8)	1 (3.8)	0	0	0
Skin discolouration	1 (3.8)	1 (3.8)	0	0	0
Skin necrosis	1 (3.8)	0	0	1 (3.8)	0
Skin ulcer	1 (3.8)	1 (3.8)	0	0	0
Vascular disorders					
-Total	10 (38.5)	2 (7.7)	3 (11.5)	4 (15.4)	1 (3.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	7 (26.9)	2 (7.7)	2 (7.7)	2 (7.7)	1 (3.8)
Hypertension	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Capillary leak syndrome	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (100)	1 (1.9)	3 (5.6)	9 (16.7)	41 (75.9)
Blood and lymphatic system disorders					
-Total	35 (64.8)	1 (1.9)	6 (11.1)	19 (35.2)	9 (16.7)
Anaemia	17 (31.5)	4 (7.4)	7 (13.0)	6 (11.1)	0
Febrile neutropenia	17 (31.5)	0	0	16 (29.6)	1 (1.9)
Neutropenia	7 (13.0)	0	1 (1.9)	1 (1.9)	5 (9.3)
Disseminated intravascular coagulation	5 (9.3)	0	4 (7.4)	1 (1.9)	0
Thrombocytopenia	5 (9.3)	0	0	1 (1.9)	4 (7.4)
Coagulopathy	4 (7.4)	1 (1.9)	2 (3.7)	1 (1.9)	0
Splenomegaly	4 (7.4)	3 (5.6)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (3.7)	0	0	2 (3.7)	0
Agranulocytosis	1 (1.9)	0	0	1 (1.9)	0
Eosinophilia	1 (1.9)	0	1 (1.9)	0	0
Hypofibrinogenaemia	1 (1.9)	0	1 (1.9)	0	0
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Cardiac disorders					
-Total	20 (37.0)	7 (13.0)	5 (9.3)	3 (5.6)	5 (9.3)
Tachycardia	11 (20.4)	4 (7.4)	6 (11.1)	1 (1.9)	0
Bradycardia	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Cardiac arrest	3 (5.6)	0	0	0	3 (5.6)
Cardiac failure	3 (5.6)	0	0	1 (1.9)	2 (3.7)
Sinus tachycardia	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Cardiac dysfunction	2 (3.7)	2 (3.7)	0	0	0
Left ventricular dysfunction	2 (3.7)	0	0	2 (3.7)	0
Atrioventricular block first degree	1 (1.9)	0	1 (1.9)	0	0
Cardiac failure congestive	1 (1.9)	0	1 (1.9)	0	0
Mitral valve incompetence	1 (1.9)	1 (1.9)	0	0	0
Pericardial effusion	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Tricuspid valve incompetence	1 (1.9)	1 (1.9)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Cerebral cavernous malformation	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Deafness unilateral	1 (1.9)	0	1 (1.9)	0	0
Ear pain	1 (1.9)	1 (1.9)	0	0	0
Ear pruritus	1 (1.9)	1 (1.9)	0	0	0
Endocrine disorders					
-Total	4 (7.4)	0	4 (7.4)	0	0
Adrenal insufficiency	3 (5.6)	0	3 (5.6)	0	0
Hypothyroidism	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	10 (18.5)	5 (9.3)	4 (7.4)	1 (1.9)	0
Cataract	2 (3.7)	2 (3.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Eyelid oedema	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Visual impairment	2 (3.7)	2 (3.7)	0	0	0
Conjunctival haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Eye oedema	1 (1.9)	1 (1.9)	0	0	0
Hypermetropia	1 (1.9)	1 (1.9)	0	0	0
Mydriasis	1 (1.9)	0	1 (1.9)	0	0
Periorbital oedema	1 (1.9)	1 (1.9)	0	0	0
Periorbital swelling	1 (1.9)	0	1 (1.9)	0	0
Retinal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	41 (75.9)	13 (24.1)	17 (31.5)	10 (18.5)	1 (1.9)
Vomiting	18 (33.3)	12 (22.2)	6 (11.1)	0	0
Diarrhoea	16 (29.6)	9 (16.7)	5 (9.3)	2 (3.7)	0
Nausea	16 (29.6)	9 (16.7)	6 (11.1)	1 (1.9)	0
Constipation	9 (16.7)	2 (3.7)	7 (13.0)	0	0
Abdominal pain	8 (14.8)	1 (1.9)	5 (9.3)	2 (3.7)	0
Mouth haemorrhage	4 (7.4)	2 (3.7)	0	2 (3.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	4 (7.4)	0	3 (5.6)	1 (1.9)	0
Abdominal pain upper	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Abdominal distension	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Gastrointestinal sounds abnormal	2 (3.7)	2 (3.7)	0	0	0
Proctalgia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Stomatitis	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Abdominal compartment syndrome	1 (1.9)	0	0	0	1 (1.9)
Abdominal rigidity	1 (1.9)	0	1 (1.9)	0	0
Anal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Ascites	1 (1.9)	1 (1.9)	0	0	0
Dry mouth	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Enteritis	1 (1.9)	0	1 (1.9)	0	0
Enterocolitis	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal inflammation	1 (1.9)	0	1 (1.9)	0	0
Gastrooesophageal reflux disease	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival bleeding	1 (1.9)	0	1 (1.9)	0	0
Gingival erythema	1 (1.9)	1 (1.9)	0	0	0
Gingivitis ulcerative	1 (1.9)	0	0	1 (1.9)	0
Haematemesis	1 (1.9)	1 (1.9)	0	0	0
Ileus	1 (1.9)	0	1 (1.9)	0	0
Lip dry	1 (1.9)	0	1 (1.9)	0	0
Lip oedema	1 (1.9)	1 (1.9)	0	0	0
Mouth swelling	1 (1.9)	1 (1.9)	0	0	0
Neutropenic colitis	1 (1.9)	0	0	1 (1.9)	0
Odynophagia	1 (1.9)	1 (1.9)	0	0	0
Trichoglossia	1 (1.9)	1 (1.9)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	35 (64.8)	19 (35.2)	6 (11.1)	8 (14.8)	2 (3.7)
Pyrexia	23 (42.6)	10 (18.5)	4 (7.4)	8 (14.8)	1 (1.9)
Fatigue	12 (22.2)	11 (20.4)	1 (1.9)	0	0
Chills	7 (13.0)	5 (9.3)	2 (3.7)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	6 (11.1)	5 (9.3)	1 (1.9)	0	0
Face oedema	4 (7.4)	4 (7.4)	0	0	0
Generalised oedema	4 (7.4)	2 (3.7)	2 (3.7)	0	0
Asthenia	3 (5.6)	3 (5.6)	0	0	0
Pain	3 (5.6)	0	1 (1.9)	2 (3.7)	0
Localised oedema	2 (3.7)	2 (3.7)	0	0	0
Malaise	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Non-cardiac chest pain	2 (3.7)	2 (3.7)	0	0	0
Catheter site erythema	1 (1.9)	1 (1.9)	0	0	0
Catheter site haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Catheter site pain	1 (1.9)	0	0	1 (1.9)	0
Chest discomfort	1 (1.9)	0	0	1 (1.9)	0
Crying	1 (1.9)	0	1 (1.9)	0	0
Drug withdrawal syndrome	1 (1.9)	0	1 (1.9)	0	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	0	0	1 (1.9)
Oedema due to hepatic disease	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sluggishness	1 (1.9)	0	1 (1.9)	0	0
Swelling face	1 (1.9)	1 (1.9)	0	0	0
Vascular device occlusion	1 (1.9)	1 (1.9)	0	0	0
Xerosis	1 (1.9)	1 (1.9)	0	0	0
Hepatobiliary disorders					
-Total	15 (27.8)	4 (7.4)	6 (11.1)	3 (5.6)	2 (3.7)
Hepatic function abnormal	5 (9.3)	0	2 (3.7)	2 (3.7)	1 (1.9)
Hyperbilirubinaemia	5 (9.3)	1 (1.9)	3 (5.6)	1 (1.9)	0
Hepatomegaly	3 (5.6)	2 (3.7)	0	0	1 (1.9)
Hypertransaminasaemia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Biliary tract disorder	1 (1.9)	1 (1.9)	0	0	0
Gallbladder enlargement	1 (1.9)	1 (1.9)	0	0	0
Liver disorder	1 (1.9)	0	1 (1.9)	0	0
Immune system disorders					
-Total	48 (88.9)	1 (1.9)	12 (22.2)	18 (33.3)	17 (31.5)
Cytokine release syndrome	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)
Hypogammaglobulinaemia	19 (35.2)	1 (1.9)	13 (24.1)	5 (9.3)	0
Haemophagocytic lymphohistiocytosis	4 (7.4)	1 (1.9)	1 (1.9)	2 (3.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Allergy to immunoglobulin therapy	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Drug hypersensitivity	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Graft versus host disease	2 (3.7)	0	0	2 (3.7)	0
Immunodeficiency	2 (3.7)	0	0	2 (3.7)	0
Chronic graft versus host disease	1 (1.9)	0	1 (1.9)	0	0
Engraftment syndrome	1 (1.9)	0	0	1 (1.9)	0
Hypersensitivity	1 (1.9)	1 (1.9)	0	0	0
Selective igg subclass deficiency	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	41 (75.9)	6 (11.1)	6 (11.1)	19 (35.2)	10 (18.5)
Upper respiratory tract infection	7 (13.0)	2 (3.7)	4 (7.4)	1 (1.9)	0
Nasopharyngitis	6 (11.1)	4 (7.4)	2 (3.7)	0	0
Gastroenteritis	5 (9.3)	4 (7.4)	0	1 (1.9)	0
Rhinovirus infection	5 (9.3)	0	5 (9.3)	0	0
Staphylococcal infection	5 (9.3)	0	3 (5.6)	2 (3.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	4 (7.4)	0	3 (5.6)	0	1 (1.9)
Conjunctivitis	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Oral herpes	4 (7.4)	1 (1.9)	2 (3.7)	1 (1.9)	0
Sinusitis	4 (7.4)	0	2 (3.7)	2 (3.7)	0
Bacteraemia	3 (5.6)	0	1 (1.9)	1 (1.9)	1 (1.9)
Nail infection	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Oral candidiasis	3 (5.6)	0	3 (5.6)	0	0
Otitis media	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Pneumonia	3 (5.6)	1 (1.9)	0	1 (1.9)	1 (1.9)
Acute sinusitis	2 (3.7)	0	2 (3.7)	0	0
Adenovirus infection	2 (3.7)	0	0	2 (3.7)	0
Bk virus infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Bronchitis	2 (3.7)	0	2 (3.7)	0	0
Clostridium difficile infection	2 (3.7)	0	0	2 (3.7)	0
Covid-19	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Ear infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Encephalitis viral	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Gastroenteritis viral	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Gingivitis	2 (3.7)	2 (3.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Herpes zoster	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Human herpesvirus 6 infection	2 (3.7)	0	0	2 (3.7)	0
Influenza	2 (3.7)	0	2 (3.7)	0	0
Metapneumovirus infection	2 (3.7)	0	0	2 (3.7)	0
Oral infection	2 (3.7)	0	2 (3.7)	0	0
Otitis externa	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	2 (3.7)	0	1 (1.9)	0	1 (1.9)
Respiratory tract infection	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Rhinitis	2 (3.7)	2 (3.7)	0	0	0
Sepsis	2 (3.7)	0	0	0	2 (3.7)
Septic shock	2 (3.7)	0	0	0	2 (3.7)
Skin infection	2 (3.7)	0	2 (3.7)	0	0
Staphylococcal bacteraemia	2 (3.7)	0	0	2 (3.7)	0
Urinary tract infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Viral infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Anal abscess	1 (1.9)	0	0	1 (1.9)	0
Atypical pneumonia	1 (1.9)	1 (1.9)	0	0	0
Bronchiolitis	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	1 (1.9)	0	0
Coronavirus infection	1 (1.9)	0	0	1 (1.9)	0
Cystitis	1 (1.9)	0	1 (1.9)	0	0
Cytomegalovirus infection reactivation	1 (1.9)	0	0	1 (1.9)	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Device related sepsis	1 (1.9)	0	0	1 (1.9)	0
Enterobacter infection	1 (1.9)	0	0	1 (1.9)	0
Folliculitis	1 (1.9)	0	1 (1.9)	0	0
Fungal infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis clostridial	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	1 (1.9)	0	0	0
Granulicatella infection	1 (1.9)	0	0	1 (1.9)	0
Herpes virus infection	1 (1.9)	0	1 (1.9)	0	0
Klebsiella bacteraemia	1 (1.9)	0	1 (1.9)	0	0
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Mastoiditis	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.9)	0	0	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	0	0	1 (1.9)	0
Myringitis	1 (1.9)	1 (1.9)	0	0	0
Ophthalmic herpes zoster	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	0	1 (1.9)	0	0
Pharyngitis streptococcal	1 (1.9)	0	0	1 (1.9)	0
Pneumocystis jirovecii pneumonia	1 (1.9)	0	0	0	1 (1.9)
Pneumonia fungal	1 (1.9)	0	0	1 (1.9)	0
Pneumonia respiratory syncytial viral	1 (1.9)	0	0	1 (1.9)	0
Pneumonia viral	1 (1.9)	0	0	1 (1.9)	0
Salmonellosis	1 (1.9)	0	1 (1.9)	0	0
Sinusitis fungal	1 (1.9)	0	0	1 (1.9)	0
Soft tissue infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Staphylococcal skin infection	1 (1.9)	0	1 (1.9)	0	0
Stomatococcal infection	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (1.9)	0	1 (1.9)	0	0
Syphilis	1 (1.9)	0	1 (1.9)	0	0
Systemic candida	1 (1.9)	0	0	1 (1.9)	0
Tinea pedis	1 (1.9)	1 (1.9)	0	0	0
Urinary tract infection pseudomonal	1 (1.9)	0	1 (1.9)	0	0
Urinary tract infection viral	1 (1.9)	1 (1.9)	0	0	0
Varicella zoster virus infection	1 (1.9)	0	0	1 (1.9)	0
Viral skin infection	1 (1.9)	1 (1.9)	0	0	0
Viral upper respiratory tract infection	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	13 (24.1)	5 (9.3)	7 (13.0)	0	1 (1.9)
Contusion	2 (3.7)	2 (3.7)	0	0	0
Fall	2 (3.7)	0	2 (3.7)	0	0
Infusion related reaction	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Ligament sprain	2 (3.7)	2 (3.7)	0	0	0
Procedural pain	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Transfusion reaction	2 (3.7)	1 (1.9)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (1.9)	0	1 (1.9)	0	0
Post-traumatic neck syndrome	1 (1.9)	0	1 (1.9)	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Transplant failure	1 (1.9)	0	0	0	1 (1.9)
Wound	1 (1.9)	0	1 (1.9)	0	0
Investigations					
-Total	42 (77.8)	3 (5.6)	7 (13.0)	12 (22.2)	20 (37.0)
Platelet count decreased	17 (31.5)	4 (7.4)	2 (3.7)	7 (13.0)	4 (7.4)
White blood cell count decreased	17 (31.5)	2 (3.7)	2 (3.7)	1 (1.9)	12 (22.2)
Neutrophil count decreased	16 (29.6)	1 (1.9)	1 (1.9)	2 (3.7)	12 (22.2)
Aspartate aminotransferase increased	14 (25.9)	1 (1.9)	4 (7.4)	7 (13.0)	2 (3.7)
Alanine aminotransferase increased	12 (22.2)	1 (1.9)	5 (9.3)	6 (11.1)	0
Lymphocyte count decreased	12 (22.2)	1 (1.9)	1 (1.9)	5 (9.3)	5 (9.3)
Blood bilirubin increased	10 (18.5)	1 (1.9)	2 (3.7)	7 (13.0)	0
Blood fibrinogen decreased	6 (11.1)	2 (3.7)	2 (3.7)	1 (1.9)	1 (1.9)
International normalised ratio increased	6 (11.1)	3 (5.6)	3 (5.6)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (9.3)	4 (7.4)	0	1 (1.9)	0
Activated partial thromboplastin time prolonged	4 (7.4)	2 (3.7)	2 (3.7)	0	0
Blood creatinine increased	4 (7.4)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Blood immunoglobulin m decreased	4 (7.4)	3 (5.6)	0	1 (1.9)	0
Blood uric acid increased	4 (7.4)	2 (3.7)	0	1 (1.9)	1 (1.9)
Serum ferritin increased	4 (7.4)	0	4 (7.4)	0	0
Weight increased	4 (7.4)	1 (1.9)	1 (1.9)	2 (3.7)	0
Blood lactate dehydrogenase increased	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Electrocardiogram qt prolonged	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Gamma-glutamyltransferase increased	2 (3.7)	0	0	2 (3.7)	0
Immunoglobulins decreased	2 (3.7)	0	2 (3.7)	0	0
Urine output decreased	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Blood alkaline phosphatase increased	1 (1.9)	1 (1.9)	0	0	0
Blood bicarbonate decreased	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (1.9)	0	0	1 (1.9)	0
Blood glucose increased	1 (1.9)	0	0	0	1 (1.9)
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Blood thyroid stimulating hormone increased	1 (1.9)	1 (1.9)	0	0	0
Blood urea increased	1 (1.9)	0	0	1 (1.9)	0
Bone density decreased	1 (1.9)	1 (1.9)	0	0	0
Breath sounds abnormal	1 (1.9)	0	1 (1.9)	0	0
C-reactive protein increased	1 (1.9)	1 (1.9)	0	0	0
Cardiac murmur	1 (1.9)	1 (1.9)	0	0	0
Coagulation test abnormal	1 (1.9)	1 (1.9)	0	0	0
Ejection fraction decreased	1 (1.9)	0	1 (1.9)	0	0
Enterovirus test positive	1 (1.9)	0	1 (1.9)	0	0
Fibrin d dimer increased	1 (1.9)	1 (1.9)	0	0	0
Haemoglobin decreased	1 (1.9)	0	0	1 (1.9)	0
Haptoglobin decreased	1 (1.9)	1 (1.9)	0	0	0
Heart sounds abnormal	1 (1.9)	1 (1.9)	0	0	0
Hepatitis b virus test positive	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oxygen saturation decreased	1 (1.9)	0	1 (1.9)	0	0
Prothrombin time prolonged	1 (1.9)	0	1 (1.9)	0	0
Staphylococcus test positive	1 (1.9)	1 (1.9)	0	0	0
Weight decreased	1 (1.9)	0	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	37 (68.5)	6 (11.1)	7 (13.0)	17 (31.5)	7 (13.0)
Decreased appetite	22 (40.7)	8 (14.8)	4 (7.4)	9 (16.7)	1 (1.9)
Hypokalaemia	15 (27.8)	2 (3.7)	6 (11.1)	7 (13.0)	0
Hypophosphataemia	13 (24.1)	3 (5.6)	3 (5.6)	6 (11.1)	1 (1.9)
Hypocalcaemia	10 (18.5)	2 (3.7)	5 (9.3)	3 (5.6)	0
Hypoalbuminaemia	9 (16.7)	0	8 (14.8)	1 (1.9)	0
Hyperglycaemia	7 (13.0)	0	4 (7.4)	3 (5.6)	0
Hyperuricaemia	6 (11.1)	4 (7.4)	1 (1.9)	1 (1.9)	0
Hypervolaemia	6 (11.1)	0	2 (3.7)	4 (7.4)	0
Hypomagnesaemia	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Hyperphosphataemia	4 (7.4)	3 (5.6)	0	0	1 (1.9)
Tumour lysis syndrome	4 (7.4)	0	0	3 (5.6)	1 (1.9)
Hyponatraemia	3 (5.6)	3 (5.6)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	3 (5.6)	0	0	0	3 (5.6)
Acidosis	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Hypercalcaemia	2 (3.7)	0	0	2 (3.7)	0
Hyperchloraemia	2 (3.7)	2 (3.7)	0	0	0
Hyperkalaemia	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Hypermagnesaemia	2 (3.7)	2 (3.7)	0	0	0
Hypernatraemia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Hyperlipidaemia	1 (1.9)	0	1 (1.9)	0	0
Hypertriglyceridaemia	1 (1.9)	0	0	1 (1.9)	0
Hypoglycaemia	1 (1.9)	0	1 (1.9)	0	0
Hypophagia	1 (1.9)	0	1 (1.9)	0	0
Iron overload	1 (1.9)	0	1 (1.9)	0	0
Malnutrition	1 (1.9)	0	0	1 (1.9)	0
Metabolic syndrome	1 (1.9)	0	1 (1.9)	0	0
Polydipsia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	33 (61.1)	13 (24.1)	15 (27.8)	5 (9.3)	0
Pain in extremity	13 (24.1)	5 (9.3)	7 (13.0)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	10 (18.5)	5 (9.3)	5 (9.3)	0	0
Myalgia	8 (14.8)	5 (9.3)	3 (5.6)	0	0
Back pain	7 (13.0)	0	5 (9.3)	2 (3.7)	0
Bone pain	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Muscular weakness	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Musculoskeletal chest pain	2 (3.7)	2 (3.7)	0	0	0
Neck pain	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Pain in jaw	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Muscle rigidity	1 (1.9)	1 (1.9)	0	0	0
Muscle spasms	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal pain	1 (1.9)	0	1 (1.9)	0	0
Osteonecrosis	1 (1.9)	1 (1.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (7.4)	1 (1.9)	2 (3.7)	1 (1.9)	0
Skin papilloma	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Cancer pain	1 (1.9)	0	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	32 (59.3)	9 (16.7)	14 (25.9)	6 (11.1)	3 (5.6)
Headache	19 (35.2)	8 (14.8)	9 (16.7)	2 (3.7)	0
Encephalopathy	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Somnolence	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Tremor	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Dizziness	4 (7.4)	4 (7.4)	0	0	0
Dysgeusia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Lethargy	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Seizure	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Amnesia	1 (1.9)	0	1 (1.9)	0	0
Aphasia	1 (1.9)	1 (1.9)	0	0	0
Cerebral haemorrhage	1 (1.9)	0	0	0	1 (1.9)
Cognitive disorder	1 (1.9)	0	0	1 (1.9)	0
Depressed level of consciousness	1 (1.9)	0	0	1 (1.9)	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	0	1 (1.9)	0
Extrapyramidal disorder	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised tonic-clonic seizure	1 (1.9)	0	1 (1.9)	0	0
Hydrocephalus	1 (1.9)	0	0	0	1 (1.9)
Hyperaesthesia	1 (1.9)	1 (1.9)	0	0	0
Hypoaesthesia	1 (1.9)	1 (1.9)	0	0	0
Migraine	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorder	1 (1.9)	0	0	1 (1.9)	0
Neuralgia	1 (1.9)	0	1 (1.9)	0	0
Neurological decompensation	1 (1.9)	0	0	0	1 (1.9)
Paraesthesia	1 (1.9)	1 (1.9)	0	0	0
Psychiatric disorders					
-Total	27 (50.0)	7 (13.0)	14 (25.9)	6 (11.1)	0
Anxiety	9 (16.7)	1 (1.9)	7 (13.0)	1 (1.9)	0
Delirium	8 (14.8)	2 (3.7)	3 (5.6)	3 (5.6)	0
Agitation	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Confusional state	5 (9.3)	5 (9.3)	0	0	0
Mental status changes	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Hallucination	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Insomnia	3 (5.6)	1 (1.9)	2 (3.7)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	2 (3.7)	2 (3.7)	0	0	0
Affect lability	1 (1.9)	0	1 (1.9)	0	0
Automatism	1 (1.9)	1 (1.9)	0	0	0
Hallucination, visual	1 (1.9)	0	1 (1.9)	0	0
Mood altered	1 (1.9)	1 (1.9)	0	0	0
Nightmare	1 (1.9)	1 (1.9)	0	0	0
Restlessness	1 (1.9)	0	1 (1.9)	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Social avoidant behaviour	1 (1.9)	0	1 (1.9)	0	0
Tearfulness	1 (1.9)	1 (1.9)	0	0	0
Tic	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	20 (37.0)	4 (7.4)	7 (13.0)	4 (7.4)	5 (9.3)
Acute kidney injury	11 (20.4)	2 (3.7)	2 (3.7)	3 (5.6)	4 (7.4)
Haematuria	3 (5.6)	2 (3.7)	0	1 (1.9)	0
Dysuria	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Pollakiuria	2 (3.7)	0	2 (3.7)	0	0
Renal failure	2 (3.7)	0	1 (1.9)	0	1 (1.9)
Anuria	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Azotaemia	1 (1.9)	0	1 (1.9)	0	0
Cystitis haemorrhagic	1 (1.9)	0	1 (1.9)	0	0
Incontinence	1 (1.9)	0	1 (1.9)	0	0
Kidney enlargement	1 (1.9)	0	1 (1.9)	0	0
Micturition urgency	1 (1.9)	0	1 (1.9)	0	0
Proteinuria	1 (1.9)	1 (1.9)	0	0	0
Renal mass	1 (1.9)	0	1 (1.9)	0	0
Renal tubular dysfunction	1 (1.9)	1 (1.9)	0	0	0
Urinary incontinence	1 (1.9)	0	1 (1.9)	0	0
Urinary retention	1 (1.9)	0	1 (1.9)	0	0
Urinary tract disorder	1 (1.9)	0	1 (1.9)	0	0
Reproductive system and breast disorders					
-Total	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Dysmenorrhoea	1 (1.9)	0	1 (1.9)	0	0
Female genital tract fistula	1 (1.9)	1 (1.9)	0	0	0
Perineal rash	1 (1.9)	0	1 (1.9)	0	0
Vaginal haemorrhage	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	39 (72.2)	11 (20.4)	5 (9.3)	10 (18.5)	13 (24.1)
Cough	17 (31.5)	15 (27.8)	2 (3.7)	0	0
Hypoxia	17 (31.5)	0	3 (5.6)	8 (14.8)	6 (11.1)
Pulmonary oedema	10 (18.5)	2 (3.7)	3 (5.6)	4 (7.4)	1 (1.9)
Oropharyngeal pain	7 (13.0)	7 (13.0)	0	0	0
Tachypnoea	7 (13.0)	3 (5.6)	1 (1.9)	3 (5.6)	0
Pleural effusion	6 (11.1)	4 (7.4)	1 (1.9)	1 (1.9)	0
Respiratory failure	6 (11.1)	0	0	0	6 (11.1)
Dyspnoea	5 (9.3)	1 (1.9)	2 (3.7)	2 (3.7)	0
Nasal congestion	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Epistaxis	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Respiratory distress	4 (7.4)	0	2 (3.7)	0	2 (3.7)
Rhinorrhoea	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Atelectasis	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Acute respiratory distress syndrome	1 (1.9)	0	0	0	1 (1.9)
Acute respiratory failure	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradypnoea	1 (1.9)	0	0	1 (1.9)	0
Bronchial oedema	1 (1.9)	1 (1.9)	0	0	0
Haemoptysis	1 (1.9)	0	1 (1.9)	0	0
Laryngeal oedema	1 (1.9)	0	0	0	1 (1.9)
Lung infiltration	1 (1.9)	0	0	1 (1.9)	0
Nasal discomfort	1 (1.9)	0	1 (1.9)	0	0
Oropharyngeal plaque	1 (1.9)	0	1 (1.9)	0	0
Painful respiration	1 (1.9)	1 (1.9)	0	0	0
Paranasal sinus discomfort	1 (1.9)	0	1 (1.9)	0	0
Paranasal sinus inflammation	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal exudate	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Pharyngeal oedema	1 (1.9)	0	1 (1.9)	0	0
Productive cough	1 (1.9)	1 (1.9)	0	0	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Respiratory disorder	1 (1.9)	0	1 (1.9)	0	0
Sleep apnoea syndrome	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract inflammation	1 (1.9)	0	1 (1.9)	0	0
Wheezing	1 (1.9)	0	1 (1.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	28 (51.9)	10 (18.5)	12 (22.2)	6 (11.1)	0
Dry skin	6 (11.1)	5 (9.3)	1 (1.9)	0	0
Pruritus	6 (11.1)	2 (3.7)	4 (7.4)	0	0
Rash	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Blister	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Dermatitis atopic	3 (5.6)	2 (3.7)	0	1 (1.9)	0
Hyperhidrosis	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Eczema	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Erythema	2 (3.7)	2 (3.7)	0	0	0
Rash papular	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Decubitus ulcer	1 (1.9)	0	0	1 (1.9)	0
Dermatitis diaper	1 (1.9)	0	1 (1.9)	0	0
Erythema nodosum	1 (1.9)	1 (1.9)	0	0	0
Hangnail	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	1 (1.9)	0	1 (1.9)	0	0
Night sweats	1 (1.9)	1 (1.9)	0	0	0
Papule	1 (1.9)	1 (1.9)	0	0	0
Petechiae	1 (1.9)	0	1 (1.9)	0	0
Photosensitivity reaction	1 (1.9)	0	1 (1.9)	0	0
Pruritus allergic	1 (1.9)	0	1 (1.9)	0	0
Purpura	1 (1.9)	1 (1.9)	0	0	0
Rash erythematous	1 (1.9)	1 (1.9)	0	0	0
Rash macular	1 (1.9)	0	0	1 (1.9)	0
Rash maculo-papular	1 (1.9)	0	0	1 (1.9)	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Rash vesicular	1 (1.9)	1 (1.9)	0	0	0
Scab	1 (1.9)	1 (1.9)	0	0	0
Skin discolouration	1 (1.9)	1 (1.9)	0	0	0
Skin hypopigmentation	1 (1.9)	1 (1.9)	0	0	0
Skin lesion	1 (1.9)	0	1 (1.9)	0	0
Skin swelling	1 (1.9)	1 (1.9)	0	0	0
Skin ulcer	1 (1.9)	0	1 (1.9)	0	0
Urticaria	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vancomycin infusion reaction	1 (1.9)	0	0	1 (1.9)	0
Social circumstances					
-Total	1 (1.9)	0	1 (1.9)	0	0
Patient uncooperative	1 (1.9)	0	1 (1.9)	0	0
Surgical and medical procedures					
-Total	1 (1.9)	0	0	1 (1.9)	0
Thrombolysis	1 (1.9)	0	0	1 (1.9)	0
Vascular disorders					
-Total	24 (44.4)	3 (5.6)	5 (9.3)	8 (14.8)	8 (14.8)
Hypotension	17 (31.5)	0	4 (7.4)	6 (11.1)	7 (13.0)
Hypertension	13 (24.1)	4 (7.4)	6 (11.1)	3 (5.6)	0
Venoocclusive disease	2 (3.7)	0	0	1 (1.9)	1 (1.9)
Capillary leak syndrome	1 (1.9)	0	1 (1.9)	0	0
Flushing	1 (1.9)	1 (1.9)	0	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0
Peripheral ischaemia	1 (1.9)	0	1 (1.9)	0	0
Thrombosis	1 (1.9)	0	1 (1.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	1 (9.1)	2 (18.2)	5 (45.5)	3 (27.3)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)	0	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Leukopenia	1 (9.1)	0	1 (9.1)	0	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypothyroidism	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Retinal haemorrhage	1 (9.1)	0	1 (9.1)	0	0
Visual field defect	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Constipation	1 (9.1)	1 (9.1)	0	0	0
Trichoglossia	1 (9.1)	0	1 (9.1)	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Pyrexia	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Face oedema	1 (9.1)	1 (9.1)	0	0	0
Influenza like illness	1 (9.1)	1 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	7 (63.6)	1 (9.1)	2 (18.2)	3 (27.3)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hypogammaglobulinaemia	3 (27.3)	1 (9.1)	0	2 (18.2)	0
Infections and infestations					
-Total	2 (18.2)	0	2 (18.2)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Platelet count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Blood bilirubin increased	1 (9.1)	0	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood testosterone decreased	1 (9.1)	1 (9.1)	0	0	0
C-reactive protein increased	1 (9.1)	0	0	1 (9.1)	0
Gamma-glutamyltransferase increased	1 (9.1)	0	0	1 (9.1)	0
Serum ferritin increased	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Decreased appetite	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Headache	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Neuralgia	1 (9.1)	0	1 (9.1)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Confusional state	1 (9.1)	1 (9.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Heavy menstrual bleeding	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0
Epistaxis	1 (9.1)	1 (9.1)	0	0	0
Nasal dryness	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (9.1)	1 (9.1)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	1 (9.1)	0	0	1 (9.1)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (98.6)	3 (4.3)	6 (8.7)	16 (23.2)	43 (62.3)
Blood and lymphatic system disorders					
-Total	45 (65.2)	3 (4.3)	6 (8.7)	24 (34.8)	12 (17.4)
Febrile neutropenia	25 (36.2)	0	0	23 (33.3)	2 (2.9)
Anaemia	20 (29.0)	5 (7.2)	7 (10.1)	8 (11.6)	0
Neutropenia	8 (11.6)	0	2 (2.9)	1 (1.4)	5 (7.2)
Thrombocytopenia	8 (11.6)	0	0	2 (2.9)	6 (8.7)
Disseminated intravascular coagulation	7 (10.1)	0	5 (7.2)	2 (2.9)	0
Coagulopathy	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Splenomegaly	4 (5.8)	3 (4.3)	1 (1.4)	0	0
Leukopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	23 (33.3)	9 (13.0)	6 (8.7)	5 (7.2)	3 (4.3)
Tachycardia	17 (24.6)	7 (10.1)	7 (10.1)	2 (2.9)	1 (1.4)
Bradycardia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Left ventricular dysfunction	3 (4.3)	0	0	3 (4.3)	0
Cardiac dysfunction	2 (2.9)	2 (2.9)	0	0	0
Sinus tachycardia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	0	0	1 (1.4)
Cardiac failure	1 (1.4)	0	0	0	1 (1.4)
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	2 (2.9)	2 (2.9)	0	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Ear pruritus	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	4 (5.8)	0	4 (5.8)	0	0
Adrenal insufficiency	4 (5.8)	0	4 (5.8)	0	0
Eye disorders					
-Total	8 (11.6)	6 (8.7)	2 (2.9)	0	0
Conjunctival haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Eyelid oedema	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Ocular hyperaemia	2 (2.9)	2 (2.9)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Eye pain	1 (1.4)	1 (1.4)	0	0	0
Periorbital oedema	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	47 (68.1)	16 (23.2)	17 (24.6)	13 (18.8)	1 (1.4)
Vomiting	20 (29.0)	11 (15.9)	8 (11.6)	1 (1.4)	0
Nausea	18 (26.1)	10 (14.5)	6 (8.7)	2 (2.9)	0
Diarrhoea	15 (21.7)	8 (11.6)	6 (8.7)	1 (1.4)	0
Abdominal pain	10 (14.5)	2 (2.9)	6 (8.7)	2 (2.9)	0
Constipation	10 (14.5)	5 (7.2)	5 (7.2)	0	0
Mouth haemorrhage	4 (5.8)	1 (1.4)	1 (1.4)	2 (2.9)	0
Pancreatitis	4 (5.8)	0	3 (4.3)	1 (1.4)	0
Abdominal distension	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Abdominal pain upper	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Ascites	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Gastrointestinal sounds abnormal	2 (2.9)	2 (2.9)	0	0	0
Stomatitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Abdominal compartment syndrome	1 (1.4)	0	0	0	1 (1.4)
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Enterocolitis	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingival bleeding	1 (1.4)	0	1 (1.4)	0	0
Gingival erythema	1 (1.4)	1 (1.4)	0	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0
Melaena	1 (1.4)	0	0	1 (1.4)	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Neutropenic colitis	1 (1.4)	0	0	1 (1.4)	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	0	0	1 (1.4)	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	36 (52.2)	17 (24.6)	8 (11.6)	7 (10.1)	4 (5.8)
Pyrexia	20 (29.0)	8 (11.6)	4 (5.8)	6 (8.7)	2 (2.9)
Fatigue	11 (15.9)	9 (13.0)	2 (2.9)	0	0
Face oedema	7 (10.1)	4 (5.8)	2 (2.9)	1 (1.4)	0
Chills	6 (8.7)	4 (5.8)	2 (2.9)	0	0
Oedema peripheral	6 (8.7)	4 (5.8)	1 (1.4)	1 (1.4)	0
Generalised oedema	5 (7.2)	2 (2.9)	3 (4.3)	0	0
Asthenia	2 (2.9)	2 (2.9)	0	0	0
Catheter site pain	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Drug withdrawal syndrome	2 (2.9)	0	2 (2.9)	0	0
Localised oedema	2 (2.9)	2 (2.9)	0	0	0
Multiple organ dysfunction syndrome	2 (2.9)	0	0	0	2 (2.9)
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Influenza like illness	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	1 (1.4)	0	1 (1.4)	0	0
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Pain	1 (1.4)	0	0	1 (1.4)	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Systemic inflammatory response syndrome	1 (1.4)	0	0	1 (1.4)	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	17 (24.6)	5 (7.2)	6 (8.7)	3 (4.3)	3 (4.3)
Hepatic function abnormal	5 (7.2)	0	2 (2.9)	2 (2.9)	1 (1.4)
Hyperbilirubinaemia	5 (7.2)	1 (1.4)	3 (4.3)	1 (1.4)	0
Hepatomegaly	3 (4.3)	2 (2.9)	0	0	1 (1.4)
Cholelithiasis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Gallbladder enlargement	2 (2.9)	2 (2.9)	0	0	0
Hypertransaminasaemia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Cholestasis	1 (1.4)	0	0	0	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	60 (87.0)	2 (2.9)	19 (27.5)	19 (27.5)	20 (29.0)
Cytokine release syndrome	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Hypogammaglobulinaemia	20 (29.0)	1 (1.4)	14 (20.3)	5 (7.2)	0
Haemophagocytic lymphohistiocytosis	5 (7.2)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Immunodeficiency	3 (4.3)	0	0	3 (4.3)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Seasonal allergy	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	33 (47.8)	6 (8.7)	8 (11.6)	16 (23.2)	3 (4.3)
Clostridium difficile infection	4 (5.8)	1 (1.4)	0	3 (4.3)	0
Conjunctivitis	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Staphylococcal infection	4 (5.8)	0	2 (2.9)	2 (2.9)	0
Candida infection	3 (4.3)	0	2 (2.9)	0	1 (1.4)
Staphylococcal bacteraemia	3 (4.3)	0	0	3 (4.3)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Nail infection	2 (2.9)	2 (2.9)	0	0	0
Oral herpes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Rhinovirus infection	2 (2.9)	0	2 (2.9)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	1 (1.4)	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes simplex	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (15.9)	3 (4.3)	6 (8.7)	0	2 (2.9)
Fall	2 (2.9)	0	2 (2.9)	0	0
Infusion related reaction	2 (2.9)	0	2 (2.9)	0	0
Procedural pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Transfusion reaction	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Wound	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Scratch	1 (1.4)	1 (1.4)	0	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Skin injury	1 (1.4)	0	1 (1.4)	0	0
Skin wound	1 (1.4)	1 (1.4)	0	0	0
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Vasoplegia syndrome	1 (1.4)	0	0	0	1 (1.4)
Investigations					
-Total	51 (73.9)	4 (5.8)	7 (10.1)	15 (21.7)	25 (36.2)
White blood cell count decreased	23 (33.3)	3 (4.3)	3 (4.3)	2 (2.9)	15 (21.7)
Aspartate aminotransferase increased	18 (26.1)	1 (1.4)	6 (8.7)	8 (11.6)	3 (4.3)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	18 (26.1)	0	3 (4.3)	2 (2.9)	13 (18.8)
Platelet count decreased	18 (26.1)	4 (5.8)	3 (4.3)	6 (8.7)	5 (7.2)
Alanine aminotransferase increased	15 (21.7)	3 (4.3)	7 (10.1)	5 (7.2)	0
Lymphocyte count decreased	13 (18.8)	2 (2.9)	0	8 (11.6)	3 (4.3)
Blood bilirubin increased	11 (15.9)	1 (1.4)	2 (2.9)	8 (11.6)	0
International normalised ratio increased	9 (13.0)	6 (8.7)	3 (4.3)	0	0
Serum ferritin increased	7 (10.1)	1 (1.4)	5 (7.2)	1 (1.4)	0
Activated partial thromboplastin time prolonged	6 (8.7)	3 (4.3)	2 (2.9)	1 (1.4)	0
Blood fibrinogen decreased	6 (8.7)	2 (2.9)	3 (4.3)	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.7)	4 (5.8)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	5 (7.2)	4 (5.8)	1 (1.4)	0	0
Electrocardiogram qt prolonged	5 (7.2)	1 (1.4)	2 (2.9)	1 (1.4)	1 (1.4)
Blood creatinine increased	4 (5.8)	1 (1.4)	0	2 (2.9)	1 (1.4)
Blood lactate dehydrogenase increased	4 (5.8)	2 (2.9)	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	4 (5.8)	2 (2.9)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	3 (4.3)	1 (1.4)	0	2 (2.9)	0
Fibrin d dimer increased	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Blood creatine phosphokinase increased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Blood immunoglobulin g decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Blood uric acid increased	2 (2.9)	2 (2.9)	0	0	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Lipase increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Urine output decreased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Amylase increased	1 (1.4)	1 (1.4)	0	0	0
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Electrocardiogram t wave abnormal	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0
Gamma-glutamyltransferase increased	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Troponin increased	1 (1.4)	0	0	1 (1.4)	0
Weight decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	44 (63.8)	7 (10.1)	9 (13.0)	21 (30.4)	7 (10.1)
Decreased appetite	23 (33.3)	8 (11.6)	4 (5.8)	10 (14.5)	1 (1.4)
Hypokalaemia	19 (27.5)	3 (4.3)	5 (7.2)	9 (13.0)	2 (2.9)
Hypocalcaemia	16 (23.2)	2 (2.9)	9 (13.0)	5 (7.2)	0
Hypophosphataemia	16 (23.2)	3 (4.3)	5 (7.2)	8 (11.6)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	11 (15.9)	0	10 (14.5)	1 (1.4)	0
Hyperglycaemia	8 (11.6)	0	4 (5.8)	4 (5.8)	0
Hyperuricaemia	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Hypervolaemia	6 (8.7)	0	2 (2.9)	4 (5.8)	0
Hypomagnesaemia	6 (8.7)	5 (7.2)	1 (1.4)	0	0
Hyperphosphataemia	5 (7.2)	4 (5.8)	0	0	1 (1.4)
Tumour lysis syndrome	4 (5.8)	0	0	4 (5.8)	0
Hypercalcaemia	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Hyponatraemia	3 (4.3)	3 (4.3)	0	0	0
Metabolic acidosis	3 (4.3)	1 (1.4)	0	0	2 (2.9)
Acidosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hyperkalaemia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hypermagnesaemia	2 (2.9)	2 (2.9)	0	0	0
Hypernatraemia	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Hypertriglyceridaemia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Calcium deficiency	1 (1.4)	1 (1.4)	0	0	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0
Haemosiderosis	1 (1.4)	0	1 (1.4)	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlactacidaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					
-Total	32 (46.4)	15 (21.7)	12 (17.4)	4 (5.8)	1 (1.4)
Pain in extremity	11 (15.9)	6 (8.7)	5 (7.2)	0	0
Arthralgia	9 (13.0)	4 (5.8)	4 (5.8)	1 (1.4)	0
Myalgia	9 (13.0)	6 (8.7)	3 (4.3)	0	0
Back pain	6 (8.7)	2 (2.9)	3 (4.3)	1 (1.4)	0
Bone pain	2 (2.9)	0	2 (2.9)	0	0
Muscular weakness	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Pain in jaw	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Haemarthrosis	1 (1.4)	0	0	1 (1.4)	0
Muscle rigidity	1 (1.4)	1 (1.4)	0	0	0
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Myositis	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (1.4)	0	1 (1.4)	0	0
Rhabdomyolysis	1 (1.4)	0	0	0	1 (1.4)
Nervous system disorders					
-Total	36 (52.2)	13 (18.8)	14 (20.3)	7 (10.1)	2 (2.9)
Headache	20 (29.0)	11 (15.9)	8 (11.6)	1 (1.4)	0
Encephalopathy	8 (11.6)	1 (1.4)	3 (4.3)	4 (5.8)	0
Tremor	6 (8.7)	5 (7.2)	1 (1.4)	0	0
Somnolence	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Cognitive disorder	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Dizziness	3 (4.3)	3 (4.3)	0	0	0
Dysgeusia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Seizure	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Monoparesis	1 (1.4)	0	1 (1.4)	0	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Paraesthesia	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	27 (39.1)	11 (15.9)	10 (14.5)	6 (8.7)	0
Delirium	7 (10.1)	2 (2.9)	2 (2.9)	3 (4.3)	0
Anxiety	6 (8.7)	1 (1.4)	3 (4.3)	2 (2.9)	0
Confusional state	6 (8.7)	6 (8.7)	0	0	0
Agitation	5 (7.2)	2 (2.9)	3 (4.3)	0	0
Insomnia	4 (5.8)	2 (2.9)	2 (2.9)	0	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Irritability	3 (4.3)	3 (4.3)	0	0	0
Mental status changes	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Sleep disorder	2 (2.9)	0	2 (2.9)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Automatism	1 (1.4)	1 (1.4)	0	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	20 (29.0)	5 (7.2)	6 (8.7)	3 (4.3)	6 (8.7)
Acute kidney injury	9 (13.0)	1 (1.4)	1 (1.4)	3 (4.3)	4 (5.8)
Dysuria	3 (4.3)	3 (4.3)	0	0	0
Anuria	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Haematuria	2 (2.9)	2 (2.9)	0	0	0
Pollakiuria	2 (2.9)	0	2 (2.9)	0	0
Renal failure	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Urinary retention	2 (2.9)	0	2 (2.9)	0	0
Azotaemia	1 (1.4)	0	1 (1.4)	0	0
Bladder dilatation	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	0	1 (1.4)
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	4 (5.8)	1 (1.4)	2 (2.9)	1 (1.4)	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0
Perineal rash	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Vaginal ulceration	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	39 (56.5)	12 (17.4)	4 (5.8)	11 (15.9)	12 (17.4)
Hypoxia	17 (24.6)	0	5 (7.2)	6 (8.7)	6 (8.7)
Pulmonary oedema	12 (17.4)	2 (2.9)	3 (4.3)	6 (8.7)	1 (1.4)
Cough	10 (14.5)	9 (13.0)	1 (1.4)	0	0
Tachypnoea	8 (11.6)	3 (4.3)	1 (1.4)	4 (5.8)	0
Pleural effusion	7 (10.1)	4 (5.8)	0	2 (2.9)	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	5 (7.2)	5 (7.2)	0	0	0
Respiratory failure	4 (5.8)	0	0	0	4 (5.8)
Atelectasis	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Dyspnoea	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Epistaxis	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Nasal congestion	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Respiratory distress	3 (4.3)	0	2 (2.9)	0	1 (1.4)
Acute respiratory distress syndrome	2 (2.9)	0	0	0	2 (2.9)
Rhinorrhoea	2 (2.9)	2 (2.9)	0	0	0
Acute respiratory failure	1 (1.4)	0	0	1 (1.4)	0
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal discomfort	1 (1.4)	0	1 (1.4)	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal erythema	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory acidosis	1 (1.4)	0	0	1 (1.4)	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	25 (36.2)	11 (15.9)	11 (15.9)	3 (4.3)	0
Pruritus	6 (8.7)	2 (2.9)	4 (5.8)	0	0
Erythema	4 (5.8)	4 (5.8)	0	0	0
Rash	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Blister	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Hyperhidrosis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Rash papular	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Dermatitis atopic	2 (2.9)	2 (2.9)	0	0	0
Petechiae	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Skin ulcer	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Decubitus ulcer	1 (1.4)	0	1 (1.4)	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	0	1 (1.4)	0	0
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Scab	1 (1.4)	1 (1.4)	0	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin necrosis	1 (1.4)	0	0	1 (1.4)	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	27 (39.1)	4 (5.8)	7 (10.1)	10 (14.5)	6 (8.7)
Hypotension	21 (30.4)	1 (1.4)	6 (8.7)	8 (11.6)	6 (8.7)
Hypertension	12 (17.4)	4 (5.8)	5 (7.2)	3 (4.3)	0
Capillary leak syndrome	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0
Thrombosis	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	2 (18.2)	5 (45.5)	2 (18.2)	1 (9.1)
Blood and lymphatic system disorders					
-Total	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Anaemia	1 (9.1)	1 (9.1)	0	0	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Disseminated intravascular coagulation	1 (9.1)	0	0	1 (9.1)	0
Leukopenia	1 (9.1)	0	1 (9.1)	0	0
Cardiac disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Left ventricular dysfunction	1 (9.1)	0	1 (9.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Constipation	2 (18.2)	0	2 (18.2)	0	0
Abdominal rigidity	1 (9.1)	0	1 (9.1)	0	0
Pancreatitis	1 (9.1)	0	0	1 (9.1)	0
Peritoneal haematoma	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	2 (18.2)	2 (18.2)	0	0	0
Pyrexia	2 (18.2)	2 (18.2)	0	0	0
Asthenia	1 (9.1)	1 (9.1)	0	0	0
Hepatobiliary disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Hepatic cytolysis	1 (9.1)	1 (9.1)	0	0	0
Immune system disorders					
-Total	3 (27.3)	0	3 (27.3)	0	0
Hypogammaglobulinaemia	3 (27.3)	0	3 (27.3)	0	0
Infections and infestations					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Injury, poisoning and procedural complications					
-Total	1 (9.1)	1 (9.1)	0	0	0
Infusion related reaction	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	2 (18.2)	0	0	2 (18.2)	0
Blood uric acid increased	1 (9.1)	0	0	1 (9.1)	0
Weight decreased	1 (9.1)	0	0	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Haemochromatosis	1 (9.1)	0	0	1 (9.1)	0
Hypophosphataemia	1 (9.1)	0	1 (9.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	0	1 (9.1)
Headache	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Autonomic neuropathy	1 (9.1)	0	0	1 (9.1)	0
Cerebral haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Memory impairment	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	0	1 (9.1)	0
Psychiatric disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Renal tubular disorder	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Lung disorder	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Dermatitis allergic	1 (9.1)	1 (9.1)	0	0	0
Photosensitivity reaction	1 (9.1)	0	1 (9.1)	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Hypotension	1 (9.1)	1 (9.1)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=64		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (92.2)	7 (10.9)	19 (29.7)	13 (20.3)	20 (31.3)
Blood and lymphatic system disorders					
-Total	14 (21.9)	3 (4.7)	2 (3.1)	5 (7.8)	4 (6.3)
Anaemia	5 (7.8)	3 (4.7)	0	2 (3.1)	0
Neutropenia	5 (7.8)	0	0	2 (3.1)	3 (4.7)
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Thrombocytopenia	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Eosinophilia	1 (1.6)	0	1 (1.6)	0	0
Leukocytosis	1 (1.6)	0	1 (1.6)	0	0
Lymphadenopathy	1 (1.6)	1 (1.6)	0	0	0
Lymphocytosis	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.6)	0	0	1 (1.6)	0
Cardiac disorders					
-Total	6 (9.4)	3 (4.7)	0	0	3 (4.7)
Cardiac arrest	2 (3.1)	0	0	0	2 (3.1)
Cardiac failure	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Tachycardia	2 (3.1)	2 (3.1)	0	0	0
Tricuspid valve incompetence	1 (1.6)	1 (1.6)	0	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Hypothyroidism	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					
-Total	4 (6.3)	4 (6.3)	0	0	0
Cataract	2 (3.1)	2 (3.1)	0	0	0
Hypermetropia	1 (1.6)	1 (1.6)	0	0	0
Ocular hyperaemia	1 (1.6)	1 (1.6)	0	0	0
Visual impairment	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal disorders					
-Total	17 (26.6)	12 (18.8)	5 (7.8)	0	0
Diarrhoea	7 (10.9)	6 (9.4)	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	6 (9.4)	6 (9.4)	0	0	0
Nausea	5 (7.8)	3 (4.7)	2 (3.1)	0	0
Abdominal pain	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Abdominal pain upper	1 (1.6)	1 (1.6)	0	0	0
Constipation	1 (1.6)	1 (1.6)	0	0	0
Dyspepsia	1 (1.6)	1 (1.6)	0	0	0
Enteritis	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal haemorrhage	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal inflammation	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Pancreatitis	1 (1.6)	1 (1.6)	0	0	0
Proctalgia	1 (1.6)	1 (1.6)	0	0	0
Stomatitis	1 (1.6)	1 (1.6)	0	0	0
Trichoglossia	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	22 (34.4)	13 (20.3)	6 (9.4)	3 (4.7)	0
Pyrexia	13 (20.3)	5 (7.8)	6 (9.4)	2 (3.1)	0
Fatigue	6 (9.4)	6 (9.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Chills	1 (1.6)	1 (1.6)	0	0	0
Malaise	1 (1.6)	1 (1.6)	0	0	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Hepatobiliary disorders					
-Total	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Hypertransaminasaemia	1 (1.6)	1 (1.6)	0	0	0
Liver disorder	1 (1.6)	0	1 (1.6)	0	0
Immune system disorders					
-Total	13 (20.3)	1 (1.6)	8 (12.5)	4 (6.3)	0
Hypogammaglobulinaemia	7 (10.9)	0	7 (10.9)	0	0
Allergy to immunoglobulin therapy	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Graft versus host disease	2 (3.1)	0	0	2 (3.1)	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Engraftment syndrome	1 (1.6)	0	0	1 (1.6)	0
Immunodeficiency	1 (1.6)	0	0	1 (1.6)	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	36 (56.3)	5 (7.8)	13 (20.3)	11 (17.2)	7 (10.9)
Nasopharyngitis	7 (10.9)	4 (6.3)	3 (4.7)	0	0
Upper respiratory tract infection	7 (10.9)	3 (4.7)	3 (4.7)	1 (1.6)	0
Gastroenteritis	5 (7.8)	3 (4.7)	0	2 (3.1)	0
Rhinovirus infection	4 (6.3)	0	4 (6.3)	0	0
Metapneumovirus infection	3 (4.7)	0	0	3 (4.7)	0
Otitis media	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Parainfluenzae virus infection	3 (4.7)	1 (1.6)	1 (1.6)	0	1 (1.6)
Sinusitis	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Bacteraemia	2 (3.1)	0	1 (1.6)	0	1 (1.6)
Ear infection	2 (3.1)	0	2 (3.1)	0	0
Otitis externa	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Pneumocystis jirovecii pneumonia	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Pneumonia	2 (3.1)	1 (1.6)	0	0	1 (1.6)
Respiratory syncytial virus infection	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Respiratory tract infection	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Rhinitis	2 (3.1)	1 (1.6)	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Adenovirus infection	1 (1.6)	0	0	1 (1.6)	0
Bk virus infection	1 (1.6)	0	0	1 (1.6)	0
Bronchopulmonary aspergillosis	1 (1.6)	0	0	0	1 (1.6)
Cellulitis	1 (1.6)	0	1 (1.6)	0	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Coronavirus infection	1 (1.6)	0	0	1 (1.6)	0
Cystitis	1 (1.6)	0	1 (1.6)	0	0
Cytomegalovirus infection reactivation	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	0	1 (1.6)	0
Ear, nose and throat infection	1 (1.6)	0	1 (1.6)	0	0
Enterobacter infection	1 (1.6)	0	0	1 (1.6)	0
Gastroenteritis clostridial	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal infection	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (1.6)	0	1 (1.6)	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	0	1 (1.6)	0
Influenza	1 (1.6)	0	1 (1.6)	0	0
Klebsiella infection	1 (1.6)	0	0	1 (1.6)	0
Mastoiditis	1 (1.6)	0	0	1 (1.6)	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Nail infection	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	0	1 (1.6)	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Pharyngitis streptococcal	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection viral	1 (1.6)	0	1 (1.6)	0	0
Salmonellosis	1 (1.6)	0	1 (1.6)	0	0
Septic shock	1 (1.6)	0	0	0	1 (1.6)
Sinusitis fungal	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	0	0	1 (1.6)
Staphylococcal skin infection	1 (1.6)	0	1 (1.6)	0	0
Tinea pedis	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=64		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	0	0	1 (1.6)	0
Injury, poisoning and procedural complications					
-Total	8 (12.5)	4 (6.3)	4 (6.3)	0	0
Infusion related reaction	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Contusion	1 (1.6)	1 (1.6)	0	0	0
Fibula fracture	1 (1.6)	0	1 (1.6)	0	0
Ligament sprain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	0	1 (1.6)	0	0
Post-traumatic neck syndrome	1 (1.6)	0	1 (1.6)	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Investigations					
-Total	28 (43.8)	7 (10.9)	7 (10.9)	9 (14.1)	5 (7.8)
Neutrophil count decreased	10 (15.6)	2 (3.1)	1 (1.6)	3 (4.7)	4 (6.3)
White blood cell count decreased	10 (15.6)	4 (6.3)	2 (3.1)	3 (4.7)	1 (1.6)
Platelet count decreased	5 (7.8)	3 (4.7)	0	1 (1.6)	1 (1.6)
Lymphocyte count decreased	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Blood bilirubin increased	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Blood immunoglobulin a decreased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Blood creatinine increased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin m decreased	1 (1.6)	0	0	1 (1.6)	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.6)	1 (1.6)	0	0	0
Blood urea increased	1 (1.6)	0	0	1 (1.6)	0
Blood uric acid increased	1 (1.6)	0	0	0	1 (1.6)
Bone density decreased	1 (1.6)	1 (1.6)	0	0	0
C-reactive protein increased	1 (1.6)	1 (1.6)	0	0	0
Ejection fraction decreased	1 (1.6)	0	1 (1.6)	0	0
Heart sounds abnormal	1 (1.6)	1 (1.6)	0	0	0
Hepatitis b virus test positive	1 (1.6)	0	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunoglobulins decreased	1 (1.6)	0	1 (1.6)	0	0
Oxygen saturation decreased	1 (1.6)	0	1 (1.6)	0	0
Weight increased	1 (1.6)	0	0	1 (1.6)	0
Metabolism and nutrition disorders					
-Total	14 (21.9)	4 (6.3)	4 (6.3)	3 (4.7)	3 (4.7)
Decreased appetite	5 (7.8)	2 (3.1)	3 (4.7)	0	0
Hyperuricaemia	3 (4.7)	3 (4.7)	0	0	0
Hypokalaemia	3 (4.7)	0	1 (1.6)	1 (1.6)	1 (1.6)
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hyperkalaemia	1 (1.6)	0	1 (1.6)	0	0
Hypervolaemia	1 (1.6)	0	0	1 (1.6)	0
Hypophagia	1 (1.6)	0	1 (1.6)	0	0
Iron overload	1 (1.6)	0	1 (1.6)	0	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	0	0	1 (1.6)
Metabolic syndrome	1 (1.6)	0	1 (1.6)	0	0
Tumour lysis syndrome	1 (1.6)	0	0	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	13 (20.3)	4 (6.3)	6 (9.4)	3 (4.7)	0
Pain in extremity	5 (7.8)	2 (3.1)	2 (3.1)	1 (1.6)	0
Back pain	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Arthralgia	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Bone pain	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Growth retardation	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal pain	1 (1.6)	0	1 (1.6)	0	0
Myalgia	1 (1.6)	0	1 (1.6)	0	0
Neck pain	1 (1.6)	1 (1.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (6.3)	1 (1.6)	2 (3.1)	1 (1.6)	0
Skin papilloma	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Cancer pain	1 (1.6)	0	1 (1.6)	0	0
Myelodysplastic syndrome	1 (1.6)	0	0	1 (1.6)	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (17.2)	6 (9.4)	4 (6.3)	0	1 (1.6)
Headache	8 (12.5)	5 (7.8)	3 (4.7)	0	0
Dizziness	1 (1.6)	1 (1.6)	0	0	0
Extrapyramidal disorder	1 (1.6)	0	1 (1.6)	0	0
Hydrocephalus	1 (1.6)	0	0	0	1 (1.6)
Migraine	1 (1.6)	0	1 (1.6)	0	0
Psychiatric disorders					
-Total	9 (14.1)	1 (1.6)	7 (10.9)	1 (1.6)	0
Anxiety	6 (9.4)	1 (1.6)	5 (7.8)	0	0
Mental status changes	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Agitation	1 (1.6)	1 (1.6)	0	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Mood altered	1 (1.6)	1 (1.6)	0	0	0
Nightmare	1 (1.6)	1 (1.6)	0	0	0
Persistent depressive disorder	1 (1.6)	0	1 (1.6)	0	0
Tearfulness	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	4 (6.3)	1 (1.6)	1 (1.6)	1 (1.6)	1 (1.6)
Acute kidney injury	3 (4.7)	1 (1.6)	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (1.6)	0	1 (1.6)	0	0
Dysuria	1 (1.6)	0	1 (1.6)	0	0
Haematuria	1 (1.6)	0	0	1 (1.6)	0
Kidney enlargement	1 (1.6)	0	1 (1.6)	0	0
Renal mass	1 (1.6)	0	1 (1.6)	0	0
Reproductive system and breast disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Dysmenorrhoea	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (34.4)	10 (15.6)	6 (9.4)	3 (4.7)	3 (4.7)
Cough	10 (15.6)	8 (12.5)	2 (3.1)	0	0
Nasal congestion	6 (9.4)	5 (7.8)	1 (1.6)	0	0
Epistaxis	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Hypoxia	3 (4.7)	0	0	3 (4.7)	0
Rhinorrhoea	3 (4.7)	3 (4.7)	0	0	0
Oropharyngeal pain	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Pleural effusion	2 (3.1)	1 (1.6)	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Acute respiratory distress syndrome	1 (1.6)	0	0	0	1 (1.6)
Bronchial oedema	1 (1.6)	1 (1.6)	0	0	0
Bronchospasm	1 (1.6)	0	1 (1.6)	0	0
Dyspnoea	1 (1.6)	0	1 (1.6)	0	0
Paranasal sinus inflammation	1 (1.6)	1 (1.6)	0	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Upper respiratory tract inflammation	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (26.6)	10 (15.6)	6 (9.4)	1 (1.6)	0
Dry skin	6 (9.4)	4 (6.3)	2 (3.1)	0	0
Rash	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Ingrowing nail	2 (3.1)	0	2 (3.1)	0	0
Decubitus ulcer	1 (1.6)	0	0	1 (1.6)	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Eczema	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (1.6)	0	1 (1.6)	0	0
Hangnail	1 (1.6)	1 (1.6)	0	0	0
Miliaria	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	1 (1.6)	0	0	0
Pruritus	1 (1.6)	0	1 (1.6)	0	0
Skin discolouration	1 (1.6)	1 (1.6)	0	0	0
Skin hypopigmentation	1 (1.6)	1 (1.6)	0	0	0
Skin swelling	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	5 (7.8)	0	0	2 (3.1)	3 (4.7)
Hypotension	3 (4.7)	0	0	1 (1.6)	2 (3.1)
Venoocclusive disease	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=9		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (55.6)	1 (11.1)	1 (11.1)	1 (11.1)	2 (22.2)
Gastrointestinal disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	1 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pain	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pyrexia	1 (11.1)	1 (11.1)	0	0	0
Infections and infestations					
-Total	4 (44.4)	1 (11.1)	2 (22.2)	1 (11.1)	0
Sinusitis	2 (22.2)	0	2 (22.2)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=9		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (11.1)	0	1 (11.1)	0	0
Rhinitis	1 (11.1)	1 (11.1)	0	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Sepsis	1 (11.1)	0	0	1 (11.1)	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0
Varicella zoster virus infection	1 (11.1)	0	1 (11.1)	0	0
Investigations					
-Total	1 (11.1)	0	0	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Metabolism and nutrition disorders					
-Total	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Decreased appetite	1 (11.1)	0	0	0	1 (11.1)
Hypercholesterolaemia	1 (11.1)	0	1 (11.1)	0	0
Hypertriglyceridaemia	1 (11.1)	0	1 (11.1)	0	0
Iron overload	1 (11.1)	0	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=9		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint effusion	1 (11.1)	0	1 (11.1)	0	0
Synovitis	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Dysarthria	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Anxiety	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Reproductive system and breast disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Endometriosis	1 (11.1)	0	0	1 (11.1)	0
Vascular disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Hypertension	1 (11.1)	0	1 (11.1)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (65.9)	2 (4.9)	9 (22.0)	11 (26.8)	5 (12.2)
Blood and lymphatic system disorders					
-Total	4 (9.8)	0	2 (4.9)	1 (2.4)	1 (2.4)
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Hypercoagulation	1 (2.4)	0	1 (2.4)	0	0
Lymphadenopathy	1 (2.4)	0	1 (2.4)	0	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.4)	1 (2.4)	0	0	0
Cerebral cavernous malformation	1 (2.4)	1 (2.4)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.4)	0	1 (2.4)	0	0
Deafness unilateral	1 (2.4)	0	1 (2.4)	0	0
Endocrine disorders					
-Total	1 (2.4)	0	1 (2.4)	0	0
Delayed puberty	1 (2.4)	0	1 (2.4)	0	0
Hypothyroidism	1 (2.4)	0	1 (2.4)	0	0
Eye disorders					
-Total	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Dry eye	1 (2.4)	1 (2.4)	0	0	0
Eye pain	1 (2.4)	0	0	1 (2.4)	0
Eyelid oedema	1 (2.4)	1 (2.4)	0	0	0
Mydriasis	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	6 (14.6)	3 (7.3)	2 (4.9)	1 (2.4)	0
Diarrhoea	4 (9.8)	2 (4.9)	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=41		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.4)	1 (2.4)	0	0	0
Irritable bowel syndrome	1 (2.4)	0	1 (2.4)	0	0
Nausea	1 (2.4)	1 (2.4)	0	0	0
Vomiting	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					
-Total	7 (17.1)	3 (7.3)	2 (4.9)	1 (2.4)	1 (2.4)
Pyrexia	4 (9.8)	1 (2.4)	2 (4.9)	1 (2.4)	0
Fatigue	1 (2.4)	0	1 (2.4)	0	0
Multiple organ dysfunction syndrome	1 (2.4)	0	0	0	1 (2.4)
Non-cardiac chest pain	1 (2.4)	1 (2.4)	0	0	0
Xerosis	1 (2.4)	1 (2.4)	0	0	0
Immune system disorders					
-Total	9 (22.0)	2 (4.9)	5 (12.2)	1 (2.4)	1 (2.4)
Hypogammaglobulinaemia	3 (7.3)	0	3 (7.3)	0	0
Seasonal allergy	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Chronic graft versus host disease	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Drug hypersensitivity	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	0	0	1 (2.4)
Infections and infestations					
-Total	19 (46.3)	1 (2.4)	5 (12.2)	9 (22.0)	4 (9.8)
Upper respiratory tract infection	5 (12.2)	2 (4.9)	2 (4.9)	1 (2.4)	0
Conjunctivitis	4 (9.8)	2 (4.9)	2 (4.9)	0	0
Sinusitis	4 (9.8)	0	4 (9.8)	0	0
Rhinovirus infection	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Skin infection	3 (7.3)	0	3 (7.3)	0	0
Bronchitis	2 (4.9)	0	2 (4.9)	0	0
Covid-19	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Fungal infection	2 (4.9)	0	2 (4.9)	0	0
Herpes zoster	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Influenza	2 (4.9)	0	1 (2.4)	0	1 (2.4)
Oral herpes	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Otitis media	2 (4.9)	0	2 (4.9)	0	0
Pneumonia	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Sepsis	2 (4.9)	0	0	0	2 (4.9)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=41		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (2.4)	0	1 (2.4)	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Candida infection	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	0	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Device related sepsis	1 (2.4)	0	0	1 (2.4)	0
Ear infection	1 (2.4)	0	0	1 (2.4)	0
Enterovirus infection	1 (2.4)	0	0	1 (2.4)	0
Folliculitis	1 (2.4)	0	1 (2.4)	0	0
Gastroenteritis	1 (2.4)	1 (2.4)	0	0	0
Gastroenteritis escherichia coli	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis viral	1 (2.4)	0	1 (2.4)	0	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Nail infection	1 (2.4)	0	1 (2.4)	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Oral candidiasis	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (2.4)	0	1 (2.4)	0	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	0	0	1 (2.4)	0
Septic shock	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal abscess	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Syphilis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection pseudomonal	1 (2.4)	0	1 (2.4)	0	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Abdominal injury	1 (2.4)	1 (2.4)	0	0	0
Infusion related reaction	1 (2.4)	0	0	1 (2.4)	0
Ligament sprain	1 (2.4)	1 (2.4)	0	0	0
Investigations					

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=41		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.2)	3 (7.3)	1 (2.4)	1 (2.4)	0
Neutrophil count decreased	2 (4.9)	2 (4.9)	0	0	0
Platelet count decreased	2 (4.9)	2 (4.9)	0	0	0
Blood bilirubin increased	1 (2.4)	1 (2.4)	0	0	0
Blood immunoglobulin g decreased	1 (2.4)	0	1 (2.4)	0	0
Oxygen saturation decreased	1 (2.4)	0	0	1 (2.4)	0
Metabolism and nutrition disorders					
-Total	4 (9.8)	0	1 (2.4)	3 (7.3)	0
Hyperglycaemia	1 (2.4)	0	0	1 (2.4)	0
Hyperlipidaemia	1 (2.4)	0	1 (2.4)	0	0
Hypernatraemia	1 (2.4)	0	0	1 (2.4)	0
Obesity	1 (2.4)	0	0	1 (2.4)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (14.6)	2 (4.9)	4 (9.8)	0	0
Pain in extremity	2 (4.9)	0	2 (4.9)	0	0
Arthralgia	1 (2.4)	0	1 (2.4)	0	0
Growth retardation	1 (2.4)	0	1 (2.4)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (2.4)	1 (2.4)	0	0	0
Osteopenia	1 (2.4)	1 (2.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.4)	0	0	1 (2.4)	0
Bone giant cell tumour benign	1 (2.4)	0	0	1 (2.4)	0
Nervous system disorders					
-Total	3 (7.3)	0	1 (2.4)	2 (4.9)	0
Headache	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Nervous system disorder	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	0	1 (2.4)	0
Psychiatric disorders					
-Total	1 (2.4)	0	1 (2.4)	0	0
Tic	1 (2.4)	0	1 (2.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (24.4)	4 (9.8)	2 (4.9)	1 (2.4)	3 (7.3)
Cough	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Dyspnoea	3 (7.3)	1 (2.4)	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Sleep apnoea syndrome	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Dyspnoea exertional	1 (2.4)	1 (2.4)	0	0	0
Epistaxis	1 (2.4)	1 (2.4)	0	0	0
Hypoxia	1 (2.4)	0	0	1 (2.4)	0
Laryngeal oedema	1 (2.4)	0	0	0	1 (2.4)
Oropharyngeal pain	1 (2.4)	1 (2.4)	0	0	0
Pharyngeal erythema	1 (2.4)	1 (2.4)	0	0	0
Pleural effusion	1 (2.4)	0	1 (2.4)	0	0
Respiratory failure	1 (2.4)	0	0	0	1 (2.4)
Tachypnoea	1 (2.4)	0	0	0	1 (2.4)
Wheezing	1 (2.4)	0	1 (2.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (17.1)	3 (7.3)	1 (2.4)	3 (7.3)	0
Rash	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Dermatitis atopic	1 (2.4)	0	0	1 (2.4)	0
Dry skin	1 (2.4)	1 (2.4)	0	0	0
Eczema	1 (2.4)	0	0	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Papule	1 (2.4)	1 (2.4)	0	0	0
Rash erythematous	1 (2.4)	1 (2.4)	0	0	0
Rash macular	1 (2.4)	0	0	1 (2.4)	0
Rash maculo-papular	1 (2.4)	1 (2.4)	0	0	0
Vascular disorders					
-Total	1 (2.4)	0	0	1 (2.4)	0
Hypertension	1 (2.4)	0	0	1 (2.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	1 (9.1)	2 (18.2)	4 (36.4)	4 (36.4)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)	0	0
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Disseminated intravascular coagulation	1 (9.1)	0	0	1 (9.1)	0
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Leukopenia	1 (9.1)	0	1 (9.1)	0	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Left ventricular dysfunction	1 (9.1)	0	1 (9.1)	0	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0	0	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypothyroidism	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Retinal haemorrhage	1 (9.1)	0	1 (9.1)	0	0
Visual field defect	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	7 (63.6)	4 (36.4)	2 (18.2)	1 (9.1)	0
Constipation	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Abdominal rigidity	1 (9.1)	0	1 (9.1)	0	0
Diarrhoea	1 (9.1)	1 (9.1)	0	0	0
Pancreatitis	1 (9.1)	0	0	1 (9.1)	0
Peritoneal haematoma	1 (9.1)	1 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Trichoglossia	1 (9.1)	0	1 (9.1)	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	5 (45.5)	3 (27.3)	2 (18.2)	0	0
Pyrexia	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Asthenia	1 (9.1)	1 (9.1)	0	0	0
Face oedema	1 (9.1)	1 (9.1)	0	0	0
Influenza like illness	1 (9.1)	1 (9.1)	0	0	0
Hepatobiliary disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Hepatic cytolysis	1 (9.1)	1 (9.1)	0	0	0
Immune system disorders					
-Total	8 (72.7)	0	4 (36.4)	3 (27.3)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hypogammaglobulinaemia	6 (54.5)	1 (9.1)	3 (27.3)	2 (18.2)	0
Infections and infestations					
-Total	7 (63.6)	1 (9.1)	4 (36.4)	1 (9.1)	1 (9.1)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Fungal skin infection	1 (9.1)	0	1 (9.1)	0	0
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Rhinitis	1 (9.1)	1 (9.1)	0	0	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	1 (9.1)	0	0
Varicella zoster virus infection	1 (9.1)	0	1 (9.1)	0	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (9.1)	1 (9.1)	0	0	0
Infusion related reaction	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	7 (63.6)	0	1 (9.1)	3 (27.3)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Platelet count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Blood bilirubin increased	1 (9.1)	0	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)
Blood testosterone decreased	1 (9.1)	1 (9.1)	0	0	0
Blood uric acid increased	1 (9.1)	0	0	1 (9.1)	0
C-reactive protein increased	1 (9.1)	0	0	1 (9.1)	0
Gamma-glutamyltransferase increased	1 (9.1)	0	0	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (9.1)	0	0	1 (9.1)	0
Weight decreased	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	4 (36.4)	1 (9.1)	1 (9.1)	0	2 (18.2)
Decreased appetite	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Hypophosphataemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Haemochromatosis	1 (9.1)	0	0	1 (9.1)	0
Hypercholesterolaemia	1 (9.1)	0	1 (9.1)	0	0
Hypertriglyceridaemia	1 (9.1)	0	1 (9.1)	0	0
Iron overload	1 (9.1)	0	1 (9.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Joint effusion	1 (9.1)	0	1 (9.1)	0	0
Synovitis	1 (9.1)	0	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	5 (45.5)	1 (9.1)	2 (18.2)	1 (9.1)	1 (9.1)
Headache	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Autonomic neuropathy	1 (9.1)	0	0	1 (9.1)	0
Cerebral haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Dysarthria	1 (9.1)	0	1 (9.1)	0	0
Memory impairment	1 (9.1)	0	1 (9.1)	0	0
Neuralgia	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	0	1 (9.1)	0
Psychiatric disorders					
-Total	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Anxiety	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Confusional state	1 (9.1)	1 (9.1)	0	0	0
Sleep disorder	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Renal tubular disorder	1 (9.1)	0	0	1 (9.1)	0
Reproductive system and breast disorders					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Endometriosis	1 (9.1)	0	0	1 (9.1)	0
Heavy menstrual bleeding	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Epistaxis	1 (9.1)	1 (9.1)	0	0	0
Lung disorder	1 (9.1)	1 (9.1)	0	0	0
Nasal dryness	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Dermatitis allergic	1 (9.1)	1 (9.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (9.1)	1 (9.1)	0	0	0
Photosensitivity reaction	1 (9.1)	0	1 (9.1)	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hypotension	1 (9.1)	1 (9.1)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (100)	0	4 (5.8)	15 (21.7)	50 (72.5)
Blood and lymphatic system disorders					
-Total	50 (72.5)	1 (1.4)	9 (13.0)	27 (39.1)	13 (18.8)
Febrile neutropenia	26 (37.7)	0	0	24 (34.8)	2 (2.9)
Anaemia	24 (34.8)	7 (10.1)	8 (11.6)	9 (13.0)	0
Neutropenia	10 (14.5)	0	2 (2.9)	2 (2.9)	6 (8.7)
Thrombocytopenia	9 (13.0)	0	0	3 (4.3)	6 (8.7)
Disseminated intravascular coagulation	7 (10.1)	0	5 (7.2)	2 (2.9)	0
Coagulopathy	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Splenomegaly	4 (5.8)	3 (4.3)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Lymphadenopathy	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Lymphopenia	2 (2.9)	0	0	2 (2.9)	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypercoagulation	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Pancytopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	26 (37.7)	9 (13.0)	6 (8.7)	5 (7.2)	6 (8.7)
Tachycardia	17 (24.6)	7 (10.1)	7 (10.1)	2 (2.9)	1 (1.4)
Bradycardia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Cardiac arrest	3 (4.3)	0	0	0	3 (4.3)
Cardiac failure	3 (4.3)	0	0	1 (1.4)	2 (2.9)
Left ventricular dysfunction	3 (4.3)	0	0	3 (4.3)	0
Cardiac dysfunction	2 (2.9)	2 (2.9)	0	0	0
Sinus tachycardia	2 (2.9)	1 (1.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Sinus bradycardia	1 (1.4)	0	0	1 (1.4)	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Cerebral cavernous malformation	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Ear pruritus	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	6 (8.7)	0	6 (8.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	4 (5.8)	0	4 (5.8)	0	0
Hypothyroidism	2 (2.9)	0	2 (2.9)	0	0
Delayed puberty	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	14 (20.3)	10 (14.5)	3 (4.3)	1 (1.4)	0
Eyelid oedema	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Ocular hyperaemia	3 (4.3)	3 (4.3)	0	0	0
Cataract	2 (2.9)	2 (2.9)	0	0	0
Conjunctival haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Eye pain	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Visual impairment	2 (2.9)	2 (2.9)	0	0	0
Dry eye	1 (1.4)	1 (1.4)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Mydriasis	1 (1.4)	0	1 (1.4)	0	0
Periorbital oedema	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	53 (76.8)	17 (24.6)	21 (30.4)	14 (20.3)	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	25 (36.2)	15 (21.7)	8 (11.6)	2 (2.9)	0
Vomiting	25 (36.2)	16 (23.2)	8 (11.6)	1 (1.4)	0
Nausea	22 (31.9)	12 (17.4)	8 (11.6)	2 (2.9)	0
Constipation	11 (15.9)	6 (8.7)	5 (7.2)	0	0
Abdominal pain	10 (14.5)	1 (1.4)	7 (10.1)	2 (2.9)	0
Mouth haemorrhage	5 (7.2)	2 (2.9)	1 (1.4)	2 (2.9)	0
Pancreatitis	5 (7.2)	1 (1.4)	3 (4.3)	1 (1.4)	0
Abdominal pain upper	4 (5.8)	3 (4.3)	1 (1.4)	0	0
Abdominal distension	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Ascites	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Stomatitis	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gastrointestinal sounds abnormal	2 (2.9)	2 (2.9)	0	0	0
Proctalgia	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Abdominal compartment syndrome	1 (1.4)	0	0	0	1 (1.4)
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Enterocolitis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingival bleeding	1 (1.4)	0	1 (1.4)	0	0
Gingival erythema	1 (1.4)	1 (1.4)	0	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0
Irritable bowel syndrome	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0
Melaena	1 (1.4)	0	0	1 (1.4)	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Neutropenic colitis	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	48 (69.6)	22 (31.9)	11 (15.9)	10 (14.5)	5 (7.2)
Pyrexia	31 (44.9)	11 (15.9)	9 (13.0)	9 (13.0)	2 (2.9)
Fatigue	17 (24.6)	14 (20.3)	3 (4.3)	0	0
Chills	7 (10.1)	5 (7.2)	2 (2.9)	0	0
Face oedema	7 (10.1)	4 (5.8)	2 (2.9)	1 (1.4)	0
Oedema peripheral	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Generalised oedema	5 (7.2)	2 (2.9)	3 (4.3)	0	0
Multiple organ dysfunction syndrome	3 (4.3)	0	0	0	3 (4.3)
Pain	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Asthenia	2 (2.9)	2 (2.9)	0	0	0
Catheter site pain	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Drug withdrawal syndrome	2 (2.9)	0	2 (2.9)	0	0
Localised oedema	2 (2.9)	2 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Non-cardiac chest pain	2 (2.9)	2 (2.9)	0	0	0
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Influenza like illness	1 (1.4)	0	1 (1.4)	0	0
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Systemic inflammatory response syndrome	1 (1.4)	0	0	1 (1.4)	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Xerosis	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	18 (26.1)	5 (7.2)	7 (10.1)	3 (4.3)	3 (4.3)
Hepatic function abnormal	5 (7.2)	0	2 (2.9)	2 (2.9)	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	5 (7.2)	1 (1.4)	3 (4.3)	1 (1.4)	0
Hepatomegaly	3 (4.3)	2 (2.9)	0	0	1 (1.4)
Cholelithiasis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Gallbladder enlargement	2 (2.9)	2 (2.9)	0	0	0
Hypertransaminasaemia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Cholestasis	1 (1.4)	0	0	0	1 (1.4)
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	63 (91.3)	2 (2.9)	19 (27.5)	21 (30.4)	21 (30.4)
Cytokine release syndrome	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Hypogammaglobulinaemia	27 (39.1)	1 (1.4)	21 (30.4)	5 (7.2)	0
Haemophagocytic lymphohistiocytosis	6 (8.7)	1 (1.4)	1 (1.4)	2 (2.9)	2 (2.9)
Immunodeficiency	4 (5.8)	0	0	4 (5.8)	0
Seasonal allergy	4 (5.8)	2 (2.9)	2 (2.9)	0	0
Allergy to immunoglobulin therapy	2 (2.9)	1 (1.4)	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Graft versus host disease	2 (2.9)	0	0	2 (2.9)	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	53 (76.8)	7 (10.1)	9 (13.0)	24 (34.8)	13 (18.8)
Upper respiratory tract infection	12 (17.4)	5 (7.2)	5 (7.2)	2 (2.9)	0
Rhinovirus infection	8 (11.6)	0	7 (10.1)	1 (1.4)	0
Conjunctivitis	7 (10.1)	2 (2.9)	5 (7.2)	0	0
Nasopharyngitis	7 (10.1)	4 (5.8)	3 (4.3)	0	0
Gastroenteritis	6 (8.7)	4 (5.8)	0	2 (2.9)	0
Otitis media	5 (7.2)	0	4 (5.8)	1 (1.4)	0
Pneumonia	5 (7.2)	1 (1.4)	0	2 (2.9)	2 (2.9)
Sinusitis	5 (7.2)	0	3 (4.3)	2 (2.9)	0
Staphylococcal bacteraemia	5 (7.2)	0	0	5 (7.2)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	4 (5.8)	0	3 (4.3)	0	1 (1.4)
Clostridium difficile infection	4 (5.8)	1 (1.4)	0	3 (4.3)	0
Nail infection	4 (5.8)	3 (4.3)	1 (1.4)	0	0
Oral herpes	4 (5.8)	1 (1.4)	2 (2.9)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.8)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Staphylococcal infection	4 (5.8)	0	2 (2.9)	2 (2.9)	0
Bacteraemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Ear infection	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Herpes zoster	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Influenza	3 (4.3)	0	2 (2.9)	0	1 (1.4)
Metapneumovirus infection	3 (4.3)	0	0	3 (4.3)	0
Oral candidiasis	3 (4.3)	0	3 (4.3)	0	0
Otitis externa	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Skin infection	3 (4.3)	0	3 (4.3)	0	0
Acute sinusitis	2 (2.9)	0	2 (2.9)	0	0
Adenovirus infection	2 (2.9)	0	0	2 (2.9)	0
Bk virus infection	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Bronchitis	2 (2.9)	0	2 (2.9)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Covid-19	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Fungal infection	2 (2.9)	0	2 (2.9)	0	0
Gastroenteritis viral	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Gingivitis	2 (2.9)	2 (2.9)	0	0	0
Herpes simplex	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.9)	0	0	2 (2.9)	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Respiratory tract infection	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Rhinitis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Sepsis	2 (2.9)	0	0	0	2 (2.9)
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	20 (29.0)	8 (11.6)	9 (13.0)	1 (1.4)	2 (2.9)
Infusion related reaction	4 (5.8)	1 (1.4)	2 (2.9)	1 (1.4)	0
Contusion	2 (2.9)	2 (2.9)	0	0	0
Fall	2 (2.9)	0	2 (2.9)	0	0
Ligament sprain	2 (2.9)	2 (2.9)	0	0	0
Procedural pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Skin abrasion	2 (2.9)	2 (2.9)	0	0	0
Transfusion reaction	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Wound	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Abdominal injury	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0

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	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scratch	1 (1.4)	1 (1.4)	0	0	0
Skin injury	1 (1.4)	0	1 (1.4)	0	0
Skin wound	1 (1.4)	1 (1.4)	0	0	0
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Vasoplegia syndrome	1 (1.4)	0	0	0	1 (1.4)
Investigations					
-Total	53 (76.8)	3 (4.3)	8 (11.6)	16 (23.2)	26 (37.7)
White blood cell count decreased	24 (34.8)	3 (4.3)	4 (5.8)	2 (2.9)	15 (21.7)
Neutrophil count decreased	22 (31.9)	1 (1.4)	2 (2.9)	4 (5.8)	15 (21.7)
Platelet count decreased	21 (30.4)	6 (8.7)	3 (4.3)	7 (10.1)	5 (7.2)
Aspartate aminotransferase increased	18 (26.1)	1 (1.4)	6 (8.7)	8 (11.6)	3 (4.3)
Alanine aminotransferase increased	15 (21.7)	2 (2.9)	7 (10.1)	6 (8.7)	0
Lymphocyte count decreased	15 (21.7)	1 (1.4)	1 (1.4)	10 (14.5)	3 (4.3)
Blood bilirubin increased	12 (17.4)	1 (1.4)	3 (4.3)	8 (11.6)	0
International normalised ratio increased	9 (13.0)	6 (8.7)	3 (4.3)	0	0

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		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	7 (10.1)	4 (5.8)	1 (1.4)	2 (2.9)	0
Serum ferritin increased	7 (10.1)	1 (1.4)	5 (7.2)	1 (1.4)	0
Activated partial thromboplastin time prolonged	6 (8.7)	3 (4.3)	2 (2.9)	1 (1.4)	0
Blood fibrinogen decreased	6 (8.7)	2 (2.9)	3 (4.3)	1 (1.4)	0
Blood creatinine increased	5 (7.2)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Blood lactate dehydrogenase increased	5 (7.2)	3 (4.3)	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	5 (7.2)	1 (1.4)	2 (2.9)	1 (1.4)	1 (1.4)
Blood immunoglobulin g decreased	4 (5.8)	1 (1.4)	3 (4.3)	0	0
C-reactive protein increased	4 (5.8)	2 (2.9)	0	2 (2.9)	0
Weight increased	4 (5.8)	1 (1.4)	1 (1.4)	2 (2.9)	0
Blood uric acid increased	3 (4.3)	2 (2.9)	0	0	1 (1.4)
Fibrin d dimer increased	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Oxygen saturation decreased	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0

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	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Lipase increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Urine output decreased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Amylase increased	1 (1.4)	1 (1.4)	0	0	0
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0

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			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram t wave abnormal	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0
Gamma-glutamyltransferase increased	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Troponin increased	1 (1.4)	0	0	1 (1.4)	0
Weight decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	48 (69.6)	8 (11.6)	9 (13.0)	22 (31.9)	9 (13.0)
Decreased appetite	28 (40.6)	10 (14.5)	7 (10.1)	10 (14.5)	1 (1.4)
Hypokalaemia	20 (29.0)	3 (4.3)	6 (8.7)	9 (13.0)	2 (2.9)
Hypocalcaemia	16 (23.2)	2 (2.9)	9 (13.0)	5 (7.2)	0
Hypophosphataemia	16 (23.2)	3 (4.3)	5 (7.2)	8 (11.6)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	11 (15.9)	0	10 (14.5)	1 (1.4)	0
Hyperglycaemia	9 (13.0)	0	4 (5.8)	5 (7.2)	0
Hyperuricaemia	9 (13.0)	7 (10.1)	1 (1.4)	1 (1.4)	0
Hypervolaemia	7 (10.1)	0	2 (2.9)	5 (7.2)	0
Hypomagnesaemia	6 (8.7)	5 (7.2)	1 (1.4)	0	0
Hyperphosphataemia	5 (7.2)	4 (5.8)	0	0	1 (1.4)
Tumour lysis syndrome	5 (7.2)	0	0	4 (5.8)	1 (1.4)
Metabolic acidosis	4 (5.8)	1 (1.4)	0	0	3 (4.3)
Hypercalcaemia	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Hyperkalaemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hypernatraemia	3 (4.3)	1 (1.4)	0	1 (1.4)	1 (1.4)
Hyponatraemia	3 (4.3)	3 (4.3)	0	0	0
Acidosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hyperchloraemia	2 (2.9)	2 (2.9)	0	0	0
Hypermagnesaemia	2 (2.9)	2 (2.9)	0	0	0
Hypertriglyceridaemia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Malnutrition	2 (2.9)	0	0	2 (2.9)	0
Calcium deficiency	1 (1.4)	1 (1.4)	0	0	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0

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		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemosiderosis	1 (1.4)	0	1 (1.4)	0	0
Hyperlactacidaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperlipidaemia	1 (1.4)	0	1 (1.4)	0	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Obesity	1 (1.4)	0	0	1 (1.4)	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					
-Total	41 (59.4)	16 (23.2)	17 (24.6)	7 (10.1)	1 (1.4)
Pain in extremity	17 (24.6)	8 (11.6)	8 (11.6)	1 (1.4)	0
Arthralgia	11 (15.9)	5 (7.2)	5 (7.2)	1 (1.4)	0
Myalgia	10 (14.5)	6 (8.7)	4 (5.8)	0	0
Back pain	8 (11.6)	1 (1.4)	4 (5.8)	3 (4.3)	0
Bone pain	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Growth retardation	2 (2.9)	0	2 (2.9)	0	0
Muscular weakness	2 (2.9)	1 (1.4)	0	1 (1.4)	0

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			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	2 (2.9)	2 (2.9)	0	0	0
Neck pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Pain in jaw	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Haemarthrosis	1 (1.4)	0	0	1 (1.4)	0
Muscle rigidity	1 (1.4)	1 (1.4)	0	0	0
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myositis	1 (1.4)	0	1 (1.4)	0	0
Osteonecrosis	1 (1.4)	1 (1.4)	0	0	0
Osteopenia	1 (1.4)	1 (1.4)	0	0	0
Rhabdomyolysis	1 (1.4)	0	0	0	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Bone giant cell tumour benign	1 (1.4)	0	0	1 (1.4)	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0

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	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	42 (60.9)	14 (20.3)	16 (23.2)	9 (13.0)	3 (4.3)
Headache	24 (34.8)	12 (17.4)	10 (14.5)	2 (2.9)	0
Encephalopathy	8 (11.6)	1 (1.4)	3 (4.3)	4 (5.8)	0
Tremor	6 (8.7)	5 (7.2)	1 (1.4)	0	0
Somnolence	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Dizziness	4 (5.8)	4 (5.8)	0	0	0
Cognitive disorder	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Dysgeusia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Seizure	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Monoparesis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorder	1 (1.4)	0	0	1 (1.4)	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Paraesthesia	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	35 (50.7)	11 (15.9)	17 (24.6)	7 (10.1)	0
Anxiety	12 (17.4)	2 (2.9)	8 (11.6)	2 (2.9)	0
Delirium	8 (11.6)	2 (2.9)	3 (4.3)	3 (4.3)	0
Agitation	6 (8.7)	3 (4.3)	3 (4.3)	0	0
Confusional state	6 (8.7)	6 (8.7)	0	0	0
Mental status changes	5 (7.2)	1 (1.4)	2 (2.9)	2 (2.9)	0
Insomnia	4 (5.8)	2 (2.9)	2 (2.9)	0	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	3 (4.3)	3 (4.3)	0	0	0
Sleep disorder	2 (2.9)	0	2 (2.9)	0	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Automatism	1 (1.4)	1 (1.4)	0	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Tic	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	24 (34.8)	6 (8.7)	7 (10.1)	4 (5.8)	7 (10.1)
Acute kidney injury	12 (17.4)	2 (2.9)	2 (2.9)	3 (4.3)	5 (7.2)
Dysuria	4 (5.8)	3 (4.3)	1 (1.4)	0	0
Haematuria	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Anuria	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Pollakiuria	2 (2.9)	0	2 (2.9)	0	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Urinary retention	2 (2.9)	0	2 (2.9)	0	0
Azotaemia	1 (1.4)	0	1 (1.4)	0	0
Bladder dilatation	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	0	1 (1.4)
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	4 (5.8)	1 (1.4)	2 (2.9)	1 (1.4)	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0

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Perineal rash	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Vaginal ulceration	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	51 (73.9)	15 (21.7)	7 (10.1)	12 (17.4)	17 (24.6)
Cough	22 (31.9)	18 (26.1)	4 (5.8)	0	0
Hypoxia	20 (29.0)	0	4 (5.8)	10 (14.5)	6 (8.7)
Pulmonary oedema	12 (17.4)	2 (2.9)	3 (4.3)	6 (8.7)	1 (1.4)
Nasal congestion	9 (13.0)	7 (10.1)	2 (2.9)	0	0
Pleural effusion	9 (13.0)	4 (5.8)	2 (2.9)	2 (2.9)	1 (1.4)
Tachypnoea	9 (13.0)	3 (4.3)	1 (1.4)	4 (5.8)	1 (1.4)
Oropharyngeal pain	8 (11.6)	7 (10.1)	1 (1.4)	0	0
Dyspnoea	7 (10.1)	1 (1.4)	2 (2.9)	2 (2.9)	2 (2.9)
Epistaxis	6 (8.7)	3 (4.3)	2 (2.9)	1 (1.4)	0
Respiratory failure	6 (8.7)	0	0	0	6 (8.7)
Rhinorrhoea	6 (8.7)	4 (5.8)	2 (2.9)	0	0
Respiratory distress	4 (5.8)	0	2 (2.9)	0	2 (2.9)

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	3 (4.3)	0	0	0	3 (4.3)
Atelectasis	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Pharyngeal erythema	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Rhinitis allergic	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Sleep apnoea syndrome	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Wheezing	2 (2.9)	0	2 (2.9)	0	0
Acute respiratory failure	1 (1.4)	0	0	1 (1.4)	0
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea exertional	1 (1.4)	1 (1.4)	0	0	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	0	0	1 (1.4)
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal discomfort	1 (1.4)	0	1 (1.4)	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0

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			All patients N=69		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory acidosis	1 (1.4)	0	0	1 (1.4)	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	36 (52.2)	14 (20.3)	15 (21.7)	7 (10.1)	0
Dry skin	8 (11.6)	6 (8.7)	2 (2.9)	0	0
Pruritus	7 (10.1)	2 (2.9)	5 (7.2)	0	0
Rash	7 (10.1)	3 (4.3)	4 (5.8)	0	0
Erythema	5 (7.2)	4 (5.8)	1 (1.4)	0	0
Blister	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Dermatitis atopic	3 (4.3)	2 (2.9)	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Hyperhidrosis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Rash maculo-papular	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Rash papular	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Decubitus ulcer	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Ingrowing nail	2 (2.9)	0	2 (2.9)	0	0
Petechiae	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Skin discolouration	2 (2.9)	2 (2.9)	0	0	0
Skin ulcer	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	0	1 (1.4)	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash erythematous	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (1.4)	0	0	1 (1.4)	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Scab	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin necrosis	1 (1.4)	0	0	1 (1.4)	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	31 (44.9)	4 (5.8)	7 (10.1)	11 (15.9)	9 (13.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	23 (33.3)	1 (1.4)	6 (8.7)	8 (11.6)	8 (11.6)
Hypertension	14 (20.3)	4 (5.8)	6 (8.7)	4 (5.8)	0
Capillary leak syndrome	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Venoocclusive disease	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0
Thrombosis	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	1 (16.7)	3 (50.0)	0
Febrile neutropenia	3 (50.0)	0	0	3 (50.0)	0
Anaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	2 (33.3)	0	2 (33.3)	0	0
Splenomegaly	1 (16.7)	1 (16.7)	0	0	0
Cardiac disorders					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Tachycardia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Bradycardia	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Ear pruritus	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Conjunctival haemorrhage	2 (33.3)	2 (33.3)	0	0	0
Ocular hyperaemia	1 (16.7)	1 (16.7)	0	0	0
Periorbital oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	1 (16.7)	1 (16.7)
Diarrhoea	2 (33.3)	2 (33.3)	0	0	0
Abdominal compartment syndrome	1 (16.7)	0	0	0	1 (16.7)
Anal fissure	1 (16.7)	0	1 (16.7)	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Dysphagia	1 (16.7)	0	0	1 (16.7)	0
Enterocolitis	1 (16.7)	0	1 (16.7)	0	0
Gingival erythema	1 (16.7)	1 (16.7)	0	0	0
Nausea	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Face oedema	2 (33.3)	2 (33.3)	0	0	0
Generalised oedema	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Fatigue	1 (16.7)	1 (16.7)	0	0	0
Localised oedema	1 (16.7)	1 (16.7)	0	0	0
Pyrexia	1 (16.7)	1 (16.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Hepatic function abnormal	1 (16.7)	0	0	0	1 (16.7)
Hyperbilirubinaemia	1 (16.7)	0	1 (16.7)	0	0
Hypertransaminasaemia	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Cytokine release syndrome	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	2 (33.3)	0	2 (33.3)	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)	0	0
Injury, poisoning and procedural complications					
-Total	2 (33.3)	0	2 (33.3)	0	0
Contusion	1 (16.7)	1 (16.7)	0	0	0
Skin abrasion	1 (16.7)	1 (16.7)	0	0	0
Transfusion reaction	1 (16.7)	0	1 (16.7)	0	0
Wound	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	6 (100)	0	0	1 (16.7)	5 (83.3)
White blood cell count decreased	4 (66.7)	1 (16.7)	0	0	3 (50.0)
Platelet count decreased	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Alanine aminotransferase increased	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Neutrophil count decreased	2 (33.3)	0	0	0	2 (33.3)
Serum ferritin increased	2 (33.3)	0	2 (33.3)	0	0
Urine output decreased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)	0	0
Aspartate aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Blood bicarbonate decreased	1 (16.7)	0	1 (16.7)	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	1 (16.7)	0
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	0	1 (16.7)	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0	0	0
Cardiac murmur	1 (16.7)	1 (16.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (16.7)	0	1 (16.7)	0	0
Oxygen saturation decreased	1 (16.7)	1 (16.7)	0	0	0
Weight increased	1 (16.7)	1 (16.7)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (100)	0	3 (50.0)	2 (33.3)	1 (16.7)
Hypocalcaemia	4 (66.7)	1 (16.7)	3 (50.0)	0	0
Hypokalaemia	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Hypophosphataemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Decreased appetite	2 (33.3)	0	0	2 (33.3)	0
Hyperphosphataemia	2 (33.3)	2 (33.3)	0	0	0
Hypoalbuminaemia	2 (33.3)	0	2 (33.3)	0	0
Hypercalcaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperchloraemia	1 (16.7)	1 (16.7)	0	0	0
Hyperglycaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperkalaemia	1 (16.7)	0	0	1 (16.7)	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypervolaemia	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Metabolic acidosis	1 (16.7)	0	0	0	1 (16.7)
Tumour lysis syndrome	1 (16.7)	0	0	1 (16.7)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Muscle rigidity	1 (16.7)	1 (16.7)	0	0	0
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	0	0	1 (16.7)
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)	0	0
Headache	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	0	1 (16.7)	0
Tremor	1 (16.7)	0	1 (16.7)	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (16.7)	0	1 (16.7)	0	0
Automatism	1 (16.7)	1 (16.7)	0	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Delirium	1 (16.7)	0	1 (16.7)	0	0
Insomnia	1 (16.7)	0	1 (16.7)	0	0
Irritability	1 (16.7)	1 (16.7)	0	0	0
Mental status changes	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Acute kidney injury	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anuria	1 (16.7)	1 (16.7)	0	0	0
Azotaemia	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Perineal rash	1 (16.7)	0	1 (16.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (83.3)	2 (33.3)	0	1 (16.7)	2 (33.3)

Timing: within 8 weeks post infusion, Down syndrome: Yes

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (50.0)	0	1 (16.7)	0	2 (33.3)
Pleural effusion	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Epistaxis	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Pulmonary oedema	2 (33.3)	0	2 (33.3)	0	0
Cough	1 (16.7)	1 (16.7)	0	0	0
Nasal discomfort	1 (16.7)	0	1 (16.7)	0	0
Pharyngeal haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Respiratory distress	1 (16.7)	0	1 (16.7)	0	0
Tachypnoea	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	4 (66.7)	1 (16.7)	3 (50.0)	0	0
Blister	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Dermatitis diaper	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	1 (16.7)	0	0
Scab	1 (16.7)	1 (16.7)	0	0	0
Skin discolouration	1 (16.7)	1 (16.7)	0	0	0
Skin ulcer	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	4 (66.7)	1 (16.7)	0	1 (16.7)	2 (33.3)
Hypertension	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Hypotension	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Thrombosis	1 (16.7)	0	1 (16.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	73 (98.6)	4 (5.4)	8 (10.8)	20 (27.0)	41 (55.4)
Blood and lymphatic system disorders					
-Total	46 (62.2)	3 (4.1)	7 (9.5)	23 (31.1)	13 (17.6)
Febrile neutropenia	23 (31.1)	0	0	21 (28.4)	2 (2.7)
Anaemia	19 (25.7)	5 (6.8)	7 (9.5)	7 (9.5)	0
Neutropenia	9 (12.2)	0	2 (2.7)	1 (1.4)	6 (8.1)
Thrombocytopenia	8 (10.8)	0	0	2 (2.7)	6 (8.1)
Coagulopathy	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Disseminated intravascular coagulation	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	21 (28.4)	10 (13.5)	4 (5.4)	4 (5.4)	3 (4.1)
Tachycardia	15 (20.3)	7 (9.5)	6 (8.1)	1 (1.4)	1 (1.4)
Left ventricular dysfunction	3 (4.1)	0	0	3 (4.1)	0
Sinus tachycardia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Bradycardia	2 (2.7)	2 (2.7)	0	0	0
Cardiac dysfunction	2 (2.7)	2 (2.7)	0	0	0
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	0	0	1 (1.4)
Cardiac failure	1 (1.4)	0	0	0	1 (1.4)
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Sinus bradycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	5 (6.8)	0	5 (6.8)	0	0
Adrenal insufficiency	4 (5.4)	0	4 (5.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	7 (9.5)	4 (5.4)	3 (4.1)	0	0
Eyelid oedema	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Eye pain	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	46 (62.2)	18 (24.3)	16 (21.6)	12 (16.2)	0
Vomiting	20 (27.0)	11 (14.9)	8 (10.8)	1 (1.4)	0
Nausea	17 (23.0)	10 (13.5)	5 (6.8)	2 (2.7)	0
Diarrhoea	13 (17.6)	6 (8.1)	6 (8.1)	1 (1.4)	0
Abdominal pain	11 (14.9)	3 (4.1)	6 (8.1)	2 (2.7)	0
Constipation	10 (13.5)	5 (6.8)	5 (6.8)	0	0
Mouth haemorrhage	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Pancreatitis	4 (5.4)	0	3 (4.1)	1 (1.4)	0
Abdominal distension	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain upper	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Ascites	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Gastrointestinal sounds abnormal	2 (2.7)	2 (2.7)	0	0	0
Stomatitis	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingival bleeding	1 (1.4)	0	1 (1.4)	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0
Melaena	1 (1.4)	0	0	1 (1.4)	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Neutropenic colitis	1 (1.4)	0	0	1 (1.4)	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	0	0	1 (1.4)	0
Trichoglossia	1 (1.4)	0	1 (1.4)	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	38 (51.4)	19 (25.7)	8 (10.8)	7 (9.5)	4 (5.4)
Pyrexia	23 (31.1)	10 (13.5)	5 (6.8)	6 (8.1)	2 (2.7)
Fatigue	10 (13.5)	8 (10.8)	2 (2.7)	0	0
Face oedema	6 (8.1)	3 (4.1)	2 (2.7)	1 (1.4)	0
Oedema peripheral	6 (8.1)	4 (5.4)	1 (1.4)	1 (1.4)	0
Chills	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Generalised oedema	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Asthenia	2 (2.7)	2 (2.7)	0	0	0
Catheter site pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Drug withdrawal syndrome	2 (2.7)	0	2 (2.7)	0	0
Influenza like illness	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	0	0	2 (2.7)
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Crying	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Localised oedema	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	0	1 (1.4)	0	0
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Pain	1 (1.4)	0	0	1 (1.4)	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Systemic inflammatory response syndrome	1 (1.4)	0	0	1 (1.4)	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	15 (20.3)	5 (6.8)	5 (6.8)	3 (4.1)	2 (2.7)
Hepatic function abnormal	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Hyperbilirubinaemia	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Hepatomegaly	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Cholelithiasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Gallbladder enlargement	2 (2.7)	2 (2.7)	0	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (1.4)	0	0	0	1 (1.4)
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	61 (82.4)	2 (2.7)	20 (27.0)	21 (28.4)	18 (24.3)
Cytokine release syndrome	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Hypogammaglobulinaemia	21 (28.4)	2 (2.7)	13 (17.6)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	4 (5.4)	1 (1.4)	0	2 (2.7)	1 (1.4)
Immunodeficiency	3 (4.1)	0	0	3 (4.1)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Seasonal allergy	1 (1.4)	0	1 (1.4)	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	33 (44.6)	6 (8.1)	8 (10.8)	16 (21.6)	3 (4.1)
Conjunctivitis	5 (6.8)	1 (1.4)	4 (5.4)	0	0
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Staphylococcal infection	4 (5.4)	0	2 (2.7)	2 (2.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Staphylococcal bacteraemia	3 (4.1)	0	0	3 (4.1)	0
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Nail infection	2 (2.7)	2 (2.7)	0	0	0
Oral herpes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Rhinovirus infection	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	1 (1.4)	0	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes simplex	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.2)	3 (4.1)	4 (5.4)	0	2 (2.7)
Fall	2 (2.7)	0	2 (2.7)	0	0
Infusion related reaction	2 (2.7)	0	2 (2.7)	0	0
Procedural pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Scratch	1 (1.4)	1 (1.4)	0	0	0
Skin injury	1 (1.4)	0	1 (1.4)	0	0
Skin wound	1 (1.4)	1 (1.4)	0	0	0
Transfusion reaction	1 (1.4)	1 (1.4)	0	0	0
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Vasoplegia syndrome	1 (1.4)	0	0	0	1 (1.4)
Wound	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	51 (68.9)	4 (5.4)	8 (10.8)	16 (21.6)	23 (31.1)
White blood cell count decreased	20 (27.0)	2 (2.7)	3 (4.1)	2 (2.7)	13 (17.6)

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	8 (10.8)	2 (2.7)
Neutrophil count decreased	18 (24.3)	0	3 (4.1)	2 (2.7)	13 (17.6)
Platelet count decreased	18 (24.3)	4 (5.4)	2 (2.7)	5 (6.8)	7 (9.5)
Alanine aminotransferase increased	16 (21.6)	3 (4.1)	7 (9.5)	6 (8.1)	0
Lymphocyte count decreased	15 (20.3)	2 (2.7)	0	8 (10.8)	5 (6.8)
Blood bilirubin increased	11 (14.9)	1 (1.4)	2 (2.7)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	6 (8.1)	2 (2.7)	0	0
Blood fibrinogen decreased	6 (8.1)	2 (2.7)	2 (2.7)	1 (1.4)	1 (1.4)
Serum ferritin increased	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Electrocardiogram qt prolonged	5 (6.8)	1 (1.4)	2 (2.7)	1 (1.4)	1 (1.4)
Blood immunoglobulin a decreased	4 (5.4)	4 (5.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Fibrin d dimer increased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Weight increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Gamma-glutamyltransferase increased	2 (2.7)	0	0	2 (2.7)	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
Lipase increased	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Amylase increased	1 (1.4)	1 (1.4)	0	0	0
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	0	1 (1.4)
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood testosterone decreased	1 (1.4)	1 (1.4)	0	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Electrocardiogram t wave abnormal	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Troponin increased	1 (1.4)	0	0	1 (1.4)	0
Weight decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	40 (54.1)	8 (10.8)	6 (8.1)	19 (25.7)	7 (9.5)
Decreased appetite	22 (29.7)	9 (12.2)	4 (5.4)	8 (10.8)	1 (1.4)
Hypokalaemia	16 (21.6)	1 (1.4)	5 (6.8)	8 (10.8)	2 (2.7)
Hypophosphataemia	14 (18.9)	2 (2.7)	3 (4.1)	8 (10.8)	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	12 (16.2)	1 (1.4)	6 (8.1)	5 (6.8)	0
Hypoalbuminaemia	9 (12.2)	0	8 (10.8)	1 (1.4)	0
Hyperglycaemia	7 (9.5)	0	4 (5.4)	3 (4.1)	0
Hyperuricaemia	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Hypervolaemia	5 (6.8)	0	1 (1.4)	4 (5.4)	0
Hyperphosphataemia	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Tumour lysis syndrome	3 (4.1)	0	0	3 (4.1)	0
Acidosis	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypercalcaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hypernatraemia	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Hypertriglyceridaemia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Metabolic acidosis	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Calcium deficiency	1 (1.4)	1 (1.4)	0	0	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0
Haemosiderosis	1 (1.4)	0	1 (1.4)	0	0
Hyperkalaemia	1 (1.4)	0	0	0	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlactacidaemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					
-Total	31 (41.9)	13 (17.6)	13 (17.6)	4 (5.4)	1 (1.4)
Pain in extremity	11 (14.9)	6 (8.1)	5 (6.8)	0	0
Arthralgia	10 (13.5)	4 (5.4)	5 (6.8)	1 (1.4)	0
Myalgia	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Back pain	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Bone pain	2 (2.7)	0	2 (2.7)	0	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Pain in jaw	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Haemarthrosis	1 (1.4)	0	0	1 (1.4)	0
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	0	1 (1.4)	0	0
Rhabdomyolysis	1 (1.4)	0	0	0	1 (1.4)
Nervous system disorders					
-Total	38 (51.4)	14 (18.9)	16 (21.6)	7 (9.5)	1 (1.4)
Headache	22 (29.7)	12 (16.2)	8 (10.8)	2 (2.7)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	5 (6.8)	0	0	0
Somnolence	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Dizziness	3 (4.1)	3 (4.1)	0	0	0
Dysgeusia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Seizure	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Monoparesis	1 (1.4)	0	1 (1.4)	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Paraesthesia	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	26 (35.1)	11 (14.9)	10 (13.5)	5 (6.8)	0
Anxiety	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Delirium	6 (8.1)	2 (2.7)	1 (1.4)	3 (4.1)	0
Agitation	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Insomnia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Irritability	2 (2.7)	2 (2.7)	0	0	0
Mental status changes	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	2 (2.7)	0	2 (2.7)	0	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	17 (23.0)	5 (6.8)	6 (8.1)	2 (2.7)	4 (5.4)
Acute kidney injury	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Dysuria	3 (4.1)	3 (4.1)	0	0	0
Haematuria	2 (2.7)	2 (2.7)	0	0	0
Pollakiuria	2 (2.7)	0	2 (2.7)	0	0
Renal failure	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Urinary retention	2 (2.7)	0	2 (2.7)	0	0
Anuria	1 (1.4)	0	0	0	1 (1.4)
Bladder dilatation	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	0	1 (1.4)
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0
Heavy menstrual bleeding	1 (1.4)	1 (1.4)	0	0	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Vaginal ulceration	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (48.6)	12 (16.2)	4 (5.4)	10 (13.5)	10 (13.5)
Hypoxia	14 (18.9)	0	4 (5.4)	6 (8.1)	4 (5.4)
Pulmonary oedema	10 (13.5)	2 (2.7)	1 (1.4)	6 (8.1)	1 (1.4)
Cough	9 (12.2)	8 (10.8)	1 (1.4)	0	0
Tachypnoea	7 (9.5)	3 (4.1)	1 (1.4)	3 (4.1)	0
Oropharyngeal pain	5 (6.8)	5 (6.8)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Respiratory failure	4 (5.4)	0	0	0	4 (5.4)
Atelectasis	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Dyspnoea	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Nasal congestion	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Acute respiratory distress syndrome	2 (2.7)	0	0	0	2 (2.7)
Epistaxis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Respiratory distress	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Rhinorrhoea	2 (2.7)	2 (2.7)	0	0	0
Acute respiratory failure	1 (1.4)	0	0	1 (1.4)	0
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal dryness	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal erythema	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory acidosis	1 (1.4)	0	0	1 (1.4)	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	23 (31.1)	12 (16.2)	8 (10.8)	3 (4.1)	0
Pruritus	6 (8.1)	2 (2.7)	4 (5.4)	0	0
Rash	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Erythema	3 (4.1)	3 (4.1)	0	0	0
Hyperhidrosis	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rash papular	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dermatitis atopic	2 (2.7)	2 (2.7)	0	0	0
Rash maculo-papular	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	1 (1.4)	1 (1.4)	0	0	0
Decubitus ulcer	1 (1.4)	0	1 (1.4)	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	0	1 (1.4)	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin necrosis	1 (1.4)	0	0	1 (1.4)	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social circumstances					
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	24 (32.4)	3 (4.1)	7 (9.5)	10 (13.5)	4 (5.4)
Hypotension	18 (24.3)	1 (1.4)	6 (8.1)	7 (9.5)	4 (5.4)
Hypertension	10 (13.5)	2 (2.7)	4 (5.4)	4 (5.4)	0
Capillary leak syndrome	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	3 (60.0)	1 (20.0)
Endocrine disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hypothyroidism	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Constipation	1 (20.0)	1 (20.0)	0	0	0
Diarrhoea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (60.0)	3 (60.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (40.0)	2 (40.0)	0	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hypertransaminasaemia	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hypogammaglobulinaemia	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Cellulitis	1 (20.0)	0	1 (20.0)	0	0
Ear infection	1 (20.0)	0	1 (20.0)	0	0
Metapneumovirus infection	1 (20.0)	0	0	1 (20.0)	0
Nasopharyngitis	1 (20.0)	1 (20.0)	0	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	4 (80.0)	0	0	3 (60.0)	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (40.0)	0	0	2 (40.0)	0
Neutrophil count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
White blood cell count decreased	2 (40.0)	0	2 (40.0)	0	0
Alanine aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood lactate dehydrogenase increased	1 (20.0)	1 (20.0)	0	0	0
Blood thyroid stimulating hormone increased	1 (20.0)	1 (20.0)	0	0	0
C-reactive protein increased	1 (20.0)	1 (20.0)	0	0	0
Weight increased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Metabolic syndrome	1 (20.0)	0	1 (20.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Bone pain	1 (20.0)	1 (20.0)	0	0	0
Pain in extremity	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Dysmenorrhoea	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Cough	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Nasal congestion	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hypoxia	1 (20.0)	0	0	1 (20.0)	0
Rhinitis allergic	1 (20.0)	0	1 (20.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (60.0)	3 (60.0)	0	0	0
Eczema	1 (20.0)	1 (20.0)	0	0	0
Miliaria	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	1 (20.0)	0	0	0
Skin swelling	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (91.4)	9 (12.9)	23 (32.9)	12 (17.1)	20 (28.6)
Blood and lymphatic system disorders					
-Total	17 (24.3)	3 (4.3)	4 (5.7)	6 (8.6)	4 (5.7)
Anaemia	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Neutropenia	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Leukopenia	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	7 (10.0)	3 (4.3)	1 (1.4)	0	3 (4.3)
Cardiac arrest	2 (2.9)	0	0	0	2 (2.9)
Cardiac failure	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Tachycardia	2 (2.9)	2 (2.9)	0	0	0
Left ventricular dysfunction	1 (1.4)	0	1 (1.4)	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Eye disorders					
-Total	4 (5.7)	4 (5.7)	0	0	0
Cataract	2 (2.9)	2 (2.9)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Visual impairment	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (25.7)	11 (15.7)	6 (8.6)	1 (1.4)	0
Diarrhoea	6 (8.6)	5 (7.1)	1 (1.4)	0	0
Nausea	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Vomiting	5 (7.1)	5 (7.1)	0	0	0
Abdominal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Constipation	2 (2.9)	0	2 (2.9)	0	0
Pancreatitis	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Abdominal pain upper	1 (1.4)	1 (1.4)	0	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	1 (1.4)	0	0	0
Stomatitis	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	21 (30.0)	12 (17.1)	6 (8.6)	3 (4.3)	0
Pyrexia	13 (18.6)	5 (7.1)	6 (8.6)	2 (2.9)	0
Fatigue	5 (7.1)	5 (7.1)	0	0	0
Pain	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Malaise	1 (1.4)	1 (1.4)	0	0	0
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	15 (21.4)	1 (1.4)	10 (14.3)	4 (5.7)	0
Hypogammaglobulinaemia	9 (12.9)	0	9 (12.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Graft versus host disease	2 (2.9)	0	0	2 (2.9)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	35 (50.0)	4 (5.7)	12 (17.1)	11 (15.7)	8 (11.4)
Upper respiratory tract infection	7 (10.0)	2 (2.9)	3 (4.3)	2 (2.9)	0
Nasopharyngitis	6 (8.6)	3 (4.3)	3 (4.3)	0	0
Gastroenteritis	5 (7.1)	3 (4.3)	0	2 (2.9)	0
Rhinovirus infection	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.7)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Pneumonia	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Respiratory tract infection	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Bacteraemia	2 (2.9)	0	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0
Otitis externa	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Rhinitis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	0	1 (1.4)
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Ear infection	1 (1.4)	0	1 (1.4)	0	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Influenza	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Oral candidiasis	1 (1.4)	0	1 (1.4)	0	0
Oral herpes	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Septic shock	1 (1.4)	0	0	0	1 (1.4)
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.9)	5 (7.1)	4 (5.7)	0	0
Infusion related reaction	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Ligament sprain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	26 (37.1)	7 (10.0)	7 (10.0)	8 (11.4)	4 (5.7)
Neutrophil count decreased	8 (11.4)	2 (2.9)	1 (1.4)	2 (2.9)	3 (4.3)
White blood cell count decreased	8 (11.4)	4 (5.7)	0	3 (4.3)	1 (1.4)
Platelet count decreased	5 (7.1)	3 (4.3)	0	1 (1.4)	1 (1.4)
Blood bilirubin increased	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0	0	0
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Immunoglobulins decreased	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Weight decreased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	14 (20.0)	4 (5.7)	3 (4.3)	4 (5.7)	3 (4.3)
Decreased appetite	6 (8.6)	2 (2.9)	3 (4.3)	1 (1.4)	0
Hyperuricaemia	3 (4.3)	3 (4.3)	0	0	0
Hypokalaemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	13 (18.6)	3 (4.3)	7 (10.0)	3 (4.3)	0
Back pain	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Pain in extremity	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Arthralgia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Growth retardation	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Neck pain	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	14 (20.0)	7 (10.0)	5 (7.1)	0	2 (2.9)
Headache	10 (14.3)	6 (8.6)	4 (5.7)	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	10 (14.3)	1 (1.4)	8 (11.4)	1 (1.4)	0
Anxiety	6 (8.6)	1 (1.4)	5 (7.1)	0	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	5 (7.1)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Acute kidney injury	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	0	0	1 (1.4)	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	21 (30.0)	11 (15.7)	5 (7.1)	2 (2.9)	3 (4.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	9 (12.9)	7 (10.0)	2 (2.9)	0	0
Nasal congestion	4 (5.7)	4 (5.7)	0	0	0
Epistaxis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Rhinorrhoea	3 (4.3)	3 (4.3)	0	0	0
Hypoxia	2 (2.9)	0	0	2 (2.9)	0
Oropharyngeal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Rhinitis allergic	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=70		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	17 (24.3)	9 (12.9)	7 (10.0)	1 (1.4)	0
Dry skin	6 (8.6)	4 (5.7)	2 (2.9)	0	0
Rash	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Ingrowing nail	2 (2.9)	0	2 (2.9)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	6 (8.6)	1 (1.4)	0	2 (2.9)	3 (4.3)
Hypotension	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	0	3 (75.0)	0
Gastrointestinal disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Seasonal allergy	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Upper respiratory tract infection	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Otitis media	2 (50.0)	0	2 (50.0)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

		All patients N=4			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (25.0)	0	0	1 (25.0)	0
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Folliculitis	1 (25.0)	0	1 (25.0)	0	0
Gastroenteritis viral	1 (25.0)	0	1 (25.0)	0	0
Nail infection	1 (25.0)	0	1 (25.0)	0	0
Pneumonia respiratory syncytial viral	1 (25.0)	0	0	1 (25.0)	0
Rhinovirus infection	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Skin infection	1 (25.0)	0	1 (25.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	1 (25.0)	0	0	0
Abdominal injury	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hyperlipidaemia	1 (25.0)	0	1 (25.0)	0	0
Obesity	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Dyspnoea	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0	1 (25.0)	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Sleep apnoea syndrome	1 (25.0)	0	1 (25.0)	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Rash	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Rash erythematous	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

			All patients N=46		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (63.0)	3 (6.5)	10 (21.7)	9 (19.6)	7 (15.2)
Blood and lymphatic system disorders					
-Total	4 (8.7)	0	2 (4.3)	1 (2.2)	1 (2.2)
Agranulocytosis	1 (2.2)	0	0	1 (2.2)	0
Anaemia	1 (2.2)	0	1 (2.2)	0	0
Hypercoagulation	1 (2.2)	0	1 (2.2)	0	0
Lymphadenopathy	1 (2.2)	0	1 (2.2)	0	0
Neutropenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	1 (2.2)	0	0
Congenital, familial and genetic disorders					

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.2)	1 (2.2)	0	0	0
Cerebral cavernous malformation	1 (2.2)	1 (2.2)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Deafness unilateral	1 (2.2)	0	1 (2.2)	0	0
Endocrine disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Delayed puberty	1 (2.2)	0	1 (2.2)	0	0
Hypothyroidism	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Dry eye	1 (2.2)	1 (2.2)	0	0	0
Eye pain	1 (2.2)	0	0	1 (2.2)	0
Eyelid oedema	1 (2.2)	1 (2.2)	0	0	0
Mydriasis	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	6 (13.0)	3 (6.5)	2 (4.3)	1 (2.2)	0
Diarrhoea	5 (10.9)	3 (6.5)	1 (2.2)	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (2.2)	0	1 (2.2)	0	0
Nausea	1 (2.2)	1 (2.2)	0	0	0
Vomiting	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	9 (19.6)	4 (8.7)	3 (6.5)	1 (2.2)	1 (2.2)
Pyrexia	5 (10.9)	2 (4.3)	2 (4.3)	1 (2.2)	0
Pain	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Fatigue	1 (2.2)	0	1 (2.2)	0	0
Multiple organ dysfunction syndrome	1 (2.2)	0	0	0	1 (2.2)
Non-cardiac chest pain	1 (2.2)	1 (2.2)	0	0	0
Xerosis	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	8 (17.4)	2 (4.3)	4 (8.7)	1 (2.2)	1 (2.2)
Hypogammaglobulinaemia	3 (6.5)	0	3 (6.5)	0	0
Chronic graft versus host disease	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Seasonal allergy	2 (4.3)	2 (4.3)	0	0	0
Drug hypersensitivity	1 (2.2)	0	0	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Infections and infestations					
-Total	20 (43.5)	2 (4.3)	6 (13.0)	8 (17.4)	4 (8.7)
Sinusitis	5 (10.9)	0	5 (10.9)	0	0
Conjunctivitis	4 (8.7)	2 (4.3)	2 (4.3)	0	0
Rhinovirus infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Sepsis	3 (6.5)	0	0	1 (2.2)	2 (4.3)
Covid-19	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Fungal infection	2 (4.3)	0	2 (4.3)	0	0
Herpes zoster	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Influenza	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Oral herpes	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Pneumonia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Skin infection	2 (4.3)	0	2 (4.3)	0	0
Upper respiratory tract infection	2 (4.3)	2 (4.3)	0	0	0
Urinary tract infection	2 (4.3)	0	2 (4.3)	0	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Candida infection	1 (2.2)	0	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	0	0	1 (2.2)
Device related sepsis	1 (2.2)	0	0	1 (2.2)	0
Ear infection	1 (2.2)	0	0	1 (2.2)	0
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis	1 (2.2)	1 (2.2)	0	0	0
Gastroenteritis escherichia coli	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	0	0	1 (2.2)	0
Herpes virus infection	1 (2.2)	0	1 (2.2)	0	0
Meningitis pneumococcal	1 (2.2)	0	0	1 (2.2)	0
Neutropenic infection	1 (2.2)	0	0	1 (2.2)	0
Ophthalmic herpes zoster	1 (2.2)	0	1 (2.2)	0	0
Oral candidiasis	1 (2.2)	0	1 (2.2)	0	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0
Rhinitis	1 (2.2)	1 (2.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (2.2)	0	0	0	1 (2.2)
Staphylococcal abscess	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Streptococcal sepsis	1 (2.2)	0	1 (2.2)	0	0
Syphilis	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection pseudomonal	1 (2.2)	0	1 (2.2)	0	0
Varicella zoster virus infection	1 (2.2)	0	1 (2.2)	0	0
Viral skin infection	1 (2.2)	1 (2.2)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Infusion related reaction	1 (2.2)	0	0	1 (2.2)	0
Ligament sprain	1 (2.2)	1 (2.2)	0	0	0
Investigations					
-Total	6 (13.0)	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)
Neutrophil count decreased	3 (6.5)	2 (4.3)	0	0	1 (2.2)
Platelet count decreased	2 (4.3)	2 (4.3)	0	0	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

			All patients N=46		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0
Oxygen saturation decreased	1 (2.2)	0	0	1 (2.2)	0
Metabolism and nutrition disorders					
-Total	4 (8.7)	0	1 (2.2)	2 (4.3)	1 (2.2)
Decreased appetite	1 (2.2)	0	0	0	1 (2.2)
Hypercholesterolaemia	1 (2.2)	0	1 (2.2)	0	0
Hyperglycaemia	1 (2.2)	0	0	1 (2.2)	0
Hypernatraemia	1 (2.2)	0	0	1 (2.2)	0
Hypertriglyceridaemia	1 (2.2)	0	1 (2.2)	0	0
Iron overload	1 (2.2)	0	1 (2.2)	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (15.2)	2 (4.3)	5 (10.9)	0	0
Pain in extremity	2 (4.3)	0	2 (4.3)	0	0
Arthralgia	1 (2.2)	0	1 (2.2)	0	0
Growth retardation	1 (2.2)	0	1 (2.2)	0	0
Joint effusion	1 (2.2)	0	1 (2.2)	0	0
Osteonecrosis	1 (2.2)	1 (2.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

			All patients N=46		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteopenia	1 (2.2)	1 (2.2)	0	0	0
Synovitis	1 (2.2)	0	1 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.2)	0	0	1 (2.2)	0
Bone giant cell tumour benign	1 (2.2)	0	0	1 (2.2)	0
Nervous system disorders					
-Total	3 (6.5)	0	1 (2.2)	2 (4.3)	0
Dysarthria	1 (2.2)	0	1 (2.2)	0	0
Headache	1 (2.2)	0	0	1 (2.2)	0
Nervous system disorder	1 (2.2)	0	0	1 (2.2)	0
Seizure	1 (2.2)	0	0	1 (2.2)	0
Psychiatric disorders					
-Total	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Anxiety	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Tic	1 (2.2)	0	1 (2.2)	0	0
Reproductive system and breast disorders					
-Total	1 (2.2)	0	0	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endometriosis	1 (2.2)	0	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (17.4)	4 (8.7)	1 (2.2)	0	3 (6.5)
Cough	4 (8.7)	3 (6.5)	1 (2.2)	0	0
Dyspnoea	2 (4.3)	1 (2.2)	0	0	1 (2.2)
Rhinorrhoea	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Dyspnoea exertional	1 (2.2)	1 (2.2)	0	0	0
Epistaxis	1 (2.2)	1 (2.2)	0	0	0
Laryngeal oedema	1 (2.2)	0	0	0	1 (2.2)
Oropharyngeal pain	1 (2.2)	1 (2.2)	0	0	0
Pharyngeal erythema	1 (2.2)	1 (2.2)	0	0	0
Pleural effusion	1 (2.2)	0	1 (2.2)	0	0
Respiratory failure	1 (2.2)	0	0	0	1 (2.2)
Sleep apnoea syndrome	1 (2.2)	1 (2.2)	0	0	0
Tachypnoea	1 (2.2)	0	0	0	1 (2.2)
Skin and subcutaneous tissue disorders					
-Total	5 (10.9)	2 (4.3)	0	3 (6.5)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis atopic	1 (2.2)	0	0	1 (2.2)	0
Dry skin	1 (2.2)	1 (2.2)	0	0	0
Eczema	1 (2.2)	0	0	1 (2.2)	0
Papule	1 (2.2)	1 (2.2)	0	0	0
Rash macular	1 (2.2)	0	0	1 (2.2)	0
Vascular disorders					
-Total	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Hypertension	2 (4.3)	0	1 (2.2)	1 (2.2)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	1 (16.7)	3 (50.0)	0
Febrile neutropenia	3 (50.0)	0	0	3 (50.0)	0
Anaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	2 (33.3)	0	2 (33.3)	0	0
Splenomegaly	1 (16.7)	1 (16.7)	0	0	0
Cardiac disorders					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Tachycardia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (16.7)	0	1 (16.7)	0	0
Ear and labyrinth disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Ear pruritus	1 (16.7)	1 (16.7)	0	0	0
Endocrine disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypothyroidism	1 (16.7)	0	1 (16.7)	0	0
Eye disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Conjunctival haemorrhage	2 (33.3)	2 (33.3)	0	0	0
Ocular hyperaemia	1 (16.7)	1 (16.7)	0	0	0
Periorbital oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	1 (16.7)	1 (16.7)
Diarrhoea	3 (50.0)	3 (50.0)	0	0	0
Constipation	2 (33.3)	2 (33.3)	0	0	0
Vomiting	2 (33.3)	2 (33.3)	0	0	0
Abdominal compartment syndrome	1 (16.7)	0	0	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (16.7)	0	1 (16.7)	0	0
Dysphagia	1 (16.7)	0	0	1 (16.7)	0
Enterocolitis	1 (16.7)	0	1 (16.7)	0	0
Gingival erythema	1 (16.7)	1 (16.7)	0	0	0
Nausea	1 (16.7)	0	1 (16.7)	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	3 (50.0)	1 (16.7)	0	0
Pyrexia	3 (50.0)	3 (50.0)	0	0	0
Face oedema	2 (33.3)	2 (33.3)	0	0	0
Fatigue	2 (33.3)	2 (33.3)	0	0	0
Generalised oedema	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Localised oedema	1 (16.7)	1 (16.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Hepatic function abnormal	1 (16.7)	0	0	0	1 (16.7)
Hyperbilirubinaemia	1 (16.7)	0	1 (16.7)	0	0
Hypertransaminasaemia	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Cytokine release syndrome	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Hypogammaglobulinaemia	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)	0	0
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	5 (83.3)	0	2 (33.3)	3 (50.0)	0
Upper respiratory tract infection	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Otitis media	2 (33.3)	0	2 (33.3)	0	0
Bronchiolitis	1 (16.7)	0	0	1 (16.7)	0
Bronchitis	1 (16.7)	0	1 (16.7)	0	0
Cellulitis	1 (16.7)	0	1 (16.7)	0	0
Ear infection	1 (16.7)	0	1 (16.7)	0	0
Folliculitis	1 (16.7)	0	1 (16.7)	0	0
Gastroenteritis viral	1 (16.7)	0	1 (16.7)	0	0
Metapneumovirus infection	1 (16.7)	0	0	1 (16.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	1 (16.7)	0	1 (16.7)	0	0
Nasopharyngitis	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia respiratory syncytial viral	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Skin infection	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)	0	0
Injury, poisoning and procedural complications					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Abdominal injury	1 (16.7)	1 (16.7)	0	0	0
Contusion	1 (16.7)	1 (16.7)	0	0	0
Skin abrasion	1 (16.7)	1 (16.7)	0	0	0
Transfusion reaction	1 (16.7)	0	1 (16.7)	0	0
Wound	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	6 (100)	0	0	1 (16.7)	5 (83.3)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Platelet count decreased	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Alanine aminotransferase increased	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood creatinine increased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Lymphocyte count decreased	2 (33.3)	0	0	2 (33.3)	0
Serum ferritin increased	2 (33.3)	0	2 (33.3)	0	0
Urine output decreased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)	0	0
Aspartate aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Blood bicarbonate decreased	1 (16.7)	0	1 (16.7)	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	1 (16.7)	0
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	0	1 (16.7)	0
Blood lactate dehydrogenase increased	1 (16.7)	1 (16.7)	0	0	0
Blood thyroid stimulating hormone increased	1 (16.7)	1 (16.7)	0	0	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0	0	0
C-reactive protein increased	1 (16.7)	1 (16.7)	0	0	0
Cardiac murmur	1 (16.7)	1 (16.7)	0	0	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)	0	0
Oxygen saturation decreased	1 (16.7)	1 (16.7)	0	0	0
Weight increased	1 (16.7)	0	0	1 (16.7)	0
Metabolism and nutrition disorders					
-Total	6 (100)	0	2 (33.3)	3 (50.0)	1 (16.7)
Hypocalcaemia	4 (66.7)	1 (16.7)	3 (50.0)	0	0
Hypokalaemia	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Hypophosphataemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (33.3)	0	0	2 (33.3)	0
Hyperphosphataemia	2 (33.3)	2 (33.3)	0	0	0
Hypoalbuminaemia	2 (33.3)	0	2 (33.3)	0	0
Hypercalcaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperchloraemia	1 (16.7)	1 (16.7)	0	0	0
Hyperglycaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperkalaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperlipidaemia	1 (16.7)	0	1 (16.7)	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypervolaemia	1 (16.7)	0	1 (16.7)	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Metabolic acidosis	1 (16.7)	0	0	0	1 (16.7)
Metabolic syndrome	1 (16.7)	0	1 (16.7)	0	0
Obesity	1 (16.7)	0	0	1 (16.7)	0
Tumour lysis syndrome	1 (16.7)	0	0	1 (16.7)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (50.0)	3 (50.0)	0	0	0
Bone pain	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle rigidity	1 (16.7)	1 (16.7)	0	0	0
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Pain in extremity	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	0	0	1 (16.7)
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)	0	0
Headache	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	0	1 (16.7)	0
Tremor	1 (16.7)	0	1 (16.7)	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Agitation	1 (16.7)	0	1 (16.7)	0	0
Automatism	1 (16.7)	1 (16.7)	0	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Delirium	1 (16.7)	0	1 (16.7)	0	0
Insomnia	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (16.7)	1 (16.7)	0	0	0
Mental status changes	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Acute kidney injury	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anuria	1 (16.7)	1 (16.7)	0	0	0
Azotaemia	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Dysmenorrhoea	1 (16.7)	0	1 (16.7)	0	0
Perineal rash	1 (16.7)	0	1 (16.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (100)	1 (16.7)	1 (16.7)	2 (33.3)	2 (33.3)
Hypoxia	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Cough	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Pleural effusion	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Epistaxis	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Pulmonary oedema	2 (33.3)	0	2 (33.3)	0	0
Dyspnoea	1 (16.7)	0	1 (16.7)	0	0
Nasal discomfort	1 (16.7)	0	1 (16.7)	0	0
Pharyngeal haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Respiratory distress	1 (16.7)	0	1 (16.7)	0	0
Rhinitis allergic	1 (16.7)	0	1 (16.7)	0	0
Rhinorrhoea	1 (16.7)	0	1 (16.7)	0	0
Sleep apnoea syndrome	1 (16.7)	0	1 (16.7)	0	0
Tachypnoea	1 (16.7)	0	0	1 (16.7)	0
Wheezing	1 (16.7)	0	1 (16.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (83.3)	2 (33.3)	3 (50.0)	0	0
Blister	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Dermatitis diaper	1 (16.7)	0	1 (16.7)	0	0
Eczema	1 (16.7)	1 (16.7)	0	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Miliaria	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	1 (16.7)	0	0
Rash erythematous	1 (16.7)	1 (16.7)	0	0	0
Rash maculo-papular	1 (16.7)	1 (16.7)	0	0	0
Scab	1 (16.7)	1 (16.7)	0	0	0
Skin discolouration	1 (16.7)	1 (16.7)	0	0	0
Skin swelling	1 (16.7)	1 (16.7)	0	0	0
Skin ulcer	1 (16.7)	0	1 (16.7)	0	0
Vascular disorders					
-Total	4 (66.7)	1 (16.7)	0	1 (16.7)	2 (33.3)
Hypertension	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Hypotension	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Thrombosis	1 (16.7)	0	1 (16.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (100)	1 (1.4)	6 (8.1)	18 (24.3)	49 (66.2)
Blood and lymphatic system disorders					
-Total	51 (68.9)	1 (1.4)	10 (13.5)	26 (35.1)	14 (18.9)
Febrile neutropenia	24 (32.4)	0	0	22 (29.7)	2 (2.7)
Anaemia	23 (31.1)	7 (9.5)	8 (10.8)	8 (10.8)	0
Neutropenia	11 (14.9)	0	2 (2.7)	2 (2.7)	7 (9.5)
Thrombocytopenia	9 (12.2)	0	0	3 (4.1)	6 (8.1)
Disseminated intravascular coagulation	6 (8.1)	0	3 (4.1)	3 (4.1)	0
Coagulopathy	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Leukopenia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Lymphadenopathy	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Lymphopenia	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	2 (2.7)	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypercoagulation	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Cardiac disorders					
-Total	25 (33.8)	10 (13.5)	5 (6.8)	4 (5.4)	6 (8.1)
Tachycardia	15 (20.3)	7 (9.5)	6 (8.1)	1 (1.4)	1 (1.4)
Left ventricular dysfunction	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Cardiac arrest	3 (4.1)	0	0	0	3 (4.1)
Cardiac failure	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Sinus tachycardia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Bradycardia	2 (2.7)	2 (2.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.7)	2 (2.7)	0	0	0
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Sinus bradycardia	1 (1.4)	0	0	1 (1.4)	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Cerebral cavernous malformation	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Endocrine disorders					
-Total	6 (8.1)	0	6 (8.1)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	4 (5.4)	0	4 (5.4)	0	0
Hypothyroidism	2 (2.7)	0	2 (2.7)	0	0
Delayed puberty	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	13 (17.6)	8 (10.8)	4 (5.4)	1 (1.4)	0
Eyelid oedema	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cataract	2 (2.7)	2 (2.7)	0	0	0
Eye pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Ocular hyperaemia	2 (2.7)	2 (2.7)	0	0	0
Visual impairment	2 (2.7)	2 (2.7)	0	0	0
Dry eye	1 (1.4)	1 (1.4)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Mydriasis	1 (1.4)	0	1 (1.4)	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0
Retinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	55 (74.3)	20 (27.0)	21 (28.4)	14 (18.9)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	24 (32.4)	15 (20.3)	8 (10.8)	1 (1.4)	0
Diarrhoea	23 (31.1)	13 (17.6)	8 (10.8)	2 (2.7)	0
Nausea	21 (28.4)	12 (16.2)	7 (9.5)	2 (2.7)	0
Constipation	12 (16.2)	5 (6.8)	7 (9.5)	0	0
Abdominal pain	11 (14.9)	2 (2.7)	7 (9.5)	2 (2.7)	0
Pancreatitis	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Mouth haemorrhage	5 (6.8)	2 (2.7)	1 (1.4)	2 (2.7)	0
Abdominal pain upper	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Abdominal distension	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Ascites	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Stomatitis	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gastrointestinal sounds abnormal	2 (2.7)	2 (2.7)	0	0	0
Proctalgia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Trichoglossia	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingival bleeding	1 (1.4)	0	1 (1.4)	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0
Irritable bowel syndrome	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0
Melaena	1 (1.4)	0	0	1 (1.4)	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Neutropenic colitis	1 (1.4)	0	0	1 (1.4)	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	49 (66.2)	22 (29.7)	12 (16.2)	10 (13.5)	5 (6.8)
Pyrexia	32 (43.2)	11 (14.9)	10 (13.5)	9 (12.2)	2 (2.7)
Fatigue	15 (20.3)	12 (16.2)	3 (4.1)	0	0
Oedema peripheral	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Chills	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Face oedema	6 (8.1)	3 (4.1)	2 (2.7)	1 (1.4)	0
Pain	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Asthenia	3 (4.1)	3 (4.1)	0	0	0
Generalised oedema	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Multiple organ dysfunction syndrome	3 (4.1)	0	0	0	3 (4.1)
Catheter site pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Drug withdrawal syndrome	2 (2.7)	0	2 (2.7)	0	0
Influenza like illness	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Malaise	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Non-cardiac chest pain	2 (2.7)	2 (2.7)	0	0	0
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Localised oedema	1 (1.4)	1 (1.4)	0	0	0
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Systemic inflammatory response syndrome	1 (1.4)	0	0	1 (1.4)	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Xerosis	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	17 (23.0)	6 (8.1)	6 (8.1)	3 (4.1)	2 (2.7)
Hepatic function abnormal	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Hyperbilirubinaemia	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Hepatomegaly	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Cholelithiasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gallbladder enlargement	2 (2.7)	2 (2.7)	0	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Cholestasis	1 (1.4)	0	0	0	1 (1.4)
Hepatic cytolysis	1 (1.4)	1 (1.4)	0	0	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	65 (87.8)	1 (1.4)	22 (29.7)	23 (31.1)	19 (25.7)
Cytokine release syndrome	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Hypogammaglobulinaemia	30 (40.5)	2 (2.7)	22 (29.7)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Immunodeficiency	4 (5.4)	0	0	4 (5.4)	0
Seasonal allergy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Allergy to immunoglobulin therapy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Chronic graft versus host disease	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	2 (2.7)	0	0	2 (2.7)	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	55 (74.3)	8 (10.8)	11 (14.9)	22 (29.7)	14 (18.9)
Upper respiratory tract infection	9 (12.2)	4 (5.4)	3 (4.1)	2 (2.7)	0
Conjunctivitis	8 (10.8)	2 (2.7)	6 (8.1)	0	0
Rhinovirus infection	8 (10.8)	0	6 (8.1)	2 (2.7)	0
Gastroenteritis	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Pneumonia	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Sinusitis	6 (8.1)	0	4 (5.4)	2 (2.7)	0
Parainfluenzae virus infection	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Staphylococcal bacteraemia	5 (6.8)	0	0	5 (6.8)	0
Candida infection	4 (5.4)	0	3 (4.1)	0	1 (1.4)
Clostridium difficile infection	4 (5.4)	1 (1.4)	0	3 (4.1)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Staphylococcal infection	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Bacteraemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Herpes zoster	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Influenza	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Nail infection	3 (4.1)	3 (4.1)	0	0	0
Oral candidiasis	3 (4.1)	0	3 (4.1)	0	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Respiratory syncytial virus infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory tract infection	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rhinitis	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Sepsis	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Urinary tract infection	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Acute sinusitis	2 (2.7)	0	2 (2.7)	0	0
Adenovirus infection	2 (2.7)	0	0	2 (2.7)	0
Bk virus infection	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Bronchopulmonary aspergillosis	2 (2.7)	0	0	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Ear infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Encephalitis	2 (2.7)	0	0	0	2 (2.7)
Encephalitis viral	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Fungal infection	2 (2.7)	0	2 (2.7)	0	0
Gingivitis	2 (2.7)	2 (2.7)	0	0	0
Herpes simplex	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.7)	0	0	2 (2.7)	0
Metapneumovirus infection	2 (2.7)	0	0	2 (2.7)	0
Oral infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Paronychia	2 (2.7)	0	2 (2.7)	0	0
Pneumocystis jirovecii pneumonia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Septic shock	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Varicella zoster virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	0	0	1 (1.4)
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	0	1 (1.4)	0
Device related infection	1 (1.4)	0	0	1 (1.4)	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	1 (1.4)	0	0
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (24.3)	8 (10.8)	7 (9.5)	1 (1.4)	2 (2.7)
Infusion related reaction	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Fall	2 (2.7)	0	2 (2.7)	0	0
Ligament sprain	2 (2.7)	2 (2.7)	0	0	0
Procedural pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Scratch	1 (1.4)	1 (1.4)	0	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Skin injury	1 (1.4)	0	1 (1.4)	0	0
Skin wound	1 (1.4)	1 (1.4)	0	0	0
Transfusion reaction	1 (1.4)	1 (1.4)	0	0	0
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Vasoplegia syndrome	1 (1.4)	0	0	0	1 (1.4)
Wound	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	54 (73.0)	3 (4.1)	9 (12.2)	18 (24.3)	24 (32.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	21 (28.4)	1 (1.4)	2 (2.7)	3 (4.1)	15 (20.3)
Platelet count decreased	21 (28.4)	6 (8.1)	2 (2.7)	6 (8.1)	7 (9.5)
White blood cell count decreased	21 (28.4)	3 (4.1)	3 (4.1)	2 (2.7)	13 (17.6)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	8 (10.8)	2 (2.7)
Alanine aminotransferase increased	16 (21.6)	3 (4.1)	7 (9.5)	6 (8.1)	0
Lymphocyte count decreased	15 (20.3)	1 (1.4)	1 (1.4)	8 (10.8)	5 (6.8)
Blood bilirubin increased	12 (16.2)	1 (1.4)	3 (4.1)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	6 (8.1)	2 (2.7)	0	0
Blood fibrinogen decreased	6 (8.1)	2 (2.7)	2 (2.7)	1 (1.4)	1 (1.4)
Blood immunoglobulin a decreased	6 (8.1)	5 (6.8)	0	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.1)	4 (5.4)	1 (1.4)	1 (1.4)	0
Serum ferritin increased	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	5 (6.8)	1 (1.4)	2 (2.7)	1 (1.4)	1 (1.4)
Blood lactate dehydrogenase increased	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Blood creatinine increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin g decreased	3 (4.1)	0	3 (4.1)	0	0
Blood uric acid increased	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Fibrin d dimer increased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Weight increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gamma-glutamyltransferase increased	2 (2.7)	0	0	2 (2.7)	0
Immunoglobulins decreased	2 (2.7)	0	2 (2.7)	0	0
Lipase increased	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Oxygen saturation decreased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Weight decreased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Amylase increased	1 (1.4)	1 (1.4)	0	0	0
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	0	1 (1.4)
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
Blood testosterone decreased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Electrocardiogram t wave abnormal	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Troponin increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	46 (62.2)	9 (12.2)	8 (10.8)	19 (25.7)	10 (13.5)
Decreased appetite	28 (37.8)	11 (14.9)	7 (9.5)	8 (10.8)	2 (2.7)
Hypokalaemia	17 (23.0)	1 (1.4)	6 (8.1)	8 (10.8)	2 (2.7)
Hypophosphataemia	15 (20.3)	2 (2.7)	4 (5.4)	8 (10.8)	1 (1.4)
Hypocalcaemia	12 (16.2)	1 (1.4)	6 (8.1)	5 (6.8)	0
Hyperuricaemia	9 (12.2)	7 (9.5)	1 (1.4)	1 (1.4)	0
Hypoalbuminaemia	9 (12.2)	0	8 (10.8)	1 (1.4)	0
Hyperglycaemia	8 (10.8)	0	4 (5.4)	4 (5.4)	0
Hypervolaemia	6 (8.1)	0	1 (1.4)	5 (6.8)	0
Hypomagnesaemia	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Tumour lysis syndrome	4 (5.4)	0	0	3 (4.1)	1 (1.4)
Hypernatraemia	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Hyperphosphataemia	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Hypertriglyceridaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Metabolic acidosis	3 (4.1)	1 (1.4)	0	0	2 (2.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Hypercalcaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyperkalaemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Iron overload	2 (2.7)	0	2 (2.7)	0	0
Malnutrition	2 (2.7)	0	0	2 (2.7)	0
Calcium deficiency	1 (1.4)	1 (1.4)	0	0	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Haemosiderosis	1 (1.4)	0	1 (1.4)	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypercholesterolaemia	1 (1.4)	0	1 (1.4)	0	0
Hyperlactacidaemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	41 (55.4)	14 (18.9)	19 (25.7)	7 (9.5)	1 (1.4)
Pain in extremity	16 (21.6)	7 (9.5)	8 (10.8)	1 (1.4)	0
Arthralgia	12 (16.2)	5 (6.8)	6 (8.1)	1 (1.4)	0
Back pain	10 (13.5)	2 (2.7)	5 (6.8)	3 (4.1)	0
Myalgia	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Bone pain	3 (4.1)	0	3 (4.1)	0	0
Growth retardation	2 (2.7)	0	2 (2.7)	0	0
Muscular weakness	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Musculoskeletal chest pain	2 (2.7)	2 (2.7)	0	0	0
Neck pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pain in jaw	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Haemarthrosis	1 (1.4)	0	0	1 (1.4)	0
Joint effusion	1 (1.4)	0	1 (1.4)	0	0
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myositis	1 (1.4)	0	1 (1.4)	0	0
Osteonecrosis	1 (1.4)	1 (1.4)	0	0	0
Osteopenia	1 (1.4)	1 (1.4)	0	0	0
Rhabdomyolysis	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Skin papilloma	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Bone giant cell tumour benign	1 (1.4)	0	0	1 (1.4)	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	45 (60.8)	15 (20.3)	18 (24.3)	9 (12.2)	3 (4.1)
Headache	26 (35.1)	13 (17.6)	10 (13.5)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	5 (6.8)	0	0	0
Dizziness	4 (5.4)	4 (5.4)	0	0	0
Seizure	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Somnolence	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cognitive disorder	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Dysgeusia	3 (4.1)	2 (2.7)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Monoparesis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorder	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	37 (50.0)	12 (16.2)	19 (25.7)	6 (8.1)	0
Anxiety	14 (18.9)	3 (4.1)	9 (12.2)	2 (2.7)	0
Delirium	7 (9.5)	2 (2.7)	2 (2.7)	3 (4.1)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Agitation	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Mental status changes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Hallucination	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Insomnia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Sleep disorder	3 (4.1)	0	3 (4.1)	0	0
Irritability	2 (2.7)	2 (2.7)	0	0	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Tic	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	22 (29.7)	6 (8.1)	7 (9.5)	4 (5.4)	5 (6.8)
Acute kidney injury	9 (12.2)	2 (2.7)	2 (2.7)	2 (2.7)	3 (4.1)
Dysuria	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Haematuria	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Pollakiuria	2 (2.7)	0	2 (2.7)	0	0
Renal failure	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Urinary retention	2 (2.7)	0	2 (2.7)	0	0
Anuria	1 (1.4)	0	0	0	1 (1.4)
Bladder dilatation	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	0	1 (1.4)
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	5 (6.8)	2 (2.7)	1 (1.4)	2 (2.7)	0
Endometriosis	1 (1.4)	0	0	1 (1.4)	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0
Heavy menstrual bleeding	1 (1.4)	1 (1.4)	0	0	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Vaginal ulceration	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	49 (66.2)	17 (23.0)	7 (9.5)	10 (13.5)	15 (20.3)
Cough	20 (27.0)	16 (21.6)	4 (5.4)	0	0
Hypoxia	16 (21.6)	0	4 (5.4)	8 (10.8)	4 (5.4)
Pulmonary oedema	10 (13.5)	2 (2.7)	1 (1.4)	6 (8.1)	1 (1.4)
Oropharyngeal pain	8 (10.8)	7 (9.5)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	8 (10.8)	3 (4.1)	1 (1.4)	3 (4.1)	1 (1.4)
Nasal congestion	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Dyspnoea	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Pleural effusion	6 (8.1)	2 (2.7)	2 (2.7)	1 (1.4)	1 (1.4)
Respiratory failure	6 (8.1)	0	0	0	6 (8.1)
Epistaxis	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Rhinorrhoea	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	3 (4.1)	0	0	0	3 (4.1)
Atelectasis	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Respiratory distress	3 (4.1)	0	1 (1.4)	0	2 (2.7)
Pharyngeal erythema	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Acute respiratory failure	1 (1.4)	0	0	1 (1.4)	0
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Bronchospasm	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea exertional	1 (1.4)	1 (1.4)	0	0	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	0	0	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal dryness	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory acidosis	1 (1.4)	0	0	1 (1.4)	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Rhinitis allergic	1 (1.4)	1 (1.4)	0	0	0
Sleep apnoea syndrome	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	35 (47.3)	15 (20.3)	13 (17.6)	7 (9.5)	0
Dry skin	8 (10.8)	6 (8.1)	2 (2.7)	0	0
Pruritus	7 (9.5)	2 (2.7)	5 (6.8)	0	0
Rash	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Erythema	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Dermatitis atopic	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Hyperhidrosis	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rash papular	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Decubitus ulcer	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Eczema	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Ingrowing nail	2 (2.7)	0	2 (2.7)	0	0
Rash maculo-papular	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blister	1 (1.4)	1 (1.4)	0	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=74		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.4)	1 (1.4)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	0	1 (1.4)	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash macular	1 (1.4)	0	0	1 (1.4)	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin necrosis	1 (1.4)	0	0	1 (1.4)	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	30 (40.5)	4 (5.4)	8 (10.8)	11 (14.9)	7 (9.5)
Hypotension	21 (28.4)	2 (2.7)	6 (8.1)	7 (9.5)	6 (8.1)
Hypertension	13 (17.6)	2 (2.7)	6 (8.1)	5 (6.8)	0
Capillary leak syndrome	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Venoocclusive disease	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (97.5)	2 (5.0)	1 (2.5)	11 (27.5)	25 (62.5)
Blood and lymphatic system disorders					
-Total	27 (67.5)	2 (5.0)	4 (10.0)	12 (30.0)	9 (22.5)
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Anaemia	10 (25.0)	1 (2.5)	3 (7.5)	6 (15.0)	0
Neutropenia	7 (17.5)	0	1 (2.5)	1 (2.5)	5 (12.5)
Thrombocytopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Disseminated intravascular coagulation	4 (10.0)	0	4 (10.0)	0	0
Coagulopathy	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Leukopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pancytopenia	2 (5.0)	0	0	2 (5.0)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Eosinophilia	1 (2.5)	0	1 (2.5)	0	0
Hypofibrinogenaemia	1 (2.5)	0	1 (2.5)	0	0
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Splenomegaly	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	7 (17.5)	4 (10.0)	2 (5.0)	1 (2.5)	0
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Cardiac dysfunction	2 (5.0)	2 (5.0)	0	0	0
Sinus tachycardia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cardiac failure congestive	1 (2.5)	0	1 (2.5)	0	0
Left ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Mitral valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Pericardial effusion	1 (2.5)	1 (2.5)	0	0	0
Right ventricular dysfunction	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	2 (5.0)	0	2 (5.0)	0	0
Adrenal insufficiency	1 (2.5)	0	1 (2.5)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Eye oedema	1 (2.5)	1 (2.5)	0	0	0
Periorbital swelling	1 (2.5)	0	1 (2.5)	0	0
Retinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Visual field defect	1 (2.5)	0	1 (2.5)	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	24 (60.0)	9 (22.5)	9 (22.5)	6 (15.0)	0
Vomiting	10 (25.0)	5 (12.5)	5 (12.5)	0	0
Diarrhoea	9 (22.5)	3 (7.5)	6 (15.0)	0	0
Nausea	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Abdominal pain	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Constipation	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Abdominal distension	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Ascites	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Mouth haemorrhage	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Pancreatitis	2 (5.0)	0	2 (5.0)	0	0
Stomatitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	1 (2.5)	1 (2.5)	0	0	0
Enterocolitis	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Gastrooesophageal reflux disease	1 (2.5)	0	1 (2.5)	0	0
Gingival bleeding	1 (2.5)	0	1 (2.5)	0	0
Gingivitis ulcerative	1 (2.5)	0	0	1 (2.5)	0
Lip dry	1 (2.5)	0	1 (2.5)	0	0
Mouth swelling	1 (2.5)	1 (2.5)	0	0	0
Odynophagia	1 (2.5)	1 (2.5)	0	0	0
Proctalgia	1 (2.5)	0	0	1 (2.5)	0
Upper gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	17 (42.5)	9 (22.5)	3 (7.5)	4 (10.0)	1 (2.5)
Pyrexia	10 (25.0)	4 (10.0)	2 (5.0)	3 (7.5)	1 (2.5)
Chills	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Asthenia	2 (5.0)	2 (5.0)	0	0	0
Fatigue	2 (5.0)	2 (5.0)	0	0	0
Generalised oedema	2 (5.0)	0	2 (5.0)	0	0
Influenza like illness	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Catheter site pain	1 (2.5)	0	0	1 (2.5)	0
Chest discomfort	1 (2.5)	0	0	1 (2.5)	0
Crying	1 (2.5)	0	1 (2.5)	0	0
Facial pain	1 (2.5)	0	1 (2.5)	0	0
Localised oedema	1 (2.5)	1 (2.5)	0	0	0
Malaise	1 (2.5)	0	1 (2.5)	0	0
Pain	1 (2.5)	0	0	1 (2.5)	0
Sluggishness	1 (2.5)	0	1 (2.5)	0	0
Swelling face	1 (2.5)	1 (2.5)	0	0	0
Vascular device occlusion	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	8 (20.0)	2 (5.0)	3 (7.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hyperbilirubinaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholelithiasis	1 (2.5)	0	1 (2.5)	0	0
Hepatomegaly	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	34 (85.0)	2 (5.0)	8 (20.0)	14 (35.0)	10 (25.0)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	14 (35.0)	1 (2.5)	7 (17.5)	6 (15.0)	0
Immunodeficiency	3 (7.5)	0	0	3 (7.5)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	1 (2.5)	0	0	0
Hypersensitivity	1 (2.5)	1 (2.5)	0	0	0
Seasonal allergy	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	21 (52.5)	3 (7.5)	5 (12.5)	11 (27.5)	2 (5.0)
Conjunctivitis	3 (7.5)	0	3 (7.5)	0	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Candida infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	1 (2.5)	0	0	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Granulicatella infection	1 (2.5)	0	0	1 (2.5)	0
Herpes simplex	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Myringitis	1 (2.5)	1 (2.5)	0	0	0
Nail infection	1 (2.5)	1 (2.5)	0	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Paronychia	1 (2.5)	0	1 (2.5)	0	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Stomatococcal infection	1 (2.5)	0	1 (2.5)	0	0
Systemic candida	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	4 (10.0)	1 (2.5)	2 (5.0)	0	1 (2.5)
Infusion related reaction	2 (5.0)	0	2 (5.0)	0	0
Fall	1 (2.5)	0	1 (2.5)	0	0
Procedural pain	1 (2.5)	1 (2.5)	0	0	0
Transplant failure	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	26 (65.0)	3 (7.5)	2 (5.0)	6 (15.0)	15 (37.5)
White blood cell count decreased	12 (30.0)	2 (5.0)	0	1 (2.5)	9 (22.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	11 (27.5)	0	1 (2.5)	1 (2.5)	9 (22.5)
Platelet count decreased	11 (27.5)	2 (5.0)	1 (2.5)	4 (10.0)	4 (10.0)
Lymphocyte count decreased	7 (17.5)	1 (2.5)	0	3 (7.5)	3 (7.5)
Alanine aminotransferase increased	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Aspartate aminotransferase increased	5 (12.5)	1 (2.5)	1 (2.5)	2 (5.0)	1 (2.5)
Serum ferritin increased	5 (12.5)	1 (2.5)	4 (10.0)	0	0
Blood bilirubin increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)	0	0
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0	0	0
C-reactive protein increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Gamma-glutamyltransferase increased	2 (5.0)	0	0	2 (5.0)	0
Weight increased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Blood alkaline phosphatase increased	1 (2.5)	1 (2.5)	0	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood glucose increased	1 (2.5)	0	0	0	1 (2.5)
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0	0	0
Breath sounds abnormal	1 (2.5)	0	1 (2.5)	0	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0	0	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0	0	0
Prothrombin time prolonged	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	18 (45.0)	3 (7.5)	4 (10.0)	10 (25.0)	1 (2.5)
Decreased appetite	9 (22.5)	4 (10.0)	2 (5.0)	2 (5.0)	1 (2.5)
Hypokalaemia	8 (20.0)	2 (5.0)	1 (2.5)	5 (12.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hypophosphataemia	6 (15.0)	1 (2.5)	2 (5.0)	3 (7.5)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypocalcaemia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	2 (5.0)	2 (5.0)	0	0	0
Hyponatraemia	2 (5.0)	2 (5.0)	0	0	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Acidosis	1 (2.5)	0	0	1 (2.5)	0
Hypernatraemia	1 (2.5)	1 (2.5)	0	0	0
Hyperuricaemia	1 (2.5)	0	0	1 (2.5)	0
Hypervolaemia	1 (2.5)	0	1 (2.5)	0	0
Polydipsia	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	16 (40.0)	8 (20.0)	6 (15.0)	2 (5.0)	0
Arthralgia	6 (15.0)	4 (10.0)	2 (5.0)	0	0
Pain in extremity	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Back pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Pain in jaw	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Bone pain	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal chest pain	1 (2.5)	1 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	18 (45.0)	7 (17.5)	8 (20.0)	3 (7.5)	0
Headache	10 (25.0)	7 (17.5)	2 (5.0)	1 (2.5)	0
Dysgeusia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Somnolence	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Tremor	3 (7.5)	3 (7.5)	0	0	0
Dizziness	2 (5.0)	2 (5.0)	0	0	0
Lethargy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Seizure	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Amnesia	1 (2.5)	0	1 (2.5)	0	0
Aphasia	1 (2.5)	1 (2.5)	0	0	0
Depressed level of consciousness	1 (2.5)	0	0	1 (2.5)	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Hyperaesthesia	1 (2.5)	1 (2.5)	0	0	0
Hypoaesthesia	1 (2.5)	1 (2.5)	0	0	0
Psychiatric disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (20.0)	1 (2.5)	6 (15.0)	1 (2.5)	0
Hallucination	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Affect lability	1 (2.5)	0	1 (2.5)	0	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Anxiety	1 (2.5)	0	0	1 (2.5)	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Hallucination, visual	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Restlessness	1 (2.5)	0	1 (2.5)	0	0
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Social avoidant behaviour	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	10 (25.0)	2 (5.0)	4 (10.0)	1 (2.5)	3 (7.5)
Acute kidney injury	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Haematuria	2 (5.0)	2 (5.0)	0	0	0
Anuria	1 (2.5)	0	0	0	1 (2.5)
Dysuria	1 (2.5)	1 (2.5)	0	0	0
Incontinence	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Proteinuria	1 (2.5)	1 (2.5)	0	0	0
Renal failure	1 (2.5)	0	1 (2.5)	0	0
Urinary incontinence	1 (2.5)	0	1 (2.5)	0	0
Urinary tract disorder	1 (2.5)	0	1 (2.5)	0	0
Reproductive system and breast disorders					
-Total	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Female genital tract fistula	1 (2.5)	1 (2.5)	0	0	0
Heavy menstrual bleeding	1 (2.5)	1 (2.5)	0	0	0
Vaginal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (45.0)	7 (17.5)	1 (2.5)	7 (17.5)	3 (7.5)
Hypoxia	7 (17.5)	0	2 (5.0)	2 (5.0)	3 (7.5)
Cough	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Pulmonary oedema	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Epistaxis	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Oropharyngeal pain	3 (7.5)	3 (7.5)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Dyspnoea	2 (5.0)	0	0	2 (5.0)	0
Pleural effusion	2 (5.0)	2 (5.0)	0	0	0
Acute respiratory failure	1 (2.5)	0	0	1 (2.5)	0
Atelectasis	1 (2.5)	0	1 (2.5)	0	0
Lung infiltration	1 (2.5)	0	0	1 (2.5)	0
Nasal congestion	1 (2.5)	1 (2.5)	0	0	0
Oropharyngeal plaque	1 (2.5)	0	1 (2.5)	0	0
Painful respiration	1 (2.5)	1 (2.5)	0	0	0
Paranasal sinus discomfort	1 (2.5)	0	1 (2.5)	0	0
Pharyngeal erythema	1 (2.5)	0	1 (2.5)	0	0
Pharyngeal exudate	1 (2.5)	0	1 (2.5)	0	0
Pharyngeal oedema	1 (2.5)	0	1 (2.5)	0	0
Pulmonary mass	1 (2.5)	0	1 (2.5)	0	0
Respiratory disorder	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (30.0)	6 (15.0)	5 (12.5)	1 (2.5)	0
Dermatitis atopic	2 (5.0)	2 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperhidrosis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rash maculo-papular	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Erythema	1 (2.5)	1 (2.5)	0	0	0
Erythema nodosum	1 (2.5)	1 (2.5)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.5)	1 (2.5)	0	0	0
Purpura	1 (2.5)	1 (2.5)	0	0	0
Rash	1 (2.5)	0	1 (2.5)	0	0
Rash papular	1 (2.5)	0	1 (2.5)	0	0
Rash vesicular	1 (2.5)	1 (2.5)	0	0	0
Skin lesion	1 (2.5)	0	1 (2.5)	0	0
Skin ulcer	1 (2.5)	0	1 (2.5)	0	0
Social circumstances					
-Total	1 (2.5)	0	1 (2.5)	0	0
Patient uncooperative	1 (2.5)	0	1 (2.5)	0	0
Vascular disorders					
-Total	9 (22.5)	3 (7.5)	3 (7.5)	3 (7.5)	0
Hypertension	5 (12.5)	3 (7.5)	2 (5.0)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Flushing	1 (2.5)	1 (2.5)	0	0	0
Hot flush	1 (2.5)	1 (2.5)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	2 (5.0)	7 (17.5)	10 (25.0)	21 (52.5)
Blood and lymphatic system disorders					
-Total	23 (57.5)	1 (2.5)	4 (10.0)	14 (35.0)	4 (10.0)
Febrile neutropenia	15 (37.5)	0	0	14 (35.0)	1 (2.5)
Anaemia	11 (27.5)	4 (10.0)	5 (12.5)	2 (5.0)	0
Disseminated intravascular coagulation	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Splenomegaly	3 (7.5)	3 (7.5)	0	0	0
Thrombocytopenia	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Coagulopathy	2 (5.0)	0	2 (5.0)	0	0
Neutropenia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Leukopenia	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	17 (42.5)	6 (15.0)	4 (10.0)	4 (10.0)	3 (7.5)
Tachycardia	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)
Bradycardia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Left ventricular dysfunction	2 (5.0)	0	0	2 (5.0)	0
Atrioventricular block first degree	1 (2.5)	0	1 (2.5)	0	0
Cardiac arrest	1 (2.5)	0	0	0	1 (2.5)
Cardiac failure	1 (2.5)	0	0	0	1 (2.5)
Sinus bradycardia	1 (2.5)	0	0	1 (2.5)	0
Sinus tachycardia	1 (2.5)	1 (2.5)	0	0	0
Ear and labyrinth disorders					
-Total	2 (5.0)	2 (5.0)	0	0	0
Ear pain	1 (2.5)	1 (2.5)	0	0	0
Ear pruritus	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	3 (7.5)	0	3 (7.5)	0	0
Adrenal insufficiency	3 (7.5)	0	3 (7.5)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Conjunctival haemorrhage	2 (5.0)	2 (5.0)	0	0	0
Eyelid oedema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Ocular hyperaemia	2 (5.0)	2 (5.0)	0	0	0
Eye pain	1 (2.5)	1 (2.5)	0	0	0
Periorbital oedema	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	27 (67.5)	10 (25.0)	9 (22.5)	7 (17.5)	1 (2.5)
Vomiting	11 (27.5)	7 (17.5)	3 (7.5)	1 (2.5)	0
Nausea	10 (25.0)	6 (15.0)	4 (10.0)	0	0
Constipation	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Diarrhoea	6 (15.0)	5 (12.5)	0	1 (2.5)	0
Abdominal pain	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Abdominal pain upper	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Mouth haemorrhage	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pancreatitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal compartment syndrome	1 (2.5)	0	0	0	1 (2.5)
Abdominal distension	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (2.5)	0	1 (2.5)	0	0
Anal haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Ascites	1 (2.5)	1 (2.5)	0	0	0
Dry mouth	1 (2.5)	0	1 (2.5)	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Haematemesis	1 (2.5)	1 (2.5)	0	0	0
Ileus	1 (2.5)	0	1 (2.5)	0	0
Lip oedema	1 (2.5)	1 (2.5)	0	0	0
Melaena	1 (2.5)	0	0	1 (2.5)	0
Neutropenic colitis	1 (2.5)	0	0	1 (2.5)	0
Trichoglossia	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	23 (57.5)	11 (27.5)	6 (15.0)	3 (7.5)	3 (7.5)
Pyrexia	14 (35.0)	7 (17.5)	3 (7.5)	3 (7.5)	1 (2.5)
Fatigue	9 (22.5)	7 (17.5)	2 (5.0)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Generalised oedema	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Oedema peripheral	3 (7.5)	3 (7.5)	0	0	0
Drug withdrawal syndrome	2 (5.0)	0	2 (5.0)	0	0
Multiple organ dysfunction syndrome	2 (5.0)	0	0	0	2 (5.0)
Catheter site erythema	1 (2.5)	1 (2.5)	0	0	0
Catheter site haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Catheter site pain	1 (2.5)	1 (2.5)	0	0	0
Chills	1 (2.5)	1 (2.5)	0	0	0
Localised oedema	1 (2.5)	1 (2.5)	0	0	0
Oedema due to hepatic disease	1 (2.5)	0	1 (2.5)	0	0
Systemic inflammatory response syndrome	1 (2.5)	0	0	1 (2.5)	0
Hepatobiliary disorders					
-Total	9 (22.5)	3 (7.5)	3 (7.5)	1 (2.5)	2 (5.0)
Hyperbilirubinaemia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Gallbladder enlargement	2 (5.0)	2 (5.0)	0	0	0
Hepatomegaly	2 (5.0)	1 (2.5)	0	0	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Biliary tract disorder	1 (2.5)	1 (2.5)	0	0	0
Cholelithiasis	1 (2.5)	1 (2.5)	0	0	0
Cholestasis	1 (2.5)	0	0	0	1 (2.5)
Hepatic function abnormal	1 (2.5)	0	1 (2.5)	0	0
Ocular icterus	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	33 (82.5)	1 (2.5)	13 (32.5)	8 (20.0)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Hypogammaglobulinaemia	9 (22.5)	1 (2.5)	7 (17.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	14 (35.0)	3 (7.5)	5 (12.5)	5 (12.5)	1 (2.5)
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Staphylococcal bacteraemia	3 (7.5)	0	0	3 (7.5)	0
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (5.0)	0	2 (5.0)	0	0
Staphylococcal infection	2 (5.0)	0	2 (5.0)	0	0
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Candida infection	1 (2.5)	0	1 (2.5)	0	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Localised infection	1 (2.5)	1 (2.5)	0	0	0
Nail infection	1 (2.5)	1 (2.5)	0	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Injury, poisoning and procedural complications					
-Total	7 (17.5)	2 (5.0)	4 (10.0)	0	1 (2.5)
Transfusion reaction	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Wound	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Contusion	1 (2.5)	1 (2.5)	0	0	0
Fall	1 (2.5)	0	1 (2.5)	0	0
Procedural pain	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scratch	1 (2.5)	1 (2.5)	0	0	0
Skin abrasion	1 (2.5)	1 (2.5)	0	0	0
Skin injury	1 (2.5)	0	1 (2.5)	0	0
Skin wound	1 (2.5)	1 (2.5)	0	0	0
Vasoplegia syndrome	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	31 (77.5)	1 (2.5)	6 (15.0)	11 (27.5)	13 (32.5)
Aspartate aminotransferase increased	14 (35.0)	1 (2.5)	5 (12.5)	6 (15.0)	2 (5.0)
Alanine aminotransferase increased	12 (30.0)	2 (5.0)	7 (17.5)	3 (7.5)	0
White blood cell count decreased	12 (30.0)	1 (2.5)	3 (7.5)	1 (2.5)	7 (17.5)
Blood bilirubin increased	10 (25.0)	1 (2.5)	1 (2.5)	8 (20.0)	0
Platelet count decreased	10 (25.0)	2 (5.0)	2 (5.0)	2 (5.0)	4 (10.0)
Neutrophil count decreased	9 (22.5)	0	2 (5.0)	1 (2.5)	6 (15.0)
International normalised ratio increased	8 (20.0)	5 (12.5)	3 (7.5)	0	0
Lymphocyte count decreased	8 (20.0)	1 (2.5)	0	5 (12.5)	2 (5.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood fibrinogen decreased	5 (12.5)	2 (5.0)	1 (2.5)	1 (2.5)	1 (2.5)
Electrocardiogram qt prolonged	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Blood immunoglobulin a decreased	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Blood creatinine increased	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Serum ferritin increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Blood immunoglobulin g decreased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Blood lactate dehydrogenase increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Blood uric acid increased	2 (5.0)	2 (5.0)	0	0	0
C-reactive protein increased	2 (5.0)	0	0	2 (5.0)	0
Fibrin d dimer increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Lipase increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Urine output decreased	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Weight increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amylase increased	1 (2.5)	1 (2.5)	0	0	0
Bacterial test positive	1 (2.5)	0	0	1 (2.5)	0
Blood bicarbonate decreased	1 (2.5)	0	1 (2.5)	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	0	1 (2.5)
Blood phosphorus increased	1 (2.5)	0	1 (2.5)	0	0
Blood testosterone decreased	1 (2.5)	1 (2.5)	0	0	0
Cardiac murmur	1 (2.5)	1 (2.5)	0	0	0
Coagulation test abnormal	1 (2.5)	1 (2.5)	0	0	0
Electrocardiogram t wave abnormal	1 (2.5)	0	1 (2.5)	0	0
Enterovirus test positive	1 (2.5)	0	1 (2.5)	0	0
Haptoglobin decreased	1 (2.5)	1 (2.5)	0	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Oxygen saturation decreased	1 (2.5)	1 (2.5)	0	0	0
Staphylococcus test positive	1 (2.5)	1 (2.5)	0	0	0
Troponin increased	1 (2.5)	0	0	1 (2.5)	0
Weight decreased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	28 (70.0)	5 (12.5)	5 (12.5)	11 (27.5)	7 (17.5)
Decreased appetite	15 (37.5)	5 (12.5)	2 (5.0)	8 (20.0)	0
Hypocalcaemia	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Hypokalaemia	11 (27.5)	1 (2.5)	4 (10.0)	4 (10.0)	2 (5.0)
Hypophosphataemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Hyperuricaemia	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Hyperphosphataemia	5 (12.5)	4 (10.0)	0	0	1 (2.5)
Hypervolaemia	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Hypoalbuminaemia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypercalcaemia	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Metabolic acidosis	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Hyperkalaemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Hypertriglyceridaemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Acidosis	1 (2.5)	0	0	0	1 (2.5)
Calcium deficiency	1 (2.5)	1 (2.5)	0	0	0
Dehydration	1 (2.5)	0	1 (2.5)	0	0
Haemosiderosis	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (2.5)	1 (2.5)	0	0	0
Hyperlactacidaemia	1 (2.5)	1 (2.5)	0	0	0
Hypernatraemia	1 (2.5)	0	0	0	1 (2.5)
Hypoglycaemia	1 (2.5)	0	1 (2.5)	0	0
Hypomagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Hyponatraemia	1 (2.5)	1 (2.5)	0	0	0
Malnutrition	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	17 (42.5)	7 (17.5)	7 (17.5)	2 (5.0)	1 (2.5)
Pain in extremity	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Arthralgia	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Myalgia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Back pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Bone pain	1 (2.5)	0	1 (2.5)	0	0
Haemarthrosis	1 (2.5)	0	0	1 (2.5)	0
Muscle rigidity	1 (2.5)	1 (2.5)	0	0	0
Muscle spasms	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (2.5)	0	1 (2.5)	0	0
Rhabdomyolysis	1 (2.5)	0	0	0	1 (2.5)
Nervous system disorders					
-Total	22 (55.0)	7 (17.5)	8 (20.0)	5 (12.5)	2 (5.0)
Headache	13 (32.5)	5 (12.5)	7 (17.5)	1 (2.5)	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Somnolence	2 (5.0)	0	0	2 (5.0)	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Monoparesis	1 (2.5)	0	1 (2.5)	0	0
Neuralgia	1 (2.5)	0	1 (2.5)	0	0
Neurological decompensation	1 (2.5)	0	0	0	1 (2.5)
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	20 (50.0)	11 (27.5)	4 (10.0)	5 (12.5)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Anxiety	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Insomnia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Mental status changes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Irritability	2 (5.0)	2 (5.0)	0	0	0
Automatism	1 (2.5)	1 (2.5)	0	0	0
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	10 (25.0)	3 (7.5)	2 (5.0)	2 (5.0)	3 (7.5)
Acute kidney injury	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Dysuria	2 (5.0)	2 (5.0)	0	0	0
Urinary retention	2 (5.0)	0	2 (5.0)	0	0
Anuria	1 (2.5)	1 (2.5)	0	0	0
Azotaemia	1 (2.5)	0	1 (2.5)	0	0
Bladder dilatation	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Micturition urgency	1 (2.5)	0	1 (2.5)	0	0
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Renal failure	1 (2.5)	0	0	0	1 (2.5)
Renal tubular dysfunction	1 (2.5)	1 (2.5)	0	0	0
Renal tubular necrosis	1 (2.5)	0	0	0	1 (2.5)
Reproductive system and breast disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Perineal rash	1 (2.5)	0	1 (2.5)	0	0
Vaginal ulceration	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	23 (57.5)	7 (17.5)	3 (7.5)	4 (10.0)	9 (22.5)
Hypoxia	10 (25.0)	0	3 (7.5)	4 (10.0)	3 (7.5)
Pulmonary oedema	7 (17.5)	1 (2.5)	3 (7.5)	2 (5.0)	1 (2.5)
Cough	5 (12.5)	5 (12.5)	0	0	0
Pleural effusion	5 (12.5)	2 (5.0)	0	2 (5.0)	1 (2.5)
Tachypnoea	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Respiratory failure	4 (10.0)	0	0	0	4 (10.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Acute respiratory distress syndrome	2 (5.0)	0	0	0	2 (5.0)
Atelectasis	2 (5.0)	0	0	2 (5.0)	0
Nasal congestion	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oropharyngeal pain	2 (5.0)	2 (5.0)	0	0	0
Rhinorrhoea	2 (5.0)	2 (5.0)	0	0	0
Bradypnoea	1 (2.5)	0	0	1 (2.5)	0
Dyspnoea	1 (2.5)	0	0	0	1 (2.5)
Epistaxis	1 (2.5)	0	1 (2.5)	0	0
Haemoptysis	1 (2.5)	0	1 (2.5)	0	0
Nasal discomfort	1 (2.5)	0	1 (2.5)	0	0
Nasal dryness	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Productive cough	1 (2.5)	1 (2.5)	0	0	0
Respiratory acidosis	1 (2.5)	0	0	1 (2.5)	0
Wheezing	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (37.5)	7 (17.5)	6 (15.0)	2 (5.0)	0
Pruritus	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Rash	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Blister	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Erythema	3 (7.5)	3 (7.5)	0	0	0
Petechiae	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Rash papular	2 (5.0)	2 (5.0)	0	0	0
Decubitus ulcer	1 (2.5)	0	1 (2.5)	0	0
Dermatitis	1 (2.5)	1 (2.5)	0	0	0
Dermatitis diaper	1 (2.5)	0	1 (2.5)	0	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0
Eczema	1 (2.5)	1 (2.5)	0	0	0
Hyperhidrosis	1 (2.5)	0	1 (2.5)	0	0
Pruritus allergic	1 (2.5)	0	1 (2.5)	0	0
Rash pruritic	1 (2.5)	1 (2.5)	0	0	0
Scab	1 (2.5)	1 (2.5)	0	0	0
Skin discolouration	1 (2.5)	1 (2.5)	0	0	0
Skin necrosis	1 (2.5)	0	0	1 (2.5)	0
Skin ulcer	1 (2.5)	1 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urticaria	1 (2.5)	0	1 (2.5)	0	0
Vancomycin infusion reaction	1 (2.5)	0	0	1 (2.5)	0
Surgical and medical procedures					
-Total	1 (2.5)	0	0	1 (2.5)	0
Thrombolysis	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	19 (47.5)	1 (2.5)	4 (10.0)	8 (20.0)	6 (15.0)
Hypotension	16 (40.0)	1 (2.5)	4 (10.0)	5 (12.5)	6 (15.0)
Hypertension	8 (20.0)	1 (2.5)	3 (7.5)	4 (10.0)	0
Capillary leak syndrome	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Peripheral ischaemia	1 (2.5)	0	1 (2.5)	0	0
Thrombosis	1 (2.5)	0	1 (2.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	4 (10.0)	12 (30.0)	7 (17.5)	15 (37.5)
Blood and lymphatic system disorders					
-Total	11 (27.5)	2 (5.0)	2 (5.0)	3 (7.5)	4 (10.0)
Neutropenia	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Anaemia	3 (7.5)	3 (7.5)	0	0	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Disseminated intravascular coagulation	1 (2.5)	0	0	1 (2.5)	0
Eosinophilia	1 (2.5)	0	1 (2.5)	0	0
Febrile neutropenia	1 (2.5)	0	0	1 (2.5)	0
Lymphadenopathy	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					
-Total	4 (10.0)	1 (2.5)	1 (2.5)	0	2 (5.0)
Cardiac arrest	1 (2.5)	0	0	0	1 (2.5)
Cardiac failure	1 (2.5)	0	0	0	1 (2.5)
Left ventricular dysfunction	1 (2.5)	0	1 (2.5)	0	0
Tricuspid valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Eye disorders					
-Total	2 (5.0)	2 (5.0)	0	0	0
Cataract	2 (5.0)	2 (5.0)	0	0	0
Hypermetropia	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	10 (25.0)	8 (20.0)	2 (5.0)	0	0
Vomiting	3 (7.5)	3 (7.5)	0	0	0
Constipation	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Diarrhoea	2 (5.0)	2 (5.0)	0	0	0
Nausea	2 (5.0)	2 (5.0)	0	0	0
Abdominal pain upper	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (2.5)	0	1 (2.5)	0	0
Dyspepsia	1 (2.5)	1 (2.5)	0	0	0
Enteritis	1 (2.5)	0	1 (2.5)	0	0
Mouth haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Pancreatitis	1 (2.5)	1 (2.5)	0	0	0
Peritoneal haematoma	1 (2.5)	1 (2.5)	0	0	0
Stomatitis	1 (2.5)	1 (2.5)	0	0	0
Trichoglossia	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	10 (25.0)	7 (17.5)	2 (5.0)	1 (2.5)	0
Pyrexia	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Fatigue	2 (5.0)	2 (5.0)	0	0	0
Asthenia	1 (2.5)	1 (2.5)	0	0	0
Non-cardiac chest pain	1 (2.5)	1 (2.5)	0	0	0
Pain	1 (2.5)	0	0	1 (2.5)	0
Hepatobiliary disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Hepatic cytolysis	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Hypogammaglobulinaemia	2 (5.0)	0	2 (5.0)	0	0
Drug hypersensitivity	1 (2.5)	0	1 (2.5)	0	0
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Infections and infestations					
-Total	26 (65.0)	5 (12.5)	9 (22.5)	7 (17.5)	5 (12.5)
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Gastroenteritis	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Upper respiratory tract infection	5 (12.5)	2 (5.0)	2 (5.0)	1 (2.5)	0
Parainfluenzae virus infection	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Respiratory tract infection	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Otitis media	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pneumonia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Rhinitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rhinovirus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinusitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Bronchopulmonary aspergillosis	1 (2.5)	0	0	0	1 (2.5)
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Cystitis	1 (2.5)	0	1 (2.5)	0	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Ear, nose and throat infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Nail infection	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	1 (2.5)	0	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection viral	1 (2.5)	0	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal skin infection	1 (2.5)	0	1 (2.5)	0	0
Tinea pedis	1 (2.5)	1 (2.5)	0	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Infusion related reaction	1 (2.5)	0	1 (2.5)	0	0
Ligament sprain	1 (2.5)	1 (2.5)	0	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (32.5)	2 (5.0)	3 (7.5)	5 (12.5)	3 (7.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Neutrophil count decreased	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Alanine aminotransferase increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Platelet count decreased	2 (5.0)	2 (5.0)	0	0	0
Blood bilirubin increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin a decreased	1 (2.5)	0	0	1 (2.5)	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Bone density decreased	1 (2.5)	1 (2.5)	0	0	0
Hepatitis b virus test positive	1 (2.5)	0	1 (2.5)	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Lymphocyte count decreased	1 (2.5)	0	0	1 (2.5)	0
Weight decreased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	8 (20.0)	3 (7.5)	1 (2.5)	3 (7.5)	1 (2.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hyperuricaemia	2 (5.0)	2 (5.0)	0	0	0
Haemochromatosis	1 (2.5)	0	0	1 (2.5)	0
Hypokalaemia	1 (2.5)	0	0	1 (2.5)	0
Hypophagia	1 (2.5)	0	1 (2.5)	0	0
Hypophosphataemia	1 (2.5)	0	1 (2.5)	0	0
Iron overload	1 (2.5)	0	1 (2.5)	0	0
Malnutrition	1 (2.5)	0	0	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	0	0	1 (2.5)
Musculoskeletal and connective tissue disorders					
-Total	6 (15.0)	2 (5.0)	2 (5.0)	2 (5.0)	0
Back pain	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Arthralgia	2 (5.0)	2 (5.0)	0	0	0
Pain in extremity	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Bone pain	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal chest pain	1 (2.5)	1 (2.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Nervous system disorders					
-Total	5 (12.5)	3 (7.5)	1 (2.5)	0	1 (2.5)
Headache	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Autonomic neuropathy	1 (2.5)	0	0	1 (2.5)	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Seizure	1 (2.5)	0	0	1 (2.5)	0
Psychiatric disorders					
-Total	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Nightmare	1 (2.5)	1 (2.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Tearfulness	1 (2.5)	1 (2.5)	0	0	0
Renal and urinary disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Cystitis haemorrhagic	1 (2.5)	0	1 (2.5)	0	0
Renal tubular disorder	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (35.0)	7 (17.5)	4 (10.0)	2 (5.0)	1 (2.5)
Cough	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Nasal congestion	3 (7.5)	3 (7.5)	0	0	0
Hypoxia	2 (5.0)	0	0	2 (5.0)	0
Bronchial oedema	1 (2.5)	1 (2.5)	0	0	0
Bronchospasm	1 (2.5)	0	1 (2.5)	0	0
Epistaxis	1 (2.5)	0	1 (2.5)	0	0
Lung disorder	1 (2.5)	1 (2.5)	0	0	0
Oropharyngeal pain	1 (2.5)	1 (2.5)	0	0	0
Paranasal sinus inflammation	1 (2.5)	1 (2.5)	0	0	0
Pleural effusion	1 (2.5)	0	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Upper respiratory tract inflammation	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (27.5)	8 (20.0)	2 (5.0)	1 (2.5)	0
Dry skin	3 (7.5)	3 (7.5)	0	0	0
Decubitus ulcer	1 (2.5)	0	0	1 (2.5)	0
Dermatitis allergic	1 (2.5)	1 (2.5)	0	0	0
Dermatitis atopic	1 (2.5)	1 (2.5)	0	0	0
Erythema	1 (2.5)	0	1 (2.5)	0	0
Hangnail	1 (2.5)	1 (2.5)	0	0	0
Night sweats	1 (2.5)	1 (2.5)	0	0	0
Photosensitivity reaction	1 (2.5)	0	1 (2.5)	0	0
Rash	1 (2.5)	1 (2.5)	0	0	0
Skin hypopigmentation	1 (2.5)	1 (2.5)	0	0	0
Skin swelling	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	3 (7.5)	1 (2.5)	0	0	2 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Venoocclusive disease	1 (2.5)	0	0	0	1 (2.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (88.6)	5 (14.3)	12 (34.3)	8 (22.9)	6 (17.1)
Blood and lymphatic system disorders					
-Total	6 (17.1)	1 (2.9)	2 (5.7)	3 (8.6)	0
Anaemia	3 (8.6)	1 (2.9)	0	2 (5.7)	0
Febrile neutropenia	2 (5.7)	0	0	2 (5.7)	0
Leukocytosis	1 (2.9)	0	1 (2.9)	0	0
Leukopenia	1 (2.9)	0	1 (2.9)	0	0
Lymphocytosis	1 (2.9)	0	1 (2.9)	0	0
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
Cardiac disorders					
-Total	3 (8.6)	2 (5.7)	0	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (5.7)	2 (5.7)	0	0	0
Cardiac arrest	1 (2.9)	0	0	0	1 (2.9)
Cardiac failure	1 (2.9)	0	0	1 (2.9)	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Hypothyroidism	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	2 (5.7)	2 (5.7)	0	0	0
Ocular hyperaemia	1 (2.9)	1 (2.9)	0	0	0
Visual impairment	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	10 (28.6)	5 (14.3)	4 (11.4)	1 (2.9)	0
Diarrhoea	5 (14.3)	4 (11.4)	1 (2.9)	0	0
Nausea	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Vomiting	3 (8.6)	3 (8.6)	0	0	0
Abdominal pain	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Constipation	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal inflammation	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (2.9)	0	0	1 (2.9)	0
Proctalgia	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	14 (40.0)	8 (22.9)	4 (11.4)	2 (5.7)	0
Pyrexia	8 (22.9)	3 (8.6)	3 (8.6)	2 (5.7)	0
Fatigue	4 (11.4)	4 (11.4)	0	0	0
Chills	1 (2.9)	1 (2.9)	0	0	0
Malaise	1 (2.9)	1 (2.9)	0	0	0
Oedema peripheral	1 (2.9)	1 (2.9)	0	0	0
Pain	1 (2.9)	0	1 (2.9)	0	0
Hepatobiliary disorders					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hypertransaminasaemia	1 (2.9)	1 (2.9)	0	0	0
Liver disorder	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	11 (31.4)	1 (2.9)	8 (22.9)	2 (5.7)	0
Hypogammaglobulinaemia	8 (22.9)	0	8 (22.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Engraftment syndrome	1 (2.9)	0	0	1 (2.9)	0
Graft versus host disease	1 (2.9)	0	0	1 (2.9)	0
Infections and infestations					
-Total	13 (37.1)	0	5 (14.3)	5 (14.3)	3 (8.6)
Rhinovirus infection	3 (8.6)	0	3 (8.6)	0	0
Upper respiratory tract infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Metapneumovirus infection	2 (5.7)	0	0	2 (5.7)	0
Pneumocystis jirovecii pneumonia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Respiratory syncytial virus infection	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	1 (2.9)	0	0
Bk virus infection	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	1 (2.9)	0	0
Coronavirus infection	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Ear infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis clostridial	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis viral	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal infection	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	0	1 (2.9)	0	0
Influenza	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Parainfluenzae virus infection	1 (2.9)	0	1 (2.9)	0	0
Pharyngitis streptococcal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia	1 (2.9)	1 (2.9)	0	0	0
Salmonellosis	1 (2.9)	0	1 (2.9)	0	0
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Sinusitis	1 (2.9)	0	1 (2.9)	0	0
Sinusitis fungal	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Viral infection	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	7 (20.0)	4 (11.4)	3 (8.6)	0	0
Infusion related reaction	2 (5.7)	2 (5.7)	0	0	0
Contusion	1 (2.9)	1 (2.9)	0	0	0
Fibula fracture	1 (2.9)	0	1 (2.9)	0	0
Limb injury	1 (2.9)	0	1 (2.9)	0	0
Post-traumatic neck syndrome	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	17 (48.6)	5 (14.3)	4 (11.4)	6 (17.1)	2 (5.7)
Neutrophil count decreased	5 (14.3)	2 (5.7)	1 (2.9)	1 (2.9)	1 (2.9)
White blood cell count decreased	4 (11.4)	2 (5.7)	1 (2.9)	0	1 (2.9)
Lymphocyte count decreased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Platelet count decreased	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Blood uric acid increased	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Blood bilirubin increased	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin a decreased	1 (2.9)	1 (2.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Blood lactate dehydrogenase increased	1 (2.9)	1 (2.9)	0	0	0
Blood thyroid stimulating hormone increased	1 (2.9)	1 (2.9)	0	0	0
Blood urea increased	1 (2.9)	0	0	1 (2.9)	0
C-reactive protein increased	1 (2.9)	1 (2.9)	0	0	0
Ejection fraction decreased	1 (2.9)	0	1 (2.9)	0	0
Heart sounds abnormal	1 (2.9)	1 (2.9)	0	0	0
Oxygen saturation decreased	1 (2.9)	0	1 (2.9)	0	0
Weight increased	1 (2.9)	0	0	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	7 (20.0)	1 (2.9)	3 (8.6)	1 (2.9)	2 (5.7)
Decreased appetite	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Hypokalaemia	2 (5.7)	0	1 (2.9)	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (2.9)	1 (2.9)	0	0	0
Hyperkalaemia	1 (2.9)	0	1 (2.9)	0	0
Hyperuricaemia	1 (2.9)	1 (2.9)	0	0	0
Hypervolaemia	1 (2.9)	0	0	1 (2.9)	0
Metabolic syndrome	1 (2.9)	0	1 (2.9)	0	0
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)
Musculoskeletal and connective tissue disorders					
-Total	9 (25.7)	3 (8.6)	5 (14.3)	1 (2.9)	0
Back pain	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Pain in extremity	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Arthralgia	1 (2.9)	0	1 (2.9)	0	0
Bone pain	1 (2.9)	0	1 (2.9)	0	0
Growth retardation	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal pain	1 (2.9)	0	1 (2.9)	0	0
Myalgia	1 (2.9)	0	1 (2.9)	0	0
Neck pain	1 (2.9)	1 (2.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	1 (2.9)	0	0
Cancer pain	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	9 (25.7)	4 (11.4)	4 (11.4)	0	1 (2.9)
Headache	7 (20.0)	4 (11.4)	3 (8.6)	0	0
Extrapyramidal disorder	1 (2.9)	0	1 (2.9)	0	0
Hydrocephalus	1 (2.9)	0	0	0	1 (2.9)
Migraine	1 (2.9)	0	1 (2.9)	0	0
Psychiatric disorders					
-Total	4 (11.4)	0	4 (11.4)	0	0
Anxiety	2 (5.7)	0	2 (5.7)	0	0
Mental status changes	1 (2.9)	0	1 (2.9)	0	0
Persistent depressive disorder	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Acute kidney injury	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Dysuria	1 (2.9)	0	1 (2.9)	0	0
Haematuria	1 (2.9)	0	0	1 (2.9)	0
Kidney enlargement	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal mass	1 (2.9)	0	1 (2.9)	0	0
Reproductive system and breast disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Dysmenorrhoea	1 (2.9)	0	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (28.6)	4 (11.4)	3 (8.6)	1 (2.9)	2 (5.7)
Cough	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Nasal congestion	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Rhinorrhoea	3 (8.6)	3 (8.6)	0	0	0
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Rhinitis allergic	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Acute respiratory distress syndrome	1 (2.9)	0	0	0	1 (2.9)
Dyspnoea	1 (2.9)	0	1 (2.9)	0	0
Hypoxia	1 (2.9)	0	0	1 (2.9)	0
Oropharyngeal pain	1 (2.9)	0	1 (2.9)	0	0
Pleural effusion	1 (2.9)	1 (2.9)	0	0	0
Respiratory distress	1 (2.9)	0	0	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	9 (25.7)	4 (11.4)	5 (14.3)	0	0
Dry skin	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Rash	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Ingrowing nail	2 (5.7)	0	2 (5.7)	0	0
Eczema	1 (2.9)	1 (2.9)	0	0	0
Miliaria	1 (2.9)	1 (2.9)	0	0	0
Pruritus	1 (2.9)	0	1 (2.9)	0	0
Skin discolouration	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	3 (8.6)	0	0	2 (5.7)	1 (2.9)
Hypotension	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Hypertension	1 (2.9)	0	1 (2.9)	0	0
Venoocclusive disease	1 (2.9)	0	0	1 (2.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (56.7)	2 (6.7)	4 (13.3)	6 (20.0)	5 (16.7)
Blood and lymphatic system disorders					
-Total	3 (10.0)	0	2 (6.7)	0	1 (3.3)
Hypercoagulation	1 (3.3)	0	1 (3.3)	0	0
Lymphadenopathy	1 (3.3)	0	1 (3.3)	0	0
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Congenital, familial and genetic disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Cerebral cavernous malformation	1 (3.3)	1 (3.3)	0	0	0
Ear and labyrinth disorders					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.3)	0	1 (3.3)	0	0
Deafness unilateral	1 (3.3)	0	1 (3.3)	0	0
Eye disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Mydriasis	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					
-Total	2 (6.7)	2 (6.7)	0	0	0
Diarrhoea	2 (6.7)	2 (6.7)	0	0	0
General disorders and administration site conditions					
-Total	5 (16.7)	4 (13.3)	0	0	1 (3.3)
Pyrexia	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	0	0	1 (3.3)
Non-cardiac chest pain	1 (3.3)	1 (3.3)	0	0	0
Pain	1 (3.3)	1 (3.3)	0	0	0
Xerosis	1 (3.3)	1 (3.3)	0	0	0
Immune system disorders					
-Total	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Drug hypersensitivity	1 (3.3)	0	0	1 (3.3)	0
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	0	0	1 (3.3)
Infections and infestations					
-Total	13 (43.3)	2 (6.7)	3 (10.0)	6 (20.0)	2 (6.7)
Sinusitis	3 (10.0)	0	3 (10.0)	0	0
Upper respiratory tract infection	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Conjunctivitis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Herpes zoster	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Influenza	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Rhinovirus infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Sepsis	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Covid-19 pneumonia	1 (3.3)	0	0	0	1 (3.3)
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	0	0	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (3.3)	0	0	1 (3.3)	0
Fungal infection	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Neutropenic infection	1 (3.3)	0	0	1 (3.3)	0
Oral herpes	1 (3.3)	1 (3.3)	0	0	0
Otitis media	1 (3.3)	0	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Pneumonia	1 (3.3)	0	0	0	1 (3.3)
Rhinitis	1 (3.3)	1 (3.3)	0	0	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal abscess	1 (3.3)	0	0	1 (3.3)	0
Urinary tract infection	1 (3.3)	0	1 (3.3)	0	0
Viral skin infection	1 (3.3)	1 (3.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.3)	1 (3.3)	0	0	0
Ligament sprain	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	5 (16.7)	2 (6.7)	1 (3.3)	1 (3.3)	1 (3.3)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Platelet count decreased	2 (6.7)	2 (6.7)	0	0	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Oxygen saturation decreased	1 (3.3)	0	0	1 (3.3)	0
Metabolism and nutrition disorders					
-Total	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Decreased appetite	1 (3.3)	0	0	0	1 (3.3)
Hyperglycaemia	1 (3.3)	0	0	1 (3.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (6.7)	0	2 (6.7)	0	0
Growth retardation	1 (3.3)	0	1 (3.3)	0	0
Pain in extremity	1 (3.3)	0	1 (3.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.3)	0	0	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone giant cell tumour benign	1 (3.3)	0	0	1 (3.3)	0
Nervous system disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Dysarthria	1 (3.3)	0	1 (3.3)	0	0
Psychiatric disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Anxiety	1 (3.3)	1 (3.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (16.7)	3 (10.0)	0	0	2 (6.7)
Cough	2 (6.7)	2 (6.7)	0	0	0
Dyspnoea	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Dyspnoea exertional	1 (3.3)	1 (3.3)	0	0	0
Epistaxis	1 (3.3)	1 (3.3)	0	0	0
Laryngeal oedema	1 (3.3)	0	0	0	1 (3.3)
Pharyngeal erythema	1 (3.3)	1 (3.3)	0	0	0
Pleural effusion	1 (3.3)	0	1 (3.3)	0	0
Rhinorrhoea	1 (3.3)	1 (3.3)	0	0	0
Sleep apnoea syndrome	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	1 (3.3)	0	0	0	1 (3.3)
Skin and subcutaneous tissue disorders					
-Total	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Dermatitis atopic	1 (3.3)	0	0	1 (3.3)	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Eczema	1 (3.3)	0	0	1 (3.3)	0
Rash macular	1 (3.3)	0	0	1 (3.3)	0
Vascular disorders					
-Total	1 (3.3)	0	0	1 (3.3)	0
Hypertension	1 (3.3)	0	0	1 (3.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (75.0)	1 (5.0)	6 (30.0)	6 (30.0)	2 (10.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Agranulocytosis	1 (5.0)	0	0	1 (5.0)	0
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Delayed puberty	1 (5.0)	0	1 (5.0)	0	0
Hypothyroidism	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Dry eye	1 (5.0)	1 (5.0)	0	0	0
Eye pain	1 (5.0)	0	0	1 (5.0)	0
Eyelid oedema	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	5 (25.0)	2 (10.0)	2 (10.0)	1 (5.0)	0
Diarrhoea	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Constipation	1 (5.0)	1 (5.0)	0	0	0
Irritable bowel syndrome	1 (5.0)	0	1 (5.0)	0	0
Nausea	1 (5.0)	1 (5.0)	0	0	0
Vomiting	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (20.0)	0	3 (15.0)	1 (5.0)	0
Pyrexia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Fatigue	1 (5.0)	0	1 (5.0)	0	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	6 (30.0)	2 (10.0)	4 (20.0)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)	0	0
Seasonal allergy	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Infections and infestations					
-Total	10 (50.0)	0	4 (20.0)	4 (20.0)	2 (10.0)
Sinusitis	3 (15.0)	0	3 (15.0)	0	0
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Covid-19	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Rhinovirus infection	2 (10.0)	0	2 (10.0)	0	0
Skin infection	2 (10.0)	0	2 (10.0)	0	0
Upper respiratory tract infection	2 (10.0)	0	2 (10.0)	0	0
Bronchiolitis	1 (5.0)	0	0	1 (5.0)	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Folliculitis	1 (5.0)	0	1 (5.0)	0	0
Fungal infection	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis escherichia coli	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis viral	1 (5.0)	0	1 (5.0)	0	0
Herpes virus infection	1 (5.0)	0	1 (5.0)	0	0
Meningitis pneumococcal	1 (5.0)	0	0	1 (5.0)	0
Nail infection	1 (5.0)	0	1 (5.0)	0	0
Ophthalmic herpes zoster	1 (5.0)	0	1 (5.0)	0	0
Oral candidiasis	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Pneumonia respiratory syncytial viral	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Septic shock	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal sepsis	1 (5.0)	0	1 (5.0)	0	0
Syphilis	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection pseudomonal	1 (5.0)	0	1 (5.0)	0	0
Varicella zoster virus infection	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Abdominal injury	1 (5.0)	1 (5.0)	0	0	0
Infusion related reaction	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	1 (5.0)	1 (5.0)	0	0	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (20.0)	0	2 (10.0)	2 (10.0)	0
Hypercholesterolaemia	1 (5.0)	0	1 (5.0)	0	0
Hyperlipidaemia	1 (5.0)	0	1 (5.0)	0	0
Hypernatraemia	1 (5.0)	0	0	1 (5.0)	0
Hypertriglyceridaemia	1 (5.0)	0	1 (5.0)	0	0
Iron overload	1 (5.0)	0	1 (5.0)	0	0
Obesity	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Arthralgia	1 (5.0)	0	1 (5.0)	0	0
Joint effusion	1 (5.0)	0	1 (5.0)	0	0
Osteonecrosis	1 (5.0)	1 (5.0)	0	0	0
Osteopenia	1 (5.0)	1 (5.0)	0	0	0
Pain in extremity	1 (5.0)	0	1 (5.0)	0	0
Synovitis	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Headache	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Nervous system disorder	1 (5.0)	0	0	1 (5.0)	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Psychiatric disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Tic	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Endometriosis	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (25.0)	1 (5.0)	2 (10.0)	1 (5.0)	1 (5.0)
Cough	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rhinorrhoea	2 (10.0)	0	2 (10.0)	0	0
Dyspnoea	1 (5.0)	0	1 (5.0)	0	0
Hypoxia	1 (5.0)	0	0	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	1 (5.0)	0	0	0
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Sleep apnoea syndrome	1 (5.0)	0	1 (5.0)	0	0
Wheezing	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Rash	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Papule	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=20 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypertension	1 (5.0)	0	1 (5.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	1 (2.5)	1 (2.5)	9 (22.5)	29 (72.5)
Blood and lymphatic system disorders					
-Total	29 (72.5)	0	6 (15.0)	13 (32.5)	10 (25.0)
Anaemia	12 (30.0)	3 (7.5)	3 (7.5)	6 (15.0)	0
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Neutropenia	9 (22.5)	0	1 (2.5)	2 (5.0)	6 (15.0)
Disseminated intravascular coagulation	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Thrombocytopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Coagulopathy	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Leukopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Lymphopenia	2 (5.0)	0	0	2 (5.0)	0
Pancytopenia	2 (5.0)	0	0	2 (5.0)	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Eosinophilia	1 (2.5)	0	1 (2.5)	0	0
Hypercoagulation	1 (2.5)	0	1 (2.5)	0	0
Hypofibrinogenaemia	1 (2.5)	0	1 (2.5)	0	0
Splenomegaly	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	10 (25.0)	4 (10.0)	3 (7.5)	1 (2.5)	2 (5.0)
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Cardiac dysfunction	2 (5.0)	2 (5.0)	0	0	0
Left ventricular dysfunction	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinus tachycardia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cardiac arrest	1 (2.5)	0	0	0	1 (2.5)
Cardiac failure	1 (2.5)	0	0	0	1 (2.5)
Cardiac failure congestive	1 (2.5)	0	1 (2.5)	0	0
Mitral valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Pericardial effusion	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (2.5)	1 (2.5)	0	0	0
Tricuspid valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Cerebral cavernous malformation	1 (2.5)	1 (2.5)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Deafness unilateral	1 (2.5)	0	1 (2.5)	0	0
Endocrine disorders					
-Total	2 (5.0)	0	2 (5.0)	0	0
Adrenal insufficiency	1 (2.5)	0	1 (2.5)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	6 (15.0)	3 (7.5)	3 (7.5)	0	0
Cataract	2 (5.0)	2 (5.0)	0	0	0
Eye oedema	1 (2.5)	1 (2.5)	0	0	0
Hypermetropia	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mydriasis	1 (2.5)	0	1 (2.5)	0	0
Periorbital swelling	1 (2.5)	0	1 (2.5)	0	0
Retinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Visual field defect	1 (2.5)	0	1 (2.5)	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	29 (72.5)	12 (30.0)	11 (27.5)	6 (15.0)	0
Diarrhoea	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Vomiting	12 (30.0)	7 (17.5)	5 (12.5)	0	0
Nausea	9 (22.5)	5 (12.5)	2 (5.0)	2 (5.0)	0
Abdominal pain	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Constipation	6 (15.0)	3 (7.5)	3 (7.5)	0	0
Mouth haemorrhage	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Pancreatitis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Stomatitis	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Abdominal distension	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Abdominal pain upper	2 (5.0)	2 (5.0)	0	0	0
Ascites	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Abdominal rigidity	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (2.5)	1 (2.5)	0	0	0
Enteritis	1 (2.5)	0	1 (2.5)	0	0
Enterocolitis	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Gastrooesophageal reflux disease	1 (2.5)	0	1 (2.5)	0	0
Gingival bleeding	1 (2.5)	0	1 (2.5)	0	0
Gingivitis ulcerative	1 (2.5)	0	0	1 (2.5)	0
Lip dry	1 (2.5)	0	1 (2.5)	0	0
Mouth swelling	1 (2.5)	1 (2.5)	0	0	0
Odynophagia	1 (2.5)	1 (2.5)	0	0	0
Peritoneal haematoma	1 (2.5)	1 (2.5)	0	0	0
Proctalgia	1 (2.5)	0	0	1 (2.5)	0
Trichoglossia	1 (2.5)	1 (2.5)	0	0	0
Upper gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	23 (57.5)	13 (32.5)	4 (10.0)	4 (10.0)	2 (5.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	15 (37.5)	7 (17.5)	4 (10.0)	3 (7.5)	1 (2.5)
Chills	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Fatigue	4 (10.0)	4 (10.0)	0	0	0
Asthenia	3 (7.5)	3 (7.5)	0	0	0
Oedema peripheral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Pain	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Generalised oedema	2 (5.0)	0	2 (5.0)	0	0
Influenza like illness	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Non-cardiac chest pain	2 (5.0)	2 (5.0)	0	0	0
Catheter site pain	1 (2.5)	0	0	1 (2.5)	0
Chest discomfort	1 (2.5)	0	0	1 (2.5)	0
Crying	1 (2.5)	0	1 (2.5)	0	0
Facial pain	1 (2.5)	0	1 (2.5)	0	0
Localised oedema	1 (2.5)	1 (2.5)	0	0	0
Malaise	1 (2.5)	0	1 (2.5)	0	0
Multiple organ dysfunction syndrome	1 (2.5)	0	0	0	1 (2.5)
Sluggishness	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Swelling face	1 (2.5)	1 (2.5)	0	0	0
Vascular device occlusion	1 (2.5)	1 (2.5)	0	0	0
Xerosis	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	9 (22.5)	3 (7.5)	3 (7.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hyperbilirubinaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cholelithiasis	1 (2.5)	0	1 (2.5)	0	0
Hepatic cytolysis	1 (2.5)	1 (2.5)	0	0	0
Hepatomegaly	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	35 (87.5)	1 (2.5)	7 (17.5)	16 (40.0)	11 (27.5)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	16 (40.0)	1 (2.5)	9 (22.5)	6 (15.0)	0
Immunodeficiency	4 (10.0)	0	0	4 (10.0)	0
Chronic graft versus host disease	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Drug hypersensitivity	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Hypersensitivity	1 (2.5)	1 (2.5)	0	0	0
Seasonal allergy	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	36 (90.0)	7 (17.5)	6 (15.0)	14 (35.0)	9 (22.5)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Gastroenteritis	6 (15.0)	4 (10.0)	0	2 (5.0)	0
Conjunctivitis	4 (10.0)	0	4 (10.0)	0	0
Parainfluenzae virus infection	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Pneumonia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Sinusitis	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Herpes zoster	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Oral herpes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Otitis media	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Respiratory tract infection	3 (7.5)	1 (2.5)	2 (5.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rhinovirus infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Bacteraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Bronchopulmonary aspergillosis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Candida infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Ear infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Gingivitis	2 (5.0)	2 (5.0)	0	0	0
Human herpesvirus 6 infection	2 (5.0)	0	0	2 (5.0)	0
Influenza	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Nail infection	2 (5.0)	2 (5.0)	0	0	0
Oral candidiasis	2 (5.0)	0	2 (5.0)	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Paronychia	2 (5.0)	0	2 (5.0)	0	0
Sepsis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Urinary tract infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	1 (2.5)	0	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Cystitis	1 (2.5)	0	1 (2.5)	0	0
Cytomegalovirus infection reactivation	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Ear, nose and throat infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Enterovirus infection	1 (2.5)	0	0	1 (2.5)	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Granulicatella infection	1 (2.5)	0	0	1 (2.5)	0
Herpes simplex	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Myringitis	1 (2.5)	1 (2.5)	0	0	0
Neutropenic infection	1 (2.5)	0	0	1 (2.5)	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection viral	1 (2.5)	0	1 (2.5)	0	0
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal skin infection	1 (2.5)	0	1 (2.5)	0	0
Stomatococcal infection	1 (2.5)	0	1 (2.5)	0	0
Systemic candida	1 (2.5)	0	0	1 (2.5)	0
Tinea pedis	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Viral skin infection	1 (2.5)	1 (2.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	6 (15.0)	3 (7.5)	2 (5.0)	0	1 (2.5)
Infusion related reaction	2 (5.0)	0	2 (5.0)	0	0
Ligament sprain	2 (5.0)	2 (5.0)	0	0	0
Fall	1 (2.5)	0	1 (2.5)	0	0
Procedural pain	1 (2.5)	1 (2.5)	0	0	0
Transplant failure	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	28 (70.0)	2 (5.0)	4 (10.0)	7 (17.5)	15 (37.5)
Neutrophil count decreased	13 (32.5)	1 (2.5)	0	2 (5.0)	10 (25.0)
Platelet count decreased	12 (30.0)	3 (7.5)	1 (2.5)	4 (10.0)	4 (10.0)
White blood cell count decreased	12 (30.0)	1 (2.5)	1 (2.5)	1 (2.5)	9 (22.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (20.0)	1 (2.5)	0	4 (10.0)	3 (7.5)
Alanine aminotransferase increased	6 (15.0)	1 (2.5)	1 (2.5)	4 (10.0)	0
Aspartate aminotransferase increased	5 (12.5)	1 (2.5)	1 (2.5)	2 (5.0)	1 (2.5)
Serum ferritin increased	5 (12.5)	1 (2.5)	4 (10.0)	0	0
Blood bilirubin increased	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)	0	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0	0	0
C-reactive protein increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Gamma-glutamyltransferase increased	2 (5.0)	0	0	2 (5.0)	0
Weight increased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Blood alkaline phosphatase increased	1 (2.5)	1 (2.5)	0	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood glucose increased	1 (2.5)	0	0	0	1 (2.5)
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Bone density decreased	1 (2.5)	1 (2.5)	0	0	0
Breath sounds abnormal	1 (2.5)	0	1 (2.5)	0	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0	0	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Hepatitis b virus test positive	1 (2.5)	0	1 (2.5)	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0	0	0
Oxygen saturation decreased	1 (2.5)	0	0	1 (2.5)	0
Prothrombin time prolonged	1 (2.5)	0	1 (2.5)	0	0
Weight decreased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	20 (50.0)	3 (7.5)	4 (10.0)	10 (25.0)	3 (7.5)
Decreased appetite	11 (27.5)	5 (12.5)	2 (5.0)	2 (5.0)	2 (5.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	8 (20.0)	2 (5.0)	1 (2.5)	5 (12.5)	0
Hypophosphataemia	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hyperglycaemia	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Hypocalcaemia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Hypermagnesaemia	2 (5.0)	2 (5.0)	0	0	0
Hyperuricaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hyponatraemia	2 (5.0)	2 (5.0)	0	0	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Acidosis	1 (2.5)	0	0	1 (2.5)	0
Haemochromatosis	1 (2.5)	0	0	1 (2.5)	0
Hypernatraemia	1 (2.5)	1 (2.5)	0	0	0
Hypervolaemia	1 (2.5)	0	1 (2.5)	0	0
Hypophagia	1 (2.5)	0	1 (2.5)	0	0
Iron overload	1 (2.5)	0	1 (2.5)	0	0
Malnutrition	1 (2.5)	0	0	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	0	0	1 (2.5)
Polydipsia	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	19 (47.5)	8 (20.0)	7 (17.5)	4 (10.0)	0
Pain in extremity	8 (20.0)	2 (5.0)	5 (12.5)	1 (2.5)	0
Arthralgia	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Back pain	6 (15.0)	1 (2.5)	3 (7.5)	2 (5.0)	0
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Bone pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Musculoskeletal chest pain	2 (5.0)	2 (5.0)	0	0	0
Pain in jaw	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Growth retardation	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	1 (2.5)	0	0	0
Neck pain	1 (2.5)	0	1 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Bone giant cell tumour benign	1 (2.5)	0	0	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	20 (50.0)	7 (17.5)	9 (22.5)	3 (7.5)	1 (2.5)
Headache	11 (27.5)	7 (17.5)	3 (7.5)	1 (2.5)	0
Dizziness	3 (7.5)	3 (7.5)	0	0	0
Dysgeusia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Seizure	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Somnolence	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Tremor	3 (7.5)	3 (7.5)	0	0	0
Lethargy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Amnesia	1 (2.5)	0	1 (2.5)	0	0
Aphasia	1 (2.5)	1 (2.5)	0	0	0
Autonomic neuropathy	1 (2.5)	0	0	1 (2.5)	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Depressed level of consciousness	1 (2.5)	0	0	1 (2.5)	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	1 (2.5)	0	0
Hyperaesthesia	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoaesthesia	1 (2.5)	1 (2.5)	0	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	13 (32.5)	2 (5.0)	9 (22.5)	2 (5.0)	0
Anxiety	6 (15.0)	2 (5.0)	3 (7.5)	1 (2.5)	0
Hallucination	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Agitation	2 (5.0)	2 (5.0)	0	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Delirium	2 (5.0)	0	2 (5.0)	0	0
Sleep disorder	2 (5.0)	0	2 (5.0)	0	0
Affect lability	1 (2.5)	0	1 (2.5)	0	0
Hallucination, visual	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Nightmare	1 (2.5)	1 (2.5)	0	0	0
Restlessness	1 (2.5)	0	1 (2.5)	0	0
Social avoidant behaviour	1 (2.5)	0	1 (2.5)	0	0
Tearfulness	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	12 (30.0)	2 (5.0)	5 (12.5)	2 (5.0)	3 (7.5)
Acute kidney injury	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Haematuria	2 (5.0)	2 (5.0)	0	0	0
Anuria	1 (2.5)	0	0	0	1 (2.5)
Cystitis haemorrhagic	1 (2.5)	0	1 (2.5)	0	0
Dysuria	1 (2.5)	1 (2.5)	0	0	0
Incontinence	1 (2.5)	0	1 (2.5)	0	0
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Proteinuria	1 (2.5)	1 (2.5)	0	0	0
Renal failure	1 (2.5)	0	1 (2.5)	0	0
Renal tubular disorder	1 (2.5)	0	0	1 (2.5)	0
Urinary incontinence	1 (2.5)	0	1 (2.5)	0	0
Urinary tract disorder	1 (2.5)	0	1 (2.5)	0	0
Reproductive system and breast disorders					
-Total	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Female genital tract fistula	1 (2.5)	1 (2.5)	0	0	0
Heavy menstrual bleeding	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (67.5)	9 (22.5)	4 (10.0)	8 (20.0)	6 (15.0)
Cough	14 (35.0)	12 (30.0)	2 (5.0)	0	0
Hypoxia	9 (22.5)	0	2 (5.0)	4 (10.0)	3 (7.5)
Pulmonary oedema	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Dyspnoea	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Epistaxis	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Nasal congestion	4 (10.0)	4 (10.0)	0	0	0
Oropharyngeal pain	4 (10.0)	4 (10.0)	0	0	0
Pleural effusion	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Tachypnoea	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Pharyngeal erythema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Acute respiratory failure	1 (2.5)	0	0	1 (2.5)	0
Atelectasis	1 (2.5)	0	1 (2.5)	0	0
Bronchial oedema	1 (2.5)	1 (2.5)	0	0	0
Bronchospasm	1 (2.5)	0	1 (2.5)	0	0
Dyspnoea exertional	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (2.5)	0	0	0	1 (2.5)
Lung disorder	1 (2.5)	1 (2.5)	0	0	0
Lung infiltration	1 (2.5)	0	0	1 (2.5)	0
Oropharyngeal plaque	1 (2.5)	0	1 (2.5)	0	0
Painful respiration	1 (2.5)	1 (2.5)	0	0	0
Paranasal sinus discomfort	1 (2.5)	0	1 (2.5)	0	0
Paranasal sinus inflammation	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal exudate	1 (2.5)	0	1 (2.5)	0	0
Pharyngeal oedema	1 (2.5)	0	1 (2.5)	0	0
Pulmonary mass	1 (2.5)	0	1 (2.5)	0	0
Respiratory disorder	1 (2.5)	0	1 (2.5)	0	0
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Rhinorrhoea	1 (2.5)	1 (2.5)	0	0	0
Sleep apnoea syndrome	1 (2.5)	1 (2.5)	0	0	0
Upper respiratory tract inflammation	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	21 (52.5)	10 (25.0)	6 (15.0)	5 (12.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	4 (10.0)	4 (10.0)	0	0	0
Dermatitis atopic	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Erythema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Hyperhidrosis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rash	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rash maculo-papular	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Decubitus ulcer	1 (2.5)	0	0	1 (2.5)	0
Dermatitis allergic	1 (2.5)	1 (2.5)	0	0	0
Eczema	1 (2.5)	0	0	1 (2.5)	0
Erythema nodosum	1 (2.5)	1 (2.5)	0	0	0
Hangnail	1 (2.5)	1 (2.5)	0	0	0
Night sweats	1 (2.5)	1 (2.5)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.5)	1 (2.5)	0	0	0
Photosensitivity reaction	1 (2.5)	0	1 (2.5)	0	0
Purpura	1 (2.5)	1 (2.5)	0	0	0
Rash macular	1 (2.5)	0	0	1 (2.5)	0
Rash papular	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash vesicular	1 (2.5)	1 (2.5)	0	0	0
Skin hypopigmentation	1 (2.5)	1 (2.5)	0	0	0
Skin lesion	1 (2.5)	0	1 (2.5)	0	0
Skin swelling	1 (2.5)	1 (2.5)	0	0	0
Skin ulcer	1 (2.5)	0	1 (2.5)	0	0
Social circumstances					
-Total	1 (2.5)	0	1 (2.5)	0	0
Patient uncooperative	1 (2.5)	0	1 (2.5)	0	0
Vascular disorders					
-Total	13 (32.5)	4 (10.0)	3 (7.5)	4 (10.0)	2 (5.0)
Hypotension	7 (17.5)	1 (2.5)	2 (5.0)	3 (7.5)	1 (2.5)
Hypertension	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Flushing	1 (2.5)	1 (2.5)	0	0	0
Hot flush	1 (2.5)	1 (2.5)	0	0	0
Venoocclusive disease	1 (2.5)	0	0	0	1 (2.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	5 (12.5)	10 (25.0)	25 (62.5)
Blood and lymphatic system disorders					
-Total	26 (65.0)	1 (2.5)	5 (12.5)	16 (40.0)	4 (10.0)
Febrile neutropenia	16 (40.0)	0	0	15 (37.5)	1 (2.5)
Anaemia	13 (32.5)	4 (10.0)	6 (15.0)	3 (7.5)	0
Thrombocytopenia	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Disseminated intravascular coagulation	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Splenomegaly	3 (7.5)	3 (7.5)	0	0	0
Coagulopathy	2 (5.0)	0	2 (5.0)	0	0
Neutropenia	2 (5.0)	0	1 (2.5)	0	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agranulocytosis	1 (2.5)	0	0	1 (2.5)	0
Leukocytosis	1 (2.5)	0	1 (2.5)	0	0
Leukopenia	1 (2.5)	0	1 (2.5)	0	0
Lymphocytosis	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	18 (45.0)	6 (15.0)	4 (10.0)	4 (10.0)	4 (10.0)
Tachycardia	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)
Bradycardia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Cardiac arrest	2 (5.0)	0	0	0	2 (5.0)
Cardiac failure	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Left ventricular dysfunction	2 (5.0)	0	0	2 (5.0)	0
Atrioventricular block first degree	1 (2.5)	0	1 (2.5)	0	0
Sinus bradycardia	1 (2.5)	0	0	1 (2.5)	0
Sinus tachycardia	1 (2.5)	1 (2.5)	0	0	0
Ear and labyrinth disorders					
-Total	2 (5.0)	2 (5.0)	0	0	0
Ear pain	1 (2.5)	1 (2.5)	0	0	0
Ear pruritus	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	5 (12.5)	0	5 (12.5)	0	0
Adrenal insufficiency	3 (7.5)	0	3 (7.5)	0	0
Hypothyroidism	2 (5.0)	0	2 (5.0)	0	0
Delayed puberty	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	9 (22.5)	7 (17.5)	1 (2.5)	1 (2.5)	0
Eyelid oedema	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Ocular hyperaemia	3 (7.5)	3 (7.5)	0	0	0
Conjunctival haemorrhage	2 (5.0)	2 (5.0)	0	0	0
Eye pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Dry eye	1 (2.5)	1 (2.5)	0	0	0
Periorbital oedema	1 (2.5)	1 (2.5)	0	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	31 (77.5)	9 (22.5)	12 (30.0)	9 (22.5)	1 (2.5)
Diarrhoea	14 (35.0)	10 (25.0)	2 (5.0)	2 (5.0)	0
Vomiting	14 (35.0)	10 (25.0)	3 (7.5)	1 (2.5)	0
Nausea	13 (32.5)	7 (17.5)	6 (15.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	8 (20.0)	4 (10.0)	4 (10.0)	0	0
Abdominal pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Pancreatitis	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Abdominal pain upper	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Mouth haemorrhage	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal compartment syndrome	1 (2.5)	0	0	0	1 (2.5)
Abdominal distension	1 (2.5)	0	1 (2.5)	0	0
Anal fissure	1 (2.5)	0	1 (2.5)	0	0
Anal haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Ascites	1 (2.5)	1 (2.5)	0	0	0
Dry mouth	1 (2.5)	0	1 (2.5)	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal inflammation	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Haematemesis	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (2.5)	0	1 (2.5)	0	0
Irritable bowel syndrome	1 (2.5)	0	1 (2.5)	0	0
Lip oedema	1 (2.5)	1 (2.5)	0	0	0
Melaena	1 (2.5)	0	0	1 (2.5)	0
Neutropenic colitis	1 (2.5)	0	0	1 (2.5)	0
Proctalgia	1 (2.5)	1 (2.5)	0	0	0
Trichoglossia	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	30 (75.0)	12 (30.0)	9 (22.5)	6 (15.0)	3 (7.5)
Pyrexia	20 (50.0)	7 (17.5)	6 (15.0)	6 (15.0)	1 (2.5)
Fatigue	13 (32.5)	10 (25.0)	3 (7.5)	0	0
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Oedema peripheral	4 (10.0)	4 (10.0)	0	0	0
Generalised oedema	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Chills	2 (5.0)	2 (5.0)	0	0	0
Drug withdrawal syndrome	2 (5.0)	0	2 (5.0)	0	0
Multiple organ dysfunction syndrome	2 (5.0)	0	0	0	2 (5.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (5.0)	0	2 (5.0)	0	0
Catheter site erythema	1 (2.5)	1 (2.5)	0	0	0
Catheter site haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Catheter site pain	1 (2.5)	1 (2.5)	0	0	0
Localised oedema	1 (2.5)	1 (2.5)	0	0	0
Malaise	1 (2.5)	1 (2.5)	0	0	0
Oedema due to hepatic disease	1 (2.5)	0	1 (2.5)	0	0
Systemic inflammatory response syndrome	1 (2.5)	0	0	1 (2.5)	0
Hepatobiliary disorders					
-Total	10 (25.0)	3 (7.5)	4 (10.0)	1 (2.5)	2 (5.0)
Hyperbilirubinaemia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Gallbladder enlargement	2 (5.0)	2 (5.0)	0	0	0
Hepatomegaly	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Hypertransaminasaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Biliary tract disorder	1 (2.5)	1 (2.5)	0	0	0
Cholelithiasis	1 (2.5)	1 (2.5)	0	0	0
Cholestasis	1 (2.5)	0	0	0	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	1 (2.5)	0	1 (2.5)	0	0
Liver disorder	1 (2.5)	0	1 (2.5)	0	0
Ocular icterus	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	36 (90.0)	1 (2.5)	16 (40.0)	8 (20.0)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Hypogammaglobulinaemia	17 (42.5)	1 (2.5)	15 (37.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Seasonal allergy	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Allergy to immunoglobulin therapy	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Engraftment syndrome	1 (2.5)	0	0	1 (2.5)	0
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	24 (60.0)	1 (2.5)	7 (17.5)	11 (27.5)	5 (12.5)
Rhinovirus infection	6 (15.0)	0	6 (15.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Conjunctivitis	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Staphylococcal bacteraemia	4 (10.0)	0	0	4 (10.0)	0
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Sinusitis	3 (7.5)	0	3 (7.5)	0	0
Candida infection	2 (5.0)	0	2 (5.0)	0	0
Covid-19	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Gastroenteritis viral	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Metapneumovirus infection	2 (5.0)	0	0	2 (5.0)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Pneumocystis jirovecii pneumonia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pneumonia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Skin infection	2 (5.0)	0	2 (5.0)	0	0
Staphylococcal infection	2 (5.0)	0	2 (5.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal skin infection	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Herpes virus infection	1 (2.5)	0	1 (2.5)	0	0
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Localised infection	1 (2.5)	1 (2.5)	0	0	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Ophthalmic herpes zoster	1 (2.5)	0	1 (2.5)	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Otitis media acute	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Salmonellosis	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Streptococcal sepsis	1 (2.5)	0	1 (2.5)	0	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection pseudomonal	1 (2.5)	0	1 (2.5)	0	0
Varicella zoster virus infection	1 (2.5)	0	1 (2.5)	0	0
Viral infection	1 (2.5)	0	1 (2.5)	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	15 (37.5)	6 (15.0)	7 (17.5)	1 (2.5)	1 (2.5)
Infusion related reaction	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Contusion	2 (5.0)	2 (5.0)	0	0	0
Skin abrasion	2 (5.0)	2 (5.0)	0	0	0
Transfusion reaction	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal injury	1 (2.5)	1 (2.5)	0	0	0
Fall	1 (2.5)	0	1 (2.5)	0	0
Fibula fracture	1 (2.5)	0	1 (2.5)	0	0
Limb injury	1 (2.5)	0	1 (2.5)	0	0
Post-traumatic neck syndrome	1 (2.5)	0	1 (2.5)	0	0
Procedural pain	1 (2.5)	0	1 (2.5)	0	0
Scratch	1 (2.5)	1 (2.5)	0	0	0
Skin injury	1 (2.5)	0	1 (2.5)	0	0
Skin wound	1 (2.5)	1 (2.5)	0	0	0
Vasoplegia syndrome	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	32 (80.0)	1 (2.5)	5 (12.5)	12 (30.0)	14 (35.0)
Aspartate aminotransferase increased	14 (35.0)	1 (2.5)	5 (12.5)	6 (15.0)	2 (5.0)
White blood cell count decreased	13 (32.5)	2 (5.0)	3 (7.5)	1 (2.5)	7 (17.5)
Alanine aminotransferase increased	12 (30.0)	2 (5.0)	7 (17.5)	3 (7.5)	0
Platelet count decreased	12 (30.0)	3 (7.5)	2 (5.0)	3 (7.5)	4 (10.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	11 (27.5)	0	2 (5.0)	2 (5.0)	7 (17.5)
Blood bilirubin increased	10 (25.0)	1 (2.5)	1 (2.5)	8 (20.0)	0
Lymphocyte count decreased	9 (22.5)	0	1 (2.5)	6 (15.0)	2 (5.0)
International normalised ratio increased	8 (20.0)	5 (12.5)	3 (7.5)	0	0
Activated partial thromboplastin time prolonged	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood fibrinogen decreased	5 (12.5)	2 (5.0)	1 (2.5)	1 (2.5)	1 (2.5)
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Electrocardiogram qt prolonged	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Blood creatinine increased	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Blood uric acid increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)
Blood immunoglobulin g decreased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Blood lactate dehydrogenase increased	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
C-reactive protein increased	3 (7.5)	1 (2.5)	0	2 (5.0)	0

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		All patients N=40			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Fibrin d dimer increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Lipase increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Oxygen saturation decreased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Urine output decreased	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Weight increased	2 (5.0)	0	0	2 (5.0)	0
Amylase increased	1 (2.5)	1 (2.5)	0	0	0
Bacterial test positive	1 (2.5)	0	0	1 (2.5)	0
Blood bicarbonate decreased	1 (2.5)	0	1 (2.5)	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	0	1 (2.5)
Blood phosphorus increased	1 (2.5)	0	1 (2.5)	0	0
Blood testosterone decreased	1 (2.5)	1 (2.5)	0	0	0
Blood thyroid stimulating hormone increased	1 (2.5)	1 (2.5)	0	0	0
Blood urea increased	1 (2.5)	0	0	1 (2.5)	0
Cardiac murmur	1 (2.5)	1 (2.5)	0	0	0
Coagulation test abnormal	1 (2.5)	1 (2.5)	0	0	0
Ejection fraction decreased	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram t wave abnormal	1 (2.5)	0	1 (2.5)	0	0
Enterovirus test positive	1 (2.5)	0	1 (2.5)	0	0
Haptoglobin decreased	1 (2.5)	1 (2.5)	0	0	0
Heart sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Staphylococcus test positive	1 (2.5)	1 (2.5)	0	0	0
Troponin increased	1 (2.5)	0	0	1 (2.5)	0
Weight decreased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	32 (80.0)	6 (15.0)	6 (15.0)	12 (30.0)	8 (20.0)
Decreased appetite	19 (47.5)	6 (15.0)	5 (12.5)	8 (20.0)	0
Hypocalcaemia	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Hypokalaemia	12 (30.0)	1 (2.5)	5 (12.5)	4 (10.0)	2 (5.0)
Hypophosphataemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Hyperuricaemia	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Hypervolaemia	6 (15.0)	0	1 (2.5)	5 (12.5)	0
Hyperphosphataemia	5 (12.5)	4 (10.0)	0	0	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypercalcaemia	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Hyperkalaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hypertriglyceridaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Metabolic acidosis	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Tumour lysis syndrome	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Hyperchloraemia	2 (5.0)	2 (5.0)	0	0	0
Hypernatraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Acidosis	1 (2.5)	0	0	0	1 (2.5)
Calcium deficiency	1 (2.5)	1 (2.5)	0	0	0
Dehydration	1 (2.5)	0	1 (2.5)	0	0
Haemosiderosis	1 (2.5)	0	1 (2.5)	0	0
Hypercholesterolaemia	1 (2.5)	0	1 (2.5)	0	0
Hyperlactacidaemia	1 (2.5)	1 (2.5)	0	0	0
Hyperlipidaemia	1 (2.5)	0	1 (2.5)	0	0
Hypoglycaemia	1 (2.5)	0	1 (2.5)	0	0
Hypomagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Hyponatraemia	1 (2.5)	1 (2.5)	0	0	0

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			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (2.5)	0	1 (2.5)	0	0
Malnutrition	1 (2.5)	0	0	1 (2.5)	0
Metabolic syndrome	1 (2.5)	0	1 (2.5)	0	0
Obesity	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	25 (62.5)	9 (22.5)	12 (30.0)	3 (7.5)	1 (2.5)
Pain in extremity	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Arthralgia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Myalgia	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Back pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Bone pain	2 (5.0)	0	2 (5.0)	0	0
Growth retardation	1 (2.5)	0	1 (2.5)	0	0
Haemarthrosis	1 (2.5)	0	0	1 (2.5)	0
Joint effusion	1 (2.5)	0	1 (2.5)	0	0
Muscle rigidity	1 (2.5)	1 (2.5)	0	0	0
Muscle spasms	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal pain	1 (2.5)	0	1 (2.5)	0	0

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			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (2.5)	0	1 (2.5)	0	0
Neck pain	1 (2.5)	1 (2.5)	0	0	0
Osteonecrosis	1 (2.5)	1 (2.5)	0	0	0
Osteopenia	1 (2.5)	1 (2.5)	0	0	0
Rhabdomyolysis	1 (2.5)	0	0	0	1 (2.5)
Synovitis	1 (2.5)	0	1 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	1 (2.5)	0	0
Cancer pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	27 (67.5)	8 (20.0)	9 (22.5)	7 (17.5)	3 (7.5)
Headache	16 (40.0)	6 (15.0)	8 (20.0)	2 (5.0)	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Somnolence	2 (5.0)	0	0	2 (5.0)	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)

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			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Extrapyramidal disorder	1 (2.5)	0	1 (2.5)	0	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Hydrocephalus	1 (2.5)	0	0	0	1 (2.5)
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Migraine	1 (2.5)	0	1 (2.5)	0	0
Monoparesis	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorder	1 (2.5)	0	0	1 (2.5)	0
Neuralgia	1 (2.5)	0	1 (2.5)	0	0
Neurological decompensation	1 (2.5)	0	0	0	1 (2.5)
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Seizure	1 (2.5)	0	0	1 (2.5)	0
Psychiatric disorders					
-Total	26 (65.0)	11 (27.5)	10 (25.0)	5 (12.5)	0
Anxiety	8 (20.0)	1 (2.5)	6 (15.0)	1 (2.5)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0

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	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Insomnia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Mental status changes	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Irritability	2 (5.0)	2 (5.0)	0	0	0
Automatism	1 (2.5)	1 (2.5)	0	0	0
Persistent depressive disorder	1 (2.5)	0	1 (2.5)	0	0
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Tic	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	13 (32.5)	4 (10.0)	2 (5.0)	3 (7.5)	4 (10.0)
Acute kidney injury	7 (17.5)	1 (2.5)	1 (2.5)	2 (5.0)	3 (7.5)
Dysuria	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Urinary retention	2 (5.0)	0	2 (5.0)	0	0
Anuria	1 (2.5)	1 (2.5)	0	0	0
Azotaemia	1 (2.5)	0	1 (2.5)	0	0
Bladder dilatation	1 (2.5)	0	1 (2.5)	0	0
Haematuria	1 (2.5)	0	0	1 (2.5)	0
Kidney enlargement	1 (2.5)	0	1 (2.5)	0	0
Micturition urgency	1 (2.5)	0	1 (2.5)	0	0

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			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Renal failure	1 (2.5)	0	0	0	1 (2.5)
Renal mass	1 (2.5)	0	1 (2.5)	0	0
Renal tubular dysfunction	1 (2.5)	1 (2.5)	0	0	0
Renal tubular necrosis	1 (2.5)	0	0	0	1 (2.5)
Reproductive system and breast disorders					
-Total	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Dysmenorrhoea	1 (2.5)	0	1 (2.5)	0	0
Endometriosis	1 (2.5)	0	0	1 (2.5)	0
Perineal rash	1 (2.5)	0	1 (2.5)	0	0
Vaginal ulceration	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (70.0)	9 (22.5)	4 (10.0)	4 (10.0)	11 (27.5)
Hypoxia	11 (27.5)	0	2 (5.0)	6 (15.0)	3 (7.5)
Cough	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Pulmonary oedema	7 (17.5)	1 (2.5)	3 (7.5)	2 (5.0)	1 (2.5)
Nasal congestion	5 (12.5)	3 (7.5)	2 (5.0)	0	0

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	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	5 (12.5)	2 (5.0)	0	2 (5.0)	1 (2.5)
Respiratory failure	5 (12.5)	0	0	0	5 (12.5)
Rhinorrhoea	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Tachypnoea	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Oropharyngeal pain	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Respiratory distress	4 (10.0)	0	2 (5.0)	0	2 (5.0)
Acute respiratory distress syndrome	3 (7.5)	0	0	0	3 (7.5)
Dyspnoea	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Atelectasis	2 (5.0)	0	0	2 (5.0)	0
Rhinitis allergic	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Wheezing	2 (5.0)	0	2 (5.0)	0	0
Bradypnoea	1 (2.5)	0	0	1 (2.5)	0
Haemoptysis	1 (2.5)	0	1 (2.5)	0	0
Nasal discomfort	1 (2.5)	0	1 (2.5)	0	0
Nasal dryness	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Productive cough	1 (2.5)	1 (2.5)	0	0	0

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			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory acidosis	1 (2.5)	0	0	1 (2.5)	0
Sleep apnoea syndrome	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (47.5)	7 (17.5)	10 (25.0)	2 (5.0)	0
Rash	6 (15.0)	3 (7.5)	3 (7.5)	0	0
Pruritus	5 (12.5)	1 (2.5)	4 (10.0)	0	0
Dry skin	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Blister	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Erythema	3 (7.5)	3 (7.5)	0	0	0
Eczema	2 (5.0)	2 (5.0)	0	0	0
Ingrowing nail	2 (5.0)	0	2 (5.0)	0	0
Petechiae	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Rash papular	2 (5.0)	2 (5.0)	0	0	0
Skin discolouration	2 (5.0)	2 (5.0)	0	0	0
Decubitus ulcer	1 (2.5)	0	1 (2.5)	0	0
Dermatitis	1 (2.5)	1 (2.5)	0	0	0
Dermatitis diaper	1 (2.5)	0	1 (2.5)	0	0
Hyperhidrosis	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Miliaria	1 (2.5)	1 (2.5)	0	0	0
Papule	1 (2.5)	1 (2.5)	0	0	0
Pruritus allergic	1 (2.5)	0	1 (2.5)	0	0
Rash erythematous	1 (2.5)	1 (2.5)	0	0	0
Rash maculo-papular	1 (2.5)	1 (2.5)	0	0	0
Rash pruritic	1 (2.5)	1 (2.5)	0	0	0
Scab	1 (2.5)	1 (2.5)	0	0	0
Skin necrosis	1 (2.5)	0	0	1 (2.5)	0
Skin ulcer	1 (2.5)	1 (2.5)	0	0	0
Urticaria	1 (2.5)	0	1 (2.5)	0	0
Vancomycin infusion reaction	1 (2.5)	0	0	1 (2.5)	0
Surgical and medical procedures					
-Total	1 (2.5)	0	0	1 (2.5)	0
Thrombolysis	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	21 (52.5)	1 (2.5)	5 (12.5)	8 (20.0)	7 (17.5)
Hypotension	17 (42.5)	1 (2.5)	4 (10.0)	5 (12.5)	7 (17.5)
Hypertension	10 (25.0)	1 (2.5)	5 (12.5)	4 (10.0)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Capillary leak syndrome	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Peripheral ischaemia	1 (2.5)	0	1 (2.5)	0	0
Thrombosis	1 (2.5)	0	1 (2.5)	0	0
Venoocclusive disease	1 (2.5)	0	0	1 (2.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	2 (33.3)	0	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Face oedema	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	1 (16.7)	1 (16.7)	0	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Nasal congestion	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	2 (9.1)	2 (9.1)	2 (9.1)	16 (72.7)
Blood and lymphatic system disorders					
-Total	13 (59.1)	2 (9.1)	2 (9.1)	3 (13.6)	6 (27.3)
Febrile neutropenia	6 (27.3)	0	0	5 (22.7)	1 (4.5)
Anaemia	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Coagulopathy	2 (9.1)	0	2 (9.1)	0	0
Disseminated intravascular coagulation	2 (9.1)	0	2 (9.1)	0	0
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Splenomegaly	1 (4.5)	1 (4.5)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	8 (36.4)	1 (4.5)	2 (9.1)	4 (18.2)	1 (4.5)
Tachycardia	7 (31.8)	2 (9.1)	3 (13.6)	2 (9.1)	0
Bradycardia	2 (9.1)	2 (9.1)	0	0	0
Left ventricular dysfunction	2 (9.1)	0	0	2 (9.1)	0
Atrioventricular block first degree	1 (4.5)	0	1 (4.5)	0	0
Cardiac failure	1 (4.5)	0	0	0	1 (4.5)
Sinus bradycardia	1 (4.5)	0	0	1 (4.5)	0
Ear and labyrinth disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Ear pain	1 (4.5)	1 (4.5)	0	0	0
Endocrine disorders					
-Total	4 (18.2)	0	4 (18.2)	0	0
Adrenal insufficiency	3 (13.6)	0	3 (13.6)	0	0
Hypothyroidism	1 (4.5)	0	1 (4.5)	0	0
Eye disorders					
-Total	2 (9.1)	2 (9.1)	0	0	0
Ocular hyperaemia	2 (9.1)	2 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	16 (72.7)	4 (18.2)	6 (27.3)	5 (22.7)	1 (4.5)
Vomiting	7 (31.8)	4 (18.2)	2 (9.1)	1 (4.5)	0
Nausea	6 (27.3)	2 (9.1)	3 (13.6)	1 (4.5)	0
Constipation	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Abdominal pain	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Diarrhoea	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pancreatitis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Abdominal compartment syndrome	1 (4.5)	0	0	0	1 (4.5)
Abdominal pain upper	1 (4.5)	1 (4.5)	0	0	0
Anal fissure	1 (4.5)	0	1 (4.5)	0	0
Anal haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Dry mouth	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal sounds abnormal	1 (4.5)	1 (4.5)	0	0	0
Haematemesis	1 (4.5)	1 (4.5)	0	0	0
Ileus	1 (4.5)	0	1 (4.5)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	1 (4.5)	0	0	1 (4.5)	0
Neutropenic colitis	1 (4.5)	0	0	1 (4.5)	0
General disorders and administration site conditions					
-Total	10 (45.5)	2 (9.1)	4 (18.2)	2 (9.1)	2 (9.1)
Pyrexia	5 (22.7)	2 (9.1)	1 (4.5)	1 (4.5)	1 (4.5)
Oedema peripheral	4 (18.2)	3 (13.6)	0	1 (4.5)	0
Face oedema	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Drug withdrawal syndrome	2 (9.1)	0	2 (9.1)	0	0
Fatigue	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Chills	1 (4.5)	1 (4.5)	0	0	0
Generalised oedema	1 (4.5)	0	1 (4.5)	0	0
Multiple organ dysfunction syndrome	1 (4.5)	0	0	0	1 (4.5)
Oedema due to hepatic disease	1 (4.5)	0	1 (4.5)	0	0
Hepatobiliary disorders					
-Total	7 (31.8)	3 (13.6)	2 (9.1)	2 (9.1)	0
Hepatic function abnormal	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyperbilirubinaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Biliary tract disorder	1 (4.5)	1 (4.5)	0	0	0
Gallbladder enlargement	1 (4.5)	1 (4.5)	0	0	0
Hepatomegaly	1 (4.5)	1 (4.5)	0	0	0
Hypertransaminasaemia	1 (4.5)	1 (4.5)	0	0	0
Ocular icterus	1 (4.5)	1 (4.5)	0	0	0
Immune system disorders					
-Total	19 (86.4)	1 (4.5)	7 (31.8)	5 (22.7)	6 (27.3)
Cytokine release syndrome	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Hypogammaglobulinaemia	9 (40.9)	1 (4.5)	7 (31.8)	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	2 (9.1)	0	0	2 (9.1)	0
Immunodeficiency	1 (4.5)	0	0	1 (4.5)	0
Infections and infestations					
-Total	9 (40.9)	1 (4.5)	4 (18.2)	3 (13.6)	1 (4.5)
Clostridium difficile infection	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Atypical pneumonia	1 (4.5)	1 (4.5)	0	0	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Candida infection	1 (4.5)	0	1 (4.5)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (4.5)	0	1 (4.5)	0	0
Encephalitis viral	1 (4.5)	0	0	0	1 (4.5)
Klebsiella bacteraemia	1 (4.5)	0	1 (4.5)	0	0
Meningitis bacterial	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal infection	1 (4.5)	0	1 (4.5)	0	0
Injury, poisoning and procedural complications					
-Total	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Transfusion reaction	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Scratch	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	16 (72.7)	1 (4.5)	0	6 (27.3)	9 (40.9)
Aspartate aminotransferase increased	8 (36.4)	0	2 (9.1)	5 (22.7)	1 (4.5)
White blood cell count decreased	8 (36.4)	0	1 (4.5)	2 (9.1)	5 (22.7)
Blood bilirubin increased	6 (27.3)	0	1 (4.5)	5 (22.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (22.7)	1 (4.5)	4 (18.2)	0	0
Platelet count decreased	5 (22.7)	1 (4.5)	1 (4.5)	1 (4.5)	2 (9.1)
Blood fibrinogen decreased	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Lymphocyte count decreased	4 (18.2)	0	0	3 (13.6)	1 (4.5)
Neutrophil count decreased	4 (18.2)	0	0	0	4 (18.2)
Serum ferritin increased	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Activated partial thromboplastin time prolonged	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin m decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Electrocardiogram qt prolonged	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
International normalised ratio increased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Blood immunoglobulin a decreased	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Blood uric acid increased	2 (9.1)	2 (9.1)	0	0	0
Fibrin d dimer increased	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Amylase increased	1 (4.5)	1 (4.5)	0	0	0
Bacterial test positive	1 (4.5)	0	0	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (4.5)	0	0	1 (4.5)	0
Blood immunoglobulin g decreased	1 (4.5)	1 (4.5)	0	0	0
Blood lactate dehydrogenase increased	1 (4.5)	0	0	1 (4.5)	0
Blood phosphorus increased	1 (4.5)	0	1 (4.5)	0	0
C-reactive protein increased	1 (4.5)	0	0	1 (4.5)	0
Coagulation test abnormal	1 (4.5)	1 (4.5)	0	0	0
Electrocardiogram t wave abnormal	1 (4.5)	0	1 (4.5)	0	0
Lipase increased	1 (4.5)	1 (4.5)	0	0	0
Oxygen saturation decreased	1 (4.5)	1 (4.5)	0	0	0
Staphylococcus test positive	1 (4.5)	1 (4.5)	0	0	0
Troponin increased	1 (4.5)	0	0	1 (4.5)	0
Urine output decreased	1 (4.5)	0	0	1 (4.5)	0
Weight increased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	14 (63.6)	2 (9.1)	3 (13.6)	6 (27.3)	3 (13.6)
Decreased appetite	7 (31.8)	1 (4.5)	1 (4.5)	5 (22.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	7 (31.8)	1 (4.5)	4 (18.2)	2 (9.1)	0
Hypokalaemia	5 (22.7)	1 (4.5)	3 (13.6)	1 (4.5)	0
Hyperglycaemia	4 (18.2)	0	2 (9.1)	2 (9.1)	0
Hypervolaemia	4 (18.2)	0	0	4 (18.2)	0
Hypoalbuminaemia	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Hyperuricaemia	3 (13.6)	3 (13.6)	0	0	0
Hypophosphataemia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Hypercalcaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hypertriglyceridaemia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Metabolic acidosis	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Tumour lysis syndrome	2 (9.1)	0	0	2 (9.1)	0
Acidosis	1 (4.5)	0	0	0	1 (4.5)
Calcium deficiency	1 (4.5)	1 (4.5)	0	0	0
Dehydration	1 (4.5)	0	1 (4.5)	0	0
Hyperkalaemia	1 (4.5)	0	0	1 (4.5)	0
Hypoglycaemia	1 (4.5)	0	1 (4.5)	0	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	9 (40.9)	6 (27.3)	2 (9.1)	1 (4.5)	0
Pain in extremity	3 (13.6)	3 (13.6)	0	0	0
Arthralgia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Back pain	1 (4.5)	1 (4.5)	0	0	0
Bone pain	1 (4.5)	0	1 (4.5)	0	0
Haemarthrosis	1 (4.5)	0	0	1 (4.5)	0
Muscle spasms	1 (4.5)	0	1 (4.5)	0	0
Muscular weakness	1 (4.5)	1 (4.5)	0	0	0
Myalgia	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					
-Total	11 (50.0)	5 (22.7)	2 (9.1)	2 (9.1)	2 (9.1)
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Headache	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Cognitive disorder	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Cerebral haemorrhage	1 (4.5)	0	0	0	1 (4.5)
Dizziness	1 (4.5)	1 (4.5)	0	0	0
Dysarthria	1 (4.5)	0	0	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysgeusia	1 (4.5)	1 (4.5)	0	0	0
Lethargy	1 (4.5)	1 (4.5)	0	0	0
Neurological decompensation	1 (4.5)	0	0	0	1 (4.5)
Paraesthesia	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	1 (4.5)	0	0
Somnolence	1 (4.5)	0	0	1 (4.5)	0
Psychiatric disorders					
-Total	10 (45.5)	5 (22.7)	1 (4.5)	4 (18.2)	0
Delirium	4 (18.2)	1 (4.5)	0	3 (13.6)	0
Agitation	2 (9.1)	0	2 (9.1)	0	0
Anxiety	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Confusional state	2 (9.1)	2 (9.1)	0	0	0
Irritability	2 (9.1)	2 (9.1)	0	0	0
Insomnia	1 (4.5)	1 (4.5)	0	0	0
Mental status changes	1 (4.5)	0	1 (4.5)	0	0
Renal and urinary disorders					
-Total	7 (31.8)	2 (9.1)	1 (4.5)	1 (4.5)	3 (13.6)
Acute kidney injury	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Dysuria	1 (4.5)	1 (4.5)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (4.5)	0	0	0	1 (4.5)
Renal tubular dysfunction	1 (4.5)	1 (4.5)	0	0	0
Urinary retention	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (59.1)	3 (13.6)	1 (4.5)	2 (9.1)	7 (31.8)
Hypoxia	6 (27.3)	0	1 (4.5)	2 (9.1)	3 (13.6)
Pulmonary oedema	6 (27.3)	1 (4.5)	2 (9.1)	2 (9.1)	1 (4.5)
Cough	4 (18.2)	4 (18.2)	0	0	0
Pleural effusion	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Respiratory failure	3 (13.6)	0	0	0	3 (13.6)
Respiratory distress	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Tachypnoea	2 (9.1)	2 (9.1)	0	0	0
Acute respiratory distress syndrome	1 (4.5)	0	0	0	1 (4.5)
Atelectasis	1 (4.5)	0	0	1 (4.5)	0
Bradypnoea	1 (4.5)	0	0	1 (4.5)	0
Rhinorrhoea	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (40.9)	5 (22.7)	3 (13.6)	1 (4.5)	0
Blister	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pruritus	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Dermatitis	1 (4.5)	1 (4.5)	0	0	0
Dermatitis atopic	1 (4.5)	1 (4.5)	0	0	0
Dry skin	1 (4.5)	1 (4.5)	0	0	0
Erythema	1 (4.5)	1 (4.5)	0	0	0
Hyperhidrosis	1 (4.5)	0	1 (4.5)	0	0
Rash papular	1 (4.5)	1 (4.5)	0	0	0
Rash pruritic	1 (4.5)	1 (4.5)	0	0	0
Rash vesicular	1 (4.5)	1 (4.5)	0	0	0
Scab	1 (4.5)	1 (4.5)	0	0	0
Skin discolouration	1 (4.5)	1 (4.5)	0	0	0
Vancomycin infusion reaction	1 (4.5)	0	0	1 (4.5)	0
Surgical and medical procedures					
-Total	1 (4.5)	0	0	1 (4.5)	0
Thrombolysis	1 (4.5)	0	0	1 (4.5)	0
Vascular disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (36.4)	0	2 (9.1)	3 (13.6)	3 (13.6)
Hypotension	8 (36.4)	0	2 (9.1)	3 (13.6)	3 (13.6)
Hypertension	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Capillary leak syndrome	1 (4.5)	0	1 (4.5)	0	0
Peripheral ischaemia	1 (4.5)	0	1 (4.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (94.1)	0	3 (17.6)	3 (17.6)	10 (58.8)
Blood and lymphatic system disorders					
-Total	11 (64.7)	0	1 (5.9)	8 (47.1)	2 (11.8)
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Anaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Neutropenia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Splenomegaly	2 (11.8)	2 (11.8)	0	0	0
Disseminated intravascular coagulation	1 (5.9)	0	0	1 (5.9)	0
Hypofibrinogenaemia	1 (5.9)	0	1 (5.9)	0	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	7 (41.2)	4 (23.5)	2 (11.8)	0	1 (5.9)
Tachycardia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Bradycardia	1 (5.9)	0	1 (5.9)	0	0
Cardiac arrest	1 (5.9)	0	0	0	1 (5.9)
Cardiac dysfunction	1 (5.9)	1 (5.9)	0	0	0
Sinus tachycardia	1 (5.9)	1 (5.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Ear pruritus	1 (5.9)	1 (5.9)	0	0	0
Eye disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Conjunctival haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Periorbital oedema	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	7 (41.2)	4 (23.5)	2 (11.8)	1 (5.9)	0
Vomiting	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Constipation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Diarrhoea	2 (11.8)	2 (11.8)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (11.8)	2 (11.8)	0	0	0
Dysphagia	1 (5.9)	0	0	1 (5.9)	0
Gingival erythema	1 (5.9)	1 (5.9)	0	0	0
Lip oedema	1 (5.9)	1 (5.9)	0	0	0
Pancreatitis	1 (5.9)	0	1 (5.9)	0	0
General disorders and administration site conditions					
-Total	10 (58.8)	6 (35.3)	2 (11.8)	2 (11.8)	0
Pyrexia	5 (29.4)	2 (11.8)	1 (5.9)	2 (11.8)	0
Fatigue	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Generalised oedema	2 (11.8)	2 (11.8)	0	0	0
Catheter site haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Face oedema	1 (5.9)	1 (5.9)	0	0	0
Localised oedema	1 (5.9)	1 (5.9)	0	0	0
Oedema peripheral	1 (5.9)	1 (5.9)	0	0	0
Hepatobiliary disorders					
-Total	3 (17.6)	0	2 (11.8)	0	1 (5.9)
Hepatic function abnormal	1 (5.9)	0	1 (5.9)	0	0
Hepatomegaly	1 (5.9)	0	0	0	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (5.9)	0	1 (5.9)	0	0
Hypertransaminasaemia	1 (5.9)	0	1 (5.9)	0	0
Immune system disorders					
-Total	13 (76.5)	0	5 (29.4)	4 (23.5)	4 (23.5)
Cytokine release syndrome	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)	0	0
Selective igg subclass deficiency	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	7 (41.2)	1 (5.9)	2 (11.8)	4 (23.5)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	2 (11.8)	0	0
Bronchopulmonary aspergillosis	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Oral herpes	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Procedural pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Contusion	1 (5.9)	1 (5.9)	0	0	0
Skin abrasion	1 (5.9)	1 (5.9)	0	0	0
Wound	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	11 (64.7)	0	1 (5.9)	3 (17.6)	7 (41.2)
Aspartate aminotransferase increased	5 (29.4)	1 (5.9)	3 (17.6)	0	1 (5.9)
Platelet count decreased	5 (29.4)	0	1 (5.9)	2 (11.8)	2 (11.8)
White blood cell count decreased	5 (29.4)	0	0	0	5 (29.4)
Alanine aminotransferase increased	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Activated partial thromboplastin time prolonged	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Blood bilirubin increased	3 (17.6)	0	0	3 (17.6)	0
Lymphocyte count decreased	3 (17.6)	0	0	2 (11.8)	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (17.6)	0	0	0	3 (17.6)
Blood creatinine increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Blood fibrinogen decreased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Gamma-glutamyltransferase increased	2 (11.8)	0	0	2 (11.8)	0
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Blood bicarbonate decreased	1 (5.9)	0	1 (5.9)	0	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0	0	0
Cardiac murmur	1 (5.9)	1 (5.9)	0	0	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Fibrin d dimer increased	1 (5.9)	1 (5.9)	0	0	0
Haptoglobin decreased	1 (5.9)	1 (5.9)	0	0	0
Urine output decreased	1 (5.9)	0	0	0	1 (5.9)
Weight increased	1 (5.9)	1 (5.9)	0	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (52.9)	0	1 (5.9)	5 (29.4)	3 (17.6)
Hypokalaemia	5 (29.4)	0	0	4 (23.5)	1 (5.9)
Hypophosphataemia	5 (29.4)	0	1 (5.9)	3 (17.6)	1 (5.9)
Decreased appetite	4 (23.5)	1 (5.9)	1 (5.9)	2 (11.8)	0
Hypocalcaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Hypoalbuminaemia	3 (17.6)	0	3 (17.6)	0	0
Hyperphosphataemia	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Hypercalcaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperchloraemia	1 (5.9)	1 (5.9)	0	0	0
Hyperkalaemia	1 (5.9)	0	0	0	1 (5.9)
Hyperuricaemia	1 (5.9)	1 (5.9)	0	0	0
Hypervolaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Hyponatraemia	1 (5.9)	1 (5.9)	0	0	0
Malnutrition	1 (5.9)	0	0	1 (5.9)	0
Metabolic acidosis	1 (5.9)	0	0	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (29.4)	2 (11.8)	2 (11.8)	1 (5.9)	0
Arthralgia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Muscle rigidity	1 (5.9)	1 (5.9)	0	0	0
Muscular weakness	1 (5.9)	0	0	1 (5.9)	0
Myalgia	1 (5.9)	0	1 (5.9)	0	0
Pain in extremity	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					
-Total	7 (41.2)	0	6 (35.3)	1 (5.9)	0
Headache	5 (29.4)	0	5 (29.4)	0	0
Cognitive disorder	1 (5.9)	0	1 (5.9)	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Generalised tonic-clonic seizure	1 (5.9)	0	1 (5.9)	0	0
Neuralgia	1 (5.9)	0	1 (5.9)	0	0
Somnolence	1 (5.9)	0	0	1 (5.9)	0
Tremor	1 (5.9)	0	1 (5.9)	0	0
Psychiatric disorders					
-Total	5 (29.4)	3 (17.6)	1 (5.9)	1 (5.9)	0
Confusional state	3 (17.6)	3 (17.6)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Delirium	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Anxiety	1 (5.9)	0	1 (5.9)	0	0
Automatism	1 (5.9)	1 (5.9)	0	0	0
Insomnia	1 (5.9)	0	1 (5.9)	0	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Renal and urinary disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Acute kidney injury	1 (5.9)	0	0	1 (5.9)	0
Anuria	1 (5.9)	1 (5.9)	0	0	0
Azotaemia	1 (5.9)	0	1 (5.9)	0	0
Reproductive system and breast disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Perineal rash	1 (5.9)	0	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (52.9)	4 (23.5)	1 (5.9)	2 (11.8)	2 (11.8)
Hypoxia	3 (17.6)	0	1 (5.9)	1 (5.9)	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	2 (11.8)	2 (11.8)	0	0	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0	0	0
Pleural effusion	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Tachypnoea	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Epistaxis	1 (5.9)	0	1 (5.9)	0	0
Haemoptysis	1 (5.9)	0	1 (5.9)	0	0
Nasal congestion	1 (5.9)	0	1 (5.9)	0	0
Nasal discomfort	1 (5.9)	0	1 (5.9)	0	0
Nasal dryness	1 (5.9)	1 (5.9)	0	0	0
Pharyngeal haemorrhage	1 (5.9)	0	1 (5.9)	0	0
Pulmonary oedema	1 (5.9)	0	1 (5.9)	0	0
Respiratory distress	1 (5.9)	0	1 (5.9)	0	0
Respiratory failure	1 (5.9)	0	0	0	1 (5.9)
Wheezing	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Blister	1 (5.9)	1 (5.9)	0	0	0
Dermatitis diaper	1 (5.9)	0	1 (5.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Petechiae	1 (5.9)	0	1 (5.9)	0	0
Pruritus	1 (5.9)	1 (5.9)	0	0	0
Vascular disorders					
-Total	8 (47.1)	0	2 (11.8)	4 (23.5)	2 (11.8)
Hypotension	5 (29.4)	0	2 (11.8)	1 (5.9)	2 (11.8)
Hypertension	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Capillary leak syndrome	1 (5.9)	0	0	1 (5.9)	0
Thrombosis	1 (5.9)	0	1 (5.9)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (100)	1 (2.9)	2 (5.7)	15 (42.9)	17 (48.6)
Blood and lymphatic system disorders					
-Total	22 (62.9)	1 (2.9)	5 (14.3)	13 (37.1)	3 (8.6)
Anaemia	10 (28.6)	2 (5.7)	2 (5.7)	6 (17.1)	0
Febrile neutropenia	9 (25.7)	0	0	9 (25.7)	0
Neutropenia	4 (11.4)	0	1 (2.9)	1 (2.9)	2 (5.7)
Disseminated intravascular coagulation	3 (8.6)	0	3 (8.6)	0	0
Thrombocytopenia	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Coagulopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Leukopenia	2 (5.7)	0	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (5.7)	0	0	2 (5.7)	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Eosinophilia	1 (2.9)	0	1 (2.9)	0	0
Lymphopenia	1 (2.9)	0	0	1 (2.9)	0
Splenomegaly	1 (2.9)	0	1 (2.9)	0	0
Cardiac disorders					
-Total	6 (17.1)	4 (11.4)	1 (2.9)	1 (2.9)	0
Tachycardia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Cardiac failure congestive	1 (2.9)	0	1 (2.9)	0	0
Left ventricular dysfunction	1 (2.9)	0	0	1 (2.9)	0
Mitral valve incompetence	1 (2.9)	1 (2.9)	0	0	0
Pericardial effusion	1 (2.9)	1 (2.9)	0	0	0
Right ventricular dysfunction	1 (2.9)	1 (2.9)	0	0	0
Sinus tachycardia	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (14.3)	2 (5.7)	3 (8.6)	0	0
Eye oedema	1 (2.9)	1 (2.9)	0	0	0
Eye pain	1 (2.9)	1 (2.9)	0	0	0
Eyelid oedema	1 (2.9)	0	1 (2.9)	0	0
Periorbital swelling	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Visual field defect	1 (2.9)	0	1 (2.9)	0	0
Visual impairment	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	26 (74.3)	10 (28.6)	10 (28.6)	6 (17.1)	0
Diarrhoea	11 (31.4)	5 (14.3)	5 (14.3)	1 (2.9)	0
Vomiting	11 (31.4)	6 (17.1)	5 (14.3)	0	0
Nausea	9 (25.7)	5 (14.3)	3 (8.6)	1 (2.9)	0
Abdominal pain	7 (20.0)	1 (2.9)	5 (14.3)	1 (2.9)	0
Constipation	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Abdominal distension	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Abdominal pain upper	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Ascites	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Mouth haemorrhage	2 (5.7)	1 (2.9)	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Enterocolitis	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal sounds abnormal	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	0	1 (2.9)	0	0
Gingival bleeding	1 (2.9)	0	1 (2.9)	0	0
Gingivitis ulcerative	1 (2.9)	0	0	1 (2.9)	0
Lip dry	1 (2.9)	0	1 (2.9)	0	0
Mouth swelling	1 (2.9)	1 (2.9)	0	0	0
Odynophagia	1 (2.9)	1 (2.9)	0	0	0
Pancreatitis	1 (2.9)	0	1 (2.9)	0	0
Proctalgia	1 (2.9)	0	0	1 (2.9)	0
Trichoglossia	1 (2.9)	0	1 (2.9)	0	0
Upper gastrointestinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	16 (45.7)	10 (28.6)	3 (8.6)	2 (5.7)	1 (2.9)
Pyrexia	11 (31.4)	6 (17.1)	2 (5.7)	2 (5.7)	1 (2.9)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	5 (14.3)	5 (14.3)	0	0	0
Chills	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Face oedema	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Asthenia	2 (5.7)	2 (5.7)	0	0	0
Influenza like illness	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Catheter site erythema	1 (2.9)	1 (2.9)	0	0	0
Catheter site pain	1 (2.9)	0	0	1 (2.9)	0
Chest discomfort	1 (2.9)	0	0	1 (2.9)	0
Crying	1 (2.9)	0	1 (2.9)	0	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0
Generalised oedema	1 (2.9)	0	1 (2.9)	0	0
Localised oedema	1 (2.9)	1 (2.9)	0	0	0
Malaise	1 (2.9)	0	1 (2.9)	0	0
Pain	1 (2.9)	0	0	1 (2.9)	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Swelling face	1 (2.9)	1 (2.9)	0	0	0
Vascular device occlusion	1 (2.9)	1 (2.9)	0	0	0
Hepatobiliary disorders					
-Total	6 (17.1)	2 (5.7)	2 (5.7)	1 (2.9)	1 (2.9)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Hyperbilirubinaemia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Cholelithiasis	1 (2.9)	0	1 (2.9)	0	0
Hepatomegaly	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	30 (85.7)	2 (5.7)	6 (17.1)	13 (37.1)	9 (25.7)
Cytokine release syndrome	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Hypogammaglobulinaemia	10 (28.6)	0	6 (17.1)	4 (11.4)	0
Immunodeficiency	2 (5.7)	0	0	2 (5.7)	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	1 (2.9)	0	0	0
Hypersensitivity	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	18 (51.4)	4 (11.4)	4 (11.4)	9 (25.7)	1 (2.9)
Candida infection	2 (5.7)	0	1 (2.9)	0	1 (2.9)
Nail infection	2 (5.7)	2 (5.7)	0	0	0
Oral infection	2 (5.7)	0	2 (5.7)	0	0
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (2.9)	0	0	1 (2.9)	0
Bk virus infection	1 (2.9)	1 (2.9)	0	0	0
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Conjunctivitis	1 (2.9)	0	1 (2.9)	0	0
Encephalitis viral	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Paronychia	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	0	1 (2.9)	0
Pneumonia fungal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Soft tissue infection	1 (2.9)	0	0	1 (2.9)	0
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Varicella zoster virus infection	1 (2.9)	0	0	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	3 (8.6)	0	2 (5.7)	0	1 (2.9)
Fall	2 (5.7)	0	2 (5.7)	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Transplant failure	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	27 (77.1)	3 (8.6)	7 (20.0)	7 (20.0)	10 (28.6)
Neutrophil count decreased	10 (28.6)	0	3 (8.6)	1 (2.9)	6 (17.1)
Platelet count decreased	10 (28.6)	3 (8.6)	1 (2.9)	3 (8.6)	3 (8.6)
White blood cell count decreased	9 (25.7)	3 (8.6)	1 (2.9)	0	5 (14.3)
Alanine aminotransferase increased	8 (22.9)	3 (8.6)	2 (5.7)	3 (8.6)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (20.0)	2 (5.7)	0	2 (5.7)	3 (8.6)
Aspartate aminotransferase increased	5 (14.3)	1 (2.9)	1 (2.9)	2 (5.7)	1 (2.9)
Serum ferritin increased	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Blood lactate dehydrogenase increased	3 (8.6)	2 (5.7)	1 (2.9)	0	0
C-reactive protein increased	3 (8.6)	1 (2.9)	0	2 (5.7)	0
International normalised ratio increased	3 (8.6)	3 (8.6)	0	0	0
Blood bilirubin increased	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0	0	0
Immunoglobulins decreased	2 (5.7)	0	2 (5.7)	0	0
Blood creatine phosphokinase increased	1 (2.9)	0	0	1 (2.9)	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)	0	0
Blood glucose increased	1 (2.9)	0	0	0	1 (2.9)
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0	0	0
Blood testosterone decreased	1 (2.9)	1 (2.9)	0	0	0
Breath sounds abnormal	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus test positive	1 (2.9)	0	1 (2.9)	0	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Prothrombin time prolonged	1 (2.9)	0	1 (2.9)	0	0
Weight decreased	1 (2.9)	0	1 (2.9)	0	0
Weight increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	18 (51.4)	5 (14.3)	4 (11.4)	8 (22.9)	1 (2.9)
Decreased appetite	11 (31.4)	6 (17.1)	1 (2.9)	3 (8.6)	1 (2.9)
Hypokalaemia	8 (22.9)	2 (5.7)	2 (5.7)	4 (11.4)	0
Hypophosphataemia	6 (17.1)	2 (5.7)	2 (5.7)	2 (5.7)	0
Hyperglycaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Hypoalbuminaemia	3 (8.6)	0	3 (8.6)	0	0
Hypocalcaemia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Hypomagnesaemia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Hypermagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hypernatraemia	1 (2.9)	1 (2.9)	0	0	0
Hyperphosphataemia	1 (2.9)	1 (2.9)	0	0	0
Hyperuricaemia	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (2.9)	0	1 (2.9)	0	0
Hyponatraemia	1 (2.9)	1 (2.9)	0	0	0
Polydipsia	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	17 (48.6)	6 (17.1)	9 (25.7)	2 (5.7)	0
Pain in extremity	7 (20.0)	3 (8.6)	4 (11.4)	0	0
Arthralgia	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Myalgia	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Back pain	5 (14.3)	1 (2.9)	3 (8.6)	1 (2.9)	0
Pain in jaw	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Bone pain	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal chest pain	1 (2.9)	1 (2.9)	0	0	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	18 (51.4)	8 (22.9)	6 (17.1)	4 (11.4)	0
Headache	12 (34.3)	8 (22.9)	2 (5.7)	2 (5.7)	0
Tremor	4 (11.4)	4 (11.4)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Dizziness	2 (5.7)	2 (5.7)	0	0	0
Dysgeusia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Lethargy	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Depressed level of consciousness	1 (2.9)	0	0	1 (2.9)	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Hyperaesthesia	1 (2.9)	1 (2.9)	0	0	0
Hypoaesthesia	1 (2.9)	1 (2.9)	0	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Psychiatric disorders					
-Total	11 (31.4)	3 (8.6)	7 (20.0)	1 (2.9)	0
Anxiety	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Hallucination	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Insomnia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Affect lability	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (2.9)	1 (2.9)	0	0	0
Confusional state	1 (2.9)	1 (2.9)	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Restlessness	1 (2.9)	0	1 (2.9)	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	10 (28.6)	3 (8.6)	5 (14.3)	0	2 (5.7)
Acute kidney injury	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Dysuria	2 (5.7)	2 (5.7)	0	0	0
Haematuria	2 (5.7)	2 (5.7)	0	0	0
Pollakiuria	2 (5.7)	0	2 (5.7)	0	0
Anuria	1 (2.9)	0	0	0	1 (2.9)
Incontinence	1 (2.9)	0	1 (2.9)	0	0
Micturition urgency	1 (2.9)	0	1 (2.9)	0	0
Proteinuria	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (2.9)	0	1 (2.9)	0	0
Urinary incontinence	1 (2.9)	0	1 (2.9)	0	0
Urinary tract disorder	1 (2.9)	0	1 (2.9)	0	0
Reproductive system and breast disorders					
-Total	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Female genital tract fistula	1 (2.9)	1 (2.9)	0	0	0
Heavy menstrual bleeding	1 (2.9)	1 (2.9)	0	0	0
Vaginal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (45.7)	6 (17.1)	2 (5.7)	6 (17.1)	2 (5.7)
Hypoxia	7 (20.0)	0	3 (8.6)	2 (5.7)	2 (5.7)
Pulmonary oedema	5 (14.3)	1 (2.9)	0	4 (11.4)	0
Cough	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Epistaxis	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Oropharyngeal pain	3 (8.6)	3 (8.6)	0	0	0
Dyspnoea	2 (5.7)	0	0	2 (5.7)	0
Pleural effusion	2 (5.7)	2 (5.7)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Atelectasis	1 (2.9)	0	1 (2.9)	0	0
Lung infiltration	1 (2.9)	0	0	1 (2.9)	0
Nasal congestion	1 (2.9)	1 (2.9)	0	0	0
Oropharyngeal plaque	1 (2.9)	0	1 (2.9)	0	0
Painful respiration	1 (2.9)	1 (2.9)	0	0	0
Paranasal sinus discomfort	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal erythema	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal exudate	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal oedema	1 (2.9)	0	1 (2.9)	0	0
Productive cough	1 (2.9)	1 (2.9)	0	0	0
Pulmonary mass	1 (2.9)	0	1 (2.9)	0	0
Respiratory disorder	1 (2.9)	0	1 (2.9)	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (37.1)	5 (14.3)	7 (20.0)	1 (2.9)	0
Rash	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Erythema	2 (5.7)	2 (5.7)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	2 (5.7)	0	2 (5.7)	0	0
Rash maculo-papular	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Rash papular	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Dermatitis atopic	1 (2.9)	1 (2.9)	0	0	0
Eczema	1 (2.9)	1 (2.9)	0	0	0
Erythema nodosum	1 (2.9)	1 (2.9)	0	0	0
Hyperhidrosis	1 (2.9)	0	1 (2.9)	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.9)	1 (2.9)	0	0	0
Pruritus allergic	1 (2.9)	0	1 (2.9)	0	0
Purpura	1 (2.9)	1 (2.9)	0	0	0
Skin lesion	1 (2.9)	0	1 (2.9)	0	0
Skin ulcer	1 (2.9)	0	1 (2.9)	0	0
Urticaria	1 (2.9)	0	1 (2.9)	0	0
Social circumstances					
-Total	1 (2.9)	0	1 (2.9)	0	0
Patient uncooperative	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	10 (28.6)	4 (11.4)	3 (8.6)	3 (8.6)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	6 (17.1)	1 (2.9)	2 (5.7)	3 (8.6)	0
Hypertension	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Hot flush	1 (2.9)	1 (2.9)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Lymphocytosis	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	2 (40.0)	0	0
Gastroenteritis	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal infection	1 (20.0)	1 (20.0)	0	0	0
Otitis externa	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Fibula fracture	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	1 (20.0)	0
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Persistent depressive disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Dry skin	2 (40.0)	2 (40.0)	0	0	0
Skin hypopigmentation	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (90.0)	4 (20.0)	4 (20.0)	5 (25.0)	5 (25.0)
Blood and lymphatic system disorders					
-Total	4 (20.0)	1 (5.0)	0	2 (10.0)	1 (5.0)
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Anaemia	1 (5.0)	0	0	1 (5.0)	0
Lymphadenopathy	1 (5.0)	1 (5.0)	0	0	0
Cardiac disorders					
-Total	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Cardiac failure	1 (5.0)	0	0	0	1 (5.0)
Tachycardia	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (40.0)	5 (25.0)	3 (15.0)	0	0
Diarrhoea	4 (20.0)	4 (20.0)	0	0	0
Vomiting	4 (20.0)	4 (20.0)	0	0	0
Nausea	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Gastrointestinal haemorrhage	1 (5.0)	0	1 (5.0)	0	0
Proctalgia	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	6 (30.0)	3 (15.0)	2 (10.0)	1 (5.0)	0
Pyrexia	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Fatigue	1 (5.0)	1 (5.0)	0	0	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Allergy to immunoglobulin therapy	1 (5.0)	0	0	1 (5.0)	0
Engraftment syndrome	1 (5.0)	0	0	1 (5.0)	0
Graft versus host disease	1 (5.0)	0	0	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	8 (40.0)	1 (5.0)	3 (15.0)	3 (15.0)	1 (5.0)
Nasopharyngitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Parainfluenzae virus infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rhinovirus infection	2 (10.0)	0	2 (10.0)	0	0
Upper respiratory tract infection	2 (10.0)	2 (10.0)	0	0	0
Acute sinusitis	1 (5.0)	0	1 (5.0)	0	0
Cellulitis	1 (5.0)	0	1 (5.0)	0	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Coronavirus infection	1 (5.0)	0	0	1 (5.0)	0
Cystitis	1 (5.0)	0	1 (5.0)	0	0
Ear infection	1 (5.0)	0	1 (5.0)	0	0
Gastroenteritis viral	1 (5.0)	1 (5.0)	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Influenza	1 (5.0)	0	1 (5.0)	0	0
Metapneumovirus infection	1 (5.0)	0	0	1 (5.0)	0
Molluscum contagiosum	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Pharyngitis streptococcal	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Injury, poisoning and procedural complications					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Post-traumatic neck syndrome	1 (5.0)	0	1 (5.0)	0	0
Skin abrasion	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	9 (45.0)	4 (20.0)	1 (5.0)	3 (15.0)	1 (5.0)
White blood cell count decreased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	3 (15.0)	0	0	0
Neutrophil count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Blood bilirubin increased	1 (5.0)	0	0	1 (5.0)	0
Blood creatinine increased	1 (5.0)	0	1 (5.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=20			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Blood lactate dehydrogenase increased	1 (5.0)	1 (5.0)	0	0	0
Blood urea increased	1 (5.0)	0	0	1 (5.0)	0
C-reactive protein increased	1 (5.0)	1 (5.0)	0	0	0
Heart sounds abnormal	1 (5.0)	1 (5.0)	0	0	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Oxygen saturation decreased	1 (5.0)	0	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	3 (15.0)	0	1 (5.0)	1 (5.0)	1 (5.0)
Decreased appetite	1 (5.0)	0	1 (5.0)	0	0
Hypervolaemia	1 (5.0)	0	0	1 (5.0)	0
Metabolic acidosis	1 (5.0)	0	0	0	1 (5.0)
Musculoskeletal and connective tissue disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (5.0)	0	1 (5.0)	0	0
Back pain	1 (5.0)	0	1 (5.0)	0	0
Bone pain	1 (5.0)	0	1 (5.0)	0	0
Neck pain	1 (5.0)	1 (5.0)	0	0	0
Nervous system disorders					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Headache	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Extrapyramidal disorder	1 (5.0)	0	1 (5.0)	0	0
Migraine	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Acute kidney injury	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (40.0)	3 (15.0)	2 (10.0)	1 (5.0)	2 (10.0)
Cough	2 (10.0)	2 (10.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Bronchospasm	1 (5.0)	0	1 (5.0)	0	0
Epistaxis	1 (5.0)	0	1 (5.0)	0	0
Hypoxia	1 (5.0)	0	0	1 (5.0)	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Respiratory distress	1 (5.0)	0	0	0	1 (5.0)
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (35.0)	4 (20.0)	3 (15.0)	0	0
Dermatitis allergic	1 (5.0)	1 (5.0)	0	0	0
Dermatitis atopic	1 (5.0)	1 (5.0)	0	0	0
Dry skin	1 (5.0)	1 (5.0)	0	0	0
Erythema	1 (5.0)	0	1 (5.0)	0	0
Ingrowing nail	1 (5.0)	0	1 (5.0)	0	0
Miliaria	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (5.0)	0	1 (5.0)	0	0
Skin discolouration	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Hypertension	1 (5.0)	0	1 (5.0)	0	0
Hypotension	1 (5.0)	0	0	0	1 (5.0)
Venoocclusive disease	1 (5.0)	0	0	1 (5.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (93.3)	2 (13.3)	4 (26.7)	3 (20.0)	5 (33.3)
Blood and lymphatic system disorders					
-Total	3 (20.0)	0	0	1 (6.7)	2 (13.3)
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Leukocytosis	1 (6.7)	0	1 (6.7)	0	0
Lymphopenia	1 (6.7)	0	0	1 (6.7)	0
Neutropenia	1 (6.7)	0	0	0	1 (6.7)
Thrombocytopenia	1 (6.7)	0	0	0	1 (6.7)
Cardiac disorders					
-Total	2 (13.3)	1 (6.7)	0	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (6.7)	0	0	0	1 (6.7)
Cardiac failure	1 (6.7)	0	0	1 (6.7)	0
Tachycardia	1 (6.7)	1 (6.7)	0	0	0
Endocrine disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Hypothyroidism	1 (6.7)	0	1 (6.7)	0	0
Eye disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Visual impairment	1 (6.7)	1 (6.7)	0	0	0
Gastrointestinal disorders					
-Total	5 (33.3)	3 (20.0)	1 (6.7)	1 (6.7)	0
Diarrhoea	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Constipation	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal inflammation	1 (6.7)	0	1 (6.7)	0	0
Nausea	1 (6.7)	1 (6.7)	0	0	0
Pancreatitis	1 (6.7)	0	0	1 (6.7)	0
Stomatitis	1 (6.7)	1 (6.7)	0	0	0
Vomiting	1 (6.7)	1 (6.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	7 (46.7)	4 (26.7)	2 (13.3)	1 (6.7)	0
Pyrexia	4 (26.7)	1 (6.7)	2 (13.3)	1 (6.7)	0
Fatigue	2 (13.3)	2 (13.3)	0	0	0
Malaise	1 (6.7)	1 (6.7)	0	0	0
Oedema peripheral	1 (6.7)	1 (6.7)	0	0	0
Hepatobiliary disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Hypertransaminasaemia	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					
-Total	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Hypogammaglobulinaemia	3 (20.0)	0	3 (20.0)	0	0
Immunodeficiency	1 (6.7)	0	0	1 (6.7)	0
Infections and infestations					
-Total	7 (46.7)	1 (6.7)	2 (13.3)	4 (26.7)	0
Respiratory syncytial virus infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Respiratory tract infection	2 (13.3)	1 (6.7)	1 (6.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Adenovirus infection	1 (6.7)	0	0	1 (6.7)	0
Bacteraemia	1 (6.7)	0	1 (6.7)	0	0
Bk virus infection	1 (6.7)	0	0	1 (6.7)	0
Cytomegalovirus infection reactivation	1 (6.7)	0	0	1 (6.7)	0
Ear infection	1 (6.7)	0	1 (6.7)	0	0
Gastroenteritis clostridial	1 (6.7)	0	1 (6.7)	0	0
Herpes simplex	1 (6.7)	0	1 (6.7)	0	0
Human herpesvirus 6 infection	1 (6.7)	0	0	1 (6.7)	0
Metapneumovirus infection	1 (6.7)	0	0	1 (6.7)	0
Nail infection	1 (6.7)	1 (6.7)	0	0	0
Nasopharyngitis	1 (6.7)	1 (6.7)	0	0	0
Oral herpes	1 (6.7)	0	1 (6.7)	0	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Pneumocystis jirovecii pneumonia	1 (6.7)	0	0	1 (6.7)	0
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Sinusitis fungal	1 (6.7)	0	0	1 (6.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (6.7)	0	0	1 (6.7)	0
Injury, poisoning and procedural complications					
-Total	1 (6.7)	1 (6.7)	0	0	0
Infusion related reaction	1 (6.7)	1 (6.7)	0	0	0
Investigations					
-Total	6 (40.0)	1 (6.7)	1 (6.7)	3 (20.0)	1 (6.7)
Neutrophil count decreased	2 (13.3)	1 (6.7)	0	0	1 (6.7)
White blood cell count decreased	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Blood thyroid stimulating hormone increased	1 (6.7)	1 (6.7)	0	0	0
Blood uric acid increased	1 (6.7)	0	0	1 (6.7)	0
Ejection fraction decreased	1 (6.7)	0	1 (6.7)	0	0
Platelet count decreased	1 (6.7)	0	0	0	1 (6.7)
Weight increased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	4 (26.7)	1 (6.7)	2 (13.3)	0	1 (6.7)
Decreased appetite	3 (20.0)	1 (6.7)	2 (13.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (6.7)	0	1 (6.7)	0	0
Hypokalaemia	1 (6.7)	0	0	0	1 (6.7)
Metabolic syndrome	1 (6.7)	0	1 (6.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (33.3)	2 (13.3)	1 (6.7)	2 (13.3)	0
Pain in extremity	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Back pain	2 (13.3)	0	0	2 (13.3)	0
Arthralgia	1 (6.7)	1 (6.7)	0	0	0
Growth retardation	1 (6.7)	0	1 (6.7)	0	0
Musculoskeletal chest pain	1 (6.7)	1 (6.7)	0	0	0
Myalgia	1 (6.7)	0	1 (6.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (6.7)	0	1 (6.7)	0	0
Cancer pain	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Headache	1 (6.7)	1 (6.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	3 (20.0)	0	3 (20.0)	0	0
Anxiety	3 (20.0)	0	3 (20.0)	0	0
Delirium	1 (6.7)	0	1 (6.7)	0	0
Renal and urinary disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Acute kidney injury	1 (6.7)	0	1 (6.7)	0	0
Dysuria	1 (6.7)	0	1 (6.7)	0	0
Haematuria	1 (6.7)	0	0	1 (6.7)	0
Kidney enlargement	1 (6.7)	0	1 (6.7)	0	0
Renal mass	1 (6.7)	0	1 (6.7)	0	0
Reproductive system and breast disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Dysmenorrhoea	1 (6.7)	0	1 (6.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Cough	1 (6.7)	0	1 (6.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (6.7)	0	1 (6.7)	0	0
Rhinorrhoea	1 (6.7)	1 (6.7)	0	0	0
Upper respiratory tract inflammation	1 (6.7)	0	1 (6.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Dry skin	1 (6.7)	1 (6.7)	0	0	0
Eczema	1 (6.7)	1 (6.7)	0	0	0
Photosensitivity reaction	1 (6.7)	0	1 (6.7)	0	0
Rash	1 (6.7)	1 (6.7)	0	0	0
Vascular disorders					
-Total	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypotension	1 (6.7)	0	0	1 (6.7)	0
Venoocclusive disease	1 (6.7)	0	0	0	1 (6.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (94.3)	2 (5.7)	14 (40.0)	6 (17.1)	11 (31.4)
Blood and lymphatic system disorders					
-Total	9 (25.7)	2 (5.7)	3 (8.6)	3 (8.6)	1 (2.9)
Anaemia	4 (11.4)	4 (11.4)	0	0	0
Neutropenia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Disseminated intravascular coagulation	1 (2.9)	0	0	1 (2.9)	0
Eosinophilia	1 (2.9)	0	1 (2.9)	0	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Leukopenia	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
Cardiac disorders					
-Total	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Cardiac arrest	1 (2.9)	0	0	0	1 (2.9)
Left ventricular dysfunction	1 (2.9)	0	1 (2.9)	0	0
Tricuspid valve incompetence	1 (2.9)	1 (2.9)	0	0	0
Eye disorders					
-Total	3 (8.6)	3 (8.6)	0	0	0
Cataract	2 (5.7)	2 (5.7)	0	0	0
Hypermetropia	1 (2.9)	1 (2.9)	0	0	0
Ocular hyperaemia	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	7 (20.0)	5 (14.3)	2 (5.7)	0	0
Constipation	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Abdominal pain upper	1 (2.9)	1 (2.9)	0	0	0
Abdominal rigidity	1 (2.9)	0	1 (2.9)	0	0
Dyspepsia	1 (2.9)	1 (2.9)	0	0	0
Enteritis	1 (2.9)	0	1 (2.9)	0	0
Mouth haemorrhage	1 (2.9)	1 (2.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.9)	1 (2.9)	0	0	0
Pancreatitis	1 (2.9)	1 (2.9)	0	0	0
Peritoneal haematoma	1 (2.9)	1 (2.9)	0	0	0
Trichoglossia	1 (2.9)	1 (2.9)	0	0	0
Vomiting	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	10 (28.6)	7 (20.0)	2 (5.7)	1 (2.9)	0
Pyrexia	7 (20.0)	4 (11.4)	3 (8.6)	0	0
Fatigue	2 (5.7)	2 (5.7)	0	0	0
Asthenia	1 (2.9)	1 (2.9)	0	0	0
Chills	1 (2.9)	1 (2.9)	0	0	0
Non-cardiac chest pain	1 (2.9)	1 (2.9)	0	0	0
Pain	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hepatic cytolysis	1 (2.9)	1 (2.9)	0	0	0
Liver disorder	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (25.7)	1 (2.9)	7 (20.0)	1 (2.9)	0
Hypogammaglobulinaemia	6 (17.1)	0	6 (17.1)	0	0
Allergy to immunoglobulin therapy	1 (2.9)	1 (2.9)	0	0	0
Drug hypersensitivity	1 (2.9)	0	1 (2.9)	0	0
Graft versus host disease	1 (2.9)	0	0	1 (2.9)	0
Infections and infestations					
-Total	22 (62.9)	3 (8.6)	7 (20.0)	5 (14.3)	7 (20.0)
Gastroenteritis	4 (11.4)	2 (5.7)	0	2 (5.7)	0
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Rhinovirus infection	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Upper respiratory tract infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Pneumonia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Rhinitis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Sinusitis	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Ear, nose and throat infection	1 (2.9)	0	1 (2.9)	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	0	0	1 (2.9)	0
Oral candidiasis	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Otitis media	1 (2.9)	0	0	1 (2.9)	0
Paronychia	1 (2.9)	0	1 (2.9)	0	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection viral	1 (2.9)	0	1 (2.9)	0	0
Salmonellosis	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal skin infection	1 (2.9)	0	1 (2.9)	0	0
Tinea pedis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	0	0	1 (2.9)	0
Viral infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Ligament sprain	1 (2.9)	1 (2.9)	0	0	0
Limb injury	1 (2.9)	0	1 (2.9)	0	0
Investigations					
-Total	13 (37.1)	1 (2.9)	5 (14.3)	4 (11.4)	3 (8.6)
Neutrophil count decreased	4 (11.4)	0	1 (2.9)	1 (2.9)	2 (5.7)
Lymphocyte count decreased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
White blood cell count decreased	3 (8.6)	2 (5.7)	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Blood bilirubin increased	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin a decreased	1 (2.9)	0	0	1 (2.9)	0
Blood immunoglobulin m decreased	1 (2.9)	0	0	1 (2.9)	0
Blood uric acid increased	1 (2.9)	0	0	0	1 (2.9)
Bone density decreased	1 (2.9)	1 (2.9)	0	0	0
Hepatitis b virus test positive	1 (2.9)	0	1 (2.9)	0	0
Immunoglobulins decreased	1 (2.9)	0	1 (2.9)	0	0
Platelet count decreased	1 (2.9)	0	0	1 (2.9)	0
Weight decreased	1 (2.9)	0	0	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	7 (20.0)	2 (5.7)	1 (2.9)	3 (8.6)	1 (2.9)
Decreased appetite	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Hyperuricaemia	2 (5.7)	2 (5.7)	0	0	0
Hypokalaemia	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Haemochromatosis	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (2.9)	1 (2.9)	0	0	0
Hypophagia	1 (2.9)	0	1 (2.9)	0	0
Hypophosphataemia	1 (2.9)	0	1 (2.9)	0	0
Iron overload	1 (2.9)	0	1 (2.9)	0	0
Malnutrition	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	0	1 (2.9)
Musculoskeletal and connective tissue disorders					
-Total	7 (20.0)	3 (8.6)	3 (8.6)	1 (2.9)	0
Back pain	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Pain in extremity	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Arthralgia	1 (2.9)	1 (2.9)	0	0	0
Bone pain	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal pain	1 (2.9)	0	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Skin papilloma	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	9 (25.7)	4 (11.4)	3 (8.6)	0	2 (5.7)
Headache	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Autonomic neuropathy	1 (2.9)	0	0	1 (2.9)	0
Cerebral haemorrhage	1 (2.9)	0	0	0	1 (2.9)
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Hydrocephalus	1 (2.9)	0	0	0	1 (2.9)
Memory impairment	1 (2.9)	0	1 (2.9)	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Psychiatric disorders					
-Total	5 (14.3)	1 (2.9)	3 (8.6)	1 (2.9)	0
Anxiety	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Mental status changes	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Agitation	1 (2.9)	1 (2.9)	0	0	0
Mood altered	1 (2.9)	1 (2.9)	0	0	0
Nightmare	1 (2.9)	1 (2.9)	0	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Tearfulness	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (8.6)	0	1 (2.9)	1 (2.9)	1 (2.9)
Acute kidney injury	1 (2.9)	0	0	0	1 (2.9)
Cystitis haemorrhagic	1 (2.9)	0	1 (2.9)	0	0
Renal tubular disorder	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (34.3)	6 (17.1)	3 (8.6)	2 (5.7)	1 (2.9)
Cough	7 (20.0)	5 (14.3)	2 (5.7)	0	0
Nasal congestion	3 (8.6)	3 (8.6)	0	0	0
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hypoxia	2 (5.7)	0	0	2 (5.7)	0
Acute respiratory distress syndrome	1 (2.9)	0	0	0	1 (2.9)
Bronchial oedema	1 (2.9)	1 (2.9)	0	0	0
Dyspnoea	1 (2.9)	0	1 (2.9)	0	0
Lung disorder	1 (2.9)	1 (2.9)	0	0	0
Paranasal sinus inflammation	1 (2.9)	1 (2.9)	0	0	0
Pleural effusion	1 (2.9)	0	1 (2.9)	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	8 (22.9)	4 (11.4)	3 (8.6)	1 (2.9)	0
Rash	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Dry skin	2 (5.7)	0	2 (5.7)	0	0
Decubitus ulcer	1 (2.9)	0	0	1 (2.9)	0
Hangnail	1 (2.9)	1 (2.9)	0	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Night sweats	1 (2.9)	1 (2.9)	0	0	0
Skin swelling	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	2 (5.7)	1 (2.9)	0	0	1 (2.9)
Hypotension	2 (5.7)	1 (2.9)	0	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Irritable bowel syndrome	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Rhinovirus infection	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (46.2)	0	3 (23.1)	2 (15.4)	1 (7.7)
Blood and lymphatic system disorders					
-Total	2 (15.4)	0	2 (15.4)	0	0
Hypercoagulation	1 (7.7)	0	1 (7.7)	0	0
Lymphadenopathy	1 (7.7)	0	1 (7.7)	0	0
Gastrointestinal disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Constipation	1 (7.7)	1 (7.7)	0	0	0
Diarrhoea	1 (7.7)	1 (7.7)	0	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=13		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.7)	0	0	0	1 (7.7)
Multiple organ dysfunction syndrome	1 (7.7)	0	0	0	1 (7.7)
Pyrexia	1 (7.7)	0	1 (7.7)	0	0
Immune system disorders					
-Total	1 (7.7)	0	0	0	1 (7.7)
Chronic graft versus host disease	1 (7.7)	0	0	1 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Infections and infestations					
-Total	5 (38.5)	0	3 (23.1)	1 (7.7)	1 (7.7)
Bronchitis	1 (7.7)	0	1 (7.7)	0	0
Conjunctivitis	1 (7.7)	1 (7.7)	0	0	0
Covid-19 pneumonia	1 (7.7)	0	0	0	1 (7.7)
Enterovirus infection	1 (7.7)	0	0	1 (7.7)	0
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Influenza	1 (7.7)	0	0	0	1 (7.7)
Otitis media acute	1 (7.7)	0	1 (7.7)	0	0
Parainfluenzae virus infection	1 (7.7)	0	0	1 (7.7)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

		All patients N=13			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Rhinovirus infection	1 (7.7)	0	0	1 (7.7)	0
Skin infection	1 (7.7)	0	1 (7.7)	0	0
Staphylococcal bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	0	1 (7.7)	0	0
Injury, poisoning and procedural complications					
-Total	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Abdominal injury	1 (7.7)	1 (7.7)	0	0	0
Infusion related reaction	1 (7.7)	0	0	1 (7.7)	0
Investigations					
-Total	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Blood immunoglobulin g decreased	1 (7.7)	0	1 (7.7)	0	0
Oxygen saturation decreased	1 (7.7)	0	0	1 (7.7)	0
Platelet count decreased	1 (7.7)	1 (7.7)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (15.4)	0	0	2 (15.4)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (7.7)	0	0	1 (7.7)	0
Obesity	1 (7.7)	0	0	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (15.4)	0	1 (7.7)	0	1 (7.7)
Cough	1 (7.7)	1 (7.7)	0	0	0
Dyspnoea	1 (7.7)	0	0	0	1 (7.7)
Pleural effusion	1 (7.7)	0	1 (7.7)	0	0
Sleep apnoea syndrome	1 (7.7)	0	1 (7.7)	0	0
Tachypnoea	1 (7.7)	0	0	0	1 (7.7)
Skin and subcutaneous tissue disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Rash	1 (7.7)	1 (7.7)	0	0	0
Rash maculo-papular	1 (7.7)	1 (7.7)	0	0	0
Vascular disorders					
-Total	1 (7.7)	0	0	1 (7.7)	0
Hypertension	1 (7.7)	0	0	1 (7.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	4 (36.4)	3 (27.3)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Delayed puberty	1 (9.1)	0	1 (9.1)	0	0
Hypothyroidism	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Dry eye	1 (9.1)	1 (9.1)	0	0	0
Mydriasis	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Diarrhoea	2 (18.2)	1 (9.1)	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (9.1)	1 (9.1)	0	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	1 (9.1)	0	1 (9.1)	0	0
Fatigue	1 (9.1)	0	1 (9.1)	0	0
Immune system disorders					
-Total	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Seasonal allergy	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hypogammaglobulinaemia	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Bronchiolitis	1 (9.1)	0	0	1 (9.1)	0
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Covid-19	1 (9.1)	1 (9.1)	0	0	0
Device related sepsis	1 (9.1)	0	0	1 (9.1)	0
Folliculitis	1 (9.1)	0	1 (9.1)	0	0
Fungal skin infection	1 (9.1)	0	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (9.1)	0	1 (9.1)	0	0
Nail infection	1 (9.1)	0	1 (9.1)	0	0
Otitis media	1 (9.1)	0	1 (9.1)	0	0
Pneumonia respiratory syncytial viral	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Syphilis	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Varicella zoster virus infection	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	1 (9.1)	1 (9.1)	0	0	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Hypercholesterolaemia	1 (9.1)	0	1 (9.1)	0	0
Hyperlipidaemia	1 (9.1)	0	1 (9.1)	0	0
Hypertriglyceridaemia	1 (9.1)	0	1 (9.1)	0	0
Iron overload	1 (9.1)	0	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Joint effusion	1 (9.1)	0	1 (9.1)	0	0
Osteopenia	1 (9.1)	1 (9.1)	0	0	0
Synovitis	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Reproductive system and breast disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Endometriosis	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Rhinorrhoea	2 (18.2)	0	2 (18.2)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Dyspnoea	1 (9.1)	0	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (9.1)	0	0	1 (9.1)	0
Wheezing	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Rash	1 (9.1)	0	1 (9.1)	0	0
Rash erythematous	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypertension	1 (9.1)	0	1 (9.1)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (73.9)	2 (8.7)	3 (13.0)	6 (26.1)	6 (26.1)
Blood and lymphatic system disorders					
-Total	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Agranulocytosis	1 (4.3)	0	0	1 (4.3)	0
Anaemia	1 (4.3)	0	1 (4.3)	0	0
Neutropenia	1 (4.3)	0	0	0	1 (4.3)
Thrombocytopenia	1 (4.3)	0	1 (4.3)	0	0
Congenital, familial and genetic disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Cerebral cavernous malformation	1 (4.3)	1 (4.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Deafness unilateral	1 (4.3)	0	1 (4.3)	0	0
Eye disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Eye pain	1 (4.3)	0	0	1 (4.3)	0
Eyelid oedema	1 (4.3)	1 (4.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Diarrhoea	2 (8.7)	1 (4.3)	0	1 (4.3)	0
General disorders and administration site conditions					
-Total	6 (26.1)	4 (17.4)	1 (4.3)	1 (4.3)	0
Pyrexia	3 (13.0)	2 (8.7)	0	1 (4.3)	0
Pain	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Non-cardiac chest pain	1 (4.3)	1 (4.3)	0	0	0
Xerosis	1 (4.3)	1 (4.3)	0	0	0
Immune system disorders					
-Total	4 (17.4)	0	3 (13.0)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (8.7)	0	2 (8.7)	0	0
Chronic graft versus host disease	1 (4.3)	0	1 (4.3)	0	0
Drug hypersensitivity	1 (4.3)	0	0	1 (4.3)	0
Infections and infestations					
-Total	13 (56.5)	2 (8.7)	2 (8.7)	6 (26.1)	3 (13.0)
Conjunctivitis	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Sepsis	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Sinusitis	3 (13.0)	0	3 (13.0)	0	0
Upper respiratory tract infection	3 (13.0)	2 (8.7)	0	1 (4.3)	0
Fungal infection	2 (8.7)	0	2 (8.7)	0	0
Herpes zoster	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Oral herpes	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Skin infection	2 (8.7)	0	2 (8.7)	0	0
Urinary tract infection	2 (8.7)	0	2 (8.7)	0	0
Acute sinusitis	1 (4.3)	0	1 (4.3)	0	0
Candida infection	1 (4.3)	0	1 (4.3)	0	0
Covid-19	1 (4.3)	0	0	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (4.3)	0	0	1 (4.3)	0
Herpes virus infection	1 (4.3)	0	1 (4.3)	0	0
Influenza	1 (4.3)	0	1 (4.3)	0	0
Meningitis pneumococcal	1 (4.3)	0	0	1 (4.3)	0
Neutropenic infection	1 (4.3)	0	0	1 (4.3)	0
Ophthalmic herpes zoster	1 (4.3)	0	1 (4.3)	0	0
Oral candidiasis	1 (4.3)	0	1 (4.3)	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Rhinitis	1 (4.3)	1 (4.3)	0	0	0
Rhinovirus infection	1 (4.3)	0	1 (4.3)	0	0
Septic shock	1 (4.3)	0	0	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	0	0	1 (4.3)	0
Streptococcal sepsis	1 (4.3)	0	1 (4.3)	0	0
Urinary tract infection pseudomonal	1 (4.3)	0	1 (4.3)	0	0
Viral skin infection	1 (4.3)	1 (4.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.3)	1 (4.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ligament sprain	1 (4.3)	1 (4.3)	0	0	0
Investigations					
-Total	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Neutrophil count decreased	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Blood bilirubin increased	1 (4.3)	1 (4.3)	0	0	0
Platelet count decreased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Decreased appetite	1 (4.3)	0	0	0	1 (4.3)
Hypernatraemia	1 (4.3)	0	0	1 (4.3)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (17.4)	1 (4.3)	3 (13.0)	0	0
Pain in extremity	2 (8.7)	0	2 (8.7)	0	0
Growth retardation	1 (4.3)	0	1 (4.3)	0	0
Osteonecrosis	1 (4.3)	1 (4.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.3)	0	0	1 (4.3)	0
Bone giant cell tumour benign	1 (4.3)	0	0	1 (4.3)	0
Nervous system disorders					
-Total	3 (13.0)	0	1 (4.3)	2 (8.7)	0
Dysarthria	1 (4.3)	0	1 (4.3)	0	0
Headache	1 (4.3)	0	0	1 (4.3)	0
Nervous system disorder	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0
Psychiatric disorders					
-Total	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Anxiety	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Tic	1 (4.3)	0	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (26.1)	4 (17.4)	0	0	2 (8.7)
Cough	2 (8.7)	2 (8.7)	0	0	0
Dyspnoea	1 (4.3)	1 (4.3)	0	0	0
Dyspnoea exertional	1 (4.3)	1 (4.3)	0	0	0
Epistaxis	1 (4.3)	1 (4.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (4.3)	0	0	0	1 (4.3)
Oropharyngeal pain	1 (4.3)	1 (4.3)	0	0	0
Pharyngeal erythema	1 (4.3)	1 (4.3)	0	0	0
Respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Rhinorrhoea	1 (4.3)	1 (4.3)	0	0	0
Sleep apnoea syndrome	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (21.7)	2 (8.7)	0	3 (13.0)	0
Dermatitis atopic	1 (4.3)	0	0	1 (4.3)	0
Dry skin	1 (4.3)	1 (4.3)	0	0	0
Eczema	1 (4.3)	0	0	1 (4.3)	0
Papule	1 (4.3)	1 (4.3)	0	0	0
Rash macular	1 (4.3)	0	0	1 (4.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders					
-Total	5 (83.3)	0	1 (16.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Lymphocytosis	1 (16.7)	0	1 (16.7)	0	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Irritable bowel syndrome	1 (16.7)	0	1 (16.7)	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	0	2 (33.3)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	2 (33.3)	2 (33.3)	0	0	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Face oedema	1 (16.7)	0	1 (16.7)	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0	0	0
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0	0	0
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

			All patients N=6		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (50.0)	0	2 (33.3)	0	1 (16.7)
Fibula fracture	1 (16.7)	0	1 (16.7)	0	0
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Persistent depressive disorder	1 (16.7)	0	1 (16.7)	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Nasal congestion	2 (33.3)	2 (33.3)	0	0	0
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Cough	1 (16.7)	1 (16.7)	0	0	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	4 (66.7)	3 (50.0)	0	1 (16.7)	0
Dry skin	2 (33.3)	2 (33.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin hypopigmentation	1 (16.7)	1 (16.7)	0	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	0	3 (13.6)	2 (9.1)	17 (77.3)
Blood and lymphatic system disorders					
-Total	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Anaemia	6 (27.3)	2 (9.1)	2 (9.1)	2 (9.1)	0
Febrile neutropenia	6 (27.3)	0	0	5 (22.7)	1 (4.5)
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Coagulopathy	2 (9.1)	0	2 (9.1)	0	0
Disseminated intravascular coagulation	2 (9.1)	0	2 (9.1)	0	0
Lymphadenopathy	2 (9.1)	1 (4.5)	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercoagulation	1 (4.5)	0	1 (4.5)	0	0
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Splenomegaly	1 (4.5)	1 (4.5)	0	0	0
Cardiac disorders					
-Total	9 (40.9)	1 (4.5)	2 (9.1)	4 (18.2)	2 (9.1)
Tachycardia	7 (31.8)	2 (9.1)	3 (13.6)	2 (9.1)	0
Bradycardia	2 (9.1)	2 (9.1)	0	0	0
Cardiac failure	2 (9.1)	0	0	0	2 (9.1)
Left ventricular dysfunction	2 (9.1)	0	0	2 (9.1)	0
Atrioventricular block first degree	1 (4.5)	0	1 (4.5)	0	0
Sinus bradycardia	1 (4.5)	0	0	1 (4.5)	0
Ear and labyrinth disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Ear pain	1 (4.5)	1 (4.5)	0	0	0
Endocrine disorders					
-Total	4 (18.2)	0	4 (18.2)	0	0
Adrenal insufficiency	3 (13.6)	0	3 (13.6)	0	0
Hypothyroidism	1 (4.5)	0	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	2 (9.1)	2 (9.1)	0	0	0
Ocular hyperaemia	2 (9.1)	2 (9.1)	0	0	0
Conjunctival haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	17 (77.3)	4 (18.2)	7 (31.8)	5 (22.7)	1 (4.5)
Vomiting	10 (45.5)	7 (31.8)	2 (9.1)	1 (4.5)	0
Nausea	8 (36.4)	2 (9.1)	5 (22.7)	1 (4.5)	0
Diarrhoea	6 (27.3)	5 (22.7)	1 (4.5)	0	0
Constipation	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Abdominal pain	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Pancreatitis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Abdominal compartment syndrome	1 (4.5)	0	0	0	1 (4.5)
Abdominal pain upper	1 (4.5)	1 (4.5)	0	0	0
Anal fissure	1 (4.5)	0	1 (4.5)	0	0
Anal haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Dry mouth	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal haemorrhage	1 (4.5)	0	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	1 (4.5)	1 (4.5)	0	0	0
Haematemesis	1 (4.5)	1 (4.5)	0	0	0
Ileus	1 (4.5)	0	1 (4.5)	0	0
Mouth haemorrhage	1 (4.5)	0	0	1 (4.5)	0
Neutropenic colitis	1 (4.5)	0	0	1 (4.5)	0
Proctalgia	1 (4.5)	1 (4.5)	0	0	0
General disorders and administration site conditions					
-Total	13 (59.1)	3 (13.6)	4 (18.2)	3 (13.6)	3 (13.6)
Pyrexia	8 (36.4)	2 (9.1)	3 (13.6)	2 (9.1)	1 (4.5)
Oedema peripheral	4 (18.2)	3 (13.6)	0	1 (4.5)	0
Face oedema	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Fatigue	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Drug withdrawal syndrome	2 (9.1)	0	2 (9.1)	0	0
Multiple organ dysfunction syndrome	2 (9.1)	0	0	0	2 (9.1)
Chills	1 (4.5)	1 (4.5)	0	0	0
Generalised oedema	1 (4.5)	0	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema due to hepatic disease	1 (4.5)	0	1 (4.5)	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Hepatobiliary disorders					
-Total	7 (31.8)	3 (13.6)	2 (9.1)	2 (9.1)	0
Hepatic function abnormal	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyperbilirubinaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Biliary tract disorder	1 (4.5)	1 (4.5)	0	0	0
Gallbladder enlargement	1 (4.5)	1 (4.5)	0	0	0
Hepatomegaly	1 (4.5)	1 (4.5)	0	0	0
Hypertransaminasaemia	1 (4.5)	1 (4.5)	0	0	0
Ocular icterus	1 (4.5)	1 (4.5)	0	0	0
Immune system disorders					
-Total	20 (90.9)	1 (4.5)	7 (31.8)	5 (22.7)	7 (31.8)
Cytokine release syndrome	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Hypogammaglobulinaemia	10 (45.5)	1 (4.5)	8 (36.4)	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	3 (13.6)	0	0	2 (9.1)	1 (4.5)
Allergy to immunoglobulin therapy	1 (4.5)	0	0	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	1 (4.5)	0	0	1 (4.5)	0
Engraftment syndrome	1 (4.5)	0	0	1 (4.5)	0
Graft versus host disease	1 (4.5)	0	0	1 (4.5)	0
Immunodeficiency	1 (4.5)	0	0	1 (4.5)	0
Infections and infestations					
-Total	15 (68.2)	2 (9.1)	6 (27.3)	4 (18.2)	3 (13.6)
Clostridium difficile infection	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Parainfluenzae virus infection	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Staphylococcal bacteraemia	3 (13.6)	0	0	3 (13.6)	0
Upper respiratory tract infection	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Influenza	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Nasopharyngitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pneumonia	2 (9.1)	0	0	0	2 (9.1)
Acute sinusitis	1 (4.5)	0	1 (4.5)	0	0
Atypical pneumonia	1 (4.5)	1 (4.5)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Candida infection	1 (4.5)	0	1 (4.5)	0	0
Cellulitis	1 (4.5)	0	1 (4.5)	0	0
Cholecystitis infective	1 (4.5)	0	1 (4.5)	0	0
Coronavirus infection	1 (4.5)	0	0	1 (4.5)	0
Covid-19 pneumonia	1 (4.5)	0	0	0	1 (4.5)
Cystitis	1 (4.5)	0	1 (4.5)	0	0
Ear infection	1 (4.5)	0	1 (4.5)	0	0
Encephalitis viral	1 (4.5)	0	0	0	1 (4.5)
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis	1 (4.5)	1 (4.5)	0	0	0
Gastroenteritis viral	1 (4.5)	1 (4.5)	0	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Klebsiella bacteraemia	1 (4.5)	0	1 (4.5)	0	0
Meningitis bacterial	1 (4.5)	0	0	1 (4.5)	0
Metapneumovirus infection	1 (4.5)	0	0	1 (4.5)	0
Molluscum contagiosum	1 (4.5)	1 (4.5)	0	0	0
Otitis media	1 (4.5)	0	1 (4.5)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (4.5)	0	1 (4.5)	0	0
Pharyngitis streptococcal	1 (4.5)	0	0	1 (4.5)	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	0	1 (4.5)	0	0
Viral upper respiratory tract infection	1 (4.5)	0	0	1 (4.5)	0
Injury, poisoning and procedural complications					
-Total	7 (31.8)	4 (18.2)	2 (9.1)	1 (4.5)	0
Transfusion reaction	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Abdominal injury	1 (4.5)	1 (4.5)	0	0	0
Contusion	1 (4.5)	1 (4.5)	0	0	0
Infusion related reaction	1 (4.5)	0	0	1 (4.5)	0
Post-traumatic neck syndrome	1 (4.5)	0	1 (4.5)	0	0
Scratch	1 (4.5)	1 (4.5)	0	0	0
Skin abrasion	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	17 (77.3)	1 (4.5)	1 (4.5)	6 (27.3)	9 (40.9)
White blood cell count decreased	9 (40.9)	1 (4.5)	1 (4.5)	2 (9.1)	5 (22.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	8 (36.4)	0	2 (9.1)	5 (22.7)	1 (4.5)
Platelet count decreased	7 (31.8)	3 (13.6)	1 (4.5)	1 (4.5)	2 (9.1)
Blood bilirubin increased	6 (27.3)	0	1 (4.5)	5 (22.7)	0
Alanine aminotransferase increased	5 (22.7)	1 (4.5)	4 (18.2)	0	0
Lymphocyte count decreased	5 (22.7)	0	0	4 (18.2)	1 (4.5)
Neutrophil count decreased	5 (22.7)	0	0	1 (4.5)	4 (18.2)
Blood fibrinogen decreased	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Serum ferritin increased	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Activated partial thromboplastin time prolonged	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin a decreased	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin g decreased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Blood immunoglobulin m decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Electrocardiogram qt prolonged	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=22			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Oxygen saturation decreased	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Blood creatinine increased	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Blood lactate dehydrogenase increased	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Blood uric acid increased	2 (9.1)	2 (9.1)	0	0	0
C-reactive protein increased	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Fibrin d dimer increased	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Amylase increased	1 (4.5)	1 (4.5)	0	0	0
Bacterial test positive	1 (4.5)	0	0	1 (4.5)	0
Blood phosphorus increased	1 (4.5)	0	1 (4.5)	0	0
Blood urea increased	1 (4.5)	0	0	1 (4.5)	0
Coagulation test abnormal	1 (4.5)	1 (4.5)	0	0	0
Electrocardiogram t wave abnormal	1 (4.5)	0	1 (4.5)	0	0
Heart sounds abnormal	1 (4.5)	1 (4.5)	0	0	0
Lipase increased	1 (4.5)	1 (4.5)	0	0	0
Staphylococcus test positive	1 (4.5)	1 (4.5)	0	0	0
Troponin increased	1 (4.5)	0	0	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urine output decreased	1 (4.5)	0	0	1 (4.5)	0
Weight increased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	14 (63.6)	1 (4.5)	2 (9.1)	7 (31.8)	4 (18.2)
Decreased appetite	8 (36.4)	1 (4.5)	2 (9.1)	5 (22.7)	0
Hypocalcaemia	7 (31.8)	1 (4.5)	4 (18.2)	2 (9.1)	0
Hyperglycaemia	5 (22.7)	0	2 (9.1)	3 (13.6)	0
Hypervolaemia	5 (22.7)	0	0	5 (22.7)	0
Hypokalaemia	5 (22.7)	1 (4.5)	3 (13.6)	1 (4.5)	0
Hypoalbuminaemia	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Hyperuricaemia	3 (13.6)	3 (13.6)	0	0	0
Hypophosphataemia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Metabolic acidosis	3 (13.6)	1 (4.5)	0	0	2 (9.1)
Hypercalcaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hypertriglyceridaemia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Tumour lysis syndrome	2 (9.1)	0	0	2 (9.1)	0
Acidosis	1 (4.5)	0	0	0	1 (4.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Calcium deficiency	1 (4.5)	1 (4.5)	0	0	0
Dehydration	1 (4.5)	0	1 (4.5)	0	0
Hyperkalaemia	1 (4.5)	0	0	1 (4.5)	0
Hypoglycaemia	1 (4.5)	0	1 (4.5)	0	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Obesity	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (45.5)	5 (22.7)	4 (18.2)	1 (4.5)	0
Pain in extremity	3 (13.6)	3 (13.6)	0	0	0
Arthralgia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Bone pain	2 (9.1)	0	2 (9.1)	0	0
Back pain	1 (4.5)	0	1 (4.5)	0	0
Haemarthrosis	1 (4.5)	0	0	1 (4.5)	0
Muscle spasms	1 (4.5)	0	1 (4.5)	0	0
Muscular weakness	1 (4.5)	1 (4.5)	0	0	0
Myalgia	1 (4.5)	1 (4.5)	0	0	0
Neck pain	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (59.1)	6 (27.3)	3 (13.6)	2 (9.1)	2 (9.1)
Headache	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Cognitive disorder	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Cerebral haemorrhage	1 (4.5)	0	0	0	1 (4.5)
Dizziness	1 (4.5)	1 (4.5)	0	0	0
Dysarthria	1 (4.5)	0	0	1 (4.5)	0
Dysgeusia	1 (4.5)	1 (4.5)	0	0	0
Extrapyramidal disorder	1 (4.5)	0	1 (4.5)	0	0
Lethargy	1 (4.5)	1 (4.5)	0	0	0
Migraine	1 (4.5)	0	1 (4.5)	0	0
Neurological decompensation	1 (4.5)	0	0	0	1 (4.5)
Paraesthesia	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	1 (4.5)	0	0
Somnolence	1 (4.5)	0	0	1 (4.5)	0
Psychiatric disorders					
-Total	11 (50.0)	5 (22.7)	2 (9.1)	4 (18.2)	0
Delirium	4 (18.2)	1 (4.5)	0	3 (13.6)	0
Anxiety	3 (13.6)	0	2 (9.1)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (9.1)	0	2 (9.1)	0	0
Confusional state	2 (9.1)	2 (9.1)	0	0	0
Irritability	2 (9.1)	2 (9.1)	0	0	0
Insomnia	1 (4.5)	1 (4.5)	0	0	0
Mental status changes	1 (4.5)	0	1 (4.5)	0	0
Renal and urinary disorders					
-Total	8 (36.4)	3 (13.6)	1 (4.5)	1 (4.5)	3 (13.6)
Acute kidney injury	4 (18.2)	1 (4.5)	0	1 (4.5)	2 (9.1)
Dysuria	1 (4.5)	1 (4.5)	0	0	0
Renal failure	1 (4.5)	0	0	0	1 (4.5)
Renal tubular dysfunction	1 (4.5)	1 (4.5)	0	0	0
Urinary retention	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (77.3)	4 (18.2)	2 (9.1)	2 (9.1)	9 (40.9)
Hypoxia	7 (31.8)	0	1 (4.5)	3 (13.6)	3 (13.6)
Cough	6 (27.3)	6 (27.3)	0	0	0
Pulmonary oedema	6 (27.3)	1 (4.5)	2 (9.1)	2 (9.1)	1 (4.5)
Pleural effusion	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	4 (18.2)	0	0	0	4 (18.2)
Respiratory distress	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Tachypnoea	3 (13.6)	2 (9.1)	0	0	1 (4.5)
Rhinitis allergic	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Acute respiratory distress syndrome	1 (4.5)	0	0	0	1 (4.5)
Atelectasis	1 (4.5)	0	0	1 (4.5)	0
Bradypnoea	1 (4.5)	0	0	1 (4.5)	0
Bronchospasm	1 (4.5)	0	1 (4.5)	0	0
Dyspnoea	1 (4.5)	0	0	0	1 (4.5)
Epistaxis	1 (4.5)	0	1 (4.5)	0	0
Nasal congestion	1 (4.5)	1 (4.5)	0	0	0
Oropharyngeal pain	1 (4.5)	0	1 (4.5)	0	0
Rhinorrhoea	1 (4.5)	1 (4.5)	0	0	0
Sleep apnoea syndrome	1 (4.5)	0	1 (4.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (63.6)	7 (31.8)	6 (27.3)	1 (4.5)	0
Pruritus	3 (13.6)	1 (4.5)	2 (9.1)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Dry skin	2 (9.1)	2 (9.1)	0	0	0
Erythema	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Skin discolouration	2 (9.1)	2 (9.1)	0	0	0
Dermatitis	1 (4.5)	1 (4.5)	0	0	0
Dermatitis allergic	1 (4.5)	1 (4.5)	0	0	0
Dermatitis atopic	1 (4.5)	1 (4.5)	0	0	0
Hyperhidrosis	1 (4.5)	0	1 (4.5)	0	0
Ingrowing nail	1 (4.5)	0	1 (4.5)	0	0
Miliaria	1 (4.5)	1 (4.5)	0	0	0
Rash	1 (4.5)	1 (4.5)	0	0	0
Rash maculo-papular	1 (4.5)	1 (4.5)	0	0	0
Rash papular	1 (4.5)	1 (4.5)	0	0	0
Rash pruritic	1 (4.5)	1 (4.5)	0	0	0
Rash vesicular	1 (4.5)	1 (4.5)	0	0	0
Scab	1 (4.5)	1 (4.5)	0	0	0
Vancomycin infusion reaction	1 (4.5)	0	0	1 (4.5)	0
Surgical and medical procedures					

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	0	0	1 (4.5)	0
Thrombolysis	1 (4.5)	0	0	1 (4.5)	0
Vascular disorders					
-Total	10 (45.5)	0	2 (9.1)	4 (18.2)	4 (18.2)
Hypotension	9 (40.9)	0	2 (9.1)	3 (13.6)	4 (18.2)
Hypertension	6 (27.3)	1 (4.5)	3 (13.6)	2 (9.1)	0
Capillary leak syndrome	1 (4.5)	0	1 (4.5)	0	0
Peripheral ischaemia	1 (4.5)	0	1 (4.5)	0	0
Venoocclusive disease	1 (4.5)	0	0	1 (4.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	2 (11.8)	3 (17.6)	12 (70.6)
Blood and lymphatic system disorders					
-Total	11 (64.7)	0	1 (5.9)	8 (47.1)	2 (11.8)
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Anaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Neutropenia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Splenomegaly	2 (11.8)	2 (11.8)	0	0	0
Disseminated intravascular coagulation	1 (5.9)	0	0	1 (5.9)	0
Hypofibrinogenaemia	1 (5.9)	0	1 (5.9)	0	0
Leukocytosis	1 (5.9)	0	1 (5.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (5.9)	0	0	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Cardiac disorders					
-Total	8 (47.1)	4 (23.5)	2 (11.8)	0	2 (11.8)
Tachycardia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Cardiac arrest	2 (11.8)	0	0	0	2 (11.8)
Bradycardia	1 (5.9)	0	1 (5.9)	0	0
Cardiac dysfunction	1 (5.9)	1 (5.9)	0	0	0
Cardiac failure	1 (5.9)	0	0	1 (5.9)	0
Sinus tachycardia	1 (5.9)	1 (5.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Ear pruritus	1 (5.9)	1 (5.9)	0	0	0
Endocrine disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0
Hypothyroidism	2 (11.8)	0	2 (11.8)	0	0
Delayed puberty	1 (5.9)	0	1 (5.9)	0	0
Eye disorders					
-Total	4 (23.5)	3 (17.6)	1 (5.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=17			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Dry eye	1 (5.9)	1 (5.9)	0	0	0
Mydriasis	1 (5.9)	0	1 (5.9)	0	0
Periorbital oedema	1 (5.9)	1 (5.9)	0	0	0
Visual impairment	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	12 (70.6)	6 (35.3)	4 (23.5)	2 (11.8)	0
Diarrhoea	7 (41.2)	5 (29.4)	2 (11.8)	0	0
Vomiting	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Nausea	4 (23.5)	4 (23.5)	0	0	0
Constipation	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Pancreatitis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Dysphagia	1 (5.9)	0	0	1 (5.9)	0
Gastrointestinal inflammation	1 (5.9)	0	1 (5.9)	0	0
Gingival erythema	1 (5.9)	1 (5.9)	0	0	0
Lip oedema	1 (5.9)	1 (5.9)	0	0	0
Stomatitis	1 (5.9)	1 (5.9)	0	0	0
General disorders and administration site conditions					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (82.4)	7 (41.2)	4 (23.5)	3 (17.6)	0
Pyrexia	9 (52.9)	3 (17.6)	3 (17.6)	3 (17.6)	0
Fatigue	6 (35.3)	4 (23.5)	2 (11.8)	0	0
Generalised oedema	2 (11.8)	2 (11.8)	0	0	0
Oedema peripheral	2 (11.8)	2 (11.8)	0	0	0
Catheter site haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Face oedema	1 (5.9)	1 (5.9)	0	0	0
Localised oedema	1 (5.9)	1 (5.9)	0	0	0
Malaise	1 (5.9)	1 (5.9)	0	0	0
Hepatobiliary disorders					
-Total	3 (17.6)	0	2 (11.8)	0	1 (5.9)
Hepatic function abnormal	1 (5.9)	0	1 (5.9)	0	0
Hepatomegaly	1 (5.9)	0	0	0	1 (5.9)
Hyperbilirubinaemia	1 (5.9)	0	1 (5.9)	0	0
Hypertransaminasaemia	1 (5.9)	0	1 (5.9)	0	0
Immune system disorders					
-Total	14 (82.4)	0	5 (29.4)	5 (29.4)	4 (23.5)
Cytokine release syndrome	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	6 (35.3)	1 (5.9)	4 (23.5)	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)	0	0
Immunodeficiency	1 (5.9)	0	0	1 (5.9)	0
Selective igg subclass deficiency	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	12 (70.6)	2 (11.8)	3 (17.6)	7 (41.2)	0
Upper respiratory tract infection	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Nail infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Otitis media	2 (11.8)	0	2 (11.8)	0	0
Respiratory syncytial virus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Sinusitis	2 (11.8)	0	2 (11.8)	0	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	2 (11.8)	0	0
Adenovirus infection	1 (5.9)	0	0	1 (5.9)	0
Bacteraemia	1 (5.9)	0	1 (5.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	1 (5.9)	0	0	1 (5.9)	0
Bronchiolitis	1 (5.9)	0	0	1 (5.9)	0
Bronchitis	1 (5.9)	0	1 (5.9)	0	0
Bronchopulmonary aspergillosis	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Covid-19	1 (5.9)	1 (5.9)	0	0	0
Cytomegalovirus infection reactivation	1 (5.9)	0	0	1 (5.9)	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Ear infection	1 (5.9)	0	1 (5.9)	0	0
Folliculitis	1 (5.9)	0	1 (5.9)	0	0
Fungal skin infection	1 (5.9)	0	1 (5.9)	0	0
Gastroenteritis clostridial	1 (5.9)	0	1 (5.9)	0	0
Gastroenteritis viral	1 (5.9)	0	1 (5.9)	0	0
Herpes simplex	1 (5.9)	0	1 (5.9)	0	0
Human herpesvirus 6 infection	1 (5.9)	0	0	1 (5.9)	0
Metapneumovirus infection	1 (5.9)	0	0	1 (5.9)	0
Nasopharyngitis	1 (5.9)	1 (5.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=17			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (5.9)	0	0	1 (5.9)	0
Pneumocystis jirovecii pneumonia	1 (5.9)	0	0	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	0	0	1 (5.9)	0
Rhinovirus infection	1 (5.9)	0	1 (5.9)	0	0
Sinusitis fungal	1 (5.9)	0	0	1 (5.9)	0
Syphilis	1 (5.9)	0	1 (5.9)	0	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0
Varicella zoster virus infection	1 (5.9)	0	1 (5.9)	0	0
Viral infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Procedural pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Contusion	1 (5.9)	1 (5.9)	0	0	0
Infusion related reaction	1 (5.9)	1 (5.9)	0	0	0
Skin abrasion	1 (5.9)	1 (5.9)	0	0	0
Wound	1 (5.9)	0	1 (5.9)	0	0
Investigations					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (70.6)	0	2 (11.8)	3 (17.6)	7 (41.2)
Aspartate aminotransferase increased	5 (29.4)	1 (5.9)	3 (17.6)	0	1 (5.9)
Platelet count decreased	5 (29.4)	0	1 (5.9)	2 (11.8)	2 (11.8)
White blood cell count decreased	5 (29.4)	0	0	0	5 (29.4)
Alanine aminotransferase increased	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Neutrophil count decreased	4 (23.5)	0	0	0	4 (23.5)
Activated partial thromboplastin time prolonged	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Blood bilirubin increased	3 (17.6)	0	0	3 (17.6)	0
Lymphocyte count decreased	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Blood creatinine increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Blood fibrinogen decreased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Gamma-glutamyltransferase increased	2 (11.8)	0	0	2 (11.8)	0
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Blood bicarbonate decreased	1 (5.9)	0	1 (5.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0	0	0
Blood thyroid stimulating hormone increased	1 (5.9)	1 (5.9)	0	0	0
Blood uric acid increased	1 (5.9)	0	0	1 (5.9)	0
Cardiac murmur	1 (5.9)	1 (5.9)	0	0	0
Ejection fraction decreased	1 (5.9)	0	1 (5.9)	0	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Fibrin d dimer increased	1 (5.9)	1 (5.9)	0	0	0
Haptoglobin decreased	1 (5.9)	1 (5.9)	0	0	0
Urine output decreased	1 (5.9)	0	0	0	1 (5.9)
Weight increased	1 (5.9)	0	0	1 (5.9)	0
Metabolism and nutrition disorders					
-Total	12 (70.6)	1 (5.9)	3 (17.6)	5 (29.4)	3 (17.6)
Decreased appetite	7 (41.2)	2 (11.8)	3 (17.6)	2 (11.8)	0
Hypokalaemia	5 (29.4)	0	0	4 (23.5)	1 (5.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	5 (29.4)	0	1 (5.9)	3 (17.6)	1 (5.9)
Hypocalcaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Hypoalbuminaemia	3 (17.6)	0	3 (17.6)	0	0
Hyperkalaemia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Hyperphosphataemia	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Hypercalcaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperchloraemia	1 (5.9)	1 (5.9)	0	0	0
Hypercholesterolaemia	1 (5.9)	0	1 (5.9)	0	0
Hyperlipidaemia	1 (5.9)	0	1 (5.9)	0	0
Hypertriglyceridaemia	1 (5.9)	0	1 (5.9)	0	0
Hyperuricaemia	1 (5.9)	1 (5.9)	0	0	0
Hypervolaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Hyponatraemia	1 (5.9)	1 (5.9)	0	0	0
Iron overload	1 (5.9)	0	1 (5.9)	0	0
Malnutrition	1 (5.9)	0	0	1 (5.9)	0
Metabolic acidosis	1 (5.9)	0	0	0	1 (5.9)
Metabolic syndrome	1 (5.9)	0	1 (5.9)	0	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=17			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	10 (58.8)	3 (17.6)	4 (23.5)	3 (17.6)	0
Arthralgia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Pain in extremity	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Back pain	2 (11.8)	0	0	2 (11.8)	0
Myalgia	2 (11.8)	0	2 (11.8)	0	0
Growth retardation	1 (5.9)	0	1 (5.9)	0	0
Joint effusion	1 (5.9)	0	1 (5.9)	0	0
Muscle rigidity	1 (5.9)	1 (5.9)	0	0	0
Muscular weakness	1 (5.9)	0	0	1 (5.9)	0
Musculoskeletal chest pain	1 (5.9)	1 (5.9)	0	0	0
Osteopenia	1 (5.9)	1 (5.9)	0	0	0
Synovitis	1 (5.9)	0	1 (5.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.9)	0	1 (5.9)	0	0
Cancer pain	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (41.2)	0	6 (35.3)	1 (5.9)	0
Headache	5 (29.4)	0	5 (29.4)	0	0
Cognitive disorder	1 (5.9)	0	1 (5.9)	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Generalised tonic-clonic seizure	1 (5.9)	0	1 (5.9)	0	0
Neuralgia	1 (5.9)	0	1 (5.9)	0	0
Somnolence	1 (5.9)	0	0	1 (5.9)	0
Tremor	1 (5.9)	0	1 (5.9)	0	0
Psychiatric disorders					
-Total	8 (47.1)	3 (17.6)	4 (23.5)	1 (5.9)	0
Anxiety	4 (23.5)	0	4 (23.5)	0	0
Confusional state	3 (17.6)	3 (17.6)	0	0	0
Delirium	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Automatism	1 (5.9)	1 (5.9)	0	0	0
Insomnia	1 (5.9)	0	1 (5.9)	0	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Renal and urinary disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.8)	0	0	2 (11.8)	0
Acute kidney injury	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Anuria	1 (5.9)	1 (5.9)	0	0	0
Azotaemia	1 (5.9)	0	1 (5.9)	0	0
Dysuria	1 (5.9)	0	1 (5.9)	0	0
Haematuria	1 (5.9)	0	0	1 (5.9)	0
Kidney enlargement	1 (5.9)	0	1 (5.9)	0	0
Renal mass	1 (5.9)	0	1 (5.9)	0	0
Reproductive system and breast disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Dysmenorrhoea	1 (5.9)	0	1 (5.9)	0	0
Endometriosis	1 (5.9)	0	0	1 (5.9)	0
Perineal rash	1 (5.9)	0	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (52.9)	3 (17.6)	2 (11.8)	2 (11.8)	2 (11.8)
Cough	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Hypoxia	3 (17.6)	0	0	2 (11.8)	1 (5.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Nasal congestion	2 (11.8)	0	2 (11.8)	0	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0	0	0
Pleural effusion	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Tachypnoea	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Wheezing	2 (11.8)	0	2 (11.8)	0	0
Dyspnoea	1 (5.9)	0	1 (5.9)	0	0
Epistaxis	1 (5.9)	0	1 (5.9)	0	0
Haemoptysis	1 (5.9)	0	1 (5.9)	0	0
Nasal discomfort	1 (5.9)	0	1 (5.9)	0	0
Nasal dryness	1 (5.9)	1 (5.9)	0	0	0
Pharyngeal haemorrhage	1 (5.9)	0	1 (5.9)	0	0
Pulmonary oedema	1 (5.9)	0	1 (5.9)	0	0
Respiratory distress	1 (5.9)	0	1 (5.9)	0	0
Respiratory failure	1 (5.9)	0	0	0	1 (5.9)
Upper respiratory tract inflammation	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Blister	1 (5.9)	1 (5.9)	0	0	0
Dermatitis diaper	1 (5.9)	0	1 (5.9)	0	0
Dry skin	1 (5.9)	1 (5.9)	0	0	0
Eczema	1 (5.9)	1 (5.9)	0	0	0
Petechiae	1 (5.9)	0	1 (5.9)	0	0
Photosensitivity reaction	1 (5.9)	0	1 (5.9)	0	0
Pruritus	1 (5.9)	1 (5.9)	0	0	0
Rash	1 (5.9)	0	1 (5.9)	0	0
Rash erythematous	1 (5.9)	1 (5.9)	0	0	0
Vascular disorders					
-Total	11 (64.7)	0	3 (17.6)	5 (29.4)	3 (17.6)
Hypotension	6 (35.3)	0	2 (11.8)	2 (11.8)	2 (11.8)
Hypertension	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Capillary leak syndrome	1 (5.9)	0	0	1 (5.9)	0
Thrombosis	1 (5.9)	0	1 (5.9)	0	0
Venoocclusive disease	1 (5.9)	0	0	0	1 (5.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 204r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (100)	1 (2.9)	0	12 (34.3)	22 (62.9)
Blood and lymphatic system disorders					
-Total	24 (68.6)	0	5 (14.3)	15 (42.9)	4 (11.4)
Anaemia	13 (37.1)	4 (11.4)	3 (8.6)	6 (17.1)	0
Febrile neutropenia	10 (28.6)	0	0	10 (28.6)	0
Neutropenia	6 (17.1)	0	1 (2.9)	2 (5.7)	3 (8.6)
Disseminated intravascular coagulation	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Thrombocytopenia	4 (11.4)	0	0	2 (5.7)	2 (5.7)
Coagulopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Leukopenia	2 (5.7)	0	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	2 (5.7)	0	0	2 (5.7)	0
Agranulocytosis	1 (2.9)	0	0	1 (2.9)	0
B-cell aplasia	1 (2.9)	0	1 (2.9)	0	0
Eosinophilia	1 (2.9)	0	1 (2.9)	0	0
Lymphopenia	1 (2.9)	0	0	1 (2.9)	0
Splenomegaly	1 (2.9)	0	1 (2.9)	0	0
Cardiac disorders					
-Total	8 (22.9)	4 (11.4)	2 (5.7)	1 (2.9)	1 (2.9)
Tachycardia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Left ventricular dysfunction	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Cardiac arrest	1 (2.9)	0	0	0	1 (2.9)
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Cardiac failure congestive	1 (2.9)	0	1 (2.9)	0	0
Mitral valve incompetence	1 (2.9)	1 (2.9)	0	0	0
Pericardial effusion	1 (2.9)	1 (2.9)	0	0	0
Right ventricular dysfunction	1 (2.9)	1 (2.9)	0	0	0
Sinus tachycardia	1 (2.9)	0	1 (2.9)	0	0
Tricuspid valve incompetence	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Congenital, familial and genetic disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Cerebral cavernous malformation	1 (2.9)	1 (2.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Deafness unilateral	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	8 (22.9)	4 (11.4)	3 (8.6)	1 (2.9)	0
Cataract	2 (5.7)	2 (5.7)	0	0	0
Eye pain	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Eyelid oedema	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Eye oedema	1 (2.9)	1 (2.9)	0	0	0
Hypermetropia	1 (2.9)	1 (2.9)	0	0	0
Ocular hyperaemia	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital swelling	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Visual field defect	1 (2.9)	0	1 (2.9)	0	0
Visual impairment	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	29 (82.9)	11 (31.4)	11 (31.4)	7 (20.0)	0
Diarrhoea	13 (37.1)	6 (17.1)	5 (14.3)	2 (5.7)	0
Vomiting	11 (31.4)	6 (17.1)	5 (14.3)	0	0
Nausea	9 (25.7)	5 (14.3)	3 (8.6)	1 (2.9)	0
Abdominal pain	7 (20.0)	1 (2.9)	5 (14.3)	1 (2.9)	0
Constipation	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Abdominal pain upper	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Mouth haemorrhage	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Abdominal distension	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Ascites	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Pancreatitis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Stomatitis	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Trichoglossia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Abdominal rigidity	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (2.9)	1 (2.9)	0	0	0
Enteritis	1 (2.9)	0	1 (2.9)	0	0
Enterocolitis	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal sounds abnormal	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	0	1 (2.9)	0	0
Gingival bleeding	1 (2.9)	0	1 (2.9)	0	0
Gingivitis ulcerative	1 (2.9)	0	0	1 (2.9)	0
Lip dry	1 (2.9)	0	1 (2.9)	0	0
Mouth swelling	1 (2.9)	1 (2.9)	0	0	0
Odynophagia	1 (2.9)	1 (2.9)	0	0	0
Peritoneal haematoma	1 (2.9)	1 (2.9)	0	0	0
Proctalgia	1 (2.9)	0	0	1 (2.9)	0
Upper gastrointestinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	22 (62.9)	14 (40.0)	4 (11.4)	3 (8.6)	1 (2.9)
Pyrexia	15 (42.9)	9 (25.7)	2 (5.7)	3 (8.6)	1 (2.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	6 (17.1)	6 (17.1)	0	0	0
Chills	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Pain	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Asthenia	3 (8.6)	3 (8.6)	0	0	0
Face oedema	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Influenza like illness	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Non-cardiac chest pain	2 (5.7)	2 (5.7)	0	0	0
Catheter site erythema	1 (2.9)	1 (2.9)	0	0	0
Catheter site pain	1 (2.9)	0	0	1 (2.9)	0
Chest discomfort	1 (2.9)	0	0	1 (2.9)	0
Crying	1 (2.9)	0	1 (2.9)	0	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0
Generalised oedema	1 (2.9)	0	1 (2.9)	0	0
Localised oedema	1 (2.9)	1 (2.9)	0	0	0
Malaise	1 (2.9)	0	1 (2.9)	0	0
Sluggishness	1 (2.9)	0	1 (2.9)	0	0
Swelling face	1 (2.9)	1 (2.9)	0	0	0
Vascular device occlusion	1 (2.9)	1 (2.9)	0	0	0
Xerosis	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	8 (22.9)	3 (8.6)	3 (8.6)	1 (2.9)	1 (2.9)
Hepatic function abnormal	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Hyperbilirubinaemia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Cholelithiasis	1 (2.9)	0	1 (2.9)	0	0
Hepatic cytolysis	1 (2.9)	1 (2.9)	0	0	0
Hepatomegaly	1 (2.9)	1 (2.9)	0	0	0
Liver disorder	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	32 (91.4)	1 (2.9)	8 (22.9)	14 (40.0)	9 (25.7)
Cytokine release syndrome	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Hypogammaglobulinaemia	15 (42.9)	0	11 (31.4)	4 (11.4)	0
Drug hypersensitivity	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Immunodeficiency	2 (5.7)	0	0	2 (5.7)	0
Allergy to immunoglobulin therapy	1 (2.9)	1 (2.9)	0	0	0
Chronic graft versus host disease	1 (2.9)	0	1 (2.9)	0	0
Graft versus host disease	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.9)	1 (2.9)	0	0	0
Hypersensitivity	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	30 (85.7)	4 (11.4)	3 (8.6)	13 (37.1)	10 (28.6)
Upper respiratory tract infection	6 (17.1)	3 (8.6)	1 (2.9)	2 (5.7)	0
Conjunctivitis	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Gastroenteritis	4 (11.4)	2 (5.7)	0	2 (5.7)	0
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Rhinovirus infection	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Sinusitis	4 (11.4)	0	2 (5.7)	2 (5.7)	0
Candida infection	3 (8.6)	0	2 (5.7)	0	1 (2.9)
Oral candidiasis	3 (8.6)	0	3 (8.6)	0	0
Oral herpes	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Pneumonia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Rhinitis	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Sepsis	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Urinary tract infection	3 (8.6)	0	2 (5.7)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal infection	2 (5.7)	0	2 (5.7)	0	0
Gingivitis	2 (5.7)	2 (5.7)	0	0	0
Herpes zoster	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Nail infection	2 (5.7)	2 (5.7)	0	0	0
Oral infection	2 (5.7)	0	2 (5.7)	0	0
Otitis externa	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Otitis media	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Paronychia	2 (5.7)	0	2 (5.7)	0	0
Septic shock	2 (5.7)	0	0	0	2 (5.7)
Skin infection	2 (5.7)	0	2 (5.7)	0	0
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Adenovirus infection	1 (2.9)	0	0	1 (2.9)	0
Anal abscess	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Bk virus infection	1 (2.9)	1 (2.9)	0	0	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	0	1 (2.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Covid-19	1 (2.9)	0	0	1 (2.9)	0
Device related infection	1 (2.9)	0	0	1 (2.9)	0
Ear infection	1 (2.9)	0	0	1 (2.9)	0
Ear, nose and throat infection	1 (2.9)	0	1 (2.9)	0	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Encephalitis viral	1 (2.9)	0	0	1 (2.9)	0
Enterobacter infection	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	1 (2.9)	0	0	0
Granulicatella infection	1 (2.9)	0	0	1 (2.9)	0
Herpes simplex	1 (2.9)	0	0	1 (2.9)	0
Herpes virus infection	1 (2.9)	0	1 (2.9)	0	0
Human herpesvirus 6 infection	1 (2.9)	0	0	1 (2.9)	0
Influenza	1 (2.9)	0	1 (2.9)	0	0
Klebsiella infection	1 (2.9)	0	0	1 (2.9)	0
Mastoiditis	1 (2.9)	0	0	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	0	0	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	0	0	1 (2.9)	0
Myringitis	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic infection	1 (2.9)	0	0	1 (2.9)	0
Ophthalmic herpes zoster	1 (2.9)	0	1 (2.9)	0	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	0	0	1 (2.9)
Pneumonia fungal	1 (2.9)	0	0	1 (2.9)	0
Pneumonia viral	1 (2.9)	0	0	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection viral	1 (2.9)	0	1 (2.9)	0	0
Salmonellosis	1 (2.9)	0	1 (2.9)	0	0
Soft tissue infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal abscess	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Staphylococcal skin infection	1 (2.9)	0	1 (2.9)	0	0
Stomatococcal infection	1 (2.9)	0	1 (2.9)	0	0
Streptococcal sepsis	1 (2.9)	0	1 (2.9)	0	0
Systemic candida	1 (2.9)	0	0	1 (2.9)	0
Tinea pedis	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection pseudomonal	1 (2.9)	0	1 (2.9)	0	0
Varicella zoster virus infection	1 (2.9)	0	0	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	0	0	1 (2.9)	0
Viral infection	1 (2.9)	0	1 (2.9)	0	0
Viral skin infection	1 (2.9)	1 (2.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	7 (20.0)	3 (8.6)	3 (8.6)	0	1 (2.9)
Fall	2 (5.7)	0	2 (5.7)	0	0
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Ligament sprain	2 (5.7)	2 (5.7)	0	0	0
Limb injury	1 (2.9)	0	1 (2.9)	0	0
Transplant failure	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	28 (80.0)	2 (5.7)	6 (17.1)	9 (25.7)	11 (31.4)
Neutrophil count decreased	12 (34.3)	1 (2.9)	2 (5.7)	2 (5.7)	7 (20.0)
Platelet count decreased	11 (31.4)	3 (8.6)	1 (2.9)	4 (11.4)	3 (8.6)
White blood cell count decreased	9 (25.7)	2 (5.7)	2 (5.7)	0	5 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	8 (22.9)	2 (5.7)	2 (5.7)	4 (11.4)	0
Lymphocyte count decreased	8 (22.9)	1 (2.9)	1 (2.9)	3 (8.6)	3 (8.6)
Aspartate aminotransferase increased	5 (14.3)	1 (2.9)	1 (2.9)	2 (5.7)	1 (2.9)
Serum ferritin increased	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Blood bilirubin increased	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Blood immunoglobulin a decreased	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Blood lactate dehydrogenase increased	3 (8.6)	2 (5.7)	1 (2.9)	0	0
C-reactive protein increased	3 (8.6)	1 (2.9)	0	2 (5.7)	0
International normalised ratio increased	3 (8.6)	3 (8.6)	0	0	0
Blood immunoglobulin m decreased	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Immunoglobulins decreased	2 (5.7)	0	2 (5.7)	0	0
Weight decreased	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Blood creatine phosphokinase increased	1 (2.9)	0	0	1 (2.9)	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood glucose increased	1 (2.9)	0	0	0	1 (2.9)
Blood testosterone decreased	1 (2.9)	1 (2.9)	0	0	0
Blood uric acid increased	1 (2.9)	0	0	0	1 (2.9)
Bone density decreased	1 (2.9)	1 (2.9)	0	0	0
Breath sounds abnormal	1 (2.9)	0	1 (2.9)	0	0
Enterovirus test positive	1 (2.9)	0	1 (2.9)	0	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Hepatitis b virus test positive	1 (2.9)	0	1 (2.9)	0	0
Prothrombin time prolonged	1 (2.9)	0	1 (2.9)	0	0
Weight increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	21 (60.0)	6 (17.1)	4 (11.4)	8 (22.9)	3 (8.6)
Decreased appetite	13 (37.1)	7 (20.0)	1 (2.9)	3 (8.6)	2 (5.7)
Hypokalaemia	9 (25.7)	2 (5.7)	3 (8.6)	4 (11.4)	0
Hypophosphataemia	7 (20.0)	2 (5.7)	3 (8.6)	2 (5.7)	0
Hyperglycaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Hyperuricaemia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Hypoalbuminaemia	3 (8.6)	0	3 (8.6)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Hypomagnesaemia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Hypernatraemia	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Tumour lysis syndrome	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Haemochromatosis	1 (2.9)	0	0	1 (2.9)	0
Hyperchloraemia	1 (2.9)	1 (2.9)	0	0	0
Hypermagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hyperphosphataemia	1 (2.9)	1 (2.9)	0	0	0
Hypervolaemia	1 (2.9)	0	1 (2.9)	0	0
Hyponatraemia	1 (2.9)	1 (2.9)	0	0	0
Hypophagia	1 (2.9)	0	1 (2.9)	0	0
Iron overload	1 (2.9)	0	1 (2.9)	0	0
Malnutrition	1 (2.9)	0	0	1 (2.9)	0
Polydipsia	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	22 (62.9)	8 (22.9)	11 (31.4)	3 (8.6)	0
Pain in extremity	10 (28.6)	3 (8.6)	6 (17.1)	1 (2.9)	0
Back pain	7 (20.0)	2 (5.7)	4 (11.4)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Myalgia	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Bone pain	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Pain in jaw	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Growth retardation	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal chest pain	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal pain	1 (2.9)	0	1 (2.9)	0	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Osteonecrosis	1 (2.9)	1 (2.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Skin papilloma	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Bone giant cell tumour benign	1 (2.9)	0	0	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	0	0	1 (2.9)	0
Nervous system disorders					
-Total	23 (65.7)	8 (22.9)	7 (20.0)	6 (17.1)	2 (5.7)
Headache	15 (42.9)	8 (22.9)	4 (11.4)	3 (8.6)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	4 (11.4)	4 (11.4)	0	0	0
Dizziness	3 (8.6)	3 (8.6)	0	0	0
Encephalopathy	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Seizure	3 (8.6)	0	0	3 (8.6)	0
Dysgeusia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Lethargy	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Amnesia	1 (2.9)	0	1 (2.9)	0	0
Aphasia	1 (2.9)	1 (2.9)	0	0	0
Autonomic neuropathy	1 (2.9)	0	0	1 (2.9)	0
Cerebral haemorrhage	1 (2.9)	0	0	0	1 (2.9)
Depressed level of consciousness	1 (2.9)	0	0	1 (2.9)	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	0	1 (2.9)	0	0
Hydrocephalus	1 (2.9)	0	0	0	1 (2.9)
Hyperaesthesia	1 (2.9)	1 (2.9)	0	0	0
Hypoaesthesia	1 (2.9)	1 (2.9)	0	0	0
Memory impairment	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorder	1 (2.9)	0	0	1 (2.9)	0
Psychiatric disorders					
-Total	17 (48.6)	4 (11.4)	11 (31.4)	2 (5.7)	0
Anxiety	7 (20.0)	3 (8.6)	3 (8.6)	1 (2.9)	0
Hallucination	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Mental status changes	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Agitation	2 (5.7)	2 (5.7)	0	0	0
Insomnia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Sleep disorder	2 (5.7)	0	2 (5.7)	0	0
Affect lability	1 (2.9)	0	1 (2.9)	0	0
Confusional state	1 (2.9)	1 (2.9)	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Hallucination, visual	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Mood altered	1 (2.9)	1 (2.9)	0	0	0
Nightmare	1 (2.9)	1 (2.9)	0	0	0
Restlessness	1 (2.9)	0	1 (2.9)	0	0
Social avoidant behaviour	1 (2.9)	0	1 (2.9)	0	0
Tearfulness	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tic	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	13 (37.1)	3 (8.6)	6 (17.1)	1 (2.9)	3 (8.6)
Acute kidney injury	4 (11.4)	1 (2.9)	1 (2.9)	0	2 (5.7)
Dysuria	2 (5.7)	2 (5.7)	0	0	0
Haematuria	2 (5.7)	2 (5.7)	0	0	0
Pollakiuria	2 (5.7)	0	2 (5.7)	0	0
Anuria	1 (2.9)	0	0	0	1 (2.9)
Cystitis haemorrhagic	1 (2.9)	0	1 (2.9)	0	0
Incontinence	1 (2.9)	0	1 (2.9)	0	0
Micturition urgency	1 (2.9)	0	1 (2.9)	0	0
Proteinuria	1 (2.9)	1 (2.9)	0	0	0
Renal failure	1 (2.9)	0	1 (2.9)	0	0
Renal tubular disorder	1 (2.9)	0	0	1 (2.9)	0
Urinary incontinence	1 (2.9)	0	1 (2.9)	0	0
Urinary tract disorder	1 (2.9)	0	1 (2.9)	0	0
Reproductive system and breast disorders					
-Total	3 (8.6)	2 (5.7)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Female genital tract fistula	1 (2.9)	1 (2.9)	0	0	0
Heavy menstrual bleeding	1 (2.9)	1 (2.9)	0	0	0
Vaginal haemorrhage	1 (2.9)	0	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	26 (74.3)	10 (28.6)	4 (11.4)	7 (20.0)	5 (14.3)
Cough	12 (34.3)	9 (25.7)	3 (8.6)	0	0
Hypoxia	9 (25.7)	0	3 (8.6)	4 (11.4)	2 (5.7)
Epistaxis	5 (14.3)	4 (11.4)	0	1 (2.9)	0
Pulmonary oedema	5 (14.3)	1 (2.9)	0	4 (11.4)	0
Dyspnoea	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Nasal congestion	4 (11.4)	4 (11.4)	0	0	0
Oropharyngeal pain	4 (11.4)	4 (11.4)	0	0	0
Pleural effusion	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Pharyngeal erythema	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Rhinorrhoea	2 (5.7)	2 (5.7)	0	0	0
Tachypnoea	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Acute respiratory distress syndrome	1 (2.9)	0	0	0	1 (2.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	1 (2.9)	0	1 (2.9)	0	0
Bronchial oedema	1 (2.9)	1 (2.9)	0	0	0
Dyspnoea exertional	1 (2.9)	1 (2.9)	0	0	0
Laryngeal oedema	1 (2.9)	0	0	0	1 (2.9)
Lung disorder	1 (2.9)	1 (2.9)	0	0	0
Lung infiltration	1 (2.9)	0	0	1 (2.9)	0
Oropharyngeal plaque	1 (2.9)	0	1 (2.9)	0	0
Painful respiration	1 (2.9)	1 (2.9)	0	0	0
Paranasal sinus discomfort	1 (2.9)	0	1 (2.9)	0	0
Paranasal sinus inflammation	1 (2.9)	1 (2.9)	0	0	0
Pharyngeal exudate	1 (2.9)	0	1 (2.9)	0	0
Pharyngeal oedema	1 (2.9)	0	1 (2.9)	0	0
Productive cough	1 (2.9)	1 (2.9)	0	0	0
Pulmonary mass	1 (2.9)	0	1 (2.9)	0	0
Respiratory disorder	1 (2.9)	0	1 (2.9)	0	0
Respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Sleep apnoea syndrome	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (54.3)	6 (17.1)	8 (22.9)	5 (14.3)	0
Rash	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Dry skin	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Dermatitis atopic	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Eczema	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Erythema	2 (5.7)	2 (5.7)	0	0	0
Pruritus	2 (5.7)	0	2 (5.7)	0	0
Rash maculo-papular	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Rash papular	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Decubitus ulcer	1 (2.9)	0	0	1 (2.9)	0
Erythema nodosum	1 (2.9)	1 (2.9)	0	0	0
Hangnail	1 (2.9)	1 (2.9)	0	0	0
Hyperhidrosis	1 (2.9)	0	1 (2.9)	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Night sweats	1 (2.9)	1 (2.9)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.9)	1 (2.9)	0	0	0
Papule	1 (2.9)	1 (2.9)	0	0	0
Pruritus allergic	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Purpura	1 (2.9)	1 (2.9)	0	0	0
Rash macular	1 (2.9)	0	0	1 (2.9)	0
Skin lesion	1 (2.9)	0	1 (2.9)	0	0
Skin swelling	1 (2.9)	1 (2.9)	0	0	0
Skin ulcer	1 (2.9)	0	1 (2.9)	0	0
Urticaria	1 (2.9)	0	1 (2.9)	0	0
Social circumstances					
-Total	1 (2.9)	0	1 (2.9)	0	0
Patient uncooperative	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	11 (31.4)	5 (14.3)	3 (8.6)	2 (5.7)	1 (2.9)
Hypotension	7 (20.0)	2 (5.7)	2 (5.7)	2 (5.7)	1 (2.9)
Hypertension	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Hot flush	1 (2.9)	1 (2.9)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205a
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (90.2)	1 (2.4)	4 (9.8)	13 (31.7)	19 (46.3)
Blood and lymphatic system disorders					
-Total	22 (53.7)	0	2 (4.9)	13 (31.7)	7 (17.1)
Febrile neutropenia	11 (26.8)	0	0	11 (26.8)	0
Anaemia	9 (22.0)	1 (2.4)	2 (4.9)	6 (14.6)	0
Neutropenia	4 (9.8)	0	0	0	4 (9.8)
Thrombocytopenia	4 (9.8)	1 (2.4)	0	1 (2.4)	2 (4.9)
Leukopenia	3 (7.3)	0	0	0	3 (7.3)
Haemolytic anaemia	1 (2.4)	0	0	0	1 (2.4)
Hyperleukocytosis	1 (2.4)	0	0	1 (2.4)	0
Lymphopenia	1 (2.4)	0	0	0	1 (2.4)
Pancytopenia	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Tachycardia	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Ear and labyrinth disorders					
-Total	1 (2.4)	0	1 (2.4)	0	0
Vertigo	1 (2.4)	0	1 (2.4)	0	0
Endocrine disorders					
-Total	3 (7.3)	0	1 (2.4)	1 (2.4)	1 (2.4)
Adrenal insufficiency	1 (2.4)	0	0	1 (2.4)	0
Hypercalcaemia of malignancy	1 (2.4)	0	0	0	1 (2.4)
Hypothyroidism	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	14 (34.1)	3 (7.3)	2 (4.9)	9 (22.0)	0
Abdominal pain	4 (9.8)	1 (2.4)	1 (2.4)	2 (4.9)	0
Diarrhoea	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Stomatitis	3 (7.3)	0	0	3 (7.3)	0
Nausea	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Anal fissure	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal inflammation	1 (2.4)	0	0	1 (2.4)	0
Duodenal perforation	1 (2.4)	0	0	1 (2.4)	0
Gastritis	1 (2.4)	0	1 (2.4)	0	0
Gastrooesophageal reflux disease	1 (2.4)	1 (2.4)	0	0	0
Haematemesis	1 (2.4)	1 (2.4)	0	0	0
Neutropenic colitis	1 (2.4)	0	0	1 (2.4)	0
Tooth pulp haemorrhage	1 (2.4)	0	0	1 (2.4)	0
General disorders and administration site conditions					
-Total	8 (19.5)	2 (4.9)	3 (7.3)	3 (7.3)	0
Pyrexia	4 (9.8)	1 (2.4)	2 (4.9)	1 (2.4)	0
Catheter site pain	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Fatigue	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Oedema peripheral	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Mucosal inflammation	1 (2.4)	0	0	1 (2.4)	0
Non-cardiac chest pain	1 (2.4)	1 (2.4)	0	0	0
Pain	1 (2.4)	0	0	1 (2.4)	0
Hepatobiliary disorders					

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Hepatosplenomegaly	1 (2.4)	0	1 (2.4)	0	0
Hyperbilirubinaemia	1 (2.4)	0	0	1 (2.4)	0
Hypertransaminasaemia	1 (2.4)	1 (2.4)	0	0	0
Immune system disorders					
-Total	7 (17.1)	0	5 (12.2)	2 (4.9)	0
Hypogammaglobulinaemia	4 (9.8)	0	3 (7.3)	1 (2.4)	0
Hypersensitivity	1 (2.4)	0	1 (2.4)	0	0
Immune system disorder	1 (2.4)	0	1 (2.4)	0	0
Immunodeficiency	1 (2.4)	0	0	1 (2.4)	0
Infections and infestations					
-Total	15 (36.6)	1 (2.4)	1 (2.4)	10 (24.4)	3 (7.3)
Escherichia bacteraemia	2 (4.9)	0	0	2 (4.9)	0
Sialoadenitis	2 (4.9)	0	0	2 (4.9)	0
Acute sinusitis	1 (2.4)	0	0	1 (2.4)	0
Aspergillus infection	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cytomegalovirus infection reactivation	1 (2.4)	0	1 (2.4)	0	0
Device related infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection reactivation	1 (2.4)	1 (2.4)	0	0	0
Fungal skin infection	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis adenovirus	1 (2.4)	0	0	1 (2.4)	0
Haemophilus bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Oral herpes	1 (2.4)	0	0	1 (2.4)	0
Parainfluenzae virus infection	1 (2.4)	0	0	1 (2.4)	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Pneumonia	1 (2.4)	0	0	1 (2.4)	0
Pneumonia fungal	1 (2.4)	0	0	0	1 (2.4)
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Systemic mycosis	1 (2.4)	0	0	1 (2.4)	0
Injury, poisoning and procedural complications					
-Total	4 (9.8)	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.4)
Fall	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infusion related reaction	1 (2.4)	0	0	1 (2.4)	0
Procedural pain	1 (2.4)	1 (2.4)	0	0	0
Tracheal obstruction	1 (2.4)	0	0	0	1 (2.4)
Investigations					
-Total	14 (34.1)	1 (2.4)	0	6 (14.6)	7 (17.1)
Neutrophil count decreased	7 (17.1)	0	0	3 (7.3)	4 (9.8)
Alanine aminotransferase increased	4 (9.8)	1 (2.4)	1 (2.4)	2 (4.9)	0
White blood cell count decreased	3 (7.3)	0	0	0	3 (7.3)
Aspartate aminotransferase increased	2 (4.9)	0	1 (2.4)	1 (2.4)	0
C-reactive protein increased	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Platelet count decreased	2 (4.9)	0	0	0	2 (4.9)
Serum ferritin increased	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Amylase increased	1 (2.4)	0	0	0	1 (2.4)
Blood glucose increased	1 (2.4)	1 (2.4)	0	0	0
Blood immunoglobulin g decreased	1 (2.4)	0	1 (2.4)	0	0
Blood immunoglobulin m decreased	1 (2.4)	0	1 (2.4)	0	0
Blood uric acid increased	1 (2.4)	1 (2.4)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eosinophil count decreased	1 (2.4)	1 (2.4)	0	0	0
Haematocrit decreased	1 (2.4)	1 (2.4)	0	0	0
Lymphocyte count decreased	1 (2.4)	0	0	1 (2.4)	0
Protein total decreased	1 (2.4)	0	1 (2.4)	0	0
Red blood cell count decreased	1 (2.4)	1 (2.4)	0	0	0
Metabolism and nutrition disorders					
-Total	12 (29.3)	1 (2.4)	5 (12.2)	4 (9.8)	2 (4.9)
Hypokalaemia	3 (7.3)	1 (2.4)	0	2 (4.9)	0
Hyponatraemia	2 (4.9)	1 (2.4)	0	0	1 (2.4)
Tumour lysis syndrome	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Decreased appetite	1 (2.4)	1 (2.4)	0	0	0
Eating disorder symptom	1 (2.4)	0	1 (2.4)	0	0
Hyperphosphataemia	1 (2.4)	1 (2.4)	0	0	0
Hyperuricaemia	1 (2.4)	0	1 (2.4)	0	0
Hypoalbuminaemia	1 (2.4)	0	1 (2.4)	0	0
Hypophagia	1 (2.4)	0	0	1 (2.4)	0
Malnutrition	1 (2.4)	0	1 (2.4)	0	0
Vitamin a deficiency	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vitamin b1 deficiency	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (9.8)	2 (4.9)	2 (4.9)	0	0
Arthralgia	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Bone pain	1 (2.4)	0	1 (2.4)	0	0
Osteopenia	1 (2.4)	1 (2.4)	0	0	0
Nervous system disorders					
-Total	5 (12.2)	2 (4.9)	1 (2.4)	1 (2.4)	1 (2.4)
Headache	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Haemorrhage intracranial	1 (2.4)	0	0	0	1 (2.4)
Psychiatric disorders					
-Total	1 (2.4)	0	0	1 (2.4)	0
Mental status changes	1 (2.4)	0	0	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (14.6)	1 (2.4)	2 (4.9)	1 (2.4)	2 (4.9)
Respiratory failure	2 (4.9)	0	0	0	2 (4.9)

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	1 (2.4)	1 (2.4)	0	0	0
Epistaxis	1 (2.4)	0	0	1 (2.4)	0
Haemothorax	1 (2.4)	0	0	0	1 (2.4)
Hypoxia	1 (2.4)	0	1 (2.4)	0	0
Nasal congestion	1 (2.4)	1 (2.4)	0	0	0
Oropharyngeal pain	1 (2.4)	0	1 (2.4)	0	0
Pneumothorax	1 (2.4)	0	0	0	1 (2.4)
Rhinorrhoea	1 (2.4)	1 (2.4)	0	0	0
Tachypnoea	1 (2.4)	0	1 (2.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Skin ulcer	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Pain of skin	1 (2.4)	1 (2.4)	0	0	0
Pruritus	1 (2.4)	0	1 (2.4)	0	0
Rash	1 (2.4)	0	1 (2.4)	0	0
Vascular disorders					
-Total	3 (7.3)	1 (2.4)	2 (4.9)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	2 (4.9)	0	2 (4.9)	0	0
Haematoma	1 (2.4)	1 (2.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205a
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	2 (5.0)	3 (7.5)	15 (37.5)	15 (37.5)
Blood and lymphatic system disorders					
-Total	16 (40.0)	1 (2.5)	0	10 (25.0)	5 (12.5)
Anaemia	10 (25.0)	1 (2.5)	1 (2.5)	7 (17.5)	1 (2.5)
Febrile neutropenia	6 (15.0)	0	0	6 (15.0)	0
Neutropenia	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Thrombocytopenia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Cardiac disorders					
-Total	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Tachycardia	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Left ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Pericardial effusion	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Vertigo	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	3 (7.5)	0	3 (7.5)	0	0
Addison's disease	1 (2.5)	0	1 (2.5)	0	0
Adrenal insufficiency	1 (2.5)	0	1 (2.5)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal disorders					
-Total	19 (47.5)	2 (5.0)	7 (17.5)	9 (22.5)	1 (2.5)
Constipation	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Abdominal pain	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Nausea	3 (7.5)	0	3 (7.5)	0	0
Stomatitis	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Neutropenic colitis	2 (5.0)	0	0	2 (5.0)	0
Oral disorder	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Oral pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal compartment syndrome	1 (2.5)	0	0	0	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	1 (2.5)	0	1 (2.5)	0	0
Anal fistula	1 (2.5)	0	0	1 (2.5)	0
Colitis	1 (2.5)	0	0	1 (2.5)	0
Diarrhoea	1 (2.5)	0	1 (2.5)	0	0
Dry mouth	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Haematemesis	1 (2.5)	1 (2.5)	0	0	0
Haemoperitoneum	1 (2.5)	0	0	0	1 (2.5)
Hypoaesthesia oral	1 (2.5)	0	1 (2.5)	0	0
Ileus	1 (2.5)	0	0	1 (2.5)	0
Ileus paralytic	1 (2.5)	1 (2.5)	0	0	0
Lip ulceration	1 (2.5)	0	1 (2.5)	0	0
Mouth haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Oral mucosal blistering	1 (2.5)	1 (2.5)	0	0	0
Tongue blistering	1 (2.5)	1 (2.5)	0	0	0
Vomiting	1 (2.5)	1 (2.5)	0	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	10 (25.0)	1 (2.5)	8 (20.0)	1 (2.5)	0
Pyrexia	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Pain	3 (7.5)	0	3 (7.5)	0	0
Catheter site pain	2 (5.0)	0	2 (5.0)	0	0
Chills	1 (2.5)	0	1 (2.5)	0	0
Complication associated with device	1 (2.5)	1 (2.5)	0	0	0
Fatigue	1 (2.5)	0	1 (2.5)	0	0
Non-cardiac chest pain	1 (2.5)	0	1 (2.5)	0	0
Hepatobiliary disorders					
-Total	5 (12.5)	2 (5.0)	0	3 (7.5)	0
Hepatic cytolysis	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hepatomegaly	1 (2.5)	1 (2.5)	0	0	0
Hyperbilirubinaemia	1 (2.5)	0	0	1 (2.5)	0
Hypertransaminasaemia	1 (2.5)	0	0	1 (2.5)	0
Immune system disorders					
-Total	3 (7.5)	0	1 (2.5)	2 (5.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Infections and infestations					
-Total	24 (60.0)	0	4 (10.0)	14 (35.0)	6 (15.0)
Bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pneumonia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Staphylococcal sepsis	2 (5.0)	0	0	0	2 (5.0)
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Catheter site infection	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Epstein-barr virus infection	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Klebsiella bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis	1 (2.5)	0	1 (2.5)	0	0
Tonsillitis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	6 (15.0)	0	4 (10.0)	2 (5.0)	0
Procedural pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Transfusion reaction	2 (5.0)	0	2 (5.0)	0	0
Post procedural haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Radius fracture	1 (2.5)	0	1 (2.5)	0	0
Traumatic haematoma	1 (2.5)	0	1 (2.5)	0	0
Wound	1 (2.5)	1 (2.5)	0	0	0
Investigations					
-Total	11 (27.5)	1 (2.5)	1 (2.5)	4 (10.0)	5 (12.5)
Neutrophil count decreased	4 (10.0)	1 (2.5)	0	0	3 (7.5)
Alanine aminotransferase increased	3 (7.5)	1 (2.5)	0	2 (5.0)	0
C-reactive protein increased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Weight decreased	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Aspartate aminotransferase increased	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Blood lactate dehydrogenase increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
Serum ferritin increased	2 (5.0)	0	0	2 (5.0)	0
White blood cell count decreased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Activated partial thromboplastin time prolonged	1 (2.5)	1 (2.5)	0	0	0
Activated partial thromboplastin time shortened	1 (2.5)	0	1 (2.5)	0	0
Blood calcium increased	1 (2.5)	0	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0
Blood fibrinogen decreased	1 (2.5)	0	0	1 (2.5)	0
Blood fibrinogen increased	1 (2.5)	1 (2.5)	0	0	0
Blood glucose increased	1 (2.5)	0	1 (2.5)	0	0
Blood magnesium decreased	1 (2.5)	0	1 (2.5)	0	0
Blood potassium decreased	1 (2.5)	0	0	1 (2.5)	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0	0	0
International normalised ratio increased	1 (2.5)	0	1 (2.5)	0	0
Lymphocyte count decreased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (27.5)	1 (2.5)	2 (5.0)	7 (17.5)	1 (2.5)
Hypocalcaemia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Hypokalaemia	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Hypomagnesaemia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Hypervolaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Metabolic acidosis	2 (5.0)	0	0	2 (5.0)	0
Decreased appetite	1 (2.5)	0	0	1 (2.5)	0
Hyperammonaemia	1 (2.5)	0	0	1 (2.5)	0
Hypercalcaemia	1 (2.5)	0	0	0	1 (2.5)
Hyperkalaemia	1 (2.5)	0	0	1 (2.5)	0
Hypoalbuminaemia	1 (2.5)	0	1 (2.5)	0	0
Hypophosphataemia	1 (2.5)	0	1 (2.5)	0	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0
Vitamin d deficiency	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (20.0)	3 (7.5)	3 (7.5)	2 (5.0)	0
Pain in extremity	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	3 (7.5)	0	3 (7.5)	0	0
Arthralgia	2 (5.0)	2 (5.0)	0	0	0
Groin pain	1 (2.5)	1 (2.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	0	0	1 (2.5)
Acute lymphocytic leukaemia	1 (2.5)	0	0	0	1 (2.5)
Skin papilloma	1 (2.5)	1 (2.5)	0	0	0
Nervous system disorders					
-Total	9 (22.5)	2 (5.0)	4 (10.0)	3 (7.5)	0
Headache	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Cognitive disorder	1 (2.5)	0	0	1 (2.5)	0
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Intraventricular haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Peripheral motor neuropathy	1 (2.5)	0	1 (2.5)	0	0
Post herpetic neuralgia	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	7 (17.5)	2 (5.0)	3 (7.5)	2 (5.0)	0
Anxiety	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Depression	1 (2.5)	0	1 (2.5)	0	0
Insomnia	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Renal and urinary disorders					
-Total	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Acute kidney injury	2 (5.0)	2 (5.0)	0	0	0
Micturition disorder	1 (2.5)	1 (2.5)	0	0	0
Urinary tract disorder	1 (2.5)	0	1 (2.5)	0	0
Reproductive system and breast disorders					
-Total	1 (2.5)	0	0	1 (2.5)	0
Prostatitis	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (22.5)	3 (7.5)	1 (2.5)	3 (7.5)	2 (5.0)
Dyspnoea	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Respiratory failure	2 (5.0)	0	0	0	2 (5.0)
Atelectasis	1 (2.5)	0	0	1 (2.5)	0
Epistaxis	1 (2.5)	1 (2.5)	0	0	0
Hypoxia	1 (2.5)	0	1 (2.5)	0	0
Nasal congestion	1 (2.5)	1 (2.5)	0	0	0
Oropharyngeal pain	1 (2.5)	1 (2.5)	0	0	0
Pulmonary oedema	1 (2.5)	0	0	0	1 (2.5)
Tachypnoea	1 (2.5)	0	0	1 (2.5)	0
Throat irritation	1 (2.5)	0	1 (2.5)	0	0
Wheezing	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Blister	1 (2.5)	1 (2.5)	0	0	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (2.5)	1 (2.5)	0	0	0
Skin ulcer	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	9 (22.5)	3 (7.5)	2 (5.0)	3 (7.5)	1 (2.5)
Hypotension	5 (12.5)	1 (2.5)	0	3 (7.5)	1 (2.5)
Hypertension	4 (10.0)	2 (5.0)	2 (5.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205a
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	3 (17.6)	6 (35.3)	8 (47.1)
Blood and lymphatic system disorders					
-Total	11 (64.7)	0	0	6 (35.3)	5 (29.4)
Febrile neutropenia	6 (35.3)	0	0	5 (29.4)	1 (5.9)
Anaemia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Neutropenia	3 (17.6)	0	0	0	3 (17.6)
Pancytopenia	3 (17.6)	0	0	1 (5.9)	2 (11.8)
Lymphadenitis	1 (5.9)	0	1 (5.9)	0	0
Thrombocytopenia	1 (5.9)	0	0	1 (5.9)	0
Cardiac disorders					
-Total	3 (17.6)	1 (5.9)	0	2 (11.8)	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (5.9)	1 (5.9)	0	0	0
Cardiac failure	1 (5.9)	0	0	1 (5.9)	0
Tachycardia	1 (5.9)	0	0	1 (5.9)	0
Endocrine disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Adrenal insufficiency	1 (5.9)	0	1 (5.9)	0	0
Eye disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Dry eye	1 (5.9)	1 (5.9)	0	0	0
Eyelid oedema	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	6 (35.3)	1 (5.9)	4 (23.5)	1 (5.9)	0
Constipation	2 (11.8)	0	2 (11.8)	0	0
Nausea	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Abdominal pain upper	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal sounds abnormal	1 (5.9)	1 (5.9)	0	0	0
Haemorrhoids	1 (5.9)	0	1 (5.9)	0	0
Stomatitis	1 (5.9)	0	0	1 (5.9)	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vomiting	1 (5.9)	1 (5.9)	0	0	0
General disorders and administration site conditions					
-Total	7 (41.2)	1 (5.9)	6 (35.3)	0	0
Pyrexia	4 (23.5)	1 (5.9)	3 (17.6)	0	0
Fatigue	2 (11.8)	0	2 (11.8)	0	0
Asthenia	1 (5.9)	0	1 (5.9)	0	0
Catheter site pain	1 (5.9)	1 (5.9)	0	0	0
Chills	1 (5.9)	0	1 (5.9)	0	0
Face oedema	1 (5.9)	1 (5.9)	0	0	0
Pain	1 (5.9)	0	1 (5.9)	0	0
Thirst	1 (5.9)	1 (5.9)	0	0	0
Hepatobiliary disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	0	0	1 (5.9)	0
Hyperbilirubinaemia	1 (5.9)	0	1 (5.9)	0	0
Immune system disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	2 (11.8)	0	2 (11.8)	0	0
Infections and infestations					
-Total	12 (70.6)	1 (5.9)	2 (11.8)	6 (35.3)	3 (17.6)
Catheter site infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Cellulitis	1 (5.9)	0	1 (5.9)	0	0
Clostridium difficile colitis	1 (5.9)	0	1 (5.9)	0	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)
Gastroenteritis	1 (5.9)	0	1 (5.9)	0	0
Gingivitis	1 (5.9)	1 (5.9)	0	0	0
Herpes simplex	1 (5.9)	0	1 (5.9)	0	0
Parainfluenzae virus infection	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	0	1 (5.9)	0
Respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Septic shock	1 (5.9)	0	0	0	1 (5.9)
Sinusitis	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	0	0	1 (5.9)	0
Stomatococcal infection	1 (5.9)	0	0	0	1 (5.9)
Urinary tract infection	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Extradural haematoma	1 (5.9)	0	1 (5.9)	0	0
Transfusion reaction	1 (5.9)	0	0	1 (5.9)	0
Investigations					
-Total	7 (41.2)	0	0	2 (11.8)	5 (29.4)
Platelet count decreased	4 (23.5)	0	0	0	4 (23.5)
White blood cell count decreased	3 (17.6)	0	0	0	3 (17.6)
C-reactive protein increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Lymphocyte count decreased	2 (11.8)	0	0	0	2 (11.8)
Alanine aminotransferase increased	1 (5.9)	0	1 (5.9)	0	0
Aspartate aminotransferase increased	1 (5.9)	0	0	1 (5.9)	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood bilirubin increased	1 (5.9)	0	0	1 (5.9)	0
Blood creatinine increased	1 (5.9)	0	0	1 (5.9)	0
Blood fibrinogen increased	1 (5.9)	0	1 (5.9)	0	0
Blood lactate dehydrogenase increased	1 (5.9)	0	0	1 (5.9)	0
Blood phosphorus decreased	1 (5.9)	0	0	1 (5.9)	0
Blood potassium decreased	1 (5.9)	0	0	0	1 (5.9)
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Fibrin d dimer increased	1 (5.9)	0	0	0	1 (5.9)
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)
Serum ferritin increased	1 (5.9)	0	0	0	1 (5.9)
Weight increased	1 (5.9)	0	1 (5.9)	0	0
Metabolism and nutrition disorders					
-Total	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Decreased appetite	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	0	0	1 (5.9)
Musculoskeletal and connective tissue disorders					
-Total	6 (35.3)	2 (11.8)	2 (11.8)	2 (11.8)	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Arthralgia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Back pain	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Joint effusion	1 (5.9)	0	0	1 (5.9)	0
Myopathy	1 (5.9)	0	0	1 (5.9)	0
Pain in extremity	1 (5.9)	0	1 (5.9)	0	0
Pain in jaw	1 (5.9)	0	0	1 (5.9)	0
Spinal pain	1 (5.9)	0	0	1 (5.9)	0
Nervous system disorders					
-Total	6 (35.3)	3 (17.6)	1 (5.9)	2 (11.8)	0
Headache	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Neuropathy peripheral	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Paraesthesia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Lethargy	1 (5.9)	1 (5.9)	0	0	0
Neuralgia	1 (5.9)	0	1 (5.9)	0	0
Psychiatric disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0
Insomnia	1 (5.9)	0	1 (5.9)	0	0
Mental status changes	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Haematuria	1 (5.9)	0	1 (5.9)	0	0
Renal tubular necrosis	1 (5.9)	0	0	1 (5.9)	0
Reproductive system and breast disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Heavy menstrual bleeding	1 (5.9)	0	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (23.5)	1 (5.9)	1 (5.9)	1 (5.9)	1 (5.9)
Epistaxis	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Hypoxia	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Acute respiratory distress syndrome	1 (5.9)	0	0	0	1 (5.9)
Cough	1 (5.9)	1 (5.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (41.2)	6 (35.3)	0	1 (5.9)	0
Dermatitis exfoliative generalised	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema nodosum	1 (5.9)	1 (5.9)	0	0	0
Pain of skin	1 (5.9)	0	0	1 (5.9)	0
Petechiae	1 (5.9)	1 (5.9)	0	0	0
Pruritus	1 (5.9)	1 (5.9)	0	0	0
Rash	1 (5.9)	1 (5.9)	0	0	0
Rash maculo-papular	1 (5.9)	1 (5.9)	0	0	0
Vascular disorders					
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Hypertension	1 (5.9)	0	1 (5.9)	0	0
Hypotension	1 (5.9)	0	0	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205b
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	48 (87.3)	3 (5.5)	4 (7.3)	16 (29.1)	25 (45.5)
Blood and lymphatic system disorders					
-Total	28 (50.9)	0	2 (3.6)	15 (27.3)	11 (20.0)
Anaemia	16 (29.1)	1 (1.8)	4 (7.3)	10 (18.2)	1 (1.8)
Febrile neutropenia	9 (16.4)	0	0	9 (16.4)	0
Neutropenia	8 (14.5)	0	0	1 (1.8)	7 (12.7)
Thrombocytopenia	6 (10.9)	1 (1.8)	1 (1.8)	2 (3.6)	2 (3.6)
Leukopenia	3 (5.5)	0	0	0	3 (5.5)
Haemolytic anaemia	1 (1.8)	0	0	0	1 (1.8)
Hyperleukocytosis	1 (1.8)	0	0	1 (1.8)	0
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	5 (9.1)	1 (1.8)	1 (1.8)	3 (5.5)	0
Tachycardia	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Left ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Ear and labyrinth disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Vertigo	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Endocrine disorders					
-Total	6 (10.9)	0	4 (7.3)	1 (1.8)	1 (1.8)
Adrenal insufficiency	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Hypothyroidism	2 (3.6)	0	2 (3.6)	0	0
Addison's disease	1 (1.8)	0	1 (1.8)	0	0
Hypercalcaemia of malignancy	1 (1.8)	0	0	0	1 (1.8)
Gastrointestinal disorders					
-Total	22 (40.0)	3 (5.5)	8 (14.5)	10 (18.2)	1 (1.8)
Abdominal pain	5 (9.1)	2 (3.6)	2 (3.6)	1 (1.8)	0
Constipation	5 (9.1)	3 (5.5)	2 (3.6)	0	0
Nausea	5 (9.1)	1 (1.8)	3 (5.5)	1 (1.8)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	3 (5.5)	0	0	3 (5.5)	0
Diarrhoea	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Vomiting	2 (3.6)	2 (3.6)	0	0	0
Abdominal compartment syndrome	1 (1.8)	0	0	0	1 (1.8)
Abdominal pain upper	1 (1.8)	0	1 (1.8)	0	0
Anal fistula	1 (1.8)	0	0	1 (1.8)	0
Anal inflammation	1 (1.8)	0	0	1 (1.8)	0
Dry mouth	1 (1.8)	0	1 (1.8)	0	0
Duodenal perforation	1 (1.8)	0	0	1 (1.8)	0
Gastritis	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Gastrooesophageal reflux disease	1 (1.8)	1 (1.8)	0	0	0
Haematemesis	1 (1.8)	1 (1.8)	0	0	0
Haemoperitoneum	1 (1.8)	0	0	0	1 (1.8)
Haemorrhoids	1 (1.8)	0	1 (1.8)	0	0
Ileus	1 (1.8)	0	0	1 (1.8)	0
Ileus paralytic	1 (1.8)	1 (1.8)	0	0	0
Oral disorder	1 (1.8)	1 (1.8)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oral mucosal blistering	1 (1.8)	1 (1.8)	0	0	0
Tongue blistering	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	12 (21.8)	2 (3.6)	7 (12.7)	3 (5.5)	0
Pyrexia	8 (14.5)	3 (5.5)	3 (5.5)	2 (3.6)	0
Pain	5 (9.1)	0	4 (7.3)	1 (1.8)	0
Catheter site pain	3 (5.5)	1 (1.8)	2 (3.6)	0	0
Fatigue	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Non-cardiac chest pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Oedema peripheral	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Face oedema	1 (1.8)	1 (1.8)	0	0	0
Hepatobiliary disorders					
-Total	8 (14.5)	3 (5.5)	1 (1.8)	4 (7.3)	0
Hepatic cytolysis	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Hyperbilirubinaemia	2 (3.6)	0	0	2 (3.6)	0
Drug-induced liver injury	1 (1.8)	0	0	1 (1.8)	0
Hepatomegaly	1 (1.8)	1 (1.8)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatosplenomegaly	1 (1.8)	0	1 (1.8)	0	0
Hypertransaminasaemia	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	6 (10.9)	0	4 (7.3)	2 (3.6)	0
Hypogammaglobulinaemia	3 (5.5)	0	3 (5.5)	0	0
Immunodeficiency	2 (3.6)	0	0	2 (3.6)	0
Immune system disorder	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	26 (47.3)	1 (1.8)	2 (3.6)	18 (32.7)	5 (9.1)
Oral herpes	3 (5.5)	0	1 (1.8)	2 (3.6)	0
Catheter site infection	2 (3.6)	0	0	2 (3.6)	0
Escherichia bacteraemia	2 (3.6)	0	0	2 (3.6)	0
Respiratory tract infection	2 (3.6)	0	0	2 (3.6)	0
Sinusitis	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Staphylococcal sepsis	2 (3.6)	0	0	0	2 (3.6)
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection reactivation	1 (1.8)	0	1 (1.8)	0	0
Device related bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Epstein-barr virus infection reactivation	1 (1.8)	1 (1.8)	0	0	0
Fungal infection	1 (1.8)	0	1 (1.8)	0	0
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	0	0	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Paronychia	1 (1.8)	0	0	1 (1.8)	0
Peritonitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (1.8)	0	0	1 (1.8)	0
Pneumonia fungal	1 (1.8)	0	0	1 (1.8)	0
Pseudomonal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Tonsillitis	1 (1.8)	0	1 (1.8)	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Injury, poisoning and procedural complications					
-Total	7 (12.7)	1 (1.8)	3 (5.5)	2 (3.6)	1 (1.8)
Fall	1 (1.8)	0	1 (1.8)	0	0
Infusion related reaction	1 (1.8)	0	0	1 (1.8)	0
Post procedural haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Procedural pain	1 (1.8)	1 (1.8)	0	0	0
Tracheal obstruction	1 (1.8)	0	0	0	1 (1.8)

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	1 (1.8)	0	1 (1.8)	0	0
Traumatic haematoma	1 (1.8)	0	1 (1.8)	0	0
Wound	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	17 (30.9)	1 (1.8)	1 (1.8)	7 (12.7)	8 (14.5)
Alanine aminotransferase increased	7 (12.7)	2 (3.6)	2 (3.6)	3 (5.5)	0
Neutrophil count decreased	7 (12.7)	1 (1.8)	0	2 (3.6)	4 (7.3)
Aspartate aminotransferase increased	4 (7.3)	0	1 (1.8)	2 (3.6)	1 (1.8)
C-reactive protein increased	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
White blood cell count decreased	4 (7.3)	1 (1.8)	0	0	3 (5.5)
Platelet count decreased	3 (5.5)	0	0	0	3 (5.5)
Blood creatinine increased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Blood glucose increased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Lymphocyte count decreased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Serum ferritin increased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Activated partial thromboplastin time shortened	1 (1.8)	0	1 (1.8)	0	0
Amylase increased	1 (1.8)	0	0	0	1 (1.8)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood bilirubin increased	1 (1.8)	0	0	1 (1.8)	0
Blood fibrinogen increased	1 (1.8)	1 (1.8)	0	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Protein total decreased	1 (1.8)	0	1 (1.8)	0	0
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Weight decreased	1 (1.8)	0	1 (1.8)	0	0
Weight increased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	17 (30.9)	1 (1.8)	5 (9.1)	9 (16.4)	2 (3.6)
Hypokalaemia	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Decreased appetite	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Hypoalbuminaemia	2 (3.6)	0	2 (3.6)	0	0
Hypocalcaemia	2 (3.6)	0	2 (3.6)	0	0
Hypomagnesaemia	2 (3.6)	2 (3.6)	0	0	0
Hyponatraemia	2 (3.6)	1 (1.8)	0	0	1 (1.8)
Metabolic acidosis	2 (3.6)	0	0	2 (3.6)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Eating disorder symptom	1 (1.8)	0	1 (1.8)	0	0
Hyperammonaemia	1 (1.8)	0	0	1 (1.8)	0
Hyperkalaemia	1 (1.8)	0	0	1 (1.8)	0
Hyperphosphataemia	1 (1.8)	1 (1.8)	0	0	0
Hypervolaemia	1 (1.8)	1 (1.8)	0	0	0
Hypophagia	1 (1.8)	0	0	1 (1.8)	0
Hypophosphataemia	1 (1.8)	0	1 (1.8)	0	0
Malnutrition	1 (1.8)	0	1 (1.8)	0	0
Vitamin a deficiency	1 (1.8)	0	1 (1.8)	0	0
Vitamin b1 deficiency	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (16.4)	4 (7.3)	5 (9.1)	0	0
Arthralgia	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Pain in extremity	3 (5.5)	0	3 (5.5)	0	0
Back pain	2 (3.6)	0	2 (3.6)	0	0
Groin pain	1 (1.8)	1 (1.8)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Osteopenia	1 (1.8)	1 (1.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.8)	0	0	0	1 (1.8)
Acute lymphocytic leukaemia	1 (1.8)	0	0	0	1 (1.8)
Skin papilloma	1 (1.8)	1 (1.8)	0	0	0
Nervous system disorders					
-Total	15 (27.3)	5 (9.1)	6 (10.9)	3 (5.5)	1 (1.8)
Headache	6 (10.9)	2 (3.6)	3 (5.5)	1 (1.8)	0
Neuropathy peripheral	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Cognitive disorder	1 (1.8)	0	0	1 (1.8)	0
Encephalopathy	1 (1.8)	0	0	1 (1.8)	0
Haemorrhage intracranial	1 (1.8)	0	0	0	1 (1.8)
Intraventricular haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Lethargy	1 (1.8)	1 (1.8)	0	0	0
Neuralgia	1 (1.8)	0	1 (1.8)	0	0
Paraesthesia	1 (1.8)	1 (1.8)	0	0	0
Peripheral motor neuropathy	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (1.8)	0	1 (1.8)	0	0
Psychiatric disorders					
-Total	5 (9.1)	1 (1.8)	3 (5.5)	1 (1.8)	0
Anxiety	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Mental status changes	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Agitation	1 (1.8)	1 (1.8)	0	0	0
Insomnia	1 (1.8)	0	1 (1.8)	0	0
Renal and urinary disorders					
-Total	5 (9.1)	2 (3.6)	2 (3.6)	1 (1.8)	0
Acute kidney injury	2 (3.6)	2 (3.6)	0	0	0
Haematuria	1 (1.8)	0	1 (1.8)	0	0
Micturition disorder	1 (1.8)	1 (1.8)	0	0	0
Renal tubular necrosis	1 (1.8)	0	0	1 (1.8)	0
Urinary tract disorder	1 (1.8)	0	1 (1.8)	0	0
Reproductive system and breast disorders					
-Total	1 (1.8)	0	0	1 (1.8)	0
Prostatitis	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	12 (21.8)	1 (1.8)	4 (7.3)	3 (5.5)	4 (7.3)
Hypoxia	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Respiratory failure	4 (7.3)	0	0	0	4 (7.3)
Epistaxis	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Tachypnoea	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Haemothorax	1 (1.8)	0	0	0	1 (1.8)
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Oropharyngeal pain	1 (1.8)	0	1 (1.8)	0	0
Pneumothorax	1 (1.8)	0	0	0	1 (1.8)
Pulmonary oedema	1 (1.8)	0	0	0	1 (1.8)
Throat irritation	1 (1.8)	0	1 (1.8)	0	0
Wheezing	1 (1.8)	1 (1.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (16.4)	5 (9.1)	3 (5.5)	1 (1.8)	0
Pruritus	3 (5.5)	1 (1.8)	2 (3.6)	0	0
Skin ulcer	3 (5.5)	1 (1.8)	1 (1.8)	1 (1.8)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blister	1 (1.8)	1 (1.8)	0	0	0
Erythema nodosum	1 (1.8)	1 (1.8)	0	0	0
Pain of skin	1 (1.8)	1 (1.8)	0	0	0
Petechiae	1 (1.8)	1 (1.8)	0	0	0
Rash	1 (1.8)	0	1 (1.8)	0	0
Rash maculo-papular	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	10 (18.2)	2 (3.6)	4 (7.3)	3 (5.5)	1 (1.8)
Hypotension	5 (9.1)	1 (1.8)	0	3 (5.5)	1 (1.8)
Hypertension	4 (7.3)	0	4 (7.3)	0	0
Haematoma	1 (1.8)	1 (1.8)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and

CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205b
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (95.3)	0	6 (14.0)	18 (41.9)	17 (39.5)
Blood and lymphatic system disorders					
-Total	21 (48.8)	1 (2.3)	0	14 (32.6)	6 (14.0)
Febrile neutropenia	14 (32.6)	0	0	13 (30.2)	1 (2.3)
Anaemia	7 (16.3)	1 (2.3)	0	6 (14.0)	0
Neutropenia	3 (7.0)	1 (2.3)	0	0	2 (4.7)
Pancytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Thrombocytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Lymphadenitis	1 (2.3)	0	1 (2.3)	0	0
Cardiac disorders					
-Total	5 (11.6)	2 (4.7)	0	3 (7.0)	0
Tachycardia	2 (4.7)	1 (2.3)	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (2.3)	1 (2.3)	0	0	0
Cardiac failure	1 (2.3)	0	0	1 (2.3)	0
Pericardial effusion	1 (2.3)	0	0	1 (2.3)	0
Endocrine disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Adrenal insufficiency	1 (2.3)	0	1 (2.3)	0	0
Eye disorders					
-Total	2 (4.7)	2 (4.7)	0	0	0
Dry eye	1 (2.3)	1 (2.3)	0	0	0
Eyelid oedema	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	17 (39.5)	3 (7.0)	5 (11.6)	9 (20.9)	0
Stomatitis	4 (9.3)	0	1 (2.3)	3 (7.0)	0
Abdominal pain	3 (7.0)	0	2 (4.7)	1 (2.3)	0
Neutropenic colitis	3 (7.0)	0	0	3 (7.0)	0
Constipation	2 (4.7)	0	2 (4.7)	0	0
Diarrhoea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Nausea	2 (4.7)	0	2 (4.7)	0	0

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral pain	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Abdominal pain upper	1 (2.3)	1 (2.3)	0	0	0
Anal fissure	1 (2.3)	0	1 (2.3)	0	0
Colitis	1 (2.3)	0	0	1 (2.3)	0
Gastrointestinal sounds abnormal	1 (2.3)	1 (2.3)	0	0	0
Gingival erythema	1 (2.3)	1 (2.3)	0	0	0
Haematemesis	1 (2.3)	1 (2.3)	0	0	0
Hypoaesthesia oral	1 (2.3)	0	1 (2.3)	0	0
Lip ulceration	1 (2.3)	0	1 (2.3)	0	0
Mouth haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Oral disorder	1 (2.3)	0	0	1 (2.3)	0
Tooth pulp haemorrhage	1 (2.3)	0	0	1 (2.3)	0
General disorders and administration site conditions					
-Total	13 (30.2)	2 (4.7)	10 (23.3)	1 (2.3)	0
Pyrexia	6 (14.0)	0	6 (14.0)	0	0
Fatigue	3 (7.0)	0	3 (7.0)	0	0
Catheter site pain	2 (4.7)	1 (2.3)	1 (2.3)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Chills	2 (4.7)	0	2 (4.7)	0	0
Asthenia	1 (2.3)	0	1 (2.3)	0	0
Complication associated with device	1 (2.3)	1 (2.3)	0	0	0
Mucosal inflammation	1 (2.3)	0	0	1 (2.3)	0
Thirst	1 (2.3)	1 (2.3)	0	0	0
Hepatobiliary disorders					
-Total	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hyperbilirubinaemia	1 (2.3)	0	1 (2.3)	0	0
Hypertransaminasaemia	1 (2.3)	0	0	1 (2.3)	0
Immune system disorders					
-Total	6 (14.0)	0	4 (9.3)	2 (4.7)	0
Hypogammaglobulinaemia	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Graft versus host disease	1 (2.3)	0	0	1 (2.3)	0
Hypersensitivity	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	25 (58.1)	1 (2.3)	5 (11.6)	12 (27.9)	7 (16.3)
Pneumonia	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Bacteraemia	2 (4.7)	0	0	2 (4.7)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	2 (4.7)	0	0	0	2 (4.7)
Staphylococcal bacteraemia	2 (4.7)	0	0	2 (4.7)	0
Urinary tract infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Acute sinusitis	1 (2.3)	0	0	1 (2.3)	0
Aspergillus infection	1 (2.3)	0	0	0	1 (2.3)
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Catheter site infection	1 (2.3)	0	1 (2.3)	0	0
Cellulitis	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	0	1 (2.3)	0	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Epstein-barr virus infection	1 (2.3)	0	1 (2.3)	0	0
Fungal sepsis	1 (2.3)	0	0	0	1 (2.3)
Fungal skin infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis adenovirus	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	0	0	1 (2.3)	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Herpes simplex	1 (2.3)	0	1 (2.3)	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Localised infection	1 (2.3)	1 (2.3)	0	0	0
Parainfluenzae virus infection	1 (2.3)	0	0	1 (2.3)	0
Pneumonia fungal	1 (2.3)	0	0	0	1 (2.3)
Sialoadenitis	1 (2.3)	0	0	1 (2.3)	0
Sinusitis	1 (2.3)	0	1 (2.3)	0	0
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Staphylococcal skin infection	1 (2.3)	0	0	1 (2.3)	0
Stomatococcal infection	1 (2.3)	0	0	0	1 (2.3)
Systemic mycosis	1 (2.3)	0	0	1 (2.3)	0
Injury, poisoning and procedural complications					
-Total	5 (11.6)	0	3 (7.0)	2 (4.7)	0
Procedural pain	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Transfusion reaction	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Extradural haematoma	1 (2.3)	0	1 (2.3)	0	0

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Radius fracture	1 (2.3)	0	1 (2.3)	0	0
Investigations					
-Total	15 (34.9)	1 (2.3)	0	5 (11.6)	9 (20.9)
Neutrophil count decreased	5 (11.6)	0	0	1 (2.3)	4 (9.3)
Platelet count decreased	5 (11.6)	0	0	0	5 (11.6)
White blood cell count decreased	4 (9.3)	0	0	0	4 (9.3)
Blood lactate dehydrogenase increased	3 (7.0)	0	1 (2.3)	2 (4.7)	0
C-reactive protein increased	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Serum ferritin increased	3 (7.0)	0	0	2 (4.7)	1 (2.3)
Blood potassium decreased	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Fibrin d dimer increased	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Lymphocyte count decreased	2 (4.7)	0	0	0	2 (4.7)
Weight decreased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Activated partial thromboplastin time prolonged	1 (2.3)	1 (2.3)	0	0	0
Alanine aminotransferase increased	1 (2.3)	0	0	1 (2.3)	0
Aspartate aminotransferase increased	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood calcium increased	1 (2.3)	0	0	1 (2.3)	0
Blood fibrinogen decreased	1 (2.3)	0	0	1 (2.3)	0
Blood fibrinogen increased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin m decreased	1 (2.3)	0	1 (2.3)	0	0
Blood magnesium decreased	1 (2.3)	0	1 (2.3)	0	0
Blood phosphorus decreased	1 (2.3)	0	0	1 (2.3)	0
Electrocardiogram qt prolonged	1 (2.3)	1 (2.3)	0	0	0
International normalised ratio increased	1 (2.3)	0	1 (2.3)	0	0
Metabolism and nutrition disorders					
-Total	8 (18.6)	1 (2.3)	2 (4.7)	3 (7.0)	2 (4.7)
Hypokalaemia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Decreased appetite	1 (2.3)	0	1 (2.3)	0	0
Hypercalcaemia	1 (2.3)	0	0	0	1 (2.3)
Hyperglycaemia	1 (2.3)	0	0	0	1 (2.3)
Hyperuricaemia	1 (2.3)	0	1 (2.3)	0	0
Hypervolaemia	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypocalcaemia	1 (2.3)	1 (2.3)	0	0	0
Hypomagnesaemia	1 (2.3)	0	1 (2.3)	0	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0
Vitamin d deficiency	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (20.9)	3 (7.0)	2 (4.7)	4 (9.3)	0
Back pain	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Pain in extremity	3 (7.0)	1 (2.3)	0	2 (4.7)	0
Arthralgia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Bone pain	1 (2.3)	0	1 (2.3)	0	0
Joint effusion	1 (2.3)	0	0	1 (2.3)	0
Myopathy	1 (2.3)	0	0	1 (2.3)	0
Pain in jaw	1 (2.3)	0	0	1 (2.3)	0
Spinal pain	1 (2.3)	0	0	1 (2.3)	0
Nervous system disorders					
-Total	5 (11.6)	2 (4.7)	0	3 (7.0)	0
Headache	2 (4.7)	1 (2.3)	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paraesthesia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Dizziness	1 (2.3)	1 (2.3)	0	0	0
Neuropathy peripheral	1 (2.3)	0	0	1 (2.3)	0
Post herpetic neuralgia	1 (2.3)	0	0	1 (2.3)	0
Psychiatric disorders					
-Total	5 (11.6)	1 (2.3)	2 (4.7)	2 (4.7)	0
Anxiety	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Depression	1 (2.3)	0	1 (2.3)	0	0
Insomnia	1 (2.3)	0	1 (2.3)	0	0
Mental status changes	1 (2.3)	0	0	1 (2.3)	0
Reproductive system and breast disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Heavy menstrual bleeding	1 (2.3)	0	1 (2.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (16.3)	4 (9.3)	0	2 (4.7)	1 (2.3)
Cough	2 (4.7)	2 (4.7)	0	0	0
Dyspnoea	2 (4.7)	1 (2.3)	0	1 (2.3)	0

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (2.3)	0	0	0	1 (2.3)
Atelectasis	1 (2.3)	0	0	1 (2.3)	0
Epistaxis	1 (2.3)	1 (2.3)	0	0	0
Nasal congestion	1 (2.3)	1 (2.3)	0	0	0
Oropharyngeal pain	1 (2.3)	1 (2.3)	0	0	0
Rhinorrhoea	1 (2.3)	1 (2.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (14.0)	5 (11.6)	0	1 (2.3)	0
Dermatitis exfoliative generalised	1 (2.3)	1 (2.3)	0	0	0
Dry skin	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	1 (2.3)	0	0	0
Pain of skin	1 (2.3)	0	0	1 (2.3)	0
Pruritus	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	4 (9.3)	2 (4.7)	1 (2.3)	0	1 (2.3)
Hypertension	3 (7.0)	2 (4.7)	1 (2.3)	0	0

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (2.3)	0	0	0	1 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205c
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (92.9)	2 (2.9)	5 (7.1)	28 (40.0)	30 (42.9)
Blood and lymphatic system disorders					
-Total	36 (51.4)	0	2 (2.9)	23 (32.9)	11 (15.7)
Anaemia	16 (22.9)	1 (1.4)	3 (4.3)	11 (15.7)	1 (1.4)
Febrile neutropenia	16 (22.9)	0	0	16 (22.9)	0
Neutropenia	7 (10.0)	1 (1.4)	0	1 (1.4)	5 (7.1)
Thrombocytopenia	6 (8.6)	1 (1.4)	1 (1.4)	2 (2.9)	2 (2.9)
Pancytopenia	4 (5.7)	0	1 (1.4)	1 (1.4)	2 (2.9)
Leukopenia	2 (2.9)	0	0	0	2 (2.9)
Haemolytic anaemia	1 (1.4)	0	0	0	1 (1.4)
Hyperleukocytosis	1 (1.4)	0	0	1 (1.4)	0
Lymphadenitis	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	8 (11.4)	3 (4.3)	0	5 (7.1)	0
Tachycardia	5 (7.1)	2 (2.9)	0	3 (4.3)	0
Bradycardia	1 (1.4)	1 (1.4)	0	0	0
Cardiac failure	1 (1.4)	0	0	1 (1.4)	0
Pericardial effusion	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Vertigo	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Endocrine disorders					
-Total	7 (10.0)	0	5 (7.1)	1 (1.4)	1 (1.4)
Adrenal insufficiency	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Hypothyroidism	2 (2.9)	0	2 (2.9)	0	0
Addison's disease	1 (1.4)	0	1 (1.4)	0	0
Hypercalcaemia of malignancy	1 (1.4)	0	0	0	1 (1.4)
Eye disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Eyelid oedema	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders					
-Total	31 (44.3)	5 (7.1)	11 (15.7)	14 (20.0)	1 (1.4)
Constipation	7 (10.0)	3 (4.3)	4 (5.7)	0	0
Abdominal pain	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Nausea	6 (8.6)	1 (1.4)	4 (5.7)	1 (1.4)	0
Stomatitis	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Diarrhoea	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Neutropenic colitis	3 (4.3)	0	0	3 (4.3)	0
Abdominal pain upper	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Oral disorder	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Vomiting	2 (2.9)	2 (2.9)	0	0	0
Abdominal compartment syndrome	1 (1.4)	0	0	0	1 (1.4)
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal fistula	1 (1.4)	0	0	1 (1.4)	0
Colitis	1 (1.4)	0	0	1 (1.4)	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal sounds abnormal	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	0	0	0
Gingival erythema	1 (1.4)	1 (1.4)	0	0	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Haemoperitoneum	1 (1.4)	0	0	0	1 (1.4)
Hypoaesthesia oral	1 (1.4)	0	1 (1.4)	0	0
Ileus	1 (1.4)	0	0	1 (1.4)	0
Ileus paralytic	1 (1.4)	1 (1.4)	0	0	0
Mouth haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0
Tongue blistering	1 (1.4)	1 (1.4)	0	0	0
Tooth pulp haemorrhage	1 (1.4)	0	0	1 (1.4)	0
General disorders and administration site conditions					
-Total	23 (32.9)	4 (5.7)	15 (21.4)	4 (5.7)	0
Pyrexia	13 (18.6)	3 (4.3)	8 (11.4)	2 (2.9)	0
Fatigue	5 (7.1)	1 (1.4)	4 (5.7)	0	0
Pain	5 (7.1)	0	4 (5.7)	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site pain	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Chills	2 (2.9)	0	2 (2.9)	0	0
Non-cardiac chest pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Oedema peripheral	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Complication associated with device	1 (1.4)	1 (1.4)	0	0	0
Face oedema	1 (1.4)	1 (1.4)	0	0	0
Mucosal inflammation	1 (1.4)	0	0	1 (1.4)	0
Thirst	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	8 (11.4)	3 (4.3)	1 (1.4)	4 (5.7)	0
Hepatic cytolysis	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Hypertransaminasaemia	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Drug-induced liver injury	1 (1.4)	0	0	1 (1.4)	0
Hepatomegaly	1 (1.4)	1 (1.4)	0	0	0
Hepatosplenomegaly	1 (1.4)	0	1 (1.4)	0	0
Hyperbilirubinaemia	1 (1.4)	0	0	1 (1.4)	0
Immune system disorders					

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (15.7)	0	7 (10.0)	4 (5.7)	0
Hypogammaglobulinaemia	6 (8.6)	0	5 (7.1)	1 (1.4)	0
Immunodeficiency	2 (2.9)	0	0	2 (2.9)	0
Graft versus host disease	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Immune system disorder	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	42 (60.0)	2 (2.9)	4 (5.7)	26 (37.1)	10 (14.3)
Pneumonia	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Staphylococcal bacteraemia	3 (4.3)	0	0	3 (4.3)	0
Acute sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Clostridium difficile colitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Localised infection	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Oral herpes	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Sialoadenitis	2 (2.9)	0	0	2 (2.9)	0
Sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	0	0	2 (2.9)
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	1 (1.4)	0	0
Device related bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epstein-barr virus infection reactivation	1 (1.4)	1 (1.4)	0	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Fungal infection	1 (1.4)	0	1 (1.4)	0	0
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0	1 (1.4)	0
Pseudomonal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Tonsillitis	1 (1.4)	0	1 (1.4)	0	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.9)	1 (1.4)	5 (7.1)	2 (2.9)	1 (1.4)
Procedural pain	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.9)	0	2 (2.9)	0	0
Fall	1 (1.4)	0	1 (1.4)	0	0
Infusion related reaction	1 (1.4)	0	0	1 (1.4)	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Tracheal obstruction	1 (1.4)	0	0	0	1 (1.4)
Traumatic haematoma	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	24 (34.3)	2 (2.9)	1 (1.4)	8 (11.4)	13 (18.6)
Neutrophil count decreased	11 (15.7)	1 (1.4)	0	3 (4.3)	7 (10.0)
Platelet count decreased	6 (8.6)	0	0	0	6 (8.6)
White blood cell count decreased	6 (8.6)	1 (1.4)	0	0	5 (7.1)
Alanine aminotransferase increased	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Aspartate aminotransferase increased	4 (5.7)	0	1 (1.4)	2 (2.9)	1 (1.4)
C-reactive protein increased	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Lymphocyte count decreased	3 (4.3)	1 (1.4)	0	1 (1.4)	1 (1.4)
Weight decreased	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Activated partial thromboplastin time prolonged	1 (1.4)	1 (1.4)	0	0	0
Activated partial thromboplastin time shortened	1 (1.4)	0	1 (1.4)	0	0
Amylase increased	1 (1.4)	0	0	0	1 (1.4)
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood fibrinogen increased	1 (1.4)	1 (1.4)	0	0	0
Blood glucose increased	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	1 (1.4)	0	0
Blood lactate dehydrogenase increased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus decreased	1 (1.4)	0	0	1 (1.4)	0
Blood potassium decreased	1 (1.4)	0	0	0	1 (1.4)
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0	0	0
Fibrin d dimer increased	1 (1.4)	1 (1.4)	0	0	0
Protein total decreased	1 (1.4)	0	1 (1.4)	0	0
Serum ferritin increased	1 (1.4)	0	1 (1.4)	0	0
Weight increased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	20 (28.6)	2 (2.9)	5 (7.1)	10 (14.3)	3 (4.3)
Decreased appetite	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Hypokalaemia	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Hypocalcaemia	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Hypervolaemia	2 (2.9)	1 (1.4)	0	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoalbuminaemia	2 (2.9)	0	2 (2.9)	0	0
Hypomagnesaemia	2 (2.9)	2 (2.9)	0	0	0
Hyponatraemia	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Metabolic acidosis	2 (2.9)	0	0	2 (2.9)	0
Tumour lysis syndrome	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Eating disorder symptom	1 (1.4)	0	1 (1.4)	0	0
Hyperammonaemia	1 (1.4)	0	0	1 (1.4)	0
Hyperglycaemia	1 (1.4)	0	0	0	1 (1.4)
Hyperkalaemia	1 (1.4)	0	0	1 (1.4)	0
Hyperphosphataemia	1 (1.4)	1 (1.4)	0	0	0
Hypophagia	1 (1.4)	0	0	1 (1.4)	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Vitamin a deficiency	1 (1.4)	0	1 (1.4)	0	0
Vitamin b1 deficiency	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (15.7)	3 (4.3)	6 (8.6)	2 (2.9)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Arthralgia	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Back pain	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Pain in extremity	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Groin pain	1 (1.4)	1 (1.4)	0	0	0
Joint effusion	1 (1.4)	0	0	1 (1.4)	0
Pain in jaw	1 (1.4)	0	0	1 (1.4)	0
Spinal pain	1 (1.4)	0	0	1 (1.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.4)	0	0	0	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)	0	0	0	1 (1.4)
Skin papilloma	1 (1.4)	1 (1.4)	0	0	0
Nervous system disorders					
-Total	16 (22.9)	6 (8.6)	5 (7.1)	5 (7.1)	0
Headache	7 (10.0)	2 (2.9)	3 (4.3)	2 (2.9)	0
Neuropathy peripheral	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Paraesthesia	2 (2.9)	2 (2.9)	0	0	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Intraventricular haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Lethargy	1 (1.4)	1 (1.4)	0	0	0
Peripheral motor neuropathy	1 (1.4)	0	1 (1.4)	0	0
Post herpetic neuralgia	1 (1.4)	0	0	1 (1.4)	0
Seizure	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	7 (10.0)	1 (1.4)	4 (5.7)	2 (2.9)	0
Mental status changes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Anxiety	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Depression	1 (1.4)	0	1 (1.4)	0	0
Insomnia	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Acute kidney injury	2 (2.9)	2 (2.9)	0	0	0
Haematuria	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Micturition disorder	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	1 (1.4)	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Heavy menstrual bleeding	1 (1.4)	0	1 (1.4)	0	0
Prostatitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (22.9)	4 (5.7)	4 (5.7)	4 (5.7)	4 (5.7)
Epistaxis	4 (5.7)	2 (2.9)	0	2 (2.9)	0
Hypoxia	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Respiratory failure	3 (4.3)	0	0	0	3 (4.3)
Oropharyngeal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	0	1 (1.4)	0
Cough	1 (1.4)	1 (1.4)	0	0	0
Dyspnoea	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemothorax	1 (1.4)	0	0	0	1 (1.4)
Nasal congestion	1 (1.4)	1 (1.4)	0	0	0
Pneumothorax	1 (1.4)	0	0	0	1 (1.4)
Pulmonary oedema	1 (1.4)	0	0	0	1 (1.4)
Tachypnoea	1 (1.4)	0	0	1 (1.4)	0
Throat irritation	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	1 (1.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (20.0)	9 (12.9)	3 (4.3)	2 (2.9)	0
Pruritus	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Skin ulcer	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pain of skin	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Rash	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Blister	1 (1.4)	1 (1.4)	0	0	0
Dermatitis exfoliative generalised	1 (1.4)	1 (1.4)	0	0	0
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Ingrowing nail	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Petechiae	1 (1.4)	1 (1.4)	0	0	0
Rash maculo-papular	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	11 (15.7)	4 (5.7)	3 (4.3)	2 (2.9)	2 (2.9)
Hypertension	5 (7.1)	2 (2.9)	3 (4.3)	0	0
Hypotension	5 (7.1)	1 (1.4)	0	2 (2.9)	2 (2.9)
Haematoma	1 (1.4)	1 (1.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205c
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (80.0)	0	3 (20.0)	4 (26.7)	5 (33.3)
Blood and lymphatic system disorders					
-Total	4 (26.7)	0	0	2 (13.3)	2 (13.3)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Thrombocytopenia	2 (13.3)	0	0	0	2 (13.3)
Leukopenia	1 (6.7)	0	0	0	1 (6.7)
Lymphopenia	1 (6.7)	0	0	0	1 (6.7)
Neutropenia	1 (6.7)	0	0	0	1 (6.7)
Cardiac disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	0	0	1 (6.7)	0

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Dry eye	1 (6.7)	1 (6.7)	0	0	0
Gastrointestinal disorders					
-Total	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Abdominal pain	1 (6.7)	0	1 (6.7)	0	0
Anal inflammation	1 (6.7)	0	0	1 (6.7)	0
Duodenal perforation	1 (6.7)	0	0	1 (6.7)	0
Gastritis	1 (6.7)	0	1 (6.7)	0	0
Haemorrhoids	1 (6.7)	0	1 (6.7)	0	0
Oral pain	1 (6.7)	0	0	1 (6.7)	0
Stomatitis	1 (6.7)	0	0	1 (6.7)	0
General disorders and administration site conditions					
-Total	2 (13.3)	0	2 (13.3)	0	0
Catheter site pain	1 (6.7)	0	1 (6.7)	0	0
Pyrexia	1 (6.7)	0	1 (6.7)	0	0
Hepatobiliary disorders					

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	0	1 (6.7)	0	0
Hyperbilirubinaemia	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	6 (40.0)	0	2 (13.3)	3 (20.0)	1 (6.7)
Bronchopulmonary aspergillosis	1 (6.7)	0	0	1 (6.7)	0
Catheter site infection	1 (6.7)	0	1 (6.7)	0	0
Epstein-barr virus infection	1 (6.7)	0	1 (6.7)	0	0
Escherichia bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Oral herpes	1 (6.7)	0	0	1 (6.7)	0
Peritonitis	1 (6.7)	0	0	1 (6.7)	0
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Injury, poisoning and procedural complications					
-Total	1 (6.7)	0	0	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	0	0	1 (6.7)	0
Investigations					

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (26.7)	0	0	4 (26.7)	0
Alanine aminotransferase increased	3 (20.0)	0	0	3 (20.0)	0
Serum ferritin increased	3 (20.0)	1 (6.7)	0	2 (13.3)	0
C-reactive protein increased	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Aspartate aminotransferase increased	1 (6.7)	0	0	1 (6.7)	0
Blood calcium increased	1 (6.7)	0	0	1 (6.7)	0
Blood fibrinogen decreased	1 (6.7)	0	0	1 (6.7)	0
Blood glucose increased	1 (6.7)	1 (6.7)	0	0	0
Blood lactate dehydrogenase increased	1 (6.7)	0	0	1 (6.7)	0
Blood magnesium decreased	1 (6.7)	0	1 (6.7)	0	0
Blood potassium decreased	1 (6.7)	0	0	1 (6.7)	0
Eosinophil count decreased	1 (6.7)	1 (6.7)	0	0	0
Haematocrit decreased	1 (6.7)	1 (6.7)	0	0	0
International normalised ratio increased	1 (6.7)	0	1 (6.7)	0	0
Red blood cell count decreased	1 (6.7)	1 (6.7)	0	0	0
Metabolism and nutrition disorders					

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (20.0)	0	1 (6.7)	1 (6.7)	1 (6.7)
Hypercalcaemia	1 (6.7)	0	0	0	1 (6.7)
Hyperuricaemia	1 (6.7)	0	1 (6.7)	0	0
Tumour lysis syndrome	1 (6.7)	0	0	1 (6.7)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (20.0)	2 (13.3)	0	1 (6.7)	0
Pain in extremity	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Arthralgia	1 (6.7)	1 (6.7)	0	0	0
Back pain	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	2 (13.3)	1 (6.7)	0	0	1 (6.7)
Haemorrhage intracranial	1 (6.7)	0	0	0	1 (6.7)
Headache	1 (6.7)	1 (6.7)	0	0	0
Psychiatric disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Anxiety	1 (6.7)	0	0	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders					

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (6.7)	0	0	1 (6.7)	0
Dyspnoea	1 (6.7)	0	0	1 (6.7)	0
Skin and subcutaneous tissue disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Erythema nodosum	1 (6.7)	1 (6.7)	0	0	0
Vascular disorders					
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Hypertension	1 (6.7)	0	1 (6.7)	0	0
Hypotension	1 (6.7)	0	0	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205c
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (92.3)	1 (7.7)	2 (15.4)	2 (15.4)	7 (53.8)
Blood and lymphatic system disorders					
-Total	9 (69.2)	1 (7.7)	0	4 (30.8)	4 (30.8)
Febrile neutropenia	5 (38.5)	0	0	4 (30.8)	1 (7.7)
Anaemia	4 (30.8)	1 (7.7)	1 (7.7)	2 (15.4)	0
Neutropenia	3 (23.1)	0	0	0	3 (23.1)
Thrombocytopenia	1 (7.7)	0	0	1 (7.7)	0
Cardiac disorders					
-Total	1 (7.7)	0	1 (7.7)	0	0
Tachycardia	1 (7.7)	0	1 (7.7)	0	0
Gastrointestinal disorders					

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (30.8)	1 (7.7)	1 (7.7)	2 (15.4)	0
Stomatitis	2 (15.4)	0	0	2 (15.4)	0
Abdominal pain	1 (7.7)	0	1 (7.7)	0	0
Diarrhoea	1 (7.7)	0	1 (7.7)	0	0
Haematemesis	1 (7.7)	1 (7.7)	0	0	0
Lip ulceration	1 (7.7)	0	1 (7.7)	0	0
Nausea	1 (7.7)	0	1 (7.7)	0	0
Hepatobiliary disorders					
-Total	1 (7.7)	0	0	1 (7.7)	0
Hyperbilirubinaemia	1 (7.7)	0	0	1 (7.7)	0
Immune system disorders					
-Total	1 (7.7)	0	1 (7.7)	0	0
Hypogammaglobulinaemia	1 (7.7)	0	1 (7.7)	0	0
Infections and infestations					
-Total	3 (23.1)	0	1 (7.7)	1 (7.7)	1 (7.7)
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Extradural haematoma	1 (7.7)	0	1 (7.7)	0	0
Transfusion reaction	1 (7.7)	0	0	1 (7.7)	0
Investigations					
-Total	4 (30.8)	0	0	0	4 (30.8)
Platelet count decreased	2 (15.4)	0	0	0	2 (15.4)
White blood cell count decreased	2 (15.4)	0	0	0	2 (15.4)
Blood fibrinogen increased	1 (7.7)	0	1 (7.7)	0	0
Blood lactate dehydrogenase increased	1 (7.7)	0	0	1 (7.7)	0
C-reactive protein increased	1 (7.7)	0	0	0	1 (7.7)
Fibrin d dimer increased	1 (7.7)	0	0	0	1 (7.7)
Lymphocyte count decreased	1 (7.7)	0	0	0	1 (7.7)
Neutrophil count decreased	1 (7.7)	0	0	0	1 (7.7)
Serum ferritin increased	1 (7.7)	0	0	0	1 (7.7)
Metabolism and nutrition disorders					
-Total	2 (15.4)	0	1 (7.7)	1 (7.7)	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Hypomagnesaemia	1 (7.7)	0	1 (7.7)	0	0
Vitamin d deficiency	1 (7.7)	1 (7.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (30.8)	2 (15.4)	1 (7.7)	1 (7.7)	0
Arthralgia	1 (7.7)	1 (7.7)	0	0	0
Bone pain	1 (7.7)	0	1 (7.7)	0	0
Myopathy	1 (7.7)	0	0	1 (7.7)	0
Osteopenia	1 (7.7)	1 (7.7)	0	0	0
Nervous system disorders					
-Total	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Neuralgia	1 (7.7)	0	1 (7.7)	0	0
Neuropathy peripheral	1 (7.7)	0	0	1 (7.7)	0
Paraesthesia	1 (7.7)	0	1 (7.7)	0	0
Psychiatric disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Anxiety	1 (7.7)	1 (7.7)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Insomnia	1 (7.7)	0	1 (7.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (15.4)	1 (7.7)	0	0	1 (7.7)
Cough	1 (7.7)	1 (7.7)	0	0	0
Nasal congestion	1 (7.7)	1 (7.7)	0	0	0
Respiratory failure	1 (7.7)	0	0	0	1 (7.7)
Rhinorrhoea	1 (7.7)	1 (7.7)	0	0	0
Tachypnoea	1 (7.7)	0	1 (7.7)	0	0
Vascular disorders					
-Total	1 (7.7)	0	1 (7.7)	0	0
Hypertension	1 (7.7)	0	1 (7.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 205d
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	2 (11.1)	1 (5.6)	6 (33.3)	8 (44.4)
Blood and lymphatic system disorders					
-Total	6 (33.3)	1 (5.6)	0	3 (16.7)	2 (11.1)
Anaemia	4 (22.2)	1 (5.6)	1 (5.6)	1 (5.6)	1 (5.6)
Febrile neutropenia	2 (11.1)	0	0	2 (11.1)	0
Thrombocytopenia	2 (11.1)	0	0	2 (11.1)	0
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Tachycardia	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypothyroidism	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	4 (22.2)	0
Nausea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Stomatitis	2 (11.1)	0	0	2 (11.1)	0
Colitis	1 (5.6)	0	0	1 (5.6)	0
Constipation	1 (5.6)	0	1 (5.6)	0	0
Diarrhoea	1 (5.6)	0	1 (5.6)	0	0
Gingival erythema	1 (5.6)	1 (5.6)	0	0	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Lip ulceration	1 (5.6)	0	1 (5.6)	0	0
Mouth haemorrhage	1 (5.6)	0	1 (5.6)	0	0
Oral disorder	1 (5.6)	0	0	1 (5.6)	0
Vomiting	1 (5.6)	1 (5.6)	0	0	0
General disorders and administration site conditions					
-Total	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Pyrexia	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (5.6)	0	1 (5.6)	0	0
Face oedema	1 (5.6)	1 (5.6)	0	0	0
Fatigue	1 (5.6)	0	1 (5.6)	0	0
Pain	1 (5.6)	0	1 (5.6)	0	0
Hepatobiliary disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Hypertransaminasaemia	1 (5.6)	0	0	1 (5.6)	0
Immune system disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Hypogammaglobulinaemia	2 (11.1)	0	2 (11.1)	0	0
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Infections and infestations					
-Total	11 (61.1)	0	1 (5.6)	8 (44.4)	2 (11.1)
Bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Acute sinusitis	1 (5.6)	0	1 (5.6)	0	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bronchitis	1 (5.6)	0	1 (5.6)	0	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	0	0	1 (5.6)	0
Localised infection	1 (5.6)	1 (5.6)	0	0	0
Oral herpes	1 (5.6)	0	1 (5.6)	0	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia fungal	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Procedural pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Extradural haematoma	1 (5.6)	0	1 (5.6)	0	0
Radius fracture	1 (5.6)	0	1 (5.6)	0	0
Transfusion reaction	1 (5.6)	0	0	1 (5.6)	0
Investigations					
-Total	7 (38.9)	1 (5.6)	0	1 (5.6)	5 (27.8)

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	3 (16.7)	0	0	0	3 (16.7)
Blood lactate dehydrogenase increased	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	0	0	0	2 (11.1)
Alanine aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Blood fibrinogen increased	1 (5.6)	0	1 (5.6)	0	0
Blood uric acid increased	1 (5.6)	1 (5.6)	0	0	0
C-reactive protein increased	1 (5.6)	0	0	0	1 (5.6)
Electrocardiogram qt prolonged	1 (5.6)	1 (5.6)	0	0	0
Fibrin d dimer increased	1 (5.6)	0	0	0	1 (5.6)
Lymphocyte count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	0	1 (5.6)
Weight decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	1 (5.6)	1 (5.6)	2 (11.1)	0
Decreased appetite	2 (11.1)	1 (5.6)	0	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperphosphataemia	1 (5.6)	1 (5.6)	0	0	0
Hypocalcaemia	1 (5.6)	0	1 (5.6)	0	0
Hypokalaemia	1 (5.6)	1 (5.6)	0	0	0
Metabolic acidosis	1 (5.6)	0	0	1 (5.6)	0
Vitamin d deficiency	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (27.8)	2 (11.1)	1 (5.6)	2 (11.1)	0
Arthralgia	2 (11.1)	2 (11.1)	0	0	0
Pain in extremity	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Myopathy	1 (5.6)	0	0	1 (5.6)	0
Nervous system disorders					
-Total	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Headache	1 (5.6)	0	0	1 (5.6)	0
Lethargy	1 (5.6)	1 (5.6)	0	0	0
Neuropathy peripheral	1 (5.6)	0	0	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	1 (5.6)	0	1 (5.6)	0	0
Psychiatric disorders					
-Total	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0
Mental status changes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Anxiety	1 (5.6)	1 (5.6)	0	0	0
Insomnia	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	1 (5.6)	0	0	0
Haematuria	1 (5.6)	0	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (27.8)	2 (11.1)	1 (5.6)	1 (5.6)	1 (5.6)
Oropharyngeal pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Dyspnoea	1 (5.6)	1 (5.6)	0	0	0
Epistaxis	1 (5.6)	0	0	1 (5.6)	0
Hypoxia	1 (5.6)	0	0	1 (5.6)	0
Respiratory failure	1 (5.6)	0	0	0	1 (5.6)

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Ingrowing nail	1 (5.6)	1 (5.6)	0	0	0
Petechiae	1 (5.6)	1 (5.6)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Hypertension	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Hypotension	1 (5.6)	0	0	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205d
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	72 (90.0)	1 (1.3)	9 (11.3)	28 (35.0)	34 (42.5)
Blood and lymphatic system disorders					
-Total	43 (53.8)	0	2 (2.5)	26 (32.5)	15 (18.8)
Febrile neutropenia	21 (26.3)	0	0	20 (25.0)	1 (1.3)
Anaemia	19 (23.8)	1 (1.3)	3 (3.8)	15 (18.8)	0
Neutropenia	10 (12.5)	1 (1.3)	0	1 (1.3)	8 (10.0)
Thrombocytopenia	7 (8.8)	1 (1.3)	1 (1.3)	1 (1.3)	4 (5.0)
Pancytopenia	4 (5.0)	0	1 (1.3)	1 (1.3)	2 (2.5)
Leukopenia	3 (3.8)	0	0	0	3 (3.8)
Haemolytic anaemia	1 (1.3)	0	0	0	1 (1.3)
Hyperleukocytosis	1 (1.3)	0	0	1 (1.3)	0
Lymphadenitis	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Cardiac disorders					
-Total	9 (11.3)	3 (3.8)	1 (1.3)	5 (6.3)	0
Tachycardia	5 (6.3)	2 (2.5)	1 (1.3)	2 (2.5)	0
Bradycardia	1 (1.3)	1 (1.3)	0	0	0
Cardiac failure	1 (1.3)	0	0	1 (1.3)	0
Left ventricular dysfunction	1 (1.3)	0	0	1 (1.3)	0
Pericardial effusion	1 (1.3)	0	0	1 (1.3)	0
Ear and labyrinth disorders					
-Total	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Vertigo	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Endocrine disorders					
-Total	6 (7.5)	0	4 (5.0)	1 (1.3)	1 (1.3)
Adrenal insufficiency	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Addison's disease	1 (1.3)	0	1 (1.3)	0	0
Hypercalcaemia of malignancy	1 (1.3)	0	0	0	1 (1.3)
Hypothyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (2.5)	2 (2.5)	0	0	0
Dry eye	1 (1.3)	1 (1.3)	0	0	0
Eyelid oedema	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	32 (40.0)	5 (6.3)	11 (13.8)	15 (18.8)	1 (1.3)
Abdominal pain	8 (10.0)	2 (2.5)	4 (5.0)	2 (2.5)	0
Constipation	6 (7.5)	3 (3.8)	3 (3.8)	0	0
Nausea	5 (6.3)	0	4 (5.0)	1 (1.3)	0
Stomatitis	5 (6.3)	0	1 (1.3)	4 (5.0)	0
Diarrhoea	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Neutropenic colitis	3 (3.8)	0	0	3 (3.8)	0
Abdominal pain upper	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Oral pain	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal fistula	1 (1.3)	0	0	1 (1.3)	0
Anal inflammation	1 (1.3)	0	0	1 (1.3)	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Duodenal perforation	1 (1.3)	0	0	1 (1.3)	0
Gastritis	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal sounds abnormal	1 (1.3)	1 (1.3)	0	0	0
Gastrooesophageal reflux disease	1 (1.3)	1 (1.3)	0	0	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Haemoperitoneum	1 (1.3)	0	0	0	1 (1.3)
Haemorrhoids	1 (1.3)	0	1 (1.3)	0	0
Hypoaesthesia oral	1 (1.3)	0	1 (1.3)	0	0
Ileus	1 (1.3)	0	0	1 (1.3)	0
Ileus paralytic	1 (1.3)	1 (1.3)	0	0	0
Oral disorder	1 (1.3)	1 (1.3)	0	0	0
Oral mucosal blistering	1 (1.3)	1 (1.3)	0	0	0
Tongue blistering	1 (1.3)	1 (1.3)	0	0	0
Tooth pulp haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Vomiting	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (25.0)	4 (5.0)	13 (16.3)	3 (3.8)	0
Pyrexia	10 (12.5)	2 (2.5)	7 (8.8)	1 (1.3)	0
Catheter site pain	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Fatigue	4 (5.0)	1 (1.3)	3 (3.8)	0	0
Pain	4 (5.0)	0	3 (3.8)	1 (1.3)	0
Non-cardiac chest pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Oedema peripheral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Asthenia	1 (1.3)	0	1 (1.3)	0	0
Chills	1 (1.3)	0	1 (1.3)	0	0
Complication associated with device	1 (1.3)	1 (1.3)	0	0	0
Mucosal inflammation	1 (1.3)	0	0	1 (1.3)	0
Thirst	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	9 (11.3)	3 (3.8)	2 (2.5)	4 (5.0)	0
Hyperbilirubinaemia	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Hepatic cytolysis	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Drug-induced liver injury	1 (1.3)	0	0	1 (1.3)	0
Hepatomegaly	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatosplenomegaly	1 (1.3)	0	1 (1.3)	0	0
Hypertransaminasaemia	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	9 (11.3)	0	6 (7.5)	3 (3.8)	0
Hypogammaglobulinaemia	5 (6.3)	0	4 (5.0)	1 (1.3)	0
Immunodeficiency	2 (2.5)	0	0	2 (2.5)	0
Hypersensitivity	1 (1.3)	0	1 (1.3)	0	0
Immune system disorder	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	40 (50.0)	2 (2.5)	6 (7.5)	22 (27.5)	10 (12.5)
Pneumonia	4 (5.0)	0	1 (1.3)	2 (2.5)	1 (1.3)
Catheter site infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Staphylococcal bacteraemia	3 (3.8)	0	0	3 (3.8)	0
Clostridium difficile colitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Device related infection	2 (2.5)	0	0	2 (2.5)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0
Oral herpes	2 (2.5)	0	0	2 (2.5)	0
Parainfluenzae virus infection	2 (2.5)	0	0	2 (2.5)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sialoadenitis	2 (2.5)	0	0	2 (2.5)	0
Sinusitis	2 (2.5)	0	2 (2.5)	0	0
Staphylococcal infection	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Staphylococcal sepsis	2 (2.5)	0	0	0	2 (2.5)
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Acute sinusitis	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Bronchiolitis	1 (1.3)	0	0	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cytomegalovirus infection reactivation	1 (1.3)	0	1 (1.3)	0	0
Device related bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Epstein-barr virus infection	1 (1.3)	0	1 (1.3)	0	0
Epstein-barr virus infection reactivation	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Fungal infection	1 (1.3)	0	1 (1.3)	0	0
Fungal pharyngitis	1 (1.3)	0	0	1 (1.3)	0
Fungal sepsis	1 (1.3)	0	0	0	1 (1.3)
Fungal skin infection	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis adenovirus	1 (1.3)	0	0	1 (1.3)	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Haemophilus bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Herpes simplex	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Localised infection	1 (1.3)	0	0	1 (1.3)	0
Paronychia	1 (1.3)	0	0	1 (1.3)	0
Peritonitis	1 (1.3)	0	0	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0	0	1 (1.3)
Pseudomonal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Sepsis	1 (1.3)	0	0	0	1 (1.3)
Serratia sepsis	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal skin infection	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatococcal infection	1 (1.3)	0	0	0	1 (1.3)
Systemic mycosis	1 (1.3)	0	0	1 (1.3)	0
Tonsillitis	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection	1 (1.3)	0	1 (1.3)	0	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	8 (10.0)	1 (1.3)	4 (5.0)	2 (2.5)	1 (1.3)
Transfusion reaction	2 (2.5)	0	2 (2.5)	0	0
Fall	1 (1.3)	0	1 (1.3)	0	0
Infusion related reaction	1 (1.3)	0	0	1 (1.3)	0
Post procedural haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Procedural pain	1 (1.3)	1 (1.3)	0	0	0
Tracheal obstruction	1 (1.3)	0	0	0	1 (1.3)
Traumatic haematoma	1 (1.3)	0	1 (1.3)	0	0
Wound	1 (1.3)	1 (1.3)	0	0	0
Investigations					
-Total	25 (31.3)	1 (1.3)	1 (1.3)	11 (13.8)	12 (15.0)

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (12.5)	1 (1.3)	0	2 (2.5)	7 (8.8)
Alanine aminotransferase increased	7 (8.8)	2 (2.5)	2 (2.5)	3 (3.8)	0
C-reactive protein increased	6 (7.5)	2 (2.5)	2 (2.5)	2 (2.5)	0
White blood cell count decreased	6 (7.5)	1 (1.3)	0	0	5 (6.3)
Platelet count decreased	5 (6.3)	0	0	0	5 (6.3)
Aspartate aminotransferase increased	4 (5.0)	0	1 (1.3)	2 (2.5)	1 (1.3)
Serum ferritin increased	4 (5.0)	1 (1.3)	1 (1.3)	2 (2.5)	0
Lymphocyte count decreased	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Blood creatinine increased	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Blood glucose increased	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Blood potassium decreased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Weight decreased	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Activated partial thromboplastin time prolonged	1 (1.3)	1 (1.3)	0	0	0
Activated partial thromboplastin time shortened	1 (1.3)	0	1 (1.3)	0	0
Amylase increased	1 (1.3)	0	0	0	1 (1.3)
Blood bilirubin increased	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood calcium increased	1 (1.3)	0	0	1 (1.3)	0
Blood fibrinogen decreased	1 (1.3)	0	0	1 (1.3)	0
Blood fibrinogen increased	1 (1.3)	1 (1.3)	0	0	0
Blood immunoglobulin g decreased	1 (1.3)	0	1 (1.3)	0	0
Blood immunoglobulin m decreased	1 (1.3)	0	1 (1.3)	0	0
Blood lactate dehydrogenase increased	1 (1.3)	0	0	1 (1.3)	0
Blood magnesium decreased	1 (1.3)	0	1 (1.3)	0	0
Blood phosphorus decreased	1 (1.3)	0	0	1 (1.3)	0
Eosinophil count decreased	1 (1.3)	1 (1.3)	0	0	0
Fibrin d dimer increased	1 (1.3)	1 (1.3)	0	0	0
Haematocrit decreased	1 (1.3)	1 (1.3)	0	0	0
International normalised ratio increased	1 (1.3)	0	1 (1.3)	0	0
Protein total decreased	1 (1.3)	0	1 (1.3)	0	0
Red blood cell count decreased	1 (1.3)	1 (1.3)	0	0	0
Weight increased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	21 (26.3)	1 (1.3)	6 (7.5)	10 (12.5)	4 (5.0)

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	5 (6.3)	1 (1.3)	1 (1.3)	3 (3.8)	0
Tumour lysis syndrome	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Decreased appetite	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Hypervolaemia	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Hypoalbuminaemia	2 (2.5)	0	2 (2.5)	0	0
Hypocalcaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Hyponatraemia	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Eating disorder symptom	1 (1.3)	0	1 (1.3)	0	0
Hyperammonaemia	1 (1.3)	0	0	1 (1.3)	0
Hypercalcaemia	1 (1.3)	0	0	0	1 (1.3)
Hyperglycaemia	1 (1.3)	0	0	0	1 (1.3)
Hyperuricaemia	1 (1.3)	0	1 (1.3)	0	0
Hypomagnesaemia	1 (1.3)	1 (1.3)	0	0	0
Hypophagia	1 (1.3)	0	0	1 (1.3)	0
Hypophosphataemia	1 (1.3)	0	1 (1.3)	0	0
Malnutrition	1 (1.3)	0	1 (1.3)	0	0
Metabolic acidosis	1 (1.3)	0	0	1 (1.3)	0
Vitamin a deficiency	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vitamin b1 deficiency	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (16.3)	5 (6.3)	6 (7.5)	2 (2.5)	0
Back pain	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Arthralgia	4 (5.0)	2 (2.5)	2 (2.5)	0	0
Pain in extremity	4 (5.0)	1 (1.3)	2 (2.5)	1 (1.3)	0
Bone pain	1 (1.3)	0	1 (1.3)	0	0
Groin pain	1 (1.3)	1 (1.3)	0	0	0
Joint effusion	1 (1.3)	0	0	1 (1.3)	0
Osteopenia	1 (1.3)	1 (1.3)	0	0	0
Pain in jaw	1 (1.3)	0	0	1 (1.3)	0
Spinal pain	1 (1.3)	0	0	1 (1.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.3)	0	0	0	1 (1.3)
Acute lymphocytic leukaemia	1 (1.3)	0	0	0	1 (1.3)
Skin papilloma	1 (1.3)	1 (1.3)	0	0	0
Nervous system disorders					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	17 (21.3)	6 (7.5)	6 (7.5)	4 (5.0)	1 (1.3)
Headache	7 (8.8)	3 (3.8)	3 (3.8)	1 (1.3)	0
Neuropathy peripheral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Paraesthesia	2 (2.5)	2 (2.5)	0	0	0
Cognitive disorder	1 (1.3)	0	0	1 (1.3)	0
Dizziness	1 (1.3)	1 (1.3)	0	0	0
Encephalopathy	1 (1.3)	0	0	1 (1.3)	0
Haemorrhage intracranial	1 (1.3)	0	0	0	1 (1.3)
Intraventricular haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Peripheral motor neuropathy	1 (1.3)	0	1 (1.3)	0	0
Post herpetic neuralgia	1 (1.3)	0	0	1 (1.3)	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Psychiatric disorders					
-Total	6 (7.5)	1 (1.3)	3 (3.8)	2 (2.5)	0
Anxiety	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Agitation	1 (1.3)	1 (1.3)	0	0	0
Depression	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (1.3)	0	1 (1.3)	0	0
Mental status changes	1 (1.3)	0	0	1 (1.3)	0
Renal and urinary disorders					
-Total	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Acute kidney injury	1 (1.3)	1 (1.3)	0	0	0
Micturition disorder	1 (1.3)	1 (1.3)	0	0	0
Renal tubular necrosis	1 (1.3)	0	0	1 (1.3)	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Heavy menstrual bleeding	1 (1.3)	0	1 (1.3)	0	0
Prostatitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (17.5)	3 (3.8)	3 (3.8)	4 (5.0)	4 (5.0)
Epistaxis	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Hypoxia	3 (3.8)	0	3 (3.8)	0	0
Respiratory failure	3 (3.8)	0	0	0	3 (3.8)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	2 (2.5)	2 (2.5)	0	0	0
Nasal congestion	2 (2.5)	2 (2.5)	0	0	0
Tachypnoea	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Acute respiratory distress syndrome	1 (1.3)	0	0	0	1 (1.3)
Atelectasis	1 (1.3)	0	0	1 (1.3)	0
Dyspnoea	1 (1.3)	0	0	1 (1.3)	0
Haemothorax	1 (1.3)	0	0	0	1 (1.3)
Pneumothorax	1 (1.3)	0	0	0	1 (1.3)
Pulmonary oedema	1 (1.3)	0	0	0	1 (1.3)
Rhinorrhoea	1 (1.3)	1 (1.3)	0	0	0
Throat irritation	1 (1.3)	0	1 (1.3)	0	0
Wheezing	1 (1.3)	1 (1.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (15.0)	7 (8.8)	3 (3.8)	2 (2.5)	0
Pruritus	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Skin ulcer	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Pain of skin	2 (2.5)	1 (1.3)	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Blister	1 (1.3)	1 (1.3)	0	0	0
Dermatitis exfoliative generalised	1 (1.3)	1 (1.3)	0	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0
Rash maculo-papular	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	10 (12.5)	2 (2.5)	4 (5.0)	2 (2.5)	2 (2.5)
Hypotension	5 (6.3)	1 (1.3)	0	2 (2.5)	2 (2.5)
Hypertension	4 (5.0)	0	4 (5.0)	0	0
Haematoma	1 (1.3)	1 (1.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and

CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205e
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	5 (62.5)	3 (37.5)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Tachycardia	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Gastrointestinal disorders					
-Total	4 (50.0)	1 (12.5)	0	2 (25.0)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
Tooth pulp haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Pyrexia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0	0	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood creatinine increased	1 (12.5)	1 (12.5)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Hypocalcaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0
Nervous system disorders					

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Acute kidney injury	2 (25.0)	2 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (37.5)	1 (12.5)	0	0	2 (25.0)
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Hypotension	2 (25.0)	0	0	2 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205e
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	81 (90.0)	3 (3.3)	10 (11.1)	29 (32.2)	39 (43.3)
Blood and lymphatic system disorders					
-Total	45 (50.0)	1 (1.1)	2 (2.2)	26 (28.9)	16 (17.8)
Anaemia	21 (23.3)	2 (2.2)	4 (4.4)	14 (15.6)	1 (1.1)
Febrile neutropenia	21 (23.3)	0	0	20 (22.2)	1 (1.1)
Neutropenia	11 (12.2)	1 (1.1)	0	1 (1.1)	9 (10.0)
Thrombocytopenia	8 (8.9)	1 (1.1)	1 (1.1)	3 (3.3)	3 (3.3)
Pancytopenia	4 (4.4)	0	1 (1.1)	1 (1.1)	2 (2.2)
Leukopenia	3 (3.3)	0	0	0	3 (3.3)
Haemolytic anaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	0	0	1 (1.1)	0
Lymphadenitis	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Cardiac disorders					
-Total	7 (7.8)	2 (2.2)	1 (1.1)	4 (4.4)	0
Tachycardia	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Bradycardia	1 (1.1)	1 (1.1)	0	0	0
Cardiac failure	1 (1.1)	0	0	1 (1.1)	0
Left ventricular dysfunction	1 (1.1)	0	0	1 (1.1)	0
Pericardial effusion	1 (1.1)	0	0	1 (1.1)	0
Ear and labyrinth disorders					
-Total	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Vertigo	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Endocrine disorders					
-Total	7 (7.8)	0	5 (5.6)	1 (1.1)	1 (1.1)
Adrenal insufficiency	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Hypothyroidism	2 (2.2)	0	2 (2.2)	0	0
Addison's disease	1 (1.1)	0	1 (1.1)	0	0
Hypercalcaemia of malignancy	1 (1.1)	0	0	0	1 (1.1)
Eye disorders					

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.2)	2 (2.2)	0	0	0
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eyelid oedema	1 (1.1)	1 (1.1)	0	0	0
Gastrointestinal disorders					
-Total	35 (38.9)	5 (5.6)	13 (14.4)	17 (18.9)	0
Abdominal pain	7 (7.8)	2 (2.2)	4 (4.4)	1 (1.1)	0
Constipation	7 (7.8)	3 (3.3)	4 (4.4)	0	0
Nausea	7 (7.8)	1 (1.1)	5 (5.6)	1 (1.1)	0
Stomatitis	6 (6.7)	0	1 (1.1)	5 (5.6)	0
Diarrhoea	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Neutropenic colitis	3 (3.3)	0	0	3 (3.3)	0
Abdominal pain upper	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Oral disorder	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Oral pain	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Vomiting	2 (2.2)	2 (2.2)	0	0	0
Anal fissure	1 (1.1)	0	1 (1.1)	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (1.1)	0	0	1 (1.1)	0
Dry mouth	1 (1.1)	0	1 (1.1)	0	0
Duodenal perforation	1 (1.1)	0	0	1 (1.1)	0
Gastritis	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Gastrooesophageal reflux disease	1 (1.1)	1 (1.1)	0	0	0
Haematemesis	1 (1.1)	1 (1.1)	0	0	0
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Hypoaesthesia oral	1 (1.1)	0	1 (1.1)	0	0
Ileus	1 (1.1)	0	0	1 (1.1)	0
Ileus paralytic	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Mouth haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Oral mucosal blistering	1 (1.1)	1 (1.1)	0	0	0
Tongue blistering	1 (1.1)	1 (1.1)	0	0	0
General disorders and administration site conditions					

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (23.3)	4 (4.4)	14 (15.6)	3 (3.3)	0
Pyrexia	11 (12.2)	3 (3.3)	7 (7.8)	1 (1.1)	0
Catheter site pain	5 (5.6)	2 (2.2)	3 (3.3)	0	0
Fatigue	5 (5.6)	1 (1.1)	4 (4.4)	0	0
Pain	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Non-cardiac chest pain	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Oedema peripheral	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Asthenia	1 (1.1)	0	1 (1.1)	0	0
Chills	1 (1.1)	0	1 (1.1)	0	0
Complication associated with device	1 (1.1)	1 (1.1)	0	0	0
Face oedema	1 (1.1)	1 (1.1)	0	0	0
Mucosal inflammation	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	10 (11.1)	3 (3.3)	2 (2.2)	5 (5.6)	0
Hyperbilirubinaemia	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Hepatic cytolysis	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Hypertransaminasaemia	2 (2.2)	1 (1.1)	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatomegaly	1 (1.1)	1 (1.1)	0	0	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Immune system disorders					
-Total	11 (12.2)	0	7 (7.8)	4 (4.4)	0
Hypogammaglobulinaemia	6 (6.7)	0	5 (5.6)	1 (1.1)	0
Immunodeficiency	2 (2.2)	0	0	2 (2.2)	0
Graft versus host disease	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	0	1 (1.1)	0	0
Immune system disorder	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	45 (50.0)	2 (2.2)	7 (7.8)	26 (28.9)	10 (11.1)
Pneumonia	4 (4.4)	0	1 (1.1)	2 (2.2)	1 (1.1)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Oral herpes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Sinusitis	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Acute sinusitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.2)	0	0	2 (2.2)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.2)	0	0	2 (2.2)	0
Escherichia bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Herpes zoster	2 (2.2)	0	0	2 (2.2)	0
Parainfluenzae virus infection	2 (2.2)	0	0	2 (2.2)	0
Pneumonia fungal	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Septic shock	2 (2.2)	0	0	0	2 (2.2)
Staphylococcal bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Staphylococcal sepsis	2 (2.2)	0	0	0	2 (2.2)
Urinary tract infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Clostridium difficile colitis	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungal infection	1 (1.1)	0	1 (1.1)	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	11 (12.2)	1 (1.1)	5 (5.6)	4 (4.4)	1 (1.1)
Transfusion reaction	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Procedural pain	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Fall	1 (1.1)	0	1 (1.1)	0	0
Infusion related reaction	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Wound	1 (1.1)	1 (1.1)	0	0	0
Investigations					
-Total	29 (32.2)	2 (2.2)	1 (1.1)	11 (12.2)	15 (16.7)
Neutrophil count decreased	11 (12.2)	1 (1.1)	0	3 (3.3)	7 (7.8)
Platelet count decreased	8 (8.9)	0	0	0	8 (8.9)
C-reactive protein increased	7 (7.8)	2 (2.2)	2 (2.2)	2 (2.2)	1 (1.1)
White blood cell count decreased	7 (7.8)	0	0	0	7 (7.8)
Alanine aminotransferase increased	6 (6.7)	1 (1.1)	2 (2.2)	3 (3.3)	0
Serum ferritin increased	5 (5.6)	1 (1.1)	1 (1.1)	2 (2.2)	1 (1.1)
Aspartate aminotransferase increased	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Blood lactate dehydrogenase increased	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Lymphocyte count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Weight decreased	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Blood fibrinogen increased	2 (2.2)	1 (1.1)	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood glucose increased	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Blood potassium decreased	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Fibrin d dimer increased	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Activated partial thromboplastin time prolonged	1 (1.1)	1 (1.1)	0	0	0
Activated partial thromboplastin time shortened	1 (1.1)	0	1 (1.1)	0	0
Amylase increased	1 (1.1)	0	0	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	0	0	1 (1.1)	0
Blood calcium increased	1 (1.1)	0	0	1 (1.1)	0
Blood creatinine increased	1 (1.1)	0	0	1 (1.1)	0
Blood fibrinogen decreased	1 (1.1)	0	0	1 (1.1)	0
Blood magnesium decreased	1 (1.1)	0	1 (1.1)	0	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0
Blood uric acid increased	1 (1.1)	1 (1.1)	0	0	0
Electrocardiogram qt prolonged	1 (1.1)	1 (1.1)	0	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (1.1)	0	1 (1.1)	0	0
Protein total decreased	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Weight increased	1 (1.1)	0	1 (1.1)	0	0
Metabolism and nutrition disorders					
-Total	22 (24.4)	2 (2.2)	7 (7.8)	9 (10.0)	4 (4.4)
Hypokalaemia	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Decreased appetite	4 (4.4)	1 (1.1)	1 (1.1)	2 (2.2)	0
Tumour lysis syndrome	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Hypervolaemia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Hypomagnesaemia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Hyponatraemia	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Hyperammonaemia	1 (1.1)	0	0	1 (1.1)	0
Hypercalcaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperglycaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperphosphataemia	1 (1.1)	1 (1.1)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (1.1)	0	1 (1.1)	0	0
Hypoalbuminaemia	1 (1.1)	0	1 (1.1)	0	0
Hypocalcaemia	1 (1.1)	1 (1.1)	0	0	0
Hypophagia	1 (1.1)	0	0	1 (1.1)	0
Hypophosphataemia	1 (1.1)	0	1 (1.1)	0	0
Malnutrition	1 (1.1)	0	1 (1.1)	0	0
Vitamin a deficiency	1 (1.1)	0	1 (1.1)	0	0
Vitamin b1 deficiency	1 (1.1)	1 (1.1)	0	0	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	17 (18.9)	7 (7.8)	7 (7.8)	3 (3.3)	0
Arthralgia	6 (6.7)	4 (4.4)	2 (2.2)	0	0
Back pain	5 (5.6)	1 (1.1)	3 (3.3)	1 (1.1)	0
Pain in extremity	5 (5.6)	1 (1.1)	3 (3.3)	1 (1.1)	0
Bone pain	1 (1.1)	0	1 (1.1)	0	0
Groin pain	1 (1.1)	1 (1.1)	0	0	0
Joint effusion	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0
Pain in jaw	1 (1.1)	0	0	1 (1.1)	0
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.1)	0	0	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	0	0	1 (1.1)
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Nervous system disorders					
-Total	18 (20.0)	7 (7.8)	5 (5.6)	5 (5.6)	1 (1.1)
Headache	8 (8.9)	3 (3.3)	3 (3.3)	2 (2.2)	0
Paraesthesia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Neuropathy peripheral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Dizziness	1 (1.1)	1 (1.1)	0	0	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	0	0	1 (1.1)
Intraventricular haemorrhage	1 (1.1)	1 (1.1)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Peripheral motor neuropathy	1 (1.1)	0	1 (1.1)	0	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	10 (11.1)	2 (2.2)	5 (5.6)	3 (3.3)	0
Anxiety	4 (4.4)	2 (2.2)	1 (1.1)	1 (1.1)	0
Mental status changes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Insomnia	2 (2.2)	0	2 (2.2)	0	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Depression	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					
-Total	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Haematuria	1 (1.1)	0	1 (1.1)	0	0
Micturition disorder	1 (1.1)	1 (1.1)	0	0	0
Renal tubular necrosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Heavy menstrual bleeding	1 (1.1)	0	1 (1.1)	0	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (17.8)	4 (4.4)	4 (4.4)	5 (5.6)	3 (3.3)
Epistaxis	4 (4.4)	2 (2.2)	0	2 (2.2)	0
Hypoxia	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Cough	2 (2.2)	2 (2.2)	0	0	0
Dyspnoea	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Nasal congestion	2 (2.2)	2 (2.2)	0	0	0
Respiratory failure	2 (2.2)	0	0	0	2 (2.2)
Tachypnoea	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Acute respiratory distress syndrome	1 (1.1)	0	0	0	1 (1.1)
Atelectasis	1 (1.1)	0	0	1 (1.1)	0
Haemothorax	1 (1.1)	0	0	0	1 (1.1)
Oropharyngeal pain	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumothorax	1 (1.1)	0	0	0	1 (1.1)
Rhinorrhoea	1 (1.1)	1 (1.1)	0	0	0
Throat irritation	1 (1.1)	0	1 (1.1)	0	0
Wheezing	1 (1.1)	1 (1.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (15.6)	9 (10.0)	3 (3.3)	2 (2.2)	0
Pruritus	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Skin ulcer	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Pain of skin	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Rash	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Blister	1 (1.1)	1 (1.1)	0	0	0
Dermatitis exfoliative generalised	1 (1.1)	1 (1.1)	0	0	0
Dry skin	1 (1.1)	1 (1.1)	0	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Petechiae	1 (1.1)	1 (1.1)	0	0	0
Rash maculo-papular	1 (1.1)	1 (1.1)	0	0	0
Vascular disorders					

Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=90 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	12 (13.3)	4 (4.4)	5 (5.6)	1 (1.1)	2 (2.2)
Hypertension	7 (7.8)	2 (2.2)	5 (5.6)	0	0
Hypotension	4 (4.4)	1 (1.1)	0	1 (1.1)	2 (2.2)
Haematoma	1 (1.1)	1 (1.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205f
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Device related bacteraemia	1 (50.0)	0	1 (50.0)	0	0
Fungal infection	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tonsillitis	1 (50.0)	0	1 (50.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	0	1 (50.0)	0	0
Transfusion reaction	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205f
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	88 (91.7)	3 (3.1)	10 (10.4)	34 (35.4)	41 (42.7)
Blood and lymphatic system disorders					
-Total	48 (50.0)	1 (1.0)	2 (2.1)	29 (30.2)	16 (16.7)
Anaemia	23 (24.0)	2 (2.1)	4 (4.2)	16 (16.7)	1 (1.0)
Febrile neutropenia	23 (24.0)	0	0	22 (22.9)	1 (1.0)
Neutropenia	10 (10.4)	1 (1.0)	0	1 (1.0)	8 (8.3)
Thrombocytopenia	9 (9.4)	1 (1.0)	1 (1.0)	3 (3.1)	4 (4.2)
Pancytopenia	4 (4.2)	0	1 (1.0)	1 (1.0)	2 (2.1)
Leukopenia	3 (3.1)	0	0	0	3 (3.1)
Haemolytic anaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperleukocytosis	1 (1.0)	0	0	1 (1.0)	0
Lymphadenitis	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.0)	0	0	0	1 (1.0)
Cardiac disorders					
-Total	10 (10.4)	3 (3.1)	1 (1.0)	6 (6.3)	0
Tachycardia	6 (6.3)	2 (2.1)	1 (1.0)	3 (3.1)	0
Bradycardia	1 (1.0)	1 (1.0)	0	0	0
Cardiac failure	1 (1.0)	0	0	1 (1.0)	0
Left ventricular dysfunction	1 (1.0)	0	0	1 (1.0)	0
Pericardial effusion	1 (1.0)	0	0	1 (1.0)	0
Ear and labyrinth disorders					
-Total	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Vertigo	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Endocrine disorders					
-Total	7 (7.3)	0	5 (5.2)	1 (1.0)	1 (1.0)
Adrenal insufficiency	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Hypothyroidism	2 (2.1)	0	2 (2.1)	0	0
Addison's disease	1 (1.0)	0	1 (1.0)	0	0
Hypercalcaemia of malignancy	1 (1.0)	0	0	0	1 (1.0)
Eye disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.1)	2 (2.1)	0	0	0
Dry eye	1 (1.0)	1 (1.0)	0	0	0
Eyelid oedema	1 (1.0)	1 (1.0)	0	0	0
Gastrointestinal disorders					
-Total	39 (40.6)	6 (6.3)	13 (13.5)	19 (19.8)	1 (1.0)
Abdominal pain	8 (8.3)	2 (2.1)	4 (4.2)	2 (2.1)	0
Constipation	7 (7.3)	3 (3.1)	4 (4.2)	0	0
Nausea	7 (7.3)	1 (1.0)	5 (5.2)	1 (1.0)	0
Stomatitis	7 (7.3)	0	1 (1.0)	6 (6.3)	0
Diarrhoea	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Neutropenic colitis	3 (3.1)	0	0	3 (3.1)	0
Abdominal pain upper	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Haematemesis	2 (2.1)	2 (2.1)	0	0	0
Oral disorder	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Oral pain	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Vomiting	2 (2.1)	2 (2.1)	0	0	0
Abdominal compartment syndrome	1 (1.0)	0	0	0	1 (1.0)
Anal fissure	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fistula	1 (1.0)	0	0	1 (1.0)	0
Anal inflammation	1 (1.0)	0	0	1 (1.0)	0
Colitis	1 (1.0)	0	0	1 (1.0)	0
Dry mouth	1 (1.0)	0	1 (1.0)	0	0
Duodenal perforation	1 (1.0)	0	0	1 (1.0)	0
Gastritis	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal sounds abnormal	1 (1.0)	1 (1.0)	0	0	0
Gastrooesophageal reflux disease	1 (1.0)	1 (1.0)	0	0	0
Gingival erythema	1 (1.0)	1 (1.0)	0	0	0
Haemoperitoneum	1 (1.0)	0	0	0	1 (1.0)
Haemorrhoids	1 (1.0)	0	1 (1.0)	0	0
Hypoaesthesia oral	1 (1.0)	0	1 (1.0)	0	0
Ileus	1 (1.0)	0	0	1 (1.0)	0
Ileus paralytic	1 (1.0)	1 (1.0)	0	0	0
Lip ulceration	1 (1.0)	0	1 (1.0)	0	0
Mouth haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Oral mucosal blistering	1 (1.0)	1 (1.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tongue blistering	1 (1.0)	1 (1.0)	0	0	0
Tooth pulp haemorrhage	1 (1.0)	0	0	1 (1.0)	0
General disorders and administration site conditions					
-Total	25 (26.0)	4 (4.2)	17 (17.7)	4 (4.2)	0
Pyrexia	14 (14.6)	3 (3.1)	9 (9.4)	2 (2.1)	0
Catheter site pain	5 (5.2)	2 (2.1)	3 (3.1)	0	0
Fatigue	5 (5.2)	1 (1.0)	4 (4.2)	0	0
Pain	5 (5.2)	0	4 (4.2)	1 (1.0)	0
Chills	2 (2.1)	0	2 (2.1)	0	0
Non-cardiac chest pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Oedema peripheral	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Asthenia	1 (1.0)	0	1 (1.0)	0	0
Complication associated with device	1 (1.0)	1 (1.0)	0	0	0
Face oedema	1 (1.0)	1 (1.0)	0	0	0
Mucosal inflammation	1 (1.0)	0	0	1 (1.0)	0
Thirst	1 (1.0)	1 (1.0)	0	0	0
Hepatobiliary disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (9.4)	2 (2.1)	2 (2.1)	5 (5.2)	0
Hyperbilirubinaemia	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Hypertransaminasaemia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Drug-induced liver injury	1 (1.0)	0	0	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	0	0	1 (1.0)	0
Hepatomegaly	1 (1.0)	1 (1.0)	0	0	0
Hepatosplenomegaly	1 (1.0)	0	1 (1.0)	0	0
Immune system disorders					
-Total	12 (12.5)	0	8 (8.3)	4 (4.2)	0
Hypogammaglobulinaemia	7 (7.3)	0	6 (6.3)	1 (1.0)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Graft versus host disease	1 (1.0)	0	0	1 (1.0)	0
Hypersensitivity	1 (1.0)	0	1 (1.0)	0	0
Immune system disorder	1 (1.0)	0	1 (1.0)	0	0
Infections and infestations					
-Total	50 (52.1)	2 (2.1)	7 (7.3)	29 (30.2)	12 (12.5)
Pneumonia	4 (4.2)	0	1 (1.0)	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Staphylococcal bacteraemia	3 (3.1)	0	0	3 (3.1)	0
Acute sinusitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchitis	1 (1.0)	0	1 (1.0)	0	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cytomegalovirus infection reactivation	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (1.0)	1 (1.0)	0	0	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes simplex	1 (1.0)	0	1 (1.0)	0	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Injury, poisoning and procedural complications					
-Total	11 (11.5)	1 (1.0)	5 (5.2)	4 (4.2)	1 (1.0)
Procedural pain	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Extradural haematoma	1 (1.0)	0	1 (1.0)	0	0
Fall	1 (1.0)	0	1 (1.0)	0	0
Infusion related reaction	1 (1.0)	0	0	1 (1.0)	0
Post procedural haemorrhage	1 (1.0)	0	0	1 (1.0)	0
Radius fracture	1 (1.0)	0	1 (1.0)	0	0
Tracheal obstruction	1 (1.0)	0	0	0	1 (1.0)
Traumatic haematoma	1 (1.0)	0	1 (1.0)	0	0
Wound	1 (1.0)	1 (1.0)	0	0	0
Investigations					
-Total	32 (33.3)	2 (2.1)	1 (1.0)	12 (12.5)	17 (17.7)
Neutrophil count decreased	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)
Alanine aminotransferase increased	8 (8.3)	2 (2.1)	2 (2.1)	4 (4.2)	0
Platelet count decreased	8 (8.3)	0	0	0	8 (8.3)
White blood cell count decreased	8 (8.3)	1 (1.0)	0	0	7 (7.3)
C-reactive protein increased	7 (7.3)	2 (2.1)	2 (2.1)	2 (2.1)	1 (1.0)
Aspartate aminotransferase increased	5 (5.2)	0	1 (1.0)	3 (3.1)	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	5 (5.2)	1 (1.0)	1 (1.0)	2 (2.1)	1 (1.0)
Lymphocyte count decreased	4 (4.2)	1 (1.0)	0	1 (1.0)	2 (2.1)
Blood lactate dehydrogenase increased	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Weight decreased	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Blood creatinine increased	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Blood fibrinogen increased	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blood glucose increased	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blood potassium decreased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fibrin d dimer increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Activated partial thromboplastin time prolonged	1 (1.0)	1 (1.0)	0	0	0
Activated partial thromboplastin time shortened	1 (1.0)	0	1 (1.0)	0	0
Amylase increased	1 (1.0)	0	0	0	1 (1.0)
Blood bilirubin increased	1 (1.0)	0	0	1 (1.0)	0
Blood calcium increased	1 (1.0)	0	0	1 (1.0)	0
Blood fibrinogen decreased	1 (1.0)	0	0	1 (1.0)	0
Blood immunoglobulin g decreased	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.0)	0	1 (1.0)	0	0
Blood magnesium decreased	1 (1.0)	0	1 (1.0)	0	0
Blood phosphorus decreased	1 (1.0)	0	0	1 (1.0)	0
Blood uric acid increased	1 (1.0)	1 (1.0)	0	0	0
Electrocardiogram qt prolonged	1 (1.0)	1 (1.0)	0	0	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
International normalised ratio increased	1 (1.0)	0	1 (1.0)	0	0
Protein total decreased	1 (1.0)	0	1 (1.0)	0	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Weight increased	1 (1.0)	0	1 (1.0)	0	0
Metabolism and nutrition disorders					
-Total	25 (26.0)	2 (2.1)	7 (7.3)	12 (12.5)	4 (4.2)
Hypokalaemia	6 (6.3)	2 (2.1)	1 (1.0)	3 (3.1)	0
Decreased appetite	4 (4.2)	1 (1.0)	1 (1.0)	2 (2.1)	0
Hypocalcaemia	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Hypomagnesaemia	3 (3.1)	2 (2.1)	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Hypervolaemia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Hypoalbuminaemia	2 (2.1)	0	2 (2.1)	0	0
Hyponatraemia	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Metabolic acidosis	2 (2.1)	0	0	2 (2.1)	0
Eating disorder symptom	1 (1.0)	0	1 (1.0)	0	0
Hyperammonaemia	1 (1.0)	0	0	1 (1.0)	0
Hypercalcaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperglycaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperkalaemia	1 (1.0)	0	0	1 (1.0)	0
Hyperphosphataemia	1 (1.0)	1 (1.0)	0	0	0
Hyperuricaemia	1 (1.0)	0	1 (1.0)	0	0
Hypophagia	1 (1.0)	0	0	1 (1.0)	0
Hypophosphataemia	1 (1.0)	0	1 (1.0)	0	0
Malnutrition	1 (1.0)	0	1 (1.0)	0	0
Vitamin a deficiency	1 (1.0)	0	1 (1.0)	0	0
Vitamin b1 deficiency	1 (1.0)	1 (1.0)	0	0	0
Vitamin d deficiency	1 (1.0)	1 (1.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	18 (18.8)	7 (7.3)	7 (7.3)	4 (4.2)	0
Arthralgia	6 (6.3)	4 (4.2)	2 (2.1)	0	0
Pain in extremity	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Back pain	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Bone pain	1 (1.0)	0	1 (1.0)	0	0
Groin pain	1 (1.0)	1 (1.0)	0	0	0
Joint effusion	1 (1.0)	0	0	1 (1.0)	0
Myopathy	1 (1.0)	0	0	1 (1.0)	0
Osteopenia	1 (1.0)	1 (1.0)	0	0	0
Pain in jaw	1 (1.0)	0	0	1 (1.0)	0
Spinal pain	1 (1.0)	0	0	1 (1.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.0)	0	0	0	1 (1.0)
Acute lymphocytic leukaemia	1 (1.0)	0	0	0	1 (1.0)
Skin papilloma	1 (1.0)	1 (1.0)	0	0	0
Nervous system disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (20.8)	7 (7.3)	6 (6.3)	6 (6.3)	1 (1.0)
Headache	8 (8.3)	3 (3.1)	3 (3.1)	2 (2.1)	0
Neuropathy peripheral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Paraesthesia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cognitive disorder	1 (1.0)	0	0	1 (1.0)	0
Dizziness	1 (1.0)	1 (1.0)	0	0	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	0	0	1 (1.0)
Intraventricular haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Lethargy	1 (1.0)	1 (1.0)	0	0	0
Neuralgia	1 (1.0)	0	1 (1.0)	0	0
Peripheral motor neuropathy	1 (1.0)	0	1 (1.0)	0	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Psychiatric disorders					
-Total	10 (10.4)	2 (2.1)	5 (5.2)	3 (3.1)	0
Anxiety	4 (4.2)	2 (2.1)	1 (1.0)	1 (1.0)	0
Mental status changes	3 (3.1)	0	1 (1.0)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	2 (2.1)	0	2 (2.1)	0	0
Agitation	1 (1.0)	1 (1.0)	0	0	0
Depression	1 (1.0)	0	1 (1.0)	0	0
Renal and urinary disorders					
-Total	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	0
Acute kidney injury	2 (2.1)	2 (2.1)	0	0	0
Haematuria	1 (1.0)	0	1 (1.0)	0	0
Micturition disorder	1 (1.0)	1 (1.0)	0	0	0
Renal tubular necrosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract disorder	1 (1.0)	0	1 (1.0)	0	0
Reproductive system and breast disorders					
-Total	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Heavy menstrual bleeding	1 (1.0)	0	1 (1.0)	0	0
Prostatitis	1 (1.0)	0	0	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (19.8)	5 (5.2)	4 (4.2)	5 (5.2)	5 (5.2)
Epistaxis	4 (4.2)	2 (2.1)	0	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (4.2)	0	3 (3.1)	1 (1.0)	0
Respiratory failure	4 (4.2)	0	0	0	4 (4.2)
Cough	2 (2.1)	2 (2.1)	0	0	0
Dyspnoea	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Nasal congestion	2 (2.1)	2 (2.1)	0	0	0
Oropharyngeal pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Tachypnoea	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Acute respiratory distress syndrome	1 (1.0)	0	0	0	1 (1.0)
Atelectasis	1 (1.0)	0	0	1 (1.0)	0
Haemothorax	1 (1.0)	0	0	0	1 (1.0)
Pneumothorax	1 (1.0)	0	0	0	1 (1.0)
Pulmonary oedema	1 (1.0)	0	0	0	1 (1.0)
Rhinorrhoea	1 (1.0)	1 (1.0)	0	0	0
Throat irritation	1 (1.0)	0	1 (1.0)	0	0
Wheezing	1 (1.0)	1 (1.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (15.6)	10 (10.4)	3 (3.1)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	4 (4.2)	2 (2.1)	2 (2.1)	0	0
Skin ulcer	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Pain of skin	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Rash	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blister	1 (1.0)	1 (1.0)	0	0	0
Dermatitis exfoliative generalised	1 (1.0)	1 (1.0)	0	0	0
Dry skin	1 (1.0)	1 (1.0)	0	0	0
Erythema nodosum	1 (1.0)	1 (1.0)	0	0	0
Ingrowing nail	1 (1.0)	1 (1.0)	0	0	0
Petechiae	1 (1.0)	1 (1.0)	0	0	0
Rash maculo-papular	1 (1.0)	1 (1.0)	0	0	0
Vascular disorders					
-Total	14 (14.6)	4 (4.2)	5 (5.2)	3 (3.1)	2 (2.1)
Hypertension	7 (7.3)	2 (2.1)	5 (5.2)	0	0
Hypotension	6 (6.3)	1 (1.0)	0	3 (3.1)	2 (2.1)
Haematoma	1 (1.0)	1 (1.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205g
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Anal fissure	1 (100)	0	1 (100)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205g
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	88 (90.7)	3 (3.1)	9 (9.3)	34 (35.1)	42 (43.3)
Blood and lymphatic system disorders					
-Total	49 (50.5)	1 (1.0)	2 (2.1)	29 (29.9)	17 (17.5)
Anaemia	23 (23.7)	2 (2.1)	4 (4.1)	16 (16.5)	1 (1.0)
Febrile neutropenia	23 (23.7)	0	0	22 (22.7)	1 (1.0)
Neutropenia	11 (11.3)	1 (1.0)	0	1 (1.0)	9 (9.3)
Thrombocytopenia	9 (9.3)	1 (1.0)	1 (1.0)	3 (3.1)	4 (4.1)
Pancytopenia	4 (4.1)	0	1 (1.0)	1 (1.0)	2 (2.1)
Leukopenia	3 (3.1)	0	0	0	3 (3.1)
Haemolytic anaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperleukocytosis	1 (1.0)	0	0	1 (1.0)	0
Lymphadenitis	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.0)	0	0	0	1 (1.0)
Cardiac disorders					
-Total	10 (10.3)	3 (3.1)	1 (1.0)	6 (6.2)	0
Tachycardia	6 (6.2)	2 (2.1)	1 (1.0)	3 (3.1)	0
Bradycardia	1 (1.0)	1 (1.0)	0	0	0
Cardiac failure	1 (1.0)	0	0	1 (1.0)	0
Left ventricular dysfunction	1 (1.0)	0	0	1 (1.0)	0
Pericardial effusion	1 (1.0)	0	0	1 (1.0)	0
Ear and labyrinth disorders					
-Total	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Vertigo	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Endocrine disorders					
-Total	7 (7.2)	0	5 (5.2)	1 (1.0)	1 (1.0)
Adrenal insufficiency	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Hypothyroidism	2 (2.1)	0	2 (2.1)	0	0
Addison's disease	1 (1.0)	0	1 (1.0)	0	0
Hypercalcaemia of malignancy	1 (1.0)	0	0	0	1 (1.0)
Eye disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.1)	2 (2.1)	0	0	0
Dry eye	1 (1.0)	1 (1.0)	0	0	0
Eyelid oedema	1 (1.0)	1 (1.0)	0	0	0
Gastrointestinal disorders					
-Total	38 (39.2)	6 (6.2)	12 (12.4)	19 (19.6)	1 (1.0)
Abdominal pain	8 (8.2)	2 (2.1)	4 (4.1)	2 (2.1)	0
Constipation	7 (7.2)	3 (3.1)	4 (4.1)	0	0
Nausea	7 (7.2)	1 (1.0)	5 (5.2)	1 (1.0)	0
Stomatitis	7 (7.2)	0	1 (1.0)	6 (6.2)	0
Diarrhoea	4 (4.1)	1 (1.0)	2 (2.1)	1 (1.0)	0
Neutropenic colitis	3 (3.1)	0	0	3 (3.1)	0
Abdominal pain upper	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Haematemesis	2 (2.1)	2 (2.1)	0	0	0
Oral disorder	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Oral pain	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Vomiting	2 (2.1)	2 (2.1)	0	0	0
Abdominal compartment syndrome	1 (1.0)	0	0	0	1 (1.0)
Anal fistula	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal inflammation	1 (1.0)	0	0	1 (1.0)	0
Colitis	1 (1.0)	0	0	1 (1.0)	0
Dry mouth	1 (1.0)	0	1 (1.0)	0	0
Duodenal perforation	1 (1.0)	0	0	1 (1.0)	0
Gastritis	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal sounds abnormal	1 (1.0)	1 (1.0)	0	0	0
Gastrooesophageal reflux disease	1 (1.0)	1 (1.0)	0	0	0
Gingival erythema	1 (1.0)	1 (1.0)	0	0	0
Haemoperitoneum	1 (1.0)	0	0	0	1 (1.0)
Haemorrhoids	1 (1.0)	0	1 (1.0)	0	0
Hypoaesthesia oral	1 (1.0)	0	1 (1.0)	0	0
Ileus	1 (1.0)	0	0	1 (1.0)	0
Ileus paralytic	1 (1.0)	1 (1.0)	0	0	0
Lip ulceration	1 (1.0)	0	1 (1.0)	0	0
Mouth haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Oral mucosal blistering	1 (1.0)	1 (1.0)	0	0	0
Tongue blistering	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tooth pulp haemorrhage	1 (1.0)	0	0	1 (1.0)	0
General disorders and administration site conditions					
-Total	25 (25.8)	4 (4.1)	17 (17.5)	4 (4.1)	0
Pyrexia	14 (14.4)	3 (3.1)	9 (9.3)	2 (2.1)	0
Catheter site pain	5 (5.2)	2 (2.1)	3 (3.1)	0	0
Fatigue	5 (5.2)	1 (1.0)	4 (4.1)	0	0
Pain	5 (5.2)	0	4 (4.1)	1 (1.0)	0
Chills	2 (2.1)	0	2 (2.1)	0	0
Non-cardiac chest pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Oedema peripheral	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Asthenia	1 (1.0)	0	1 (1.0)	0	0
Complication associated with device	1 (1.0)	1 (1.0)	0	0	0
Face oedema	1 (1.0)	1 (1.0)	0	0	0
Mucosal inflammation	1 (1.0)	0	0	1 (1.0)	0
Thirst	1 (1.0)	1 (1.0)	0	0	0
Hepatobiliary disorders					
-Total	10 (10.3)	3 (3.1)	2 (2.1)	5 (5.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Hepatic cytolysis	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Hypertransaminasaemia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Drug-induced liver injury	1 (1.0)	0	0	1 (1.0)	0
Hepatomegaly	1 (1.0)	1 (1.0)	0	0	0
Hepatosplenomegaly	1 (1.0)	0	1 (1.0)	0	0
Immune system disorders					
-Total	12 (12.4)	0	8 (8.2)	4 (4.1)	0
Hypogammaglobulinaemia	7 (7.2)	0	6 (6.2)	1 (1.0)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Graft versus host disease	1 (1.0)	0	0	1 (1.0)	0
Hypersensitivity	1 (1.0)	0	1 (1.0)	0	0
Immune system disorder	1 (1.0)	0	1 (1.0)	0	0
Infections and infestations					
-Total	51 (52.6)	2 (2.1)	7 (7.2)	30 (30.9)	12 (12.4)
Pneumonia	4 (4.1)	0	1 (1.0)	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Oral herpes	3 (3.1)	0	1 (1.0)	2 (2.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Staphylococcal bacteraemia	3 (3.1)	0	0	3 (3.1)	0
Acute sinusitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchitis	1 (1.0)	0	1 (1.0)	0	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cytomegalovirus infection reactivation	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Fungal infection	1 (1.0)	0	1 (1.0)	0	0
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Fungal skin infection	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Gingivitis	1 (1.0)	1 (1.0)	0	0	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes simplex	1 (1.0)	0	1 (1.0)	0	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Tonsillitis	1 (1.0)	0	1 (1.0)	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	12 (12.4)	1 (1.0)	6 (6.2)	4 (4.1)	1 (1.0)
Procedural pain	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Transfusion reaction	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Extradural haematoma	1 (1.0)	0	1 (1.0)	0	0
Fall	1 (1.0)	0	1 (1.0)	0	0
Infusion related reaction	1 (1.0)	0	0	1 (1.0)	0
Post procedural haemorrhage	1 (1.0)	0	0	1 (1.0)	0
Radius fracture	1 (1.0)	0	1 (1.0)	0	0
Tracheal obstruction	1 (1.0)	0	0	0	1 (1.0)
Traumatic haematoma	1 (1.0)	0	1 (1.0)	0	0
Wound	1 (1.0)	1 (1.0)	0	0	0
Investigations					
-Total	32 (33.0)	2 (2.1)	1 (1.0)	12 (12.4)	17 (17.5)
Neutrophil count decreased	12 (12.4)	1 (1.0)	0	3 (3.1)	8 (8.2)
Alanine aminotransferase increased	8 (8.2)	2 (2.1)	2 (2.1)	4 (4.1)	0
Platelet count decreased	8 (8.2)	0	0	0	8 (8.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	8 (8.2)	1 (1.0)	0	0	7 (7.2)
C-reactive protein increased	7 (7.2)	2 (2.1)	2 (2.1)	2 (2.1)	1 (1.0)
Aspartate aminotransferase increased	5 (5.2)	0	1 (1.0)	3 (3.1)	1 (1.0)
Serum ferritin increased	5 (5.2)	1 (1.0)	1 (1.0)	2 (2.1)	1 (1.0)
Lymphocyte count decreased	4 (4.1)	1 (1.0)	0	1 (1.0)	2 (2.1)
Blood lactate dehydrogenase increased	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Weight decreased	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Blood creatinine increased	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Blood fibrinogen increased	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blood glucose increased	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blood potassium decreased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fibrin d dimer increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Activated partial thromboplastin time prolonged	1 (1.0)	1 (1.0)	0	0	0
Activated partial thromboplastin time shortened	1 (1.0)	0	1 (1.0)	0	0
Amylase increased	1 (1.0)	0	0	0	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (1.0)	0	0	1 (1.0)	0
Blood calcium increased	1 (1.0)	0	0	1 (1.0)	0
Blood fibrinogen decreased	1 (1.0)	0	0	1 (1.0)	0
Blood immunoglobulin g decreased	1 (1.0)	0	1 (1.0)	0	0
Blood immunoglobulin m decreased	1 (1.0)	0	1 (1.0)	0	0
Blood magnesium decreased	1 (1.0)	0	1 (1.0)	0	0
Blood phosphorus decreased	1 (1.0)	0	0	1 (1.0)	0
Blood uric acid increased	1 (1.0)	1 (1.0)	0	0	0
Electrocardiogram qt prolonged	1 (1.0)	1 (1.0)	0	0	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
International normalised ratio increased	1 (1.0)	0	1 (1.0)	0	0
Protein total decreased	1 (1.0)	0	1 (1.0)	0	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Weight increased	1 (1.0)	0	1 (1.0)	0	0
Metabolism and nutrition disorders					
-Total	25 (25.8)	2 (2.1)	7 (7.2)	12 (12.4)	4 (4.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	6 (6.2)	2 (2.1)	1 (1.0)	3 (3.1)	0
Decreased appetite	4 (4.1)	1 (1.0)	1 (1.0)	2 (2.1)	0
Hypocalcaemia	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Hypomagnesaemia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Tumour lysis syndrome	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Hypervolaemia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Hypoalbuminaemia	2 (2.1)	0	2 (2.1)	0	0
Hyponatraemia	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Metabolic acidosis	2 (2.1)	0	0	2 (2.1)	0
Eating disorder symptom	1 (1.0)	0	1 (1.0)	0	0
Hyperammonaemia	1 (1.0)	0	0	1 (1.0)	0
Hypercalcaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperglycaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperkalaemia	1 (1.0)	0	0	1 (1.0)	0
Hyperphosphataemia	1 (1.0)	1 (1.0)	0	0	0
Hyperuricaemia	1 (1.0)	0	1 (1.0)	0	0
Hypophagia	1 (1.0)	0	0	1 (1.0)	0
Hypophosphataemia	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (1.0)	0	1 (1.0)	0	0
Vitamin a deficiency	1 (1.0)	0	1 (1.0)	0	0
Vitamin b1 deficiency	1 (1.0)	1 (1.0)	0	0	0
Vitamin d deficiency	1 (1.0)	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (18.6)	7 (7.2)	7 (7.2)	4 (4.1)	0
Arthralgia	6 (6.2)	4 (4.1)	2 (2.1)	0	0
Pain in extremity	6 (6.2)	1 (1.0)	3 (3.1)	2 (2.1)	0
Back pain	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Bone pain	1 (1.0)	0	1 (1.0)	0	0
Groin pain	1 (1.0)	1 (1.0)	0	0	0
Joint effusion	1 (1.0)	0	0	1 (1.0)	0
Myopathy	1 (1.0)	0	0	1 (1.0)	0
Osteopenia	1 (1.0)	1 (1.0)	0	0	0
Pain in jaw	1 (1.0)	0	0	1 (1.0)	0
Spinal pain	1 (1.0)	0	0	1 (1.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.0)	0	0	0	1 (1.0)
Acute lymphocytic leukaemia	1 (1.0)	0	0	0	1 (1.0)
Skin papilloma	1 (1.0)	1 (1.0)	0	0	0
Nervous system disorders					
-Total	20 (20.6)	7 (7.2)	6 (6.2)	6 (6.2)	1 (1.0)
Headache	8 (8.2)	3 (3.1)	3 (3.1)	2 (2.1)	0
Neuropathy peripheral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Paraesthesia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cognitive disorder	1 (1.0)	0	0	1 (1.0)	0
Dizziness	1 (1.0)	1 (1.0)	0	0	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	0	0	1 (1.0)
Intraventricular haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Lethargy	1 (1.0)	1 (1.0)	0	0	0
Neuralgia	1 (1.0)	0	1 (1.0)	0	0
Peripheral motor neuropathy	1 (1.0)	0	1 (1.0)	0	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Seizure	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	10 (10.3)	2 (2.1)	5 (5.2)	3 (3.1)	0
Anxiety	4 (4.1)	2 (2.1)	1 (1.0)	1 (1.0)	0
Mental status changes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Insomnia	2 (2.1)	0	2 (2.1)	0	0
Agitation	1 (1.0)	1 (1.0)	0	0	0
Depression	1 (1.0)	0	1 (1.0)	0	0
Renal and urinary disorders					
-Total	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	0
Acute kidney injury	2 (2.1)	2 (2.1)	0	0	0
Haematuria	1 (1.0)	0	1 (1.0)	0	0
Micturition disorder	1 (1.0)	1 (1.0)	0	0	0
Renal tubular necrosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract disorder	1 (1.0)	0	1 (1.0)	0	0
Reproductive system and breast disorders					
-Total	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Heavy menstrual bleeding	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prostatitis	1 (1.0)	0	0	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (19.6)	5 (5.2)	4 (4.1)	5 (5.2)	5 (5.2)
Epistaxis	4 (4.1)	2 (2.1)	0	2 (2.1)	0
Hypoxia	4 (4.1)	0	3 (3.1)	1 (1.0)	0
Respiratory failure	4 (4.1)	0	0	0	4 (4.1)
Cough	2 (2.1)	2 (2.1)	0	0	0
Dyspnoea	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Nasal congestion	2 (2.1)	2 (2.1)	0	0	0
Oropharyngeal pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Tachypnoea	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Acute respiratory distress syndrome	1 (1.0)	0	0	0	1 (1.0)
Atelectasis	1 (1.0)	0	0	1 (1.0)	0
Haemothorax	1 (1.0)	0	0	0	1 (1.0)
Pneumothorax	1 (1.0)	0	0	0	1 (1.0)
Pulmonary oedema	1 (1.0)	0	0	0	1 (1.0)
Rhinorrhoea	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Throat irritation	1 (1.0)	0	1 (1.0)	0	0
Wheezing	1 (1.0)	1 (1.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (15.5)	10 (10.3)	3 (3.1)	2 (2.1)	0
Pruritus	4 (4.1)	2 (2.1)	2 (2.1)	0	0
Skin ulcer	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Pain of skin	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Rash	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blister	1 (1.0)	1 (1.0)	0	0	0
Dermatitis exfoliative generalised	1 (1.0)	1 (1.0)	0	0	0
Dry skin	1 (1.0)	1 (1.0)	0	0	0
Erythema nodosum	1 (1.0)	1 (1.0)	0	0	0
Ingrowing nail	1 (1.0)	1 (1.0)	0	0	0
Petechiae	1 (1.0)	1 (1.0)	0	0	0
Rash maculo-papular	1 (1.0)	1 (1.0)	0	0	0
Vascular disorders					
-Total	14 (14.4)	4 (4.1)	5 (5.2)	3 (3.1)	2 (2.1)

Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=97 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	7 (7.2)	2 (2.1)	5 (5.2)	0	0
Hypotension	6 (6.2)	1 (1.0)	0	3 (3.1)	2 (2.1)
Haematoma	1 (1.0)	1 (1.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205h
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Cardiac disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	0	0	1 (33.3)
Haemoperitoneum	1 (33.3)	0	0	0	1 (33.3)

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pain	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Injury, poisoning and procedural complications					
-Total	1 (33.3)	0	0	1 (33.3)	0
Post procedural haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0

Hypodiploidy: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (33.3)	0	0	0	1 (33.3)
Blood creatinine increased	1 (33.3)	1 (33.3)	0	0	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Acute kidney injury	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypotension	2 (66.7)	0	0	2 (66.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205h
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	86 (90.5)	3 (3.2)	10 (10.5)	33 (34.7)	40 (42.1)
Blood and lymphatic system disorders					
-Total	48 (50.5)	1 (1.1)	2 (2.1)	28 (29.5)	17 (17.9)
Febrile neutropenia	23 (24.2)	0	0	22 (23.2)	1 (1.1)
Anaemia	22 (23.2)	2 (2.1)	4 (4.2)	15 (15.8)	1 (1.1)
Neutropenia	11 (11.6)	1 (1.1)	0	1 (1.1)	9 (9.5)
Thrombocytopenia	9 (9.5)	1 (1.1)	1 (1.1)	3 (3.2)	4 (4.2)
Pancytopenia	4 (4.2)	0	1 (1.1)	1 (1.1)	2 (2.1)
Leukopenia	3 (3.2)	0	0	0	3 (3.2)
Haemolytic anaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	0	0	1 (1.1)	0
Lymphadenitis	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Cardiac disorders					
-Total	8 (8.4)	3 (3.2)	1 (1.1)	4 (4.2)	0
Tachycardia	5 (5.3)	2 (2.1)	1 (1.1)	2 (2.1)	0
Bradycardia	1 (1.1)	1 (1.1)	0	0	0
Cardiac failure	1 (1.1)	0	0	1 (1.1)	0
Pericardial effusion	1 (1.1)	0	0	1 (1.1)	0
Ear and labyrinth disorders					
-Total	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Vertigo	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Endocrine disorders					
-Total	7 (7.4)	0	5 (5.3)	1 (1.1)	1 (1.1)
Adrenal insufficiency	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Hypothyroidism	2 (2.1)	0	2 (2.1)	0	0
Addison's disease	1 (1.1)	0	1 (1.1)	0	0
Hypercalcaemia of malignancy	1 (1.1)	0	0	0	1 (1.1)
Eye disorders					
-Total	2 (2.1)	2 (2.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eyelid oedema	1 (1.1)	1 (1.1)	0	0	0
Gastrointestinal disorders					
-Total	38 (40.0)	6 (6.3)	13 (13.7)	19 (20.0)	0
Abdominal pain	8 (8.4)	2 (2.1)	4 (4.2)	2 (2.1)	0
Constipation	7 (7.4)	3 (3.2)	4 (4.2)	0	0
Nausea	7 (7.4)	1 (1.1)	5 (5.3)	1 (1.1)	0
Stomatitis	7 (7.4)	0	1 (1.1)	6 (6.3)	0
Diarrhoea	4 (4.2)	1 (1.1)	2 (2.1)	1 (1.1)	0
Neutropenic colitis	3 (3.2)	0	0	3 (3.2)	0
Abdominal pain upper	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Haematemesis	2 (2.1)	2 (2.1)	0	0	0
Oral disorder	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Oral pain	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Vomiting	2 (2.1)	2 (2.1)	0	0	0
Anal fissure	1 (1.1)	0	1 (1.1)	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Colitis	1 (1.1)	0	0	1 (1.1)	0
Dry mouth	1 (1.1)	0	1 (1.1)	0	0
Duodenal perforation	1 (1.1)	0	0	1 (1.1)	0
Gastritis	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Gastrooesophageal reflux disease	1 (1.1)	1 (1.1)	0	0	0
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Hypoaesthesia oral	1 (1.1)	0	1 (1.1)	0	0
Ileus	1 (1.1)	0	0	1 (1.1)	0
Ileus paralytic	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Mouth haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Oral mucosal blistering	1 (1.1)	1 (1.1)	0	0	0
Tongue blistering	1 (1.1)	1 (1.1)	0	0	0
Tooth pulp haemorrhage	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	24 (25.3)	4 (4.2)	16 (16.8)	4 (4.2)	0
Pyrexia	13 (13.7)	3 (3.2)	8 (8.4)	2 (2.1)	0
Catheter site pain	5 (5.3)	2 (2.1)	3 (3.2)	0	0
Fatigue	5 (5.3)	1 (1.1)	4 (4.2)	0	0
Pain	4 (4.2)	0	3 (3.2)	1 (1.1)	0
Chills	2 (2.1)	0	2 (2.1)	0	0
Non-cardiac chest pain	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Oedema peripheral	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Asthenia	1 (1.1)	0	1 (1.1)	0	0
Complication associated with device	1 (1.1)	1 (1.1)	0	0	0
Face oedema	1 (1.1)	1 (1.1)	0	0	0
Mucosal inflammation	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	10 (10.5)	3 (3.2)	2 (2.1)	5 (5.3)	0
Hyperbilirubinaemia	3 (3.2)	0	1 (1.1)	2 (2.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic cytolysis	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Hypertransaminasaemia	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatomegaly	1 (1.1)	1 (1.1)	0	0	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Immune system disorders					
-Total	12 (12.6)	0	8 (8.4)	4 (4.2)	0
Hypogammaglobulinaemia	7 (7.4)	0	6 (6.3)	1 (1.1)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Graft versus host disease	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	0	1 (1.1)	0	0
Immune system disorder	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	48 (50.5)	2 (2.1)	7 (7.4)	29 (30.5)	10 (10.5)
Pneumonia	4 (4.2)	0	1 (1.1)	2 (2.1)	1 (1.1)
Catheter site infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Oral herpes	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Sinusitis	3 (3.2)	0	2 (2.1)	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	3 (3.2)	0	0	3 (3.2)	0
Acute sinusitis	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungal infection	1 (1.1)	0	1 (1.1)	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	11 (11.6)	1 (1.1)	6 (6.3)	3 (3.2)	1 (1.1)
Procedural pain	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Transfusion reaction	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fall	1 (1.1)	0	1 (1.1)	0	0
Infusion related reaction	1 (1.1)	0	0	1 (1.1)	0
Radius fracture	1 (1.1)	0	1 (1.1)	0	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Wound	1 (1.1)	1 (1.1)	0	0	0
Investigations					
-Total	30 (31.6)	2 (2.1)	1 (1.1)	11 (11.6)	16 (16.8)
Neutrophil count decreased	11 (11.6)	1 (1.1)	0	2 (2.1)	8 (8.4)
Platelet count decreased	8 (8.4)	0	0	0	8 (8.4)
Alanine aminotransferase increased	7 (7.4)	1 (1.1)	2 (2.1)	4 (4.2)	0
C-reactive protein increased	7 (7.4)	2 (2.1)	2 (2.1)	2 (2.1)	1 (1.1)
White blood cell count decreased	7 (7.4)	0	0	0	7 (7.4)
Serum ferritin increased	5 (5.3)	1 (1.1)	1 (1.1)	2 (2.1)	1 (1.1)
Aspartate aminotransferase increased	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Blood lactate dehydrogenase increased	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Lymphocyte count decreased	3 (3.2)	0	0	1 (1.1)	2 (2.1)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Weight decreased	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Blood fibrinogen increased	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Blood glucose increased	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Blood potassium decreased	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Fibrin d dimer increased	2 (2.1)	1 (1.1)	0	0	1 (1.1)
Activated partial thromboplastin time prolonged	1 (1.1)	1 (1.1)	0	0	0
Activated partial thromboplastin time shortened	1 (1.1)	0	1 (1.1)	0	0
Amylase increased	1 (1.1)	0	0	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	0	0	1 (1.1)	0
Blood calcium increased	1 (1.1)	0	0	1 (1.1)	0
Blood creatinine increased	1 (1.1)	0	0	1 (1.1)	0
Blood fibrinogen decreased	1 (1.1)	0	0	1 (1.1)	0
Blood immunoglobulin g decreased	1 (1.1)	0	1 (1.1)	0	0
Blood immunoglobulin m decreased	1 (1.1)	0	1 (1.1)	0	0
Blood magnesium decreased	1 (1.1)	0	1 (1.1)	0	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0
Blood uric acid increased	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	1 (1.1)	1 (1.1)	0	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
International normalised ratio increased	1 (1.1)	0	1 (1.1)	0	0
Protein total decreased	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Weight increased	1 (1.1)	0	1 (1.1)	0	0
Metabolism and nutrition disorders					
-Total	24 (25.3)	2 (2.1)	7 (7.4)	11 (11.6)	4 (4.2)
Hypokalaemia	6 (6.3)	2 (2.1)	1 (1.1)	3 (3.2)	0
Decreased appetite	4 (4.2)	1 (1.1)	1 (1.1)	2 (2.1)	0
Hypomagnesaemia	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Tumour lysis syndrome	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Hypervolaemia	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Hypocalcaemia	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Hyponatraemia	2 (2.1)	1 (1.1)	0	0	1 (1.1)
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperammonaemia	1 (1.1)	0	0	1 (1.1)	0
Hypercalcaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperglycaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperkalaemia	1 (1.1)	0	0	1 (1.1)	0
Hyperphosphataemia	1 (1.1)	1 (1.1)	0	0	0
Hyperuricaemia	1 (1.1)	0	1 (1.1)	0	0
Hypoalbuminaemia	1 (1.1)	0	1 (1.1)	0	0
Hypophagia	1 (1.1)	0	0	1 (1.1)	0
Hypophosphataemia	1 (1.1)	0	1 (1.1)	0	0
Malnutrition	1 (1.1)	0	1 (1.1)	0	0
Metabolic acidosis	1 (1.1)	0	0	1 (1.1)	0
Vitamin a deficiency	1 (1.1)	0	1 (1.1)	0	0
Vitamin b1 deficiency	1 (1.1)	1 (1.1)	0	0	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (18.9)	7 (7.4)	7 (7.4)	4 (4.2)	0
Arthralgia	6 (6.3)	4 (4.2)	2 (2.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	6 (6.3)	1 (1.1)	3 (3.2)	2 (2.1)	0
Back pain	5 (5.3)	1 (1.1)	3 (3.2)	1 (1.1)	0
Bone pain	1 (1.1)	0	1 (1.1)	0	0
Groin pain	1 (1.1)	1 (1.1)	0	0	0
Joint effusion	1 (1.1)	0	0	1 (1.1)	0
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0
Pain in jaw	1 (1.1)	0	0	1 (1.1)	0
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.1)	0	0	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	0	0	1 (1.1)
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Nervous system disorders					
-Total	19 (20.0)	7 (7.4)	6 (6.3)	5 (5.3)	1 (1.1)
Headache	8 (8.4)	3 (3.2)	3 (3.2)	2 (2.1)	0
Neuropathy peripheral	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paraesthesia	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Dizziness	1 (1.1)	1 (1.1)	0	0	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	0	0	1 (1.1)
Intraventricular haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Peripheral motor neuropathy	1 (1.1)	0	1 (1.1)	0	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	10 (10.5)	2 (2.1)	5 (5.3)	3 (3.2)	0
Anxiety	4 (4.2)	2 (2.1)	1 (1.1)	1 (1.1)	0
Mental status changes	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Insomnia	2 (2.1)	0	2 (2.1)	0	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Depression	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (4.2)	1 (1.1)	2 (2.1)	1 (1.1)	0
Acute kidney injury	1 (1.1)	1 (1.1)	0	0	0
Haematuria	1 (1.1)	0	1 (1.1)	0	0
Micturition disorder	1 (1.1)	1 (1.1)	0	0	0
Renal tubular necrosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0
Reproductive system and breast disorders					
-Total	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Heavy menstrual bleeding	1 (1.1)	0	1 (1.1)	0	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (18.9)	5 (5.3)	4 (4.2)	5 (5.3)	4 (4.2)
Epistaxis	4 (4.2)	2 (2.1)	0	2 (2.1)	0
Hypoxia	4 (4.2)	0	3 (3.2)	1 (1.1)	0
Respiratory failure	3 (3.2)	0	0	0	3 (3.2)
Cough	2 (2.1)	2 (2.1)	0	0	0
Dyspnoea	2 (2.1)	1 (1.1)	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasal congestion	2 (2.1)	2 (2.1)	0	0	0
Oropharyngeal pain	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Tachypnoea	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Acute respiratory distress syndrome	1 (1.1)	0	0	0	1 (1.1)
Atelectasis	1 (1.1)	0	0	1 (1.1)	0
Haemothorax	1 (1.1)	0	0	0	1 (1.1)
Pneumothorax	1 (1.1)	0	0	0	1 (1.1)
Rhinorrhoea	1 (1.1)	1 (1.1)	0	0	0
Throat irritation	1 (1.1)	0	1 (1.1)	0	0
Wheezing	1 (1.1)	1 (1.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (15.8)	10 (10.5)	3 (3.2)	2 (2.1)	0
Pruritus	4 (4.2)	2 (2.1)	2 (2.1)	0	0
Skin ulcer	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Pain of skin	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Rash	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Blister	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dermatitis exfoliative generalised	1 (1.1)	1 (1.1)	0	0	0
Dry skin	1 (1.1)	1 (1.1)	0	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Ingrowing nail	1 (1.1)	1 (1.1)	0	0	0
Petechiae	1 (1.1)	1 (1.1)	0	0	0
Rash maculo-papular	1 (1.1)	1 (1.1)	0	0	0
Vascular disorders					
-Total	12 (12.6)	4 (4.2)	5 (5.3)	1 (1.1)	2 (2.1)
Hypertension	7 (7.4)	2 (2.1)	5 (5.3)	0	0
Hypotension	4 (4.2)	1 (1.1)	0	1 (1.1)	2 (2.1)
Haematoma	1 (1.1)	1 (1.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and

CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205i
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	2 (100)	0	0	2 (100)	0
Immune system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypersensitivity	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Acute sinusitis	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205i
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	87 (90.6)	3 (3.1)	10 (10.4)	33 (34.4)	41 (42.7)
Blood and lymphatic system disorders					
-Total	47 (49.0)	1 (1.0)	2 (2.1)	27 (28.1)	17 (17.7)
Anaemia	23 (24.0)	2 (2.1)	4 (4.2)	16 (16.7)	1 (1.0)
Febrile neutropenia	21 (21.9)	0	0	20 (20.8)	1 (1.0)
Neutropenia	11 (11.5)	1 (1.0)	0	1 (1.0)	9 (9.4)
Thrombocytopenia	9 (9.4)	1 (1.0)	1 (1.0)	3 (3.1)	4 (4.2)
Pancytopenia	4 (4.2)	0	1 (1.0)	1 (1.0)	2 (2.1)
Leukopenia	3 (3.1)	0	0	0	3 (3.1)
Haemolytic anaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperleukocytosis	1 (1.0)	0	0	1 (1.0)	0
Lymphadenitis	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.0)	0	0	0	1 (1.0)
Cardiac disorders					
-Total	10 (10.4)	3 (3.1)	1 (1.0)	6 (6.3)	0
Tachycardia	6 (6.3)	2 (2.1)	1 (1.0)	3 (3.1)	0
Bradycardia	1 (1.0)	1 (1.0)	0	0	0
Cardiac failure	1 (1.0)	0	0	1 (1.0)	0
Left ventricular dysfunction	1 (1.0)	0	0	1 (1.0)	0
Pericardial effusion	1 (1.0)	0	0	1 (1.0)	0
Ear and labyrinth disorders					
-Total	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Vertigo	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Endocrine disorders					
-Total	7 (7.3)	0	5 (5.2)	1 (1.0)	1 (1.0)
Adrenal insufficiency	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Hypothyroidism	2 (2.1)	0	2 (2.1)	0	0
Addison's disease	1 (1.0)	0	1 (1.0)	0	0
Hypercalcaemia of malignancy	1 (1.0)	0	0	0	1 (1.0)
Eye disorders					

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.1)	2 (2.1)	0	0	0
Dry eye	1 (1.0)	1 (1.0)	0	0	0
Eyelid oedema	1 (1.0)	1 (1.0)	0	0	0
Gastrointestinal disorders					
-Total	39 (40.6)	6 (6.3)	13 (13.5)	19 (19.8)	1 (1.0)
Abdominal pain	8 (8.3)	2 (2.1)	4 (4.2)	2 (2.1)	0
Constipation	7 (7.3)	3 (3.1)	4 (4.2)	0	0
Nausea	7 (7.3)	1 (1.0)	5 (5.2)	1 (1.0)	0
Stomatitis	7 (7.3)	0	1 (1.0)	6 (6.3)	0
Diarrhoea	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Neutropenic colitis	3 (3.1)	0	0	3 (3.1)	0
Abdominal pain upper	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Haematemesis	2 (2.1)	2 (2.1)	0	0	0
Oral disorder	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Oral pain	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Vomiting	2 (2.1)	2 (2.1)	0	0	0
Abdominal compartment syndrome	1 (1.0)	0	0	0	1 (1.0)
Anal fissure	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fistula	1 (1.0)	0	0	1 (1.0)	0
Anal inflammation	1 (1.0)	0	0	1 (1.0)	0
Colitis	1 (1.0)	0	0	1 (1.0)	0
Dry mouth	1 (1.0)	0	1 (1.0)	0	0
Duodenal perforation	1 (1.0)	0	0	1 (1.0)	0
Gastritis	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal sounds abnormal	1 (1.0)	1 (1.0)	0	0	0
Gastrooesophageal reflux disease	1 (1.0)	1 (1.0)	0	0	0
Gingival erythema	1 (1.0)	1 (1.0)	0	0	0
Haemoperitoneum	1 (1.0)	0	0	0	1 (1.0)
Haemorrhoids	1 (1.0)	0	1 (1.0)	0	0
Hypoaesthesia oral	1 (1.0)	0	1 (1.0)	0	0
Ileus	1 (1.0)	0	0	1 (1.0)	0
Ileus paralytic	1 (1.0)	1 (1.0)	0	0	0
Lip ulceration	1 (1.0)	0	1 (1.0)	0	0
Mouth haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Oral mucosal blistering	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tongue blistering	1 (1.0)	1 (1.0)	0	0	0
Tooth pulp haemorrhage	1 (1.0)	0	0	1 (1.0)	0
General disorders and administration site conditions					
-Total	25 (26.0)	4 (4.2)	17 (17.7)	4 (4.2)	0
Pyrexia	14 (14.6)	3 (3.1)	9 (9.4)	2 (2.1)	0
Catheter site pain	5 (5.2)	2 (2.1)	3 (3.1)	0	0
Fatigue	5 (5.2)	1 (1.0)	4 (4.2)	0	0
Pain	5 (5.2)	0	4 (4.2)	1 (1.0)	0
Chills	2 (2.1)	0	2 (2.1)	0	0
Non-cardiac chest pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Oedema peripheral	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Asthenia	1 (1.0)	0	1 (1.0)	0	0
Complication associated with device	1 (1.0)	1 (1.0)	0	0	0
Face oedema	1 (1.0)	1 (1.0)	0	0	0
Mucosal inflammation	1 (1.0)	0	0	1 (1.0)	0
Thirst	1 (1.0)	1 (1.0)	0	0	0
Hepatobiliary disorders					

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (10.4)	3 (3.1)	2 (2.1)	5 (5.2)	0
Hyperbilirubinaemia	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Hepatic cytolysis	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Hypertransaminasaemia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Drug-induced liver injury	1 (1.0)	0	0	1 (1.0)	0
Hepatomegaly	1 (1.0)	1 (1.0)	0	0	0
Hepatosplenomegaly	1 (1.0)	0	1 (1.0)	0	0
Immune system disorders					
-Total	11 (11.5)	0	7 (7.3)	4 (4.2)	0
Hypogammaglobulinaemia	7 (7.3)	0	6 (6.3)	1 (1.0)	0
Immunodeficiency	2 (2.1)	0	0	2 (2.1)	0
Graft versus host disease	1 (1.0)	0	0	1 (1.0)	0
Immune system disorder	1 (1.0)	0	1 (1.0)	0	0
Infections and infestations					
-Total	50 (52.1)	2 (2.1)	7 (7.3)	29 (30.2)	12 (12.5)
Pneumonia	4 (4.2)	0	1 (1.0)	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Oral herpes	3 (3.1)	0	1 (1.0)	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Staphylococcal bacteraemia	3 (3.1)	0	0	3 (3.1)	0
Bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Clostridium difficile colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Device related infection	2 (2.1)	0	0	2 (2.1)	0
Escherichia bacteraemia	2 (2.1)	0	0	2 (2.1)	0
Herpes zoster	2 (2.1)	0	0	2 (2.1)	0
Localised infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Parainfluenzae virus infection	2 (2.1)	0	0	2 (2.1)	0
Pneumonia fungal	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	0	0	2 (2.1)	0
Septic shock	2 (2.1)	0	0	0	2 (2.1)
Sialoadenitis	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal infection	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	0	0	2 (2.1)
Urinary tract infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Abscess limb	1 (1.0)	0	0	1 (1.0)	0
Acute sinusitis	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Bacterial sepsis	1 (1.0)	0	0	0	1 (1.0)
Bronchiolitis	1 (1.0)	0	0	1 (1.0)	0
Bronchitis	1 (1.0)	0	1 (1.0)	0	0
Bronchopulmonary aspergillosis	1 (1.0)	0	0	1 (1.0)	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cytomegalovirus infection reactivation	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Epstein-barr virus infection reactivation	1 (1.0)	1 (1.0)	0	0	0
Fungal infection	1 (1.0)	0	1 (1.0)	0	0
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	0	0	1 (1.0)
Gastroenteritis	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (1.0)	0	0	1 (1.0)	0
Gingivitis	1 (1.0)	1 (1.0)	0	0	0
Haemophilus bacteraemia	1 (1.0)	0	0	0	1 (1.0)
Herpes simplex	1 (1.0)	0	1 (1.0)	0	0
Klebsiella bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Paronychia	1 (1.0)	0	0	1 (1.0)	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pseudomonal bacteraemia	1 (1.0)	0	0	1 (1.0)	0
Sepsis	1 (1.0)	0	0	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Staphylococcal skin infection	1 (1.0)	0	0	1 (1.0)	0
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Tonsillitis	1 (1.0)	0	1 (1.0)	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Injury, poisoning and procedural complications					
-Total	12 (12.5)	1 (1.0)	6 (6.3)	4 (4.2)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Transfusion reaction	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Extradural haematoma	1 (1.0)	0	1 (1.0)	0	0
Fall	1 (1.0)	0	1 (1.0)	0	0
Infusion related reaction	1 (1.0)	0	0	1 (1.0)	0
Post procedural haemorrhage	1 (1.0)	0	0	1 (1.0)	0
Radius fracture	1 (1.0)	0	1 (1.0)	0	0
Tracheal obstruction	1 (1.0)	0	0	0	1 (1.0)
Traumatic haematoma	1 (1.0)	0	1 (1.0)	0	0
Wound	1 (1.0)	1 (1.0)	0	0	0
Investigations					
-Total	31 (32.3)	2 (2.1)	1 (1.0)	12 (12.5)	16 (16.7)
Neutrophil count decreased	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)
Platelet count decreased	8 (8.3)	0	0	0	8 (8.3)
Alanine aminotransferase increased	7 (7.3)	1 (1.0)	2 (2.1)	4 (4.2)	0
C-reactive protein increased	7 (7.3)	2 (2.1)	2 (2.1)	2 (2.1)	1 (1.0)
White blood cell count decreased	7 (7.3)	1 (1.0)	0	0	6 (6.3)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	5 (5.2)	0	1 (1.0)	3 (3.1)	1 (1.0)
Serum ferritin increased	5 (5.2)	1 (1.0)	1 (1.0)	2 (2.1)	1 (1.0)
Lymphocyte count decreased	4 (4.2)	1 (1.0)	0	1 (1.0)	2 (2.1)
Blood lactate dehydrogenase increased	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Weight decreased	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Blood creatinine increased	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Blood fibrinogen increased	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blood glucose increased	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blood potassium decreased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fibrin d dimer increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Activated partial thromboplastin time prolonged	1 (1.0)	1 (1.0)	0	0	0
Activated partial thromboplastin time shortened	1 (1.0)	0	1 (1.0)	0	0
Amylase increased	1 (1.0)	0	0	0	1 (1.0)
Blood bilirubin increased	1 (1.0)	0	0	1 (1.0)	0
Blood calcium increased	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (1.0)	0	0	1 (1.0)	0
Blood immunoglobulin g decreased	1 (1.0)	0	1 (1.0)	0	0
Blood immunoglobulin m decreased	1 (1.0)	0	1 (1.0)	0	0
Blood magnesium decreased	1 (1.0)	0	1 (1.0)	0	0
Blood phosphorus decreased	1 (1.0)	0	0	1 (1.0)	0
Blood uric acid increased	1 (1.0)	1 (1.0)	0	0	0
Electrocardiogram qt prolonged	1 (1.0)	1 (1.0)	0	0	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
International normalised ratio increased	1 (1.0)	0	1 (1.0)	0	0
Protein total decreased	1 (1.0)	0	1 (1.0)	0	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Weight increased	1 (1.0)	0	1 (1.0)	0	0
Metabolism and nutrition disorders					
-Total	25 (26.0)	2 (2.1)	7 (7.3)	12 (12.5)	4 (4.2)
Hypokalaemia	6 (6.3)	2 (2.1)	1 (1.0)	3 (3.1)	0
Decreased appetite	4 (4.2)	1 (1.0)	1 (1.0)	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Hypomagnesaemia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Tumour lysis syndrome	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Hypervolaemia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Hypoalbuminaemia	2 (2.1)	0	2 (2.1)	0	0
Hyponatraemia	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Metabolic acidosis	2 (2.1)	0	0	2 (2.1)	0
Eating disorder symptom	1 (1.0)	0	1 (1.0)	0	0
Hyperammonaemia	1 (1.0)	0	0	1 (1.0)	0
Hypercalcaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperglycaemia	1 (1.0)	0	0	0	1 (1.0)
Hyperkalaemia	1 (1.0)	0	0	1 (1.0)	0
Hyperphosphataemia	1 (1.0)	1 (1.0)	0	0	0
Hyperuricaemia	1 (1.0)	0	1 (1.0)	0	0
Hypophagia	1 (1.0)	0	0	1 (1.0)	0
Hypophosphataemia	1 (1.0)	0	1 (1.0)	0	0
Malnutrition	1 (1.0)	0	1 (1.0)	0	0
Vitamin a deficiency	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin b1 deficiency	1 (1.0)	1 (1.0)	0	0	0
Vitamin d deficiency	1 (1.0)	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (18.8)	7 (7.3)	7 (7.3)	4 (4.2)	0
Arthralgia	6 (6.3)	4 (4.2)	2 (2.1)	0	0
Pain in extremity	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Back pain	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Bone pain	1 (1.0)	0	1 (1.0)	0	0
Groin pain	1 (1.0)	1 (1.0)	0	0	0
Joint effusion	1 (1.0)	0	0	1 (1.0)	0
Myopathy	1 (1.0)	0	0	1 (1.0)	0
Osteopenia	1 (1.0)	1 (1.0)	0	0	0
Pain in jaw	1 (1.0)	0	0	1 (1.0)	0
Spinal pain	1 (1.0)	0	0	1 (1.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.0)	0	0	0	1 (1.0)
Acute lymphocytic leukaemia	1 (1.0)	0	0	0	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	1 (1.0)	1 (1.0)	0	0	0
Nervous system disorders					
-Total	20 (20.8)	7 (7.3)	6 (6.3)	6 (6.3)	1 (1.0)
Headache	8 (8.3)	3 (3.1)	3 (3.1)	2 (2.1)	0
Neuropathy peripheral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Paraesthesia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cognitive disorder	1 (1.0)	0	0	1 (1.0)	0
Dizziness	1 (1.0)	1 (1.0)	0	0	0
Encephalopathy	1 (1.0)	0	0	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	0	0	1 (1.0)
Intraventricular haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Lethargy	1 (1.0)	1 (1.0)	0	0	0
Neuralgia	1 (1.0)	0	1 (1.0)	0	0
Peripheral motor neuropathy	1 (1.0)	0	1 (1.0)	0	0
Post herpetic neuralgia	1 (1.0)	0	0	1 (1.0)	0
Seizure	1 (1.0)	0	1 (1.0)	0	0
Psychiatric disorders					
-Total	10 (10.4)	2 (2.1)	5 (5.2)	3 (3.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (4.2)	2 (2.1)	1 (1.0)	1 (1.0)	0
Mental status changes	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Insomnia	2 (2.1)	0	2 (2.1)	0	0
Agitation	1 (1.0)	1 (1.0)	0	0	0
Depression	1 (1.0)	0	1 (1.0)	0	0
Renal and urinary disorders					
-Total	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	0
Acute kidney injury	2 (2.1)	2 (2.1)	0	0	0
Haematuria	1 (1.0)	0	1 (1.0)	0	0
Micturition disorder	1 (1.0)	1 (1.0)	0	0	0
Renal tubular necrosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract disorder	1 (1.0)	0	1 (1.0)	0	0
Reproductive system and breast disorders					
-Total	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Heavy menstrual bleeding	1 (1.0)	0	1 (1.0)	0	0
Prostatitis	1 (1.0)	0	0	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders					

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (19.8)	5 (5.2)	4 (4.2)	5 (5.2)	5 (5.2)
Epistaxis	4 (4.2)	2 (2.1)	0	2 (2.1)	0
Hypoxia	4 (4.2)	0	3 (3.1)	1 (1.0)	0
Respiratory failure	4 (4.2)	0	0	0	4 (4.2)
Cough	2 (2.1)	2 (2.1)	0	0	0
Dyspnoea	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Nasal congestion	2 (2.1)	2 (2.1)	0	0	0
Oropharyngeal pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Tachypnoea	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Acute respiratory distress syndrome	1 (1.0)	0	0	0	1 (1.0)
Atelectasis	1 (1.0)	0	0	1 (1.0)	0
Haemothorax	1 (1.0)	0	0	0	1 (1.0)
Pneumothorax	1 (1.0)	0	0	0	1 (1.0)
Pulmonary oedema	1 (1.0)	0	0	0	1 (1.0)
Rhinorrhoea	1 (1.0)	1 (1.0)	0	0	0
Throat irritation	1 (1.0)	0	1 (1.0)	0	0
Wheezing	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	15 (15.6)	10 (10.4)	3 (3.1)	2 (2.1)	0
Pruritus	4 (4.2)	2 (2.1)	2 (2.1)	0	0
Skin ulcer	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Pain of skin	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Rash	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Blister	1 (1.0)	1 (1.0)	0	0	0
Dermatitis exfoliative generalised	1 (1.0)	1 (1.0)	0	0	0
Dry skin	1 (1.0)	1 (1.0)	0	0	0
Erythema nodosum	1 (1.0)	1 (1.0)	0	0	0
Ingrowing nail	1 (1.0)	1 (1.0)	0	0	0
Petechiae	1 (1.0)	1 (1.0)	0	0	0
Rash maculo-papular	1 (1.0)	1 (1.0)	0	0	0
Vascular disorders					
-Total	14 (14.6)	4 (4.2)	5 (5.2)	3 (3.1)	2 (2.1)
Hypertension	7 (7.3)	2 (2.1)	5 (5.2)	0	0
Hypotension	6 (6.3)	1 (1.0)	0	3 (3.1)	2 (2.1)

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematoma	1 (1.0)	1 (1.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205j
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (90.0)	0	5 (16.7)	8 (26.7)	14 (46.7)
Blood and lymphatic system disorders					
-Total	14 (46.7)	0	2 (6.7)	8 (26.7)	4 (13.3)
Anaemia	9 (30.0)	1 (3.3)	2 (6.7)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	0	0	6 (20.0)	0
Neutropenia	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Thrombocytopenia	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Haemolytic anaemia	1 (3.3)	0	0	0	1 (3.3)
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	1 (3.3)	0	0
Cardiac disorders					
-Total	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Ear and labyrinth disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Vertigo	1 (3.3)	0	1 (3.3)	0	0
Endocrine disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Addison's disease	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					
-Total	15 (50.0)	2 (6.7)	6 (20.0)	6 (20.0)	1 (3.3)
Abdominal pain	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0
Constipation	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Neutropenic colitis	2 (6.7)	0	0	2 (6.7)	0
Stomatitis	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Abdominal compartment syndrome	1 (3.3)	0	0	0	1 (3.3)
Anal fissure	1 (3.3)	0	1 (3.3)	0	0
Anal fistula	1 (3.3)	0	0	1 (3.3)	0
Diarrhoea	1 (3.3)	0	1 (3.3)	0	0
Dry mouth	1 (3.3)	0	1 (3.3)	0	0
Gastrooesophageal reflux disease	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (3.3)	0	0	0	1 (3.3)
Haemorrhoids	1 (3.3)	0	1 (3.3)	0	0
Hypoaesthesia oral	1 (3.3)	0	1 (3.3)	0	0
Ileus paralytic	1 (3.3)	1 (3.3)	0	0	0
Mouth haemorrhage	1 (3.3)	0	1 (3.3)	0	0
Nausea	1 (3.3)	0	1 (3.3)	0	0
Oral disorder	1 (3.3)	0	0	1 (3.3)	0
Oral pain	1 (3.3)	0	1 (3.3)	0	0
Tooth pulp haemorrhage	1 (3.3)	0	0	1 (3.3)	0
General disorders and administration site conditions					
-Total	9 (30.0)	2 (6.7)	7 (23.3)	0	0
Pyrexia	6 (20.0)	1 (3.3)	5 (16.7)	0	0
Fatigue	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Pain	2 (6.7)	0	2 (6.7)	0	0
Catheter site pain	1 (3.3)	0	1 (3.3)	0	0
Complication associated with device	1 (3.3)	1 (3.3)	0	0	0
Non-cardiac chest pain	1 (3.3)	1 (3.3)	0	0	0
Hepatobiliary disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Hypertransaminasaemia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Hepatic cytolysis	1 (3.3)	0	0	1 (3.3)	0
Hyperbilirubinaemia	1 (3.3)	0	0	1 (3.3)	0
Immune system disorders					
-Total	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0
Immune system disorder	1 (3.3)	0	1 (3.3)	0	0
Immunodeficiency	1 (3.3)	0	0	1 (3.3)	0
Infections and infestations					
-Total	16 (53.3)	1 (3.3)	3 (10.0)	8 (26.7)	4 (13.3)
Pneumonia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Staphylococcal infection	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Staphylococcal sepsis	2 (6.7)	0	0	0	2 (6.7)
Urinary tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Aspergillus infection	1 (3.3)	0	0	0	1 (3.3)
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Bronchiolitis	1 (3.3)	0	0	1 (3.3)	0
Catheter site infection	1 (3.3)	0	0	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (3.3)	0	1 (3.3)	0	0
Epstein-barr virus infection reactivation	1 (3.3)	1 (3.3)	0	0	0
Fungal pharyngitis	1 (3.3)	0	0	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Paronychia	1 (3.3)	0	0	1 (3.3)	0
Respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Serratia sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Injury, poisoning and procedural complications					
-Total	5 (16.7)	0	2 (6.7)	2 (6.7)	1 (3.3)
Fall	1 (3.3)	0	1 (3.3)	0	0
Infusion related reaction	1 (3.3)	0	0	1 (3.3)	0
Procedural pain	1 (3.3)	0	0	1 (3.3)	0
Tracheal obstruction	1 (3.3)	0	0	0	1 (3.3)
Transfusion reaction	1 (3.3)	0	1 (3.3)	0	0
Investigations					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (36.7)	1 (3.3)	0	2 (6.7)	8 (26.7)
Neutrophil count decreased	6 (20.0)	1 (3.3)	0	0	5 (16.7)
Platelet count decreased	4 (13.3)	0	0	0	4 (13.3)
Aspartate aminotransferase increased	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Lymphocyte count decreased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
White blood cell count decreased	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Alanine aminotransferase increased	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Weight decreased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Activated partial thromboplastin time prolonged	1 (3.3)	1 (3.3)	0	0	0
Blood creatinine increased	1 (3.3)	1 (3.3)	0	0	0
Blood fibrinogen increased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Blood immunoglobulin m decreased	1 (3.3)	0	1 (3.3)	0	0
Blood lactate dehydrogenase increased	1 (3.3)	0	1 (3.3)	0	0
C-reactive protein increased	1 (3.3)	1 (3.3)	0	0	0
Electrocardiogram qt prolonged	1 (3.3)	1 (3.3)	0	0	0
Fibrin d dimer increased	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Protein total decreased	1 (3.3)	0	1 (3.3)	0	0
Serum ferritin increased	1 (3.3)	0	1 (3.3)	0	0
Metabolism and nutrition disorders					
-Total	11 (36.7)	1 (3.3)	4 (13.3)	6 (20.0)	0
Hypokalaemia	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Hypoalbuminaemia	2 (6.7)	0	2 (6.7)	0	0
Hypocalcaemia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Decreased appetite	1 (3.3)	0	0	1 (3.3)	0
Eating disorder symptom	1 (3.3)	0	1 (3.3)	0	0
Hyponatraemia	1 (3.3)	1 (3.3)	0	0	0
Malnutrition	1 (3.3)	0	1 (3.3)	0	0
Metabolic acidosis	1 (3.3)	0	0	1 (3.3)	0
Tumour lysis syndrome	1 (3.3)	0	0	1 (3.3)	0
Vitamin a deficiency	1 (3.3)	0	1 (3.3)	0	0
Vitamin b1 deficiency	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Pain in extremity	2 (6.7)	1 (3.3)	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (3.3)	0	1 (3.3)	0	0
Osteopenia	1 (3.3)	1 (3.3)	0	0	0
Nervous system disorders					
-Total	6 (20.0)	2 (6.7)	3 (10.0)	1 (3.3)	0
Headache	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Cognitive disorder	1 (3.3)	0	0	1 (3.3)	0
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Neuralgia	1 (3.3)	0	1 (3.3)	0	0
Peripheral motor neuropathy	1 (3.3)	0	1 (3.3)	0	0
Psychiatric disorders					
-Total	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Anxiety	1 (3.3)	0	1 (3.3)	0	0
Depression	1 (3.3)	0	1 (3.3)	0	0
Mental status changes	1 (3.3)	0	0	1 (3.3)	0
Renal and urinary disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Acute kidney injury	1 (3.3)	1 (3.3)	0	0	0
Reproductive system and breast disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.3)	0	0	1 (3.3)	0
Prostatitis	1 (3.3)	0	0	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (16.7)	1 (3.3)	0	1 (3.3)	3 (10.0)
Respiratory failure	3 (10.0)	0	0	0	3 (10.0)
Atelectasis	1 (3.3)	0	0	1 (3.3)	0
Dyspnoea	1 (3.3)	1 (3.3)	0	0	0
Haemothorax	1 (3.3)	0	0	0	1 (3.3)
Pneumothorax	1 (3.3)	0	0	0	1 (3.3)
Pulmonary oedema	1 (3.3)	0	0	0	1 (3.3)
Tachypnoea	1 (3.3)	0	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (20.0)	4 (13.3)	1 (3.3)	1 (3.3)	0
Pruritus	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Skin ulcer	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Erythema nodosum	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	1 (3.3)	0	1 (3.3)	0	0
Vascular disorders					
-Total	5 (16.7)	3 (10.0)	1 (3.3)	1 (3.3)	0
Hypertension	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Hypotension	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Haematoma	1 (3.3)	1 (3.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205j
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (91.2)	3 (4.4)	5 (7.4)	26 (38.2)	28 (41.2)
Blood and lymphatic system disorders					
-Total	35 (51.5)	1 (1.5)	0	21 (30.9)	13 (19.1)
Febrile neutropenia	17 (25.0)	0	0	16 (23.5)	1 (1.5)
Anaemia	14 (20.6)	1 (1.5)	2 (2.9)	10 (14.7)	1 (1.5)
Neutropenia	8 (11.8)	0	0	1 (1.5)	7 (10.3)
Thrombocytopenia	7 (10.3)	0	1 (1.5)	3 (4.4)	3 (4.4)
Pancytopenia	3 (4.4)	0	0	1 (1.5)	2 (2.9)
Leukopenia	2 (2.9)	0	0	0	2 (2.9)
Hyperleukocytosis	1 (1.5)	0	0	1 (1.5)	0
Lymphadenitis	1 (1.5)	0	1 (1.5)	0	0
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	6 (8.8)	1 (1.5)	0	5 (7.4)	0
Tachycardia	2 (2.9)	0	0	2 (2.9)	0
Bradycardia	1 (1.5)	1 (1.5)	0	0	0
Cardiac failure	1 (1.5)	0	0	1 (1.5)	0
Left ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Pericardial effusion	1 (1.5)	0	0	1 (1.5)	0
Ear and labyrinth disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Vertigo	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					
-Total	6 (8.8)	0	4 (5.9)	1 (1.5)	1 (1.5)
Adrenal insufficiency	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Hypothyroidism	2 (2.9)	0	2 (2.9)	0	0
Hypercalcaemia of malignancy	1 (1.5)	0	0	0	1 (1.5)
Eye disorders					
-Total	2 (2.9)	2 (2.9)	0	0	0
Dry eye	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eyelid oedema	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	24 (35.3)	4 (5.9)	7 (10.3)	13 (19.1)	0
Nausea	6 (8.8)	1 (1.5)	4 (5.9)	1 (1.5)	0
Constipation	5 (7.4)	2 (2.9)	3 (4.4)	0	0
Stomatitis	5 (7.4)	0	0	5 (7.4)	0
Abdominal pain	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Diarrhoea	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Abdominal pain upper	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Haematemesis	2 (2.9)	2 (2.9)	0	0	0
Vomiting	2 (2.9)	2 (2.9)	0	0	0
Anal inflammation	1 (1.5)	0	0	1 (1.5)	0
Colitis	1 (1.5)	0	0	1 (1.5)	0
Duodenal perforation	1 (1.5)	0	0	1 (1.5)	0
Gastritis	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal sounds abnormal	1 (1.5)	1 (1.5)	0	0	0
Gingival erythema	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (1.5)	0	0	1 (1.5)	0
Lip ulceration	1 (1.5)	0	1 (1.5)	0	0
Neutropenic colitis	1 (1.5)	0	0	1 (1.5)	0
Oral disorder	1 (1.5)	1 (1.5)	0	0	0
Oral mucosal blistering	1 (1.5)	1 (1.5)	0	0	0
Oral pain	1 (1.5)	0	0	1 (1.5)	0
Tongue blistering	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	16 (23.5)	2 (2.9)	10 (14.7)	4 (5.9)	0
Pyrexia	8 (11.8)	2 (2.9)	4 (5.9)	2 (2.9)	0
Catheter site pain	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Pain	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Chills	2 (2.9)	0	2 (2.9)	0	0
Fatigue	2 (2.9)	0	2 (2.9)	0	0
Oedema peripheral	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Asthenia	1 (1.5)	0	1 (1.5)	0	0
Face oedema	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mucosal inflammation	1 (1.5)	0	0	1 (1.5)	0
Non-cardiac chest pain	1 (1.5)	0	1 (1.5)	0	0
Thirst	1 (1.5)	1 (1.5)	0	0	0
Hepatobiliary disorders					
-Total	6 (8.8)	2 (2.9)	2 (2.9)	2 (2.9)	0
Hyperbilirubinaemia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Drug-induced liver injury	1 (1.5)	0	0	1 (1.5)	0
Hepatic cytolysis	1 (1.5)	1 (1.5)	0	0	0
Hepatomegaly	1 (1.5)	1 (1.5)	0	0	0
Hepatosplenomegaly	1 (1.5)	0	1 (1.5)	0	0
Immune system disorders					
-Total	8 (11.8)	0	5 (7.4)	3 (4.4)	0
Hypogammaglobulinaemia	5 (7.4)	0	4 (5.9)	1 (1.5)	0
Graft versus host disease	1 (1.5)	0	0	1 (1.5)	0
Hypersensitivity	1 (1.5)	0	1 (1.5)	0	0
Immunodeficiency	1 (1.5)	0	0	1 (1.5)	0
Infections and infestations					
-Total	35 (51.5)	1 (1.5)	4 (5.9)	22 (32.4)	8 (11.8)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Sinusitis	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Acute sinusitis	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Catheter site infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Clostridium difficile colitis	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Escherichia bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Localised infection	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Pneumonia fungal	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Device related sepsis	1 (1.5)	0	0	1 (1.5)	0
Disseminated trichosporonosis	1 (1.5)	0	0	0	1 (1.5)
Epstein-barr virus infection	1 (1.5)	0	1 (1.5)	0	0
Fungal infection	1 (1.5)	0	1 (1.5)	0	0
Fungal sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis adenovirus	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	0	0	1 (1.5)	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Haemophilus bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Herpes simplex	1 (1.5)	0	1 (1.5)	0	0
Klebsiella bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	0	1 (1.5)	0
Peritonitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis	1 (1.5)	0	0	1 (1.5)	0
Pneumonia	1 (1.5)	0	0	0	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pseudomonal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Sialoadenitis	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal skin infection	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	0	0	1 (1.5)
Systemic mycosis	1 (1.5)	0	0	1 (1.5)	0
Tonsillitis	1 (1.5)	0	1 (1.5)	0	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	7 (10.3)	1 (1.5)	4 (5.9)	2 (2.9)	0
Procedural pain	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Transfusion reaction	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Extradural haematoma	1 (1.5)	0	1 (1.5)	0	0
Post procedural haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Radius fracture	1 (1.5)	0	1 (1.5)	0	0
Traumatic haematoma	1 (1.5)	0	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (1.5)	1 (1.5)	0	0	0
Investigations					
-Total	21 (30.9)	1 (1.5)	1 (1.5)	10 (14.7)	9 (13.2)
Alanine aminotransferase increased	6 (8.8)	1 (1.5)	1 (1.5)	4 (5.9)	0
C-reactive protein increased	6 (8.8)	1 (1.5)	2 (2.9)	2 (2.9)	1 (1.5)
Neutrophil count decreased	6 (8.8)	0	0	3 (4.4)	3 (4.4)
White blood cell count decreased	5 (7.4)	0	0	0	5 (7.4)
Platelet count decreased	4 (5.9)	0	0	0	4 (5.9)
Serum ferritin increased	4 (5.9)	1 (1.5)	0	2 (2.9)	1 (1.5)
Aspartate aminotransferase increased	2 (2.9)	0	0	2 (2.9)	0
Blood glucose increased	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Blood lactate dehydrogenase increased	2 (2.9)	0	0	2 (2.9)	0
Blood potassium decreased	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Activated partial thromboplastin time shortened	1 (1.5)	0	1 (1.5)	0	0
Amylase increased	1 (1.5)	0	0	0	1 (1.5)
Blood bilirubin increased	1 (1.5)	0	0	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood calcium increased	1 (1.5)	0	0	1 (1.5)	0
Blood creatinine increased	1 (1.5)	0	0	1 (1.5)	0
Blood fibrinogen decreased	1 (1.5)	0	0	1 (1.5)	0
Blood fibrinogen increased	1 (1.5)	0	1 (1.5)	0	0
Blood magnesium decreased	1 (1.5)	0	1 (1.5)	0	0
Blood phosphorus decreased	1 (1.5)	0	0	1 (1.5)	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Eosinophil count decreased	1 (1.5)	1 (1.5)	0	0	0
Fibrin d dimer increased	1 (1.5)	0	0	0	1 (1.5)
Haematocrit decreased	1 (1.5)	1 (1.5)	0	0	0
International normalised ratio increased	1 (1.5)	0	1 (1.5)	0	0
Lymphocyte count decreased	1 (1.5)	0	0	0	1 (1.5)
Red blood cell count decreased	1 (1.5)	1 (1.5)	0	0	0
Weight decreased	1 (1.5)	0	1 (1.5)	0	0
Weight increased	1 (1.5)	0	1 (1.5)	0	0
Metabolism and nutrition disorders					
-Total	14 (20.6)	1 (1.5)	3 (4.4)	6 (8.8)	4 (5.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Hypomagnesaemia	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Hypervolaemia	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Hypokalaemia	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Tumour lysis syndrome	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Hyperammonaemia	1 (1.5)	0	0	1 (1.5)	0
Hypercalcaemia	1 (1.5)	0	0	0	1 (1.5)
Hyperglycaemia	1 (1.5)	0	0	0	1 (1.5)
Hyperkalaemia	1 (1.5)	0	0	1 (1.5)	0
Hyperphosphataemia	1 (1.5)	1 (1.5)	0	0	0
Hyperuricaemia	1 (1.5)	0	1 (1.5)	0	0
Hypocalcaemia	1 (1.5)	0	1 (1.5)	0	0
Hyponatraemia	1 (1.5)	0	0	0	1 (1.5)
Hypophagia	1 (1.5)	0	0	1 (1.5)	0
Hypophosphataemia	1 (1.5)	0	1 (1.5)	0	0
Metabolic acidosis	1 (1.5)	0	0	1 (1.5)	0
Vitamin d deficiency	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	14 (20.6)	5 (7.4)	5 (7.4)	4 (5.9)	0
Arthralgia	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Back pain	5 (7.4)	1 (1.5)	3 (4.4)	1 (1.5)	0
Pain in extremity	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Bone pain	1 (1.5)	0	1 (1.5)	0	0
Groin pain	1 (1.5)	1 (1.5)	0	0	0
Joint effusion	1 (1.5)	0	0	1 (1.5)	0
Myopathy	1 (1.5)	0	0	1 (1.5)	0
Pain in jaw	1 (1.5)	0	0	1 (1.5)	0
Spinal pain	1 (1.5)	0	0	1 (1.5)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.5)	0	0	0	1 (1.5)
Acute lymphocytic leukaemia	1 (1.5)	0	0	0	1 (1.5)
Skin papilloma	1 (1.5)	1 (1.5)	0	0	0
Nervous system disorders					
-Total	14 (20.6)	5 (7.4)	3 (4.4)	5 (7.4)	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	6 (8.8)	2 (2.9)	2 (2.9)	2 (2.9)	0
Neuropathy peripheral	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Paraesthesia	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Encephalopathy	1 (1.5)	0	0	1 (1.5)	0
Haemorrhage intracranial	1 (1.5)	0	0	0	1 (1.5)
Intraventricular haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Lethargy	1 (1.5)	1 (1.5)	0	0	0
Post herpetic neuralgia	1 (1.5)	0	0	1 (1.5)	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Psychiatric disorders					
-Total	7 (10.3)	2 (2.9)	3 (4.4)	2 (2.9)	0
Anxiety	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Insomnia	2 (2.9)	0	2 (2.9)	0	0
Mental status changes	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Agitation	1 (1.5)	1 (1.5)	0	0	0
Renal and urinary disorders					
-Total	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Acute kidney injury	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (1.5)	0	1 (1.5)	0	0
Micturition disorder	1 (1.5)	1 (1.5)	0	0	0
Renal tubular necrosis	1 (1.5)	0	0	1 (1.5)	0
Urinary tract disorder	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Heavy menstrual bleeding	1 (1.5)	0	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (20.6)	4 (5.9)	4 (5.9)	4 (5.9)	2 (2.9)
Epistaxis	4 (5.9)	2 (2.9)	0	2 (2.9)	0
Hypoxia	4 (5.9)	0	3 (4.4)	1 (1.5)	0
Cough	2 (2.9)	2 (2.9)	0	0	0
Nasal congestion	2 (2.9)	2 (2.9)	0	0	0
Oropharyngeal pain	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Acute respiratory distress syndrome	1 (1.5)	0	0	0	1 (1.5)
Dyspnoea	1 (1.5)	0	0	1 (1.5)	0
Respiratory failure	1 (1.5)	0	0	0	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (1.5)	1 (1.5)	0	0	0
Tachypnoea	1 (1.5)	0	0	1 (1.5)	0
Throat irritation	1 (1.5)	0	1 (1.5)	0	0
Wheezing	1 (1.5)	1 (1.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (13.2)	6 (8.8)	2 (2.9)	1 (1.5)	0
Pain of skin	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Pruritus	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Blister	1 (1.5)	1 (1.5)	0	0	0
Dermatitis exfoliative generalised	1 (1.5)	1 (1.5)	0	0	0
Ingrowing nail	1 (1.5)	1 (1.5)	0	0	0
Petechiae	1 (1.5)	1 (1.5)	0	0	0
Rash	1 (1.5)	1 (1.5)	0	0	0
Rash maculo-papular	1 (1.5)	1 (1.5)	0	0	0
Skin ulcer	1 (1.5)	0	1 (1.5)	0	0
Vascular disorders					
-Total	9 (13.2)	1 (1.5)	4 (5.9)	2 (2.9)	2 (2.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	5 (7.4)	1 (1.5)	4 (5.9)	0	0
Hypotension	4 (5.9)	0	0	2 (2.9)	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205k
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (93.8)	1 (3.1)	1 (3.1)	9 (28.1)	19 (59.4)
Blood and lymphatic system disorders					
-Total	20 (62.5)	0	0	10 (31.3)	10 (31.3)
Febrile neutropenia	8 (25.0)	0	0	7 (21.9)	1 (3.1)
Anaemia	7 (21.9)	0	1 (3.1)	6 (18.8)	0
Neutropenia	7 (21.9)	0	0	0	7 (21.9)
Leukopenia	2 (6.3)	0	0	0	2 (6.3)
Haemolytic anaemia	1 (3.1)	0	0	0	1 (3.1)
Pancytopenia	1 (3.1)	0	0	1 (3.1)	0
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Cardiac disorders					
-Total	2 (6.3)	2 (6.3)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (3.1)	1 (3.1)	0	0	0
Tachycardia	1 (3.1)	1 (3.1)	0	0	0
Ear and labyrinth disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Vertigo	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Endocrine disorders					
-Total	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Addison's disease	1 (3.1)	0	1 (3.1)	0	0
Adrenal insufficiency	1 (3.1)	0	0	1 (3.1)	0
Hypothyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Eyelid oedema	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	11 (34.4)	2 (6.3)	2 (6.3)	7 (21.9)	0
Abdominal pain	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Abdominal pain upper	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Nausea	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenic colitis	2 (6.3)	0	0	2 (6.3)	0
Stomatitis	2 (6.3)	0	0	2 (6.3)	0
Constipation	1 (3.1)	1 (3.1)	0	0	0
Diarrhoea	1 (3.1)	0	0	1 (3.1)	0
Ileus	1 (3.1)	0	0	1 (3.1)	0
Ileus paralytic	1 (3.1)	1 (3.1)	0	0	0
Oral disorder	1 (3.1)	1 (3.1)	0	0	0
Oral mucosal blistering	1 (3.1)	1 (3.1)	0	0	0
Tongue blistering	1 (3.1)	1 (3.1)	0	0	0
Vomiting	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	7 (21.9)	3 (9.4)	1 (3.1)	3 (9.4)	0
Pyrexia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Catheter site pain	2 (6.3)	2 (6.3)	0	0	0
Oedema peripheral	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Fatigue	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mucosal inflammation	1 (3.1)	0	0	1 (3.1)	0
Non-cardiac chest pain	1 (3.1)	0	1 (3.1)	0	0
Hepatobiliary disorders					
-Total	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Hepatic cytolysis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Hepatomegaly	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	7 (21.9)	0	4 (12.5)	3 (9.4)	0
Hypogammaglobulinaemia	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Immunodeficiency	2 (6.3)	0	0	2 (6.3)	0
Infections and infestations					
-Total	20 (62.5)	2 (6.3)	3 (9.4)	11 (34.4)	4 (12.5)
Pneumonia	3 (9.4)	0	0	2 (6.3)	1 (3.1)
Device related infection	2 (6.3)	0	0	2 (6.3)	0
Herpes zoster	2 (6.3)	0	0	2 (6.3)	0
Respiratory tract infection	2 (6.3)	0	0	2 (6.3)	0
Staphylococcal sepsis	2 (6.3)	0	0	0	2 (6.3)
Abscess limb	1 (3.1)	0	0	1 (3.1)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus infection reactivation	1 (3.1)	0	1 (3.1)	0	0
Device related bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Device related sepsis	1 (3.1)	0	0	1 (3.1)	0
Epstein-barr virus infection reactivation	1 (3.1)	1 (3.1)	0	0	0
Fungal infection	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis adenovirus	1 (3.1)	0	0	1 (3.1)	0
Gingivitis	1 (3.1)	1 (3.1)	0	0	0
Haemophilus bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Localised infection	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Paronychia	1 (3.1)	0	0	1 (3.1)	0
Sialoadenitis	1 (3.1)	0	0	1 (3.1)	0
Tonsillitis	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection	1 (3.1)	0	1 (3.1)	0	0
Injury, poisoning and procedural complications					

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (18.8)	1 (3.1)	4 (12.5)	1 (3.1)	0
Extradural haematoma	1 (3.1)	0	1 (3.1)	0	0
Fall	1 (3.1)	0	1 (3.1)	0	0
Infusion related reaction	1 (3.1)	0	0	1 (3.1)	0
Procedural pain	1 (3.1)	1 (3.1)	0	0	0
Transfusion reaction	1 (3.1)	0	1 (3.1)	0	0
Traumatic haematoma	1 (3.1)	0	1 (3.1)	0	0
Wound	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	12 (37.5)	0	0	4 (12.5)	8 (25.0)
Neutrophil count decreased	6 (18.8)	1 (3.1)	0	1 (3.1)	4 (12.5)
White blood cell count decreased	5 (15.6)	0	0	0	5 (15.6)
Platelet count decreased	4 (12.5)	0	0	0	4 (12.5)
C-reactive protein increased	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Lymphocyte count decreased	2 (6.3)	0	0	0	2 (6.3)
Activated partial thromboplastin time shortened	1 (3.1)	0	1 (3.1)	0	0
Alanine aminotransferase increased	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Amylase increased	1 (3.1)	0	0	0	1 (3.1)
Blood glucose increased	1 (3.1)	0	1 (3.1)	0	0
Weight decreased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	7 (21.9)	0	2 (6.3)	3 (9.4)	2 (6.3)
Hyponatraemia	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Tumour lysis syndrome	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Eating disorder symptom	1 (3.1)	0	1 (3.1)	0	0
Hypokalaemia	1 (3.1)	0	0	1 (3.1)	0
Hypophagia	1 (3.1)	0	0	1 (3.1)	0
Vitamin a deficiency	1 (3.1)	0	1 (3.1)	0	0
Vitamin b1 deficiency	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (18.8)	3 (9.4)	2 (6.3)	1 (3.1)	0
Arthralgia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Back pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Myopathy	1 (3.1)	0	0	1 (3.1)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Osteopenia	1 (3.1)	1 (3.1)	0	0	0
Pain in extremity	1 (3.1)	0	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.1)	0	0	0	1 (3.1)
Acute lymphocytic leukaemia	1 (3.1)	0	0	0	1 (3.1)
Skin papilloma	1 (3.1)	1 (3.1)	0	0	0
Nervous system disorders					
-Total	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Headache	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Paraesthesia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Neuralgia	1 (3.1)	0	1 (3.1)	0	0
Neuropathy peripheral	1 (3.1)	0	0	1 (3.1)	0
Peripheral motor neuropathy	1 (3.1)	0	1 (3.1)	0	0
Post herpetic neuralgia	1 (3.1)	0	0	1 (3.1)	0
Psychiatric disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anxiety	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Agitation	1 (3.1)	1 (3.1)	0	0	0
Renal and urinary disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Micturition disorder	1 (3.1)	1 (3.1)	0	0	0
Urinary tract disorder	1 (3.1)	0	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (6.3)	0	2 (6.3)	0	0
Hypoxia	2 (6.3)	0	2 (6.3)	0	0
Epistaxis	1 (3.1)	1 (3.1)	0	0	0
Throat irritation	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Pruritus	2 (6.3)	0	2 (6.3)	0	0
Blister	1 (3.1)	1 (3.1)	0	0	0
Dermatitis exfoliative generalised	1 (3.1)	1 (3.1)	0	0	0
Pain of skin	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	1 (3.1)	0	1 (3.1)	0	0
Skin ulcer	1 (3.1)	0	1 (3.1)	0	0
Vascular disorders					
-Total	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Haematoma	1 (3.1)	1 (3.1)	0	0	0
Hypertension	1 (3.1)	0	1 (3.1)	0	0
Hypotension	1 (3.1)	1 (3.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205k
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (93.0)	2 (3.5)	7 (12.3)	22 (38.6)	22 (38.6)
Blood and lymphatic system disorders					
-Total	28 (49.1)	1 (1.8)	2 (3.5)	18 (31.6)	7 (12.3)
Anaemia	16 (28.1)	2 (3.5)	3 (5.3)	10 (17.5)	1 (1.8)
Febrile neutropenia	14 (24.6)	0	0	14 (24.6)	0
Thrombocytopenia	8 (14.0)	1 (1.8)	1 (1.8)	2 (3.5)	4 (7.0)
Neutropenia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Pancytopenia	3 (5.3)	0	1 (1.8)	0	2 (3.5)
Hyperleukocytosis	1 (1.8)	0	0	1 (1.8)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphadenitis	1 (1.8)	0	1 (1.8)	0	0
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	8 (14.0)	1 (1.8)	1 (1.8)	6 (10.5)	0
Tachycardia	5 (8.8)	1 (1.8)	1 (1.8)	3 (5.3)	0
Cardiac failure	1 (1.8)	0	0	1 (1.8)	0
Left ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Pericardial effusion	1 (1.8)	0	0	1 (1.8)	0
Endocrine disorders					
-Total	4 (7.0)	0	3 (5.3)	0	1 (1.8)
Adrenal insufficiency	2 (3.5)	0	2 (3.5)	0	0
Hypercalcaemia of malignancy	1 (1.8)	0	0	0	1 (1.8)
Hypothyroidism	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Dry eye	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	26 (45.6)	4 (7.0)	10 (17.5)	11 (19.3)	1 (1.8)
Constipation	6 (10.5)	2 (3.5)	4 (7.0)	0	0
Nausea	5 (8.8)	1 (1.8)	4 (7.0)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	5 (8.8)	0	1 (1.8)	4 (7.0)	0
Abdominal pain	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Diarrhoea	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Haematemesis	2 (3.5)	2 (3.5)	0	0	0
Oral pain	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Abdominal compartment syndrome	1 (1.8)	0	0	0	1 (1.8)
Anal fissure	1 (1.8)	0	1 (1.8)	0	0
Anal fistula	1 (1.8)	0	0	1 (1.8)	0
Anal inflammation	1 (1.8)	0	0	1 (1.8)	0
Colitis	1 (1.8)	0	0	1 (1.8)	0
Dry mouth	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Gastrointestinal sounds abnormal	1 (1.8)	1 (1.8)	0	0	0
Gastrooesophageal reflux disease	1 (1.8)	1 (1.8)	0	0	0
Gingival erythema	1 (1.8)	1 (1.8)	0	0	0
Haemoperitoneum	1 (1.8)	0	0	0	1 (1.8)
Hypoaesthesia oral	1 (1.8)	0	1 (1.8)	0	0
Lip ulceration	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mouth haemorrhage	1 (1.8)	0	1 (1.8)	0	0
Neutropenic colitis	1 (1.8)	0	0	1 (1.8)	0
Oral disorder	1 (1.8)	0	0	1 (1.8)	0
Tooth pulp haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Vomiting	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	17 (29.8)	1 (1.8)	15 (26.3)	1 (1.8)	0
Pyrexia	11 (19.3)	2 (3.5)	8 (14.0)	1 (1.8)	0
Catheter site pain	3 (5.3)	0	3 (5.3)	0	0
Fatigue	3 (5.3)	0	3 (5.3)	0	0
Pain	3 (5.3)	0	3 (5.3)	0	0
Chills	2 (3.5)	0	2 (3.5)	0	0
Asthenia	1 (1.8)	0	1 (1.8)	0	0
Complication associated with device	1 (1.8)	1 (1.8)	0	0	0
Face oedema	1 (1.8)	1 (1.8)	0	0	0
Non-cardiac chest pain	1 (1.8)	1 (1.8)	0	0	0
Thirst	1 (1.8)	1 (1.8)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	7 (12.3)	1 (1.8)	2 (3.5)	4 (7.0)	0
Hyperbilirubinaemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Hypertransaminasaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Drug-induced liver injury	1 (1.8)	0	0	1 (1.8)	0
Hepatosplenomegaly	1 (1.8)	0	1 (1.8)	0	0
Immune system disorders					
-Total	5 (8.8)	0	4 (7.0)	1 (1.8)	0
Hypogammaglobulinaemia	2 (3.5)	0	2 (3.5)	0	0
Graft versus host disease	1 (1.8)	0	0	1 (1.8)	0
Hypersensitivity	1 (1.8)	0	1 (1.8)	0	0
Immune system disorder	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	28 (49.1)	0	3 (5.3)	17 (29.8)	8 (14.0)
Catheter site infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Oral herpes	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Sinusitis	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Staphylococcal bacteraemia	3 (5.3)	0	0	3 (5.3)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute sinusitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Clostridium difficile colitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Pneumonia fungal	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Septic shock	2 (3.5)	0	0	0	2 (3.5)
Staphylococcal infection	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Aspergillus infection	1 (1.8)	0	0	0	1 (1.8)
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Fungal sepsis	1 (1.8)	0	0	0	1 (1.8)
Fungal skin infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	0	0	1 (1.8)	0
Herpes simplex	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	1 (1.8)	0	0	0
Parainfluenzae virus infection	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Pseudomonal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Stomatococcal infection	1 (1.8)	0	0	0	1 (1.8)
Systemic mycosis	1 (1.8)	0	0	1 (1.8)	0
Urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Injury, poisoning and procedural complications					
-Total	6 (10.5)	0	2 (3.5)	3 (5.3)	1 (1.8)
Procedural pain	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Transfusion reaction	2 (3.5)	0	1 (1.8)	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Post procedural haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Radius fracture	1 (1.8)	0	1 (1.8)	0	0
Tracheal obstruction	1 (1.8)	0	0	0	1 (1.8)
Investigations					
-Total	20 (35.1)	2 (3.5)	1 (1.8)	8 (14.0)	9 (15.8)
Alanine aminotransferase increased	7 (12.3)	1 (1.8)	2 (3.5)	4 (7.0)	0
Neutrophil count decreased	6 (10.5)	0	0	2 (3.5)	4 (7.0)
Aspartate aminotransferase increased	5 (8.8)	0	1 (1.8)	3 (5.3)	1 (1.8)
Serum ferritin increased	5 (8.8)	1 (1.8)	1 (1.8)	2 (3.5)	1 (1.8)
C-reactive protein increased	4 (7.0)	2 (3.5)	1 (1.8)	0	1 (1.8)
Platelet count decreased	4 (7.0)	0	0	0	4 (7.0)
Blood lactate dehydrogenase increased	3 (5.3)	0	1 (1.8)	2 (3.5)	0
White blood cell count decreased	3 (5.3)	1 (1.8)	0	0	2 (3.5)
Blood creatinine increased	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Blood fibrinogen increased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Blood potassium decreased	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Fibrin d dimer increased	2 (3.5)	1 (1.8)	0	0	1 (1.8)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphocyte count decreased	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Weight decreased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Activated partial thromboplastin time prolonged	1 (1.8)	1 (1.8)	0	0	0
Blood bilirubin increased	1 (1.8)	0	0	1 (1.8)	0
Blood calcium increased	1 (1.8)	0	0	1 (1.8)	0
Blood fibrinogen decreased	1 (1.8)	0	0	1 (1.8)	0
Blood glucose increased	1 (1.8)	1 (1.8)	0	0	0
Blood immunoglobulin g decreased	1 (1.8)	0	1 (1.8)	0	0
Blood immunoglobulin m decreased	1 (1.8)	0	1 (1.8)	0	0
Blood magnesium decreased	1 (1.8)	0	1 (1.8)	0	0
Blood phosphorus decreased	1 (1.8)	0	0	1 (1.8)	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Electrocardiogram qt prolonged	1 (1.8)	1 (1.8)	0	0	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
International normalised ratio increased	1 (1.8)	0	1 (1.8)	0	0
Protein total decreased	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Weight increased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	17 (29.8)	2 (3.5)	5 (8.8)	8 (14.0)	2 (3.5)
Hypokalaemia	5 (8.8)	2 (3.5)	1 (1.8)	2 (3.5)	0
Decreased appetite	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Hypocalcaemia	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Hypomagnesaemia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Hypervolaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypoalbuminaemia	2 (3.5)	0	2 (3.5)	0	0
Metabolic acidosis	2 (3.5)	0	0	2 (3.5)	0
Hyperammonaemia	1 (1.8)	0	0	1 (1.8)	0
Hypercalcaemia	1 (1.8)	0	0	0	1 (1.8)
Hyperglycaemia	1 (1.8)	0	0	0	1 (1.8)
Hyperkalaemia	1 (1.8)	0	0	1 (1.8)	0
Hyperphosphataemia	1 (1.8)	1 (1.8)	0	0	0
Hyperuricaemia	1 (1.8)	0	1 (1.8)	0	0
Hypophosphataemia	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Malnutrition	1 (1.8)	0	1 (1.8)	0	0
Vitamin d deficiency	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (17.5)	2 (3.5)	5 (8.8)	3 (5.3)	0
Pain in extremity	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Arthralgia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Back pain	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Bone pain	1 (1.8)	0	1 (1.8)	0	0
Groin pain	1 (1.8)	1 (1.8)	0	0	0
Joint effusion	1 (1.8)	0	0	1 (1.8)	0
Pain in jaw	1 (1.8)	0	0	1 (1.8)	0
Spinal pain	1 (1.8)	0	0	1 (1.8)	0
Nervous system disorders					
-Total	10 (17.5)	5 (8.8)	2 (3.5)	3 (5.3)	0
Headache	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Neuropathy peripheral	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Cognitive disorder	1 (1.8)	0	0	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dizziness	1 (1.8)	1 (1.8)	0	0	0
Intraventricular haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Lethargy	1 (1.8)	1 (1.8)	0	0	0
Paraesthesia	1 (1.8)	1 (1.8)	0	0	0
Seizure	1 (1.8)	0	1 (1.8)	0	0
Psychiatric disorders					
-Total	8 (14.0)	1 (1.8)	4 (7.0)	3 (5.3)	0
Mental status changes	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Anxiety	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Insomnia	2 (3.5)	0	2 (3.5)	0	0
Depression	1 (1.8)	0	1 (1.8)	0	0
Renal and urinary disorders					
-Total	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Acute kidney injury	2 (3.5)	2 (3.5)	0	0	0
Haematuria	1 (1.8)	0	1 (1.8)	0	0
Renal tubular necrosis	1 (1.8)	0	0	1 (1.8)	0
Reproductive system and breast disorders					

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.8)	0	0	1 (1.8)	0
Prostatitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (29.8)	5 (8.8)	2 (3.5)	5 (8.8)	5 (8.8)
Respiratory failure	4 (7.0)	0	0	0	4 (7.0)
Epistaxis	3 (5.3)	1 (1.8)	0	2 (3.5)	0
Cough	2 (3.5)	2 (3.5)	0	0	0
Dyspnoea	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypoxia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Nasal congestion	2 (3.5)	2 (3.5)	0	0	0
Oropharyngeal pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Tachypnoea	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Acute respiratory distress syndrome	1 (1.8)	0	0	0	1 (1.8)
Atelectasis	1 (1.8)	0	0	1 (1.8)	0
Haemothorax	1 (1.8)	0	0	0	1 (1.8)
Pneumothorax	1 (1.8)	0	0	0	1 (1.8)
Pulmonary oedema	1 (1.8)	0	0	0	1 (1.8)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinorrhoea	1 (1.8)	1 (1.8)	0	0	0
Wheezing	1 (1.8)	1 (1.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (17.5)	8 (14.0)	0	2 (3.5)	0
Pruritus	2 (3.5)	2 (3.5)	0	0	0
Skin ulcer	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Dry skin	1 (1.8)	1 (1.8)	0	0	0
Ingrowing nail	1 (1.8)	1 (1.8)	0	0	0
Pain of skin	1 (1.8)	0	0	1 (1.8)	0
Petechiae	1 (1.8)	1 (1.8)	0	0	0
Rash	1 (1.8)	1 (1.8)	0	0	0
Rash maculo-papular	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	11 (19.3)	2 (3.5)	4 (7.0)	3 (5.3)	2 (3.5)
Hypertension	6 (10.5)	2 (3.5)	4 (7.0)	0	0
Hypotension	5 (8.8)	0	0	3 (5.3)	2 (3.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205k
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (66.7)	0	2 (22.2)	3 (33.3)	1 (11.1)
Blood and lymphatic system disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Gastrointestinal disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Duodenal perforation	1 (11.1)	0	0	1 (11.1)	0
Gastritis	1 (11.1)	0	1 (11.1)	0	0
Haemorrhoids	1 (11.1)	0	1 (11.1)	0	0
General disorders and administration site conditions					

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	0	1 (11.1)	0	0
Fatigue	1 (11.1)	0	1 (11.1)	0	0
Infections and infestations					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (22.2)	2 (22.2)	0	0	0
Arthralgia	1 (11.1)	1 (11.1)	0	0	0
Pain in extremity	1 (11.1)	1 (11.1)	0	0	0
Nervous system disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Haemorrhage intracranial	1 (11.1)	0	0	0	1 (11.1)

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Reproductive system and breast disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Heavy menstrual bleeding	1 (11.1)	0	1 (11.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Erythema nodosum	1 (11.1)	1 (11.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205l
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (89.7)	2 (3.4)	7 (12.1)	20 (34.5)	23 (39.7)
Blood and lymphatic system disorders					
-Total	27 (46.6)	0	1 (1.7)	17 (29.3)	9 (15.5)
Febrile neutropenia	14 (24.1)	0	0	13 (22.4)	1 (1.7)
Anaemia	10 (17.2)	0	2 (3.4)	8 (13.8)	0
Neutropenia	6 (10.3)	0	0	0	6 (10.3)
Pancytopenia	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Thrombocytopenia	3 (5.2)	0	1 (1.7)	1 (1.7)	1 (1.7)
Leukopenia	2 (3.4)	0	0	0	2 (3.4)
Haemolytic anaemia	1 (1.7)	0	0	0	1 (1.7)
Lymphadenitis	1 (1.7)	0	1 (1.7)	0	0
Lymphopenia	1 (1.7)	0	0	0	1 (1.7)

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	7 (12.1)	2 (3.4)	1 (1.7)	4 (6.9)	0
Tachycardia	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Bradycardia	1 (1.7)	1 (1.7)	0	0	0
Cardiac failure	1 (1.7)	0	0	1 (1.7)	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Pericardial effusion	1 (1.7)	0	0	1 (1.7)	0
Ear and labyrinth disorders					
-Total	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Vertigo	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Endocrine disorders					
-Total	5 (8.6)	0	4 (6.9)	1 (1.7)	0
Adrenal insufficiency	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Addison's disease	1 (1.7)	0	1 (1.7)	0	0
Hypothyroidism	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					
-Total	2 (3.4)	2 (3.4)	0	0	0
Dry eye	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eyelid oedema	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	24 (41.4)	4 (6.9)	8 (13.8)	12 (20.7)	0
Abdominal pain	5 (8.6)	2 (3.4)	2 (3.4)	1 (1.7)	0
Diarrhoea	4 (6.9)	1 (1.7)	2 (3.4)	1 (1.7)	0
Nausea	4 (6.9)	0	3 (5.2)	1 (1.7)	0
Constipation	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Stomatitis	3 (5.2)	0	0	3 (5.2)	0
Abdominal pain upper	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Neutropenic colitis	2 (3.4)	0	0	2 (3.4)	0
Oral disorder	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Anal fissure	1 (1.7)	0	1 (1.7)	0	0
Anal fistula	1 (1.7)	0	0	1 (1.7)	0
Anal inflammation	1 (1.7)	0	0	1 (1.7)	0
Colitis	1 (1.7)	0	0	1 (1.7)	0
Dry mouth	1 (1.7)	0	1 (1.7)	0	0
Duodenal perforation	1 (1.7)	0	0	1 (1.7)	0
Gastritis	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	1 (1.7)	1 (1.7)	0	0	0
Haematemesis	1 (1.7)	1 (1.7)	0	0	0
Haemorrhoids	1 (1.7)	0	1 (1.7)	0	0
Ileus paralytic	1 (1.7)	1 (1.7)	0	0	0
Mouth haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Oral mucosal blistering	1 (1.7)	1 (1.7)	0	0	0
Tongue blistering	1 (1.7)	1 (1.7)	0	0	0
Vomiting	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	13 (22.4)	3 (5.2)	7 (12.1)	3 (5.2)	0
Pyrexia	6 (10.3)	1 (1.7)	4 (6.9)	1 (1.7)	0
Catheter site pain	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Fatigue	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Oedema peripheral	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Pain	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Asthenia	1 (1.7)	0	1 (1.7)	0	0
Chills	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mucosal inflammation	1 (1.7)	0	0	1 (1.7)	0
Non-cardiac chest pain	1 (1.7)	0	1 (1.7)	0	0
Thirst	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	8 (13.8)	2 (3.4)	2 (3.4)	4 (6.9)	0
Hepatic cytolysis	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hyperbilirubinaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Drug-induced liver injury	1 (1.7)	0	0	1 (1.7)	0
Hepatomegaly	1 (1.7)	1 (1.7)	0	0	0
Hepatosplenomegaly	1 (1.7)	0	1 (1.7)	0	0
Hypertransaminasaemia	1 (1.7)	0	0	1 (1.7)	0
Immune system disorders					
-Total	8 (13.8)	0	5 (8.6)	3 (5.2)	0
Hypogammaglobulinaemia	6 (10.3)	0	5 (8.6)	1 (1.7)	0
Graft versus host disease	1 (1.7)	0	0	1 (1.7)	0
Immunodeficiency	1 (1.7)	0	0	1 (1.7)	0
Infections and infestations					
-Total	32 (55.2)	2 (3.4)	6 (10.3)	17 (29.3)	7 (12.1)

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Pneumonia	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Sinusitis	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Device related infection	2 (3.4)	0	0	2 (3.4)	0
Herpes zoster	2 (3.4)	0	0	2 (3.4)	0
Parainfluenzae virus infection	2 (3.4)	0	0	2 (3.4)	0
Septic shock	2 (3.4)	0	0	0	2 (3.4)
Staphylococcal sepsis	2 (3.4)	0	0	0	2 (3.4)
Abscess limb	1 (1.7)	0	0	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	1 (1.7)	0	0
Clostridium difficile colitis	1 (1.7)	0	1 (1.7)	0	0
Cytomegalovirus infection reactivation	1 (1.7)	0	1 (1.7)	0	0
Device related bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epstein-barr virus infection	1 (1.7)	0	1 (1.7)	0	0
Epstein-barr virus infection reactivation	1 (1.7)	1 (1.7)	0	0	0
Escherichia bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Fungal infection	1 (1.7)	0	1 (1.7)	0	0
Fungal pharyngitis	1 (1.7)	0	0	1 (1.7)	0
Fungal sepsis	1 (1.7)	0	0	0	1 (1.7)
Gastroenteritis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis adenovirus	1 (1.7)	0	0	1 (1.7)	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Haemophilus bacteraemia	1 (1.7)	0	0	0	1 (1.7)
Herpes simplex	1 (1.7)	0	1 (1.7)	0	0
Klebsiella bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Oral herpes	1 (1.7)	0	0	1 (1.7)	0
Paronychia	1 (1.7)	0	0	1 (1.7)	0
Peritonitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (1.7)	0	0	1 (1.7)	0
Stomatococcal infection	1 (1.7)	0	0	0	1 (1.7)
Tonsillitis	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection	1 (1.7)	0	1 (1.7)	0	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Injury, poisoning and procedural complications					
-Total	9 (15.5)	1 (1.7)	4 (6.9)	3 (5.2)	1 (1.7)
Procedural pain	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Extradural haematoma	1 (1.7)	0	1 (1.7)	0	0
Fall	1 (1.7)	0	1 (1.7)	0	0
Infusion related reaction	1 (1.7)	0	0	1 (1.7)	0
Post procedural haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Tracheal obstruction	1 (1.7)	0	0	0	1 (1.7)
Transfusion reaction	1 (1.7)	0	1 (1.7)	0	0
Traumatic haematoma	1 (1.7)	0	1 (1.7)	0	0
Wound	1 (1.7)	1 (1.7)	0	0	0
Investigations					

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (31.0)	0	0	8 (13.8)	10 (17.2)
Neutrophil count decreased	11 (19.0)	1 (1.7)	0	3 (5.2)	7 (12.1)
Platelet count decreased	6 (10.3)	0	0	0	6 (10.3)
C-reactive protein increased	5 (8.6)	2 (3.4)	1 (1.7)	2 (3.4)	0
White blood cell count decreased	5 (8.6)	0	0	0	5 (8.6)
Alanine aminotransferase increased	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Aspartate aminotransferase increased	3 (5.2)	0	0	3 (5.2)	0
Blood glucose increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Lymphocyte count decreased	2 (3.4)	0	0	0	2 (3.4)
Weight decreased	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Activated partial thromboplastin time shortened	1 (1.7)	0	1 (1.7)	0	0
Blood bilirubin increased	1 (1.7)	0	0	1 (1.7)	0
Blood creatinine increased	1 (1.7)	0	0	1 (1.7)	0
Blood fibrinogen increased	1 (1.7)	1 (1.7)	0	0	0
Blood lactate dehydrogenase increased	1 (1.7)	0	1 (1.7)	0	0
Blood phosphorus decreased	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood potassium decreased	1 (1.7)	0	0	0	1 (1.7)
Eosinophil count decreased	1 (1.7)	1 (1.7)	0	0	0
Haematocrit decreased	1 (1.7)	1 (1.7)	0	0	0
Red blood cell count decreased	1 (1.7)	1 (1.7)	0	0	0
Serum ferritin increased	1 (1.7)	1 (1.7)	0	0	0
Weight increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	11 (19.0)	0	4 (6.9)	5 (8.6)	2 (3.4)
Hypokalaemia	3 (5.2)	1 (1.7)	0	2 (3.4)	0
Hypervolaemia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Tumour lysis syndrome	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Decreased appetite	1 (1.7)	0	1 (1.7)	0	0
Eating disorder symptom	1 (1.7)	0	1 (1.7)	0	0
Hyperglycaemia	1 (1.7)	0	0	0	1 (1.7)
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hyponatraemia	1 (1.7)	1 (1.7)	0	0	0
Hypophagia	1 (1.7)	0	0	1 (1.7)	0
Hypophosphataemia	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (1.7)	0	1 (1.7)	0	0
Vitamin a deficiency	1 (1.7)	0	1 (1.7)	0	0
Vitamin b1 deficiency	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (19.0)	4 (6.9)	5 (8.6)	2 (3.4)	0
Arthralgia	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Back pain	4 (6.9)	1 (1.7)	2 (3.4)	1 (1.7)	0
Bone pain	1 (1.7)	0	1 (1.7)	0	0
Groin pain	1 (1.7)	1 (1.7)	0	0	0
Joint effusion	1 (1.7)	0	0	1 (1.7)	0
Myopathy	1 (1.7)	0	0	1 (1.7)	0
Osteopenia	1 (1.7)	1 (1.7)	0	0	0
Pain in extremity	1 (1.7)	0	1 (1.7)	0	0
Pain in jaw	1 (1.7)	0	0	1 (1.7)	0
Spinal pain	1 (1.7)	0	0	1 (1.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.7)	0	0	0	1 (1.7)

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute lymphocytic leukaemia	1 (1.7)	0	0	0	1 (1.7)
Skin papilloma	1 (1.7)	1 (1.7)	0	0	0
Nervous system disorders					
-Total	13 (22.4)	4 (6.9)	4 (6.9)	4 (6.9)	1 (1.7)
Headache	7 (12.1)	3 (5.2)	3 (5.2)	1 (1.7)	0
Paraesthesia	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Neuropathy peripheral	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Encephalopathy	1 (1.7)	0	0	1 (1.7)	0
Haemorrhage intracranial	1 (1.7)	0	0	0	1 (1.7)
Peripheral motor neuropathy	1 (1.7)	0	1 (1.7)	0	0
Post herpetic neuralgia	1 (1.7)	0	0	1 (1.7)	0
Seizure	1 (1.7)	0	1 (1.7)	0	0
Psychiatric disorders					
-Total	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Anxiety	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Agitation	1 (1.7)	1 (1.7)	0	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Renal and urinary disorders					

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Micturition disorder	1 (1.7)	1 (1.7)	0	0	0
Renal tubular necrosis	1 (1.7)	0	0	1 (1.7)	0
Urinary tract disorder	1 (1.7)	0	1 (1.7)	0	0
Reproductive system and breast disorders					
-Total	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Heavy menstrual bleeding	1 (1.7)	0	1 (1.7)	0	0
Prostatitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (19.0)	4 (6.9)	3 (5.2)	1 (1.7)	3 (5.2)
Epistaxis	3 (5.2)	2 (3.4)	0	1 (1.7)	0
Hypoxia	3 (5.2)	0	3 (5.2)	0	0
Cough	2 (3.4)	2 (3.4)	0	0	0
Nasal congestion	2 (3.4)	2 (3.4)	0	0	0
Respiratory failure	2 (3.4)	0	0	0	2 (3.4)
Acute respiratory distress syndrome	1 (1.7)	0	0	0	1 (1.7)
Dyspnoea	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemothorax	1 (1.7)	0	0	0	1 (1.7)
Pneumothorax	1 (1.7)	0	0	0	1 (1.7)
Rhinorrhoea	1 (1.7)	1 (1.7)	0	0	0
Tachypnoea	1 (1.7)	0	1 (1.7)	0	0
Throat irritation	1 (1.7)	0	1 (1.7)	0	0
Wheezing	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (17.2)	6 (10.3)	3 (5.2)	1 (1.7)	0
Pruritus	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Pain of skin	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Rash	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Skin ulcer	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Blister	1 (1.7)	1 (1.7)	0	0	0
Dermatitis exfoliative generalised	1 (1.7)	1 (1.7)	0	0	0
Erythema nodosum	1 (1.7)	1 (1.7)	0	0	0
Rash maculo-papular	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (15.5)	4 (6.9)	3 (5.2)	1 (1.7)	1 (1.7)
Hypertension	5 (8.6)	2 (3.4)	3 (5.2)	0	0
Hypotension	3 (5.2)	1 (1.7)	0	1 (1.7)	1 (1.7)
Haematoma	1 (1.7)	1 (1.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205l
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (92.5)	1 (2.5)	3 (7.5)	14 (35.0)	19 (47.5)
Blood and lymphatic system disorders					
-Total	22 (55.0)	1 (2.5)	1 (2.5)	12 (30.0)	8 (20.0)
Anaemia	13 (32.5)	2 (5.0)	2 (5.0)	8 (20.0)	1 (2.5)
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	0	2 (5.0)	3 (7.5)
Neutropenia	5 (12.5)	1 (2.5)	0	1 (2.5)	3 (7.5)
Hyperleukocytosis	1 (2.5)	0	0	1 (2.5)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	3 (7.5)	1 (2.5)	0	2 (5.0)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Endocrine disorders					
-Total	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Hypercalcaemia of malignancy	1 (2.5)	0	0	0	1 (2.5)
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal disorders					
-Total	15 (37.5)	2 (5.0)	5 (12.5)	7 (17.5)	1 (2.5)
Constipation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Stomatitis	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Abdominal pain	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Nausea	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Oral pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal compartment syndrome	1 (2.5)	0	0	0	1 (2.5)
Gastrointestinal haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Gastrooesophageal reflux disease	1 (2.5)	1 (2.5)	0	0	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Haematemesis	1 (2.5)	1 (2.5)	0	0	0
Haemoperitoneum	1 (2.5)	0	0	0	1 (2.5)

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoaesthesia oral	1 (2.5)	0	1 (2.5)	0	0
Ileus	1 (2.5)	0	0	1 (2.5)	0
Lip ulceration	1 (2.5)	0	1 (2.5)	0	0
Neutropenic colitis	1 (2.5)	0	0	1 (2.5)	0
Tooth pulp haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Vomiting	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	12 (30.0)	1 (2.5)	10 (25.0)	1 (2.5)	0
Pyrexia	8 (20.0)	2 (5.0)	5 (12.5)	1 (2.5)	0
Pain	3 (7.5)	0	3 (7.5)	0	0
Fatigue	2 (5.0)	0	2 (5.0)	0	0
Catheter site pain	1 (2.5)	0	1 (2.5)	0	0
Chills	1 (2.5)	0	1 (2.5)	0	0
Complication associated with device	1 (2.5)	1 (2.5)	0	0	0
Face oedema	1 (2.5)	1 (2.5)	0	0	0
Non-cardiac chest pain	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hyperbilirubinaemia	1 (2.5)	0	0	1 (2.5)	0
Hypertransaminasaemia	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Hypersensitivity	1 (2.5)	0	1 (2.5)	0	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Immune system disorder	1 (2.5)	0	1 (2.5)	0	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Infections and infestations					
-Total	19 (47.5)	0	1 (2.5)	13 (32.5)	5 (12.5)
Acute sinusitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Oral herpes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pneumonia fungal	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Sialoadenitis	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal infection	2 (5.0)	0	0	1 (2.5)	1 (2.5)

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (2.5)	0	0	0	1 (2.5)
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungal skin infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	0	1 (2.5)	0	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Systemic mycosis	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	3 (7.5)	0	2 (5.0)	1 (2.5)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Transfusion reaction	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Procedural pain	1 (2.5)	0	1 (2.5)	0	0
Radius fracture	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	14 (35.0)	2 (5.0)	1 (2.5)	4 (10.0)	7 (17.5)
Alanine aminotransferase increased	5 (12.5)	2 (5.0)	1 (2.5)	2 (5.0)	0
Serum ferritin increased	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
White blood cell count decreased	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Aspartate aminotransferase increased	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Blood lactate dehydrogenase increased	2 (5.0)	0	0	2 (5.0)	0
C-reactive protein increased	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Fibrin d dimer increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Lymphocyte count decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
Activated partial thromboplastin time prolonged	1 (2.5)	1 (2.5)	0	0	0
Amylase increased	1 (2.5)	0	0	0	1 (2.5)

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood calcium increased	1 (2.5)	0	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0
Blood fibrinogen decreased	1 (2.5)	0	0	1 (2.5)	0
Blood fibrinogen increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	1 (2.5)	0	0
Blood magnesium decreased	1 (2.5)	0	1 (2.5)	0	0
Blood potassium decreased	1 (2.5)	0	0	1 (2.5)	0
Blood uric acid increased	1 (2.5)	1 (2.5)	0	0	0
Electrocardiogram qt prolonged	1 (2.5)	1 (2.5)	0	0	0
International normalised ratio increased	1 (2.5)	0	1 (2.5)	0	0
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Protein total decreased	1 (2.5)	0	1 (2.5)	0	0
Weight decreased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	14 (35.0)	2 (5.0)	3 (7.5)	7 (17.5)	2 (5.0)
Decreased appetite	3 (7.5)	1 (2.5)	0	2 (5.0)	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Hypokalaemia	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Hypoalbuminaemia	2 (5.0)	0	2 (5.0)	0	0
Hypomagnesaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Metabolic acidosis	2 (5.0)	0	0	2 (5.0)	0
Hyperammonaemia	1 (2.5)	0	0	1 (2.5)	0
Hypercalcaemia	1 (2.5)	0	0	0	1 (2.5)
Hyperkalaemia	1 (2.5)	0	0	1 (2.5)	0
Hyperphosphataemia	1 (2.5)	1 (2.5)	0	0	0
Hyperuricaemia	1 (2.5)	0	1 (2.5)	0	0
Hyponatraemia	1 (2.5)	0	0	0	1 (2.5)
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0
Vitamin d deficiency	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (17.5)	3 (7.5)	2 (5.0)	2 (5.0)	0
Pain in extremity	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Arthralgia	2 (5.0)	2 (5.0)	0	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	7 (17.5)	3 (7.5)	2 (5.0)	2 (5.0)	0
Cognitive disorder	1 (2.5)	0	0	1 (2.5)	0
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Headache	1 (2.5)	0	0	1 (2.5)	0
Intraventricular haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Neuralgia	1 (2.5)	0	1 (2.5)	0	0
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Mental status changes	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Anxiety	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Depression	1 (2.5)	0	1 (2.5)	0	0
Insomnia	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	3 (7.5)	2 (5.0)	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (5.0)	2 (5.0)	0	0	0
Haematuria	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (20.0)	1 (2.5)	1 (2.5)	4 (10.0)	2 (5.0)
Oropharyngeal pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Respiratory failure	2 (5.0)	0	0	0	2 (5.0)
Atelectasis	1 (2.5)	0	0	1 (2.5)	0
Dyspnoea	1 (2.5)	0	0	1 (2.5)	0
Epistaxis	1 (2.5)	0	0	1 (2.5)	0
Hypoxia	1 (2.5)	0	0	1 (2.5)	0
Pulmonary oedema	1 (2.5)	0	0	0	1 (2.5)
Tachypnoea	1 (2.5)	0	0	1 (2.5)	0
Skin and subcutaneous tissue disorders					
-Total	5 (12.5)	4 (10.0)	0	1 (2.5)	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0
Ingrowing nail	1 (2.5)	1 (2.5)	0	0	0
Petechiae	1 (2.5)	1 (2.5)	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	1 (2.5)	1 (2.5)	0	0	0
Skin ulcer	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	5 (12.5)	0	2 (5.0)	2 (5.0)	1 (2.5)
Hypotension	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Hypertension	2 (5.0)	0	2 (5.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205m
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (76.5)	0	3 (17.6)	7 (41.2)	3 (17.6)
Blood and lymphatic system disorders					
-Total	7 (41.2)	0	0	7 (41.2)	0
Febrile neutropenia	7 (41.2)	0	0	7 (41.2)	0
Gastrointestinal disorders					
-Total	8 (47.1)	2 (11.8)	2 (11.8)	4 (23.5)	0
Abdominal pain	1 (5.9)	0	1 (5.9)	0	0
Anal fissure	1 (5.9)	0	1 (5.9)	0	0
Anal fistula	1 (5.9)	0	0	1 (5.9)	0
Diarrhoea	1 (5.9)	1 (5.9)	0	0	0
Duodenal perforation	1 (5.9)	0	0	1 (5.9)	0
Gastritis	1 (5.9)	0	1 (5.9)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematemesis	1 (5.9)	1 (5.9)	0	0	0
Haemorrhoids	1 (5.9)	0	1 (5.9)	0	0
Neutropenic colitis	1 (5.9)	0	0	1 (5.9)	0
Stomatitis	1 (5.9)	0	0	1 (5.9)	0
Hepatobiliary disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	0	0	1 (5.9)	0
Immune system disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Hypersensitivity	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	7 (41.2)	0	1 (5.9)	5 (29.4)	1 (5.9)
Catheter site infection	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Acute sinusitis	1 (5.9)	0	0	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)
Epstein-barr virus infection	1 (5.9)	0	1 (5.9)	0	0
Fungal pharyngitis	1 (5.9)	0	0	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0
Peritonitis	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	1 (5.9)	0	0	1 (5.9)	0
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	1 (5.9)	0	1 (5.9)	0	0
Transfusion reaction	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Alanine aminotransferase increased	1 (5.9)	0	1 (5.9)	0	0
Aspartate aminotransferase increased	1 (5.9)	0	0	1 (5.9)	0
Blood bilirubin increased	1 (5.9)	0	0	1 (5.9)	0
Blood creatinine increased	1 (5.9)	0	0	1 (5.9)	0
Blood fibrinogen increased	1 (5.9)	1 (5.9)	0	0	0
C-reactive protein increased	1 (5.9)	1 (5.9)	0	0	0
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (5.9)	0	1 (5.9)	0	0
Metabolism and nutrition disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Hypokalaemia	1 (5.9)	0	0	1 (5.9)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Arthralgia	1 (5.9)	1 (5.9)	0	0	0
Nervous system disorders					
-Total	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Haemorrhage intracranial	1 (5.9)	0	0	0	1 (5.9)
Neuropathy peripheral	1 (5.9)	1 (5.9)	0	0	0
Psychiatric disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Depression	1 (5.9)	0	1 (5.9)	0	0
Mental status changes	1 (5.9)	0	0	1 (5.9)	0
Renal and urinary disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal tubular necrosis	1 (5.9)	0	0	1 (5.9)	0
Reproductive system and breast disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Prostatitis	1 (5.9)	0	0	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Cough	1 (5.9)	1 (5.9)	0	0	0
Epistaxis	1 (5.9)	0	0	1 (5.9)	0
Hypoxia	1 (5.9)	0	1 (5.9)	0	0
Nasal congestion	1 (5.9)	1 (5.9)	0	0	0
Rhinorrhoea	1 (5.9)	1 (5.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (17.6)	3 (17.6)	0	0	0
Erythema nodosum	1 (5.9)	1 (5.9)	0	0	0
Rash maculo-papular	1 (5.9)	1 (5.9)	0	0	0
Skin ulcer	1 (5.9)	1 (5.9)	0	0	0

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Table 205m
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	76 (93.8)	3 (3.7)	7 (8.6)	27 (33.3)	39 (48.1)
Blood and lymphatic system disorders					
-Total	42 (51.9)	1 (1.2)	2 (2.5)	22 (27.2)	17 (21.0)
Anaemia	23 (28.4)	2 (2.5)	4 (4.9)	16 (19.8)	1 (1.2)
Febrile neutropenia	16 (19.8)	0	0	15 (18.5)	1 (1.2)
Neutropenia	11 (13.6)	1 (1.2)	0	1 (1.2)	9 (11.1)
Thrombocytopenia	9 (11.1)	1 (1.2)	1 (1.2)	3 (3.7)	4 (4.9)
Pancytopenia	4 (4.9)	0	1 (1.2)	1 (1.2)	2 (2.5)
Leukopenia	3 (3.7)	0	0	0	3 (3.7)
Haemolytic anaemia	1 (1.2)	0	0	0	1 (1.2)
Hyperleukocytosis	1 (1.2)	0	0	1 (1.2)	0
Lymphadenitis	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.2)	0	0	0	1 (1.2)
Cardiac disorders					
-Total	10 (12.3)	3 (3.7)	1 (1.2)	6 (7.4)	0
Tachycardia	6 (7.4)	2 (2.5)	1 (1.2)	3 (3.7)	0
Bradycardia	1 (1.2)	1 (1.2)	0	0	0
Cardiac failure	1 (1.2)	0	0	1 (1.2)	0
Left ventricular dysfunction	1 (1.2)	0	0	1 (1.2)	0
Pericardial effusion	1 (1.2)	0	0	1 (1.2)	0
Ear and labyrinth disorders					
-Total	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Vertigo	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Endocrine disorders					
-Total	7 (8.6)	0	5 (6.2)	1 (1.2)	1 (1.2)
Adrenal insufficiency	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Hypothyroidism	2 (2.5)	0	2 (2.5)	0	0
Addison's disease	1 (1.2)	0	1 (1.2)	0	0
Hypercalcaemia of malignancy	1 (1.2)	0	0	0	1 (1.2)
Eye disorders					

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.5)	2 (2.5)	0	0	0
Dry eye	1 (1.2)	1 (1.2)	0	0	0
Eyelid oedema	1 (1.2)	1 (1.2)	0	0	0
Gastrointestinal disorders					
-Total	31 (38.3)	4 (4.9)	11 (13.6)	15 (18.5)	1 (1.2)
Abdominal pain	7 (8.6)	2 (2.5)	3 (3.7)	2 (2.5)	0
Constipation	7 (8.6)	3 (3.7)	4 (4.9)	0	0
Nausea	7 (8.6)	1 (1.2)	5 (6.2)	1 (1.2)	0
Stomatitis	6 (7.4)	0	1 (1.2)	5 (6.2)	0
Diarrhoea	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Abdominal pain upper	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Neutropenic colitis	2 (2.5)	0	0	2 (2.5)	0
Oral disorder	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Oral pain	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Vomiting	2 (2.5)	2 (2.5)	0	0	0
Abdominal compartment syndrome	1 (1.2)	0	0	0	1 (1.2)
Anal inflammation	1 (1.2)	0	0	1 (1.2)	0
Colitis	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (1.2)	0	1 (1.2)	0	0
Gastrointestinal haemorrhage	1 (1.2)	0	0	1 (1.2)	0
Gastrointestinal sounds abnormal	1 (1.2)	1 (1.2)	0	0	0
Gastrooesophageal reflux disease	1 (1.2)	1 (1.2)	0	0	0
Gingival erythema	1 (1.2)	1 (1.2)	0	0	0
Haematemesis	1 (1.2)	1 (1.2)	0	0	0
Haemoperitoneum	1 (1.2)	0	0	0	1 (1.2)
Hypoaesthesia oral	1 (1.2)	0	1 (1.2)	0	0
Ileus	1 (1.2)	0	0	1 (1.2)	0
Ileus paralytic	1 (1.2)	1 (1.2)	0	0	0
Lip ulceration	1 (1.2)	0	1 (1.2)	0	0
Mouth haemorrhage	1 (1.2)	0	1 (1.2)	0	0
Oral mucosal blistering	1 (1.2)	1 (1.2)	0	0	0
Tongue blistering	1 (1.2)	1 (1.2)	0	0	0
Tooth pulp haemorrhage	1 (1.2)	0	0	1 (1.2)	0
General disorders and administration site conditions					
-Total	25 (30.9)	4 (4.9)	17 (21.0)	4 (4.9)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	14 (17.3)	3 (3.7)	9 (11.1)	2 (2.5)	0
Catheter site pain	5 (6.2)	2 (2.5)	3 (3.7)	0	0
Fatigue	5 (6.2)	1 (1.2)	4 (4.9)	0	0
Pain	5 (6.2)	0	4 (4.9)	1 (1.2)	0
Chills	2 (2.5)	0	2 (2.5)	0	0
Non-cardiac chest pain	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Oedema peripheral	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Asthenia	1 (1.2)	0	1 (1.2)	0	0
Complication associated with device	1 (1.2)	1 (1.2)	0	0	0
Face oedema	1 (1.2)	1 (1.2)	0	0	0
Mucosal inflammation	1 (1.2)	0	0	1 (1.2)	0
Thirst	1 (1.2)	1 (1.2)	0	0	0
Hepatobiliary disorders					
-Total	9 (11.1)	3 (3.7)	2 (2.5)	4 (4.9)	0
Hyperbilirubinaemia	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Hepatic cytolysis	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Hypertransaminasaemia	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Hepatomegaly	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatosplenomegaly	1 (1.2)	0	1 (1.2)	0	0
Immune system disorders					
-Total	11 (13.6)	0	7 (8.6)	4 (4.9)	0
Hypogammaglobulinaemia	7 (8.6)	0	6 (7.4)	1 (1.2)	0
Immunodeficiency	2 (2.5)	0	0	2 (2.5)	0
Graft versus host disease	1 (1.2)	0	0	1 (1.2)	0
Immune system disorder	1 (1.2)	0	1 (1.2)	0	0
Infections and infestations					
-Total	44 (54.3)	2 (2.5)	6 (7.4)	25 (30.9)	11 (13.6)
Pneumonia	4 (4.9)	0	1 (1.2)	2 (2.5)	1 (1.2)
Oral herpes	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Sinusitis	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Clostridium difficile colitis	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Device related infection	2 (2.5)	0	0	2 (2.5)	0
Escherichia bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Herpes zoster	2 (2.5)	0	0	2 (2.5)	0
Localised infection	2 (2.5)	1 (1.2)	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (2.5)	0	0	2 (2.5)	0
Pneumonia fungal	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Respiratory tract infection	2 (2.5)	0	0	2 (2.5)	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Sialoadenitis	2 (2.5)	0	0	2 (2.5)	0
Staphylococcal sepsis	2 (2.5)	0	0	0	2 (2.5)
Urinary tract infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Abscess limb	1 (1.2)	0	0	1 (1.2)	0
Acute sinusitis	1 (1.2)	0	1 (1.2)	0	0
Bacterial sepsis	1 (1.2)	0	0	0	1 (1.2)
Bronchiolitis	1 (1.2)	0	0	1 (1.2)	0
Bronchitis	1 (1.2)	0	1 (1.2)	0	0
Bronchopulmonary aspergillosis	1 (1.2)	0	0	1 (1.2)	0
Catheter site infection	1 (1.2)	0	1 (1.2)	0	0
Cellulitis	1 (1.2)	0	1 (1.2)	0	0
Cytomegalovirus infection reactivation	1 (1.2)	0	1 (1.2)	0	0
Device related bacteraemia	1 (1.2)	0	1 (1.2)	0	0
Device related sepsis	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (1.2)	0	0	0	1 (1.2)
Epstein-barr virus infection reactivation	1 (1.2)	1 (1.2)	0	0	0
Fungal infection	1 (1.2)	0	1 (1.2)	0	0
Fungal sepsis	1 (1.2)	0	0	0	1 (1.2)
Gastroenteritis	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis adenovirus	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis viral	1 (1.2)	0	0	1 (1.2)	0
Gingivitis	1 (1.2)	1 (1.2)	0	0	0
Haemophilus bacteraemia	1 (1.2)	0	0	0	1 (1.2)
Herpes simplex	1 (1.2)	0	1 (1.2)	0	0
Klebsiella bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Paronychia	1 (1.2)	0	0	1 (1.2)	0
Pharyngitis	1 (1.2)	0	0	1 (1.2)	0
Pseudomonal bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Sepsis	1 (1.2)	0	0	0	1 (1.2)
Serratia sepsis	1 (1.2)	0	0	0	1 (1.2)
Staphylococcal bacteraemia	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.2)	0	0	0	1 (1.2)
Staphylococcal skin infection	1 (1.2)	0	0	1 (1.2)	0
Stomatococcal infection	1 (1.2)	0	0	0	1 (1.2)
Tonsillitis	1 (1.2)	0	1 (1.2)	0	0
Injury, poisoning and procedural complications					
-Total	11 (13.6)	1 (1.2)	5 (6.2)	4 (4.9)	1 (1.2)
Procedural pain	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Transfusion reaction	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Extradural haematoma	1 (1.2)	0	1 (1.2)	0	0
Fall	1 (1.2)	0	1 (1.2)	0	0
Infusion related reaction	1 (1.2)	0	0	1 (1.2)	0
Post procedural haemorrhage	1 (1.2)	0	0	1 (1.2)	0
Radius fracture	1 (1.2)	0	1 (1.2)	0	0
Tracheal obstruction	1 (1.2)	0	0	0	1 (1.2)
Traumatic haematoma	1 (1.2)	0	1 (1.2)	0	0
Wound	1 (1.2)	1 (1.2)	0	0	0
Investigations					

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	30 (37.0)	2 (2.5)	1 (1.2)	11 (13.6)	16 (19.8)
Neutrophil count decreased	11 (13.6)	1 (1.2)	0	3 (3.7)	7 (8.6)
Platelet count decreased	8 (9.9)	0	0	0	8 (9.9)
White blood cell count decreased	8 (9.9)	1 (1.2)	0	0	7 (8.6)
Alanine aminotransferase increased	7 (8.6)	2 (2.5)	1 (1.2)	4 (4.9)	0
C-reactive protein increased	6 (7.4)	1 (1.2)	2 (2.5)	2 (2.5)	1 (1.2)
Serum ferritin increased	5 (6.2)	1 (1.2)	1 (1.2)	2 (2.5)	1 (1.2)
Aspartate aminotransferase increased	4 (4.9)	0	1 (1.2)	2 (2.5)	1 (1.2)
Lymphocyte count decreased	4 (4.9)	1 (1.2)	0	1 (1.2)	2 (2.5)
Blood lactate dehydrogenase increased	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Weight decreased	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Blood glucose increased	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Blood potassium decreased	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Fibrin d dimer increased	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Activated partial thromboplastin time prolonged	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time shortened	1 (1.2)	0	1 (1.2)	0	0
Amylase increased	1 (1.2)	0	0	0	1 (1.2)
Blood calcium increased	1 (1.2)	0	0	1 (1.2)	0
Blood creatinine increased	1 (1.2)	1 (1.2)	0	0	0
Blood fibrinogen decreased	1 (1.2)	0	0	1 (1.2)	0
Blood fibrinogen increased	1 (1.2)	0	1 (1.2)	0	0
Blood immunoglobulin g decreased	1 (1.2)	0	1 (1.2)	0	0
Blood immunoglobulin m decreased	1 (1.2)	0	1 (1.2)	0	0
Blood magnesium decreased	1 (1.2)	0	1 (1.2)	0	0
Blood phosphorus decreased	1 (1.2)	0	0	1 (1.2)	0
Blood uric acid increased	1 (1.2)	1 (1.2)	0	0	0
Electrocardiogram qt prolonged	1 (1.2)	1 (1.2)	0	0	0
Eosinophil count decreased	1 (1.2)	1 (1.2)	0	0	0
Haematocrit decreased	1 (1.2)	1 (1.2)	0	0	0
International normalised ratio increased	1 (1.2)	0	1 (1.2)	0	0
Protein total decreased	1 (1.2)	0	1 (1.2)	0	0
Red blood cell count decreased	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	24 (29.6)	2 (2.5)	7 (8.6)	11 (13.6)	4 (4.9)
Hypokalaemia	5 (6.2)	2 (2.5)	1 (1.2)	2 (2.5)	0
Decreased appetite	4 (4.9)	1 (1.2)	1 (1.2)	2 (2.5)	0
Hypocalcaemia	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Hypomagnesaemia	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Tumour lysis syndrome	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Hypervolaemia	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Hypoalbuminaemia	2 (2.5)	0	2 (2.5)	0	0
Hyponatraemia	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Metabolic acidosis	2 (2.5)	0	0	2 (2.5)	0
Eating disorder symptom	1 (1.2)	0	1 (1.2)	0	0
Hyperammonaemia	1 (1.2)	0	0	1 (1.2)	0
Hypercalcaemia	1 (1.2)	0	0	0	1 (1.2)
Hyperglycaemia	1 (1.2)	0	0	0	1 (1.2)
Hyperkalaemia	1 (1.2)	0	0	1 (1.2)	0
Hyperphosphataemia	1 (1.2)	1 (1.2)	0	0	0
Hyperuricaemia	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophagia	1 (1.2)	0	0	1 (1.2)	0
Hypophosphataemia	1 (1.2)	0	1 (1.2)	0	0
Malnutrition	1 (1.2)	0	1 (1.2)	0	0
Vitamin a deficiency	1 (1.2)	0	1 (1.2)	0	0
Vitamin b1 deficiency	1 (1.2)	1 (1.2)	0	0	0
Vitamin d deficiency	1 (1.2)	1 (1.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	17 (21.0)	6 (7.4)	7 (8.6)	4 (4.9)	0
Pain in extremity	6 (7.4)	1 (1.2)	3 (3.7)	2 (2.5)	0
Arthralgia	5 (6.2)	3 (3.7)	2 (2.5)	0	0
Back pain	5 (6.2)	1 (1.2)	3 (3.7)	1 (1.2)	0
Bone pain	1 (1.2)	0	1 (1.2)	0	0
Groin pain	1 (1.2)	1 (1.2)	0	0	0
Joint effusion	1 (1.2)	0	0	1 (1.2)	0
Myopathy	1 (1.2)	0	0	1 (1.2)	0
Osteopenia	1 (1.2)	1 (1.2)	0	0	0
Pain in jaw	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Spinal pain	1 (1.2)	0	0	1 (1.2)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.2)	0	0	0	1 (1.2)
Acute lymphocytic leukaemia	1 (1.2)	0	0	0	1 (1.2)
Skin papilloma	1 (1.2)	1 (1.2)	0	0	0
Nervous system disorders					
-Total	18 (22.2)	6 (7.4)	6 (7.4)	6 (7.4)	0
Headache	8 (9.9)	3 (3.7)	3 (3.7)	2 (2.5)	0
Paraesthesia	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Neuropathy peripheral	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Cognitive disorder	1 (1.2)	0	0	1 (1.2)	0
Dizziness	1 (1.2)	1 (1.2)	0	0	0
Encephalopathy	1 (1.2)	0	0	1 (1.2)	0
Intraventricular haemorrhage	1 (1.2)	1 (1.2)	0	0	0
Lethargy	1 (1.2)	1 (1.2)	0	0	0
Neuralgia	1 (1.2)	0	1 (1.2)	0	0
Peripheral motor neuropathy	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post herpetic neuralgia	1 (1.2)	0	0	1 (1.2)	0
Seizure	1 (1.2)	0	1 (1.2)	0	0
Psychiatric disorders					
-Total	8 (9.9)	2 (2.5)	4 (4.9)	2 (2.5)	0
Anxiety	4 (4.9)	2 (2.5)	1 (1.2)	1 (1.2)	0
Insomnia	2 (2.5)	0	2 (2.5)	0	0
Mental status changes	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Agitation	1 (1.2)	1 (1.2)	0	0	0
Renal and urinary disorders					
-Total	4 (4.9)	2 (2.5)	2 (2.5)	0	0
Acute kidney injury	2 (2.5)	2 (2.5)	0	0	0
Haematuria	1 (1.2)	0	1 (1.2)	0	0
Micturition disorder	1 (1.2)	1 (1.2)	0	0	0
Urinary tract disorder	1 (1.2)	0	1 (1.2)	0	0
Reproductive system and breast disorders					
-Total	1 (1.2)	0	1 (1.2)	0	0
Heavy menstrual bleeding	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	16 (19.8)	4 (4.9)	3 (3.7)	4 (4.9)	5 (6.2)
Respiratory failure	4 (4.9)	0	0	0	4 (4.9)
Epistaxis	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Hypoxia	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Dyspnoea	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Oropharyngeal pain	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Tachypnoea	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Acute respiratory distress syndrome	1 (1.2)	0	0	0	1 (1.2)
Atelectasis	1 (1.2)	0	0	1 (1.2)	0
Cough	1 (1.2)	1 (1.2)	0	0	0
Haemothorax	1 (1.2)	0	0	0	1 (1.2)
Nasal congestion	1 (1.2)	1 (1.2)	0	0	0
Pneumothorax	1 (1.2)	0	0	0	1 (1.2)
Pulmonary oedema	1 (1.2)	0	0	0	1 (1.2)
Throat irritation	1 (1.2)	0	1 (1.2)	0	0
Wheezing	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	12 (14.8)	7 (8.6)	3 (3.7)	2 (2.5)	0
Pruritus	4 (4.9)	2 (2.5)	2 (2.5)	0	0
Pain of skin	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Rash	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Skin ulcer	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Blister	1 (1.2)	1 (1.2)	0	0	0
Dermatitis exfoliative generalised	1 (1.2)	1 (1.2)	0	0	0
Dry skin	1 (1.2)	1 (1.2)	0	0	0
Ingrowing nail	1 (1.2)	1 (1.2)	0	0	0
Petechiae	1 (1.2)	1 (1.2)	0	0	0
Vascular disorders					
-Total	14 (17.3)	4 (4.9)	5 (6.2)	3 (3.7)	2 (2.5)
Hypertension	7 (8.6)	2 (2.5)	5 (6.2)	0	0
Hypotension	6 (7.4)	1 (1.2)	0	3 (3.7)	2 (2.5)
Haematoma	1 (1.2)	1 (1.2)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205n
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (78.6)	1 (3.6)	3 (10.7)	12 (42.9)	6 (21.4)
Blood and lymphatic system disorders					
-Total	14 (50.0)	1 (3.6)	0	8 (28.6)	5 (17.9)
Anaemia	7 (25.0)	1 (3.6)	1 (3.6)	5 (17.9)	0
Febrile neutropenia	5 (17.9)	0	0	5 (17.9)	0
Thrombocytopenia	5 (17.9)	0	1 (3.6)	2 (7.1)	2 (7.1)
Neutropenia	3 (10.7)	0	0	0	3 (10.7)
Cardiac disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Tachycardia	1 (3.6)	1 (3.6)	0	0	0
Endocrine disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (3.6)	0	1 (3.6)	0	0
Eye disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Dry eye	1 (3.6)	1 (3.6)	0	0	0
Gastrointestinal disorders					
-Total	7 (25.0)	2 (7.1)	2 (7.1)	3 (10.7)	0
Nausea	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Constipation	2 (7.1)	2 (7.1)	0	0	0
Abdominal pain	1 (3.6)	0	0	1 (3.6)	0
Diarrhoea	1 (3.6)	1 (3.6)	0	0	0
Ileus	1 (3.6)	0	0	1 (3.6)	0
Lip ulceration	1 (3.6)	0	1 (3.6)	0	0
Tooth pulp haemorrhage	1 (3.6)	0	0	1 (3.6)	0
General disorders and administration site conditions					
-Total	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Pyrexia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Catheter site pain	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fatigue	1 (3.6)	0	1 (3.6)	0	0
Pain	1 (3.6)	0	1 (3.6)	0	0
Hepatobiliary disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hepatic cytolysis	1 (3.6)	1 (3.6)	0	0	0
Hyperbilirubinaemia	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					
-Total	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Hypogammaglobulinaemia	1 (3.6)	0	0	1 (3.6)	0
Immune system disorder	1 (3.6)	0	1 (3.6)	0	0
Immunodeficiency	1 (3.6)	0	0	1 (3.6)	0
Infections and infestations					
-Total	11 (39.3)	1 (3.6)	3 (10.7)	7 (25.0)	0
Sinusitis	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Abscess limb	1 (3.6)	0	0	1 (3.6)	0
Catheter site infection	1 (3.6)	0	1 (3.6)	0	0
Clostridium difficile colitis	1 (3.6)	0	0	1 (3.6)	0
Device related bacteraemia	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epstein-barr virus infection	1 (3.6)	0	1 (3.6)	0	0
Fungal infection	1 (3.6)	0	1 (3.6)	0	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Localised infection	1 (3.6)	0	0	1 (3.6)	0
Pseudomonal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Sialoadenitis	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Staphylococcal skin infection	1 (3.6)	0	0	1 (3.6)	0
Tonsillitis	1 (3.6)	0	1 (3.6)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.6)	0	1 (3.6)	0	0
Transfusion reaction	1 (3.6)	0	1 (3.6)	0	0
Investigations					
-Total	6 (21.4)	0	0	4 (14.3)	2 (7.1)
Alanine aminotransferase increased	4 (14.3)	0	1 (3.6)	3 (10.7)	0
Neutrophil count decreased	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Serum ferritin increased	2 (7.1)	0	1 (3.6)	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.6)	0	1 (3.6)	0	0
Blood immunoglobulin g decreased	1 (3.6)	0	1 (3.6)	0	0
Blood immunoglobulin m decreased	1 (3.6)	0	1 (3.6)	0	0
Blood magnesium decreased	1 (3.6)	0	1 (3.6)	0	0
Blood potassium decreased	1 (3.6)	0	0	1 (3.6)	0
Lymphocyte count decreased	1 (3.6)	0	0	1 (3.6)	0
Protein total decreased	1 (3.6)	0	1 (3.6)	0	0
White blood cell count decreased	1 (3.6)	0	0	0	1 (3.6)
Metabolism and nutrition disorders					
-Total	6 (21.4)	0	3 (10.7)	3 (10.7)	0
Hypokalaemia	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Hypomagnesaemia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Decreased appetite	1 (3.6)	0	0	1 (3.6)	0
Hypervolaemia	1 (3.6)	1 (3.6)	0	0	0
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)	0	0
Hypophagia	1 (3.6)	0	0	1 (3.6)	0
Hypophosphataemia	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Arthralgia	1 (3.6)	1 (3.6)	0	0	0
Back pain	1 (3.6)	0	1 (3.6)	0	0
Groin pain	1 (3.6)	1 (3.6)	0	0	0
Pain in extremity	1 (3.6)	0	1 (3.6)	0	0
Nervous system disorders					
-Total	2 (7.1)	0	2 (7.1)	0	0
Headache	1 (3.6)	0	1 (3.6)	0	0
Neuropathy peripheral	1 (3.6)	0	1 (3.6)	0	0
Paraesthesia	1 (3.6)	1 (3.6)	0	0	0
Seizure	1 (3.6)	0	1 (3.6)	0	0
Psychiatric disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Anxiety	1 (3.6)	1 (3.6)	0	0	0
Insomnia	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Heavy menstrual bleeding	1 (3.6)	0	1 (3.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Nasal congestion	1 (3.6)	1 (3.6)	0	0	0
Wheezing	1 (3.6)	1 (3.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Dermatitis exfoliative generalised	1 (3.6)	1 (3.6)	0	0	0
Pruritus	1 (3.6)	1 (3.6)	0	0	0
Skin ulcer	1 (3.6)	0	0	1 (3.6)	0
Vascular disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Hypertension	1 (3.6)	0	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205n
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (95.7)	2 (2.9)	7 (10.0)	22 (31.4)	36 (51.4)
Blood and lymphatic system disorders					
-Total	35 (50.0)	0	2 (2.9)	21 (30.0)	12 (17.1)
Febrile neutropenia	18 (25.7)	0	0	17 (24.3)	1 (1.4)
Anaemia	16 (22.9)	1 (1.4)	3 (4.3)	11 (15.7)	1 (1.4)
Neutropenia	8 (11.4)	1 (1.4)	0	1 (1.4)	6 (8.6)
Pancytopenia	4 (5.7)	0	1 (1.4)	1 (1.4)	2 (2.9)
Thrombocytopenia	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)
Leukopenia	3 (4.3)	0	0	0	3 (4.3)
Haemolytic anaemia	1 (1.4)	0	0	0	1 (1.4)
Hyperleukocytosis	1 (1.4)	0	0	1 (1.4)	0
Lymphadenitis	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Cardiac disorders					
-Total	9 (12.9)	2 (2.9)	1 (1.4)	6 (8.6)	0
Tachycardia	5 (7.1)	1 (1.4)	1 (1.4)	3 (4.3)	0
Bradycardia	1 (1.4)	1 (1.4)	0	0	0
Cardiac failure	1 (1.4)	0	0	1 (1.4)	0
Left ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Pericardial effusion	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Vertigo	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Endocrine disorders					
-Total	6 (8.6)	0	4 (5.7)	1 (1.4)	1 (1.4)
Adrenal insufficiency	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Hypothyroidism	2 (2.9)	0	2 (2.9)	0	0
Addison's disease	1 (1.4)	0	1 (1.4)	0	0
Hypercalcaemia of malignancy	1 (1.4)	0	0	0	1 (1.4)
Eye disorders					

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0	0	0
Eyelid oedema	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	32 (45.7)	4 (5.7)	11 (15.7)	16 (22.9)	1 (1.4)
Abdominal pain	7 (10.0)	2 (2.9)	4 (5.7)	1 (1.4)	0
Stomatitis	7 (10.0)	0	1 (1.4)	6 (8.6)	0
Constipation	5 (7.1)	1 (1.4)	4 (5.7)	0	0
Nausea	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Diarrhoea	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Neutropenic colitis	3 (4.3)	0	0	3 (4.3)	0
Abdominal pain upper	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Haematemesis	2 (2.9)	2 (2.9)	0	0	0
Oral disorder	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Oral pain	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Vomiting	2 (2.9)	2 (2.9)	0	0	0
Abdominal compartment syndrome	1 (1.4)	0	0	0	1 (1.4)
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal fistula	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal inflammation	1 (1.4)	0	0	1 (1.4)	0
Colitis	1 (1.4)	0	0	1 (1.4)	0
Dry mouth	1 (1.4)	0	1 (1.4)	0	0
Duodenal perforation	1 (1.4)	0	0	1 (1.4)	0
Gastritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	0	0	0
Gingival erythema	1 (1.4)	1 (1.4)	0	0	0
Haemoperitoneum	1 (1.4)	0	0	0	1 (1.4)
Haemorrhoids	1 (1.4)	0	1 (1.4)	0	0
Hypoaesthesia oral	1 (1.4)	0	1 (1.4)	0	0
Ileus paralytic	1 (1.4)	1 (1.4)	0	0	0
Mouth haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Tongue blistering	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (28.6)	3 (4.3)	13 (18.6)	4 (5.7)	0
Pyrexia	11 (15.7)	1 (1.4)	8 (11.4)	2 (2.9)	0
Catheter site pain	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Fatigue	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Pain	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Chills	2 (2.9)	0	2 (2.9)	0	0
Non-cardiac chest pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Oedema peripheral	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Complication associated with device	1 (1.4)	1 (1.4)	0	0	0
Face oedema	1 (1.4)	1 (1.4)	0	0	0
Mucosal inflammation	1 (1.4)	0	0	1 (1.4)	0
Thirst	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	8 (11.4)	2 (2.9)	1 (1.4)	5 (7.1)	0
Hyperbilirubinaemia	2 (2.9)	0	0	2 (2.9)	0
Hypertransaminasaemia	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Drug-induced liver injury	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic cytolysis	1 (1.4)	0	0	1 (1.4)	0
Hepatomegaly	1 (1.4)	1 (1.4)	0	0	0
Hepatosplenomegaly	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	9 (12.9)	0	7 (10.0)	2 (2.9)	0
Hypogammaglobulinaemia	6 (8.6)	0	6 (8.6)	0	0
Graft versus host disease	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	0	1 (1.4)	0
Infections and infestations					
-Total	40 (57.1)	1 (1.4)	4 (5.7)	23 (32.9)	12 (17.1)
Pneumonia	4 (5.7)	0	1 (1.4)	2 (2.9)	1 (1.4)
Oral herpes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Acute sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Escherichia bacteraemia	2 (2.9)	0	0	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (2.9)	0	0	2 (2.9)	0
Parainfluenzae virus infection	2 (2.9)	0	0	2 (2.9)	0
Pneumonia fungal	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Respiratory tract infection	2 (2.9)	0	0	2 (2.9)	0
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Staphylococcal infection	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	0	0	2 (2.9)
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Bronchiolitis	1 (1.4)	0	0	1 (1.4)	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	1 (1.4)	0	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Epstein-barr virus infection reactivation	1 (1.4)	1 (1.4)	0	0	0
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis adenovirus	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	0	0	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Herpes simplex	1 (1.4)	0	1 (1.4)	0	0
Klebsiella bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Paronychia	1 (1.4)	0	0	1 (1.4)	0
Peritonitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	11 (15.7)	1 (1.4)	5 (7.1)	4 (5.7)	1 (1.4)
Procedural pain	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Extradural haematoma	1 (1.4)	0	1 (1.4)	0	0
Fall	1 (1.4)	0	1 (1.4)	0	0
Infusion related reaction	1 (1.4)	0	0	1 (1.4)	0
Post procedural haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Tracheal obstruction	1 (1.4)	0	0	0	1 (1.4)
Traumatic haematoma	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	26 (37.1)	2 (2.9)	1 (1.4)	8 (11.4)	15 (21.4)
Neutrophil count decreased	10 (14.3)	1 (1.4)	0	2 (2.9)	7 (10.0)
Platelet count decreased	8 (11.4)	0	0	0	8 (11.4)
C-reactive protein increased	7 (10.0)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.4)
White blood cell count decreased	7 (10.0)	1 (1.4)	0	0	6 (8.6)
Alanine aminotransferase increased	4 (5.7)	2 (2.9)	1 (1.4)	1 (1.4)	0
Aspartate aminotransferase increased	4 (5.7)	0	0	3 (4.3)	1 (1.4)
Blood lactate dehydrogenase increased	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Lymphocyte count decreased	3 (4.3)	1 (1.4)	0	0	2 (2.9)
Serum ferritin increased	3 (4.3)	1 (1.4)	0	1 (1.4)	1 (1.4)
Weight decreased	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Blood fibrinogen increased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Blood glucose increased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Fibrin d dimer increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Activated partial thromboplastin time prolonged	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time shortened	1 (1.4)	0	1 (1.4)	0	0
Amylase increased	1 (1.4)	0	0	0	1 (1.4)
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood calcium increased	1 (1.4)	0	0	1 (1.4)	0
Blood fibrinogen decreased	1 (1.4)	0	0	1 (1.4)	0
Blood phosphorus decreased	1 (1.4)	0	0	1 (1.4)	0
Blood potassium decreased	1 (1.4)	0	0	0	1 (1.4)
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0	0	0
Eosinophil count decreased	1 (1.4)	1 (1.4)	0	0	0
Haematocrit decreased	1 (1.4)	1 (1.4)	0	0	0
International normalised ratio increased	1 (1.4)	0	1 (1.4)	0	0
Red blood cell count decreased	1 (1.4)	1 (1.4)	0	0	0
Weight increased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	19 (27.1)	2 (2.9)	4 (5.7)	9 (12.9)	4 (5.7)
Hypokalaemia	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Decreased appetite	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hypocalcaemia	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Tumour lysis syndrome	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Hyponatraemia	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Metabolic acidosis	2 (2.9)	0	0	2 (2.9)	0
Eating disorder symptom	1 (1.4)	0	1 (1.4)	0	0
Hyperammonaemia	1 (1.4)	0	0	1 (1.4)	0
Hypercalcaemia	1 (1.4)	0	0	0	1 (1.4)
Hyperglycaemia	1 (1.4)	0	0	0	1 (1.4)
Hyperkalaemia	1 (1.4)	0	0	1 (1.4)	0
Hyperphosphataemia	1 (1.4)	1 (1.4)	0	0	0
Hyperuricaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypoalbuminaemia	1 (1.4)	0	1 (1.4)	0	0
Hypomagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Vitamin a deficiency	1 (1.4)	0	1 (1.4)	0	0
Vitamin b1 deficiency	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	15 (21.4)	6 (8.6)	5 (7.1)	4 (5.7)	0
Arthralgia	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Pain in extremity	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Back pain	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Joint effusion	1 (1.4)	0	0	1 (1.4)	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Osteopenia	1 (1.4)	1 (1.4)	0	0	0
Pain in jaw	1 (1.4)	0	0	1 (1.4)	0
Spinal pain	1 (1.4)	0	0	1 (1.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.4)	0	0	0	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)	0	0	0	1 (1.4)
Skin papilloma	1 (1.4)	1 (1.4)	0	0	0
Nervous system disorders					
-Total	18 (25.7)	7 (10.0)	4 (5.7)	6 (8.6)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	7 (10.0)	3 (4.3)	2 (2.9)	2 (2.9)	0
Neuropathy peripheral	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Paraesthesia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0
Dizziness	1 (1.4)	1 (1.4)	0	0	0
Encephalopathy	1 (1.4)	0	0	1 (1.4)	0
Haemorrhage intracranial	1 (1.4)	0	0	0	1 (1.4)
Intraventricular haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Lethargy	1 (1.4)	1 (1.4)	0	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Peripheral motor neuropathy	1 (1.4)	0	1 (1.4)	0	0
Post herpetic neuralgia	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	8 (11.4)	1 (1.4)	4 (5.7)	3 (4.3)	0
Anxiety	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Mental status changes	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Depression	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Acute kidney injury	2 (2.9)	2 (2.9)	0	0	0
Haematuria	1 (1.4)	0	1 (1.4)	0	0
Micturition disorder	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	1 (1.4)	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	0	1 (1.4)	0
Prostatitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (25.7)	4 (5.7)	4 (5.7)	5 (7.1)	5 (7.1)
Epistaxis	4 (5.7)	2 (2.9)	0	2 (2.9)	0
Hypoxia	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Respiratory failure	4 (5.7)	0	0	0	4 (5.7)
Cough	2 (2.9)	2 (2.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Oropharyngeal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Tachypnoea	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	0	1 (1.4)	0
Haemothorax	1 (1.4)	0	0	0	1 (1.4)
Nasal congestion	1 (1.4)	1 (1.4)	0	0	0
Pneumothorax	1 (1.4)	0	0	0	1 (1.4)
Pulmonary oedema	1 (1.4)	0	0	0	1 (1.4)
Rhinorrhoea	1 (1.4)	1 (1.4)	0	0	0
Throat irritation	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (17.1)	8 (11.4)	3 (4.3)	1 (1.4)	0
Pruritus	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Pain of skin	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Rash	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Skin ulcer	2 (2.9)	1 (1.4)	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blister	1 (1.4)	1 (1.4)	0	0	0
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Ingrowing nail	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	1 (1.4)	0	0	0
Rash maculo-papular	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	13 (18.6)	4 (5.7)	4 (5.7)	3 (4.3)	2 (2.9)
Hypertension	6 (8.6)	2 (2.9)	4 (5.7)	0	0
Hypotension	6 (8.6)	1 (1.4)	0	3 (4.3)	2 (2.9)
Haematoma	1 (1.4)	1 (1.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and

CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205o
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	1 (9.1)	5 (45.5)	4 (36.4)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	4 (36.4)	1 (9.1)
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)	0	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry eye	1 (9.1)	1 (9.1)	0	0	0
Gastrointestinal disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Nausea	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Constipation	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	4 (36.4)	1 (9.1)	3 (27.3)	0	0
Pyrexia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Catheter site pain	1 (9.1)	0	1 (9.1)	0	0
Fatigue	1 (9.1)	0	1 (9.1)	0	0
Hepatobiliary disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Hepatic cytolysis	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hyperbilirubinaemia	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	7 (63.6)	0	2 (18.2)	4 (36.4)	1 (9.1)
Sinusitis	2 (18.2)	0	2 (18.2)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (9.1)	0	0	1 (9.1)	0
Catheter site infection	1 (9.1)	0	1 (9.1)	0	0
Device related bacteraemia	1 (9.1)	0	1 (9.1)	0	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Fungal infection	1 (9.1)	0	1 (9.1)	0	0
Herpes zoster	1 (9.1)	0	0	1 (9.1)	0
Paronychia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	0	0	1 (9.1)	0
Tonsillitis	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	0	1 (9.1)	0
Injury, poisoning and procedural complications					
-Total	1 (9.1)	0	1 (9.1)	0	0
Transfusion reaction	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Hypervolaemia	1 (9.1)	1 (9.1)	0	0	0
Hypokalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophagia	1 (9.1)	0	0	1 (9.1)	0
Hypophosphataemia	1 (9.1)	0	1 (9.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Back pain	1 (9.1)	0	1 (9.1)	0	0
Groin pain	1 (9.1)	1 (9.1)	0	0	0
Osteopenia	1 (9.1)	1 (9.1)	0	0	0
Nervous system disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	1 (9.1)	0	0
Paraesthesia	1 (9.1)	1 (9.1)	0	0	0
Post herpetic neuralgia	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Anxiety	1 (9.1)	0	1 (9.1)	0	0
Insomnia	1 (9.1)	0	1 (9.1)	0	0
Reproductive system and breast disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Heavy menstrual bleeding	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Nasal congestion	1 (9.1)	1 (9.1)	0	0	0
Wheezing	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (18.2)	2 (18.2)	0	0	0
Pruritus	2 (18.2)	2 (18.2)	0	0	0
Vascular disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypertension	1 (9.1)	0	1 (9.1)	0	0

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Table 205o
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (90.8)	3 (3.4)	9 (10.3)	29 (33.3)	38 (43.7)
Blood and lymphatic system disorders					
-Total	44 (50.6)	1 (1.1)	2 (2.3)	25 (28.7)	16 (18.4)
Anaemia	22 (25.3)	2 (2.3)	4 (4.6)	15 (17.2)	1 (1.1)
Febrile neutropenia	20 (23.0)	0	0	19 (21.8)	1 (1.1)
Neutropenia	10 (11.5)	1 (1.1)	0	1 (1.1)	8 (9.2)
Thrombocytopenia	8 (9.2)	1 (1.1)	0	3 (3.4)	4 (4.6)
Pancytopenia	4 (4.6)	0	1 (1.1)	1 (1.1)	2 (2.3)
Leukopenia	3 (3.4)	0	0	0	3 (3.4)
Haemolytic anaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	0	0	1 (1.1)	0
Lymphadenitis	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Cardiac disorders					
-Total	10 (11.5)	3 (3.4)	1 (1.1)	6 (6.9)	0
Tachycardia	6 (6.9)	2 (2.3)	1 (1.1)	3 (3.4)	0
Bradycardia	1 (1.1)	1 (1.1)	0	0	0
Cardiac failure	1 (1.1)	0	0	1 (1.1)	0
Left ventricular dysfunction	1 (1.1)	0	0	1 (1.1)	0
Pericardial effusion	1 (1.1)	0	0	1 (1.1)	0
Ear and labyrinth disorders					
-Total	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Vertigo	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Endocrine disorders					
-Total	6 (6.9)	0	4 (4.6)	1 (1.1)	1 (1.1)
Adrenal insufficiency	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Hypothyroidism	2 (2.3)	0	2 (2.3)	0	0
Addison's disease	1 (1.1)	0	1 (1.1)	0	0
Hypercalcaemia of malignancy	1 (1.1)	0	0	0	1 (1.1)
Eye disorders					

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.1)	1 (1.1)	0	0	0
Eyelid oedema	1 (1.1)	1 (1.1)	0	0	0
Gastrointestinal disorders					
-Total	37 (42.5)	6 (6.9)	12 (13.8)	18 (20.7)	1 (1.1)
Abdominal pain	8 (9.2)	2 (2.3)	4 (4.6)	2 (2.3)	0
Stomatitis	7 (8.0)	0	1 (1.1)	6 (6.9)	0
Constipation	6 (6.9)	2 (2.3)	4 (4.6)	0	0
Nausea	5 (5.7)	1 (1.1)	4 (4.6)	0	0
Diarrhoea	4 (4.6)	1 (1.1)	2 (2.3)	1 (1.1)	0
Neutropenic colitis	3 (3.4)	0	0	3 (3.4)	0
Abdominal pain upper	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Haematemesis	2 (2.3)	2 (2.3)	0	0	0
Oral disorder	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Oral pain	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Vomiting	2 (2.3)	2 (2.3)	0	0	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
Anal fissure	1 (1.1)	0	1 (1.1)	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0
Colitis	1 (1.1)	0	0	1 (1.1)	0
Dry mouth	1 (1.1)	0	1 (1.1)	0	0
Duodenal perforation	1 (1.1)	0	0	1 (1.1)	0
Gastritis	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Gastrooesophageal reflux disease	1 (1.1)	1 (1.1)	0	0	0
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
Haemoperitoneum	1 (1.1)	0	0	0	1 (1.1)
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Hypoaesthesia oral	1 (1.1)	0	1 (1.1)	0	0
Ileus	1 (1.1)	0	0	1 (1.1)	0
Ileus paralytic	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Mouth haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Oral mucosal blistering	1 (1.1)	1 (1.1)	0	0	0
Tongue blistering	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tooth pulp haemorrhage	1 (1.1)	0	0	1 (1.1)	0
General disorders and administration site conditions					
-Total	21 (24.1)	3 (3.4)	14 (16.1)	4 (4.6)	0
Pyrexia	12 (13.8)	2 (2.3)	8 (9.2)	2 (2.3)	0
Pain	5 (5.7)	0	4 (4.6)	1 (1.1)	0
Catheter site pain	4 (4.6)	2 (2.3)	2 (2.3)	0	0
Fatigue	4 (4.6)	1 (1.1)	3 (3.4)	0	0
Chills	2 (2.3)	0	2 (2.3)	0	0
Non-cardiac chest pain	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Oedema peripheral	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Asthenia	1 (1.1)	0	1 (1.1)	0	0
Complication associated with device	1 (1.1)	1 (1.1)	0	0	0
Face oedema	1 (1.1)	1 (1.1)	0	0	0
Mucosal inflammation	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	7 (8.0)	2 (2.3)	1 (1.1)	4 (4.6)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperbilirubinaemia	2 (2.3)	0	0	2 (2.3)	0
Hypertransaminasaemia	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatomegaly	1 (1.1)	1 (1.1)	0	0	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Immune system disorders					
-Total	12 (13.8)	0	8 (9.2)	4 (4.6)	0
Hypogammaglobulinaemia	7 (8.0)	0	6 (6.9)	1 (1.1)	0
Immunodeficiency	2 (2.3)	0	0	2 (2.3)	0
Graft versus host disease	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	0	1 (1.1)	0	0
Immune system disorder	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	44 (50.6)	2 (2.3)	5 (5.7)	26 (29.9)	11 (12.6)
Pneumonia	4 (4.6)	0	1 (1.1)	2 (2.3)	1 (1.1)
Oral herpes	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Staphylococcal bacteraemia	3 (3.4)	0	0	3 (3.4)	0
Acute sinusitis	2 (2.3)	0	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	2 (2.3)	0	0	2 (2.3)	0
Catheter site infection	2 (2.3)	0	0	2 (2.3)	0
Clostridium difficile colitis	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Escherichia bacteraemia	2 (2.3)	0	0	2 (2.3)	0
Localised infection	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.3)	0	0	2 (2.3)	0
Pneumonia fungal	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.3)	0	0	2 (2.3)	0
Septic shock	2 (2.3)	0	0	0	2 (2.3)
Sialoadenitis	2 (2.3)	0	0	2 (2.3)	0
Staphylococcal infection	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.1)	0	0	1 (1.1)	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Herpes zoster	1 (1.1)	0	0	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	11 (12.6)	1 (1.1)	5 (5.7)	4 (4.6)	1 (1.1)
Procedural pain	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Transfusion reaction	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Fall	1 (1.1)	0	1 (1.1)	0	0
Infusion related reaction	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Radius fracture	1 (1.1)	0	1 (1.1)	0	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Wound	1 (1.1)	1 (1.1)	0	0	0
Investigations					
-Total	30 (34.5)	2 (2.3)	1 (1.1)	12 (13.8)	15 (17.2)
Neutrophil count decreased	12 (13.8)	1 (1.1)	0	3 (3.4)	8 (9.2)
Alanine aminotransferase increased	7 (8.0)	1 (1.1)	2 (2.3)	4 (4.6)	0
C-reactive protein increased	7 (8.0)	2 (2.3)	2 (2.3)	2 (2.3)	1 (1.1)
Platelet count decreased	7 (8.0)	0	0	0	7 (8.0)
White blood cell count decreased	7 (8.0)	1 (1.1)	0	0	6 (6.9)
Aspartate aminotransferase increased	5 (5.7)	0	1 (1.1)	3 (3.4)	1 (1.1)
Serum ferritin increased	5 (5.7)	1 (1.1)	1 (1.1)	2 (2.3)	1 (1.1)
Lymphocyte count decreased	4 (4.6)	1 (1.1)	0	1 (1.1)	2 (2.3)
Blood lactate dehydrogenase increased	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Weight decreased	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Blood fibrinogen increased	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Blood glucose increased	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Blood potassium decreased	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Fibrin d dimer increased	2 (2.3)	1 (1.1)	0	0	1 (1.1)
Activated partial thromboplastin time prolonged	1 (1.1)	1 (1.1)	0	0	0
Activated partial thromboplastin time shortened	1 (1.1)	0	1 (1.1)	0	0
Amylase increased	1 (1.1)	0	0	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	0	0	1 (1.1)	0
Blood calcium increased	1 (1.1)	0	0	1 (1.1)	0
Blood fibrinogen decreased	1 (1.1)	0	0	1 (1.1)	0
Blood immunoglobulin g decreased	1 (1.1)	0	1 (1.1)	0	0
Blood immunoglobulin m decreased	1 (1.1)	0	1 (1.1)	0	0
Blood magnesium decreased	1 (1.1)	0	1 (1.1)	0	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0
Blood uric acid increased	1 (1.1)	1 (1.1)	0	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
International normalised ratio increased	1 (1.1)	0	1 (1.1)	0	0
Protein total decreased	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Weight increased	1 (1.1)	0	1 (1.1)	0	0
Metabolism and nutrition disorders					
-Total	22 (25.3)	2 (2.3)	6 (6.9)	10 (11.5)	4 (4.6)
Hypokalaemia	5 (5.7)	2 (2.3)	1 (1.1)	2 (2.3)	0
Decreased appetite	4 (4.6)	1 (1.1)	1 (1.1)	2 (2.3)	0
Hypocalcaemia	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Tumour lysis syndrome	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Hypoalbuminaemia	2 (2.3)	0	2 (2.3)	0	0
Hypomagnesaemia	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Hyponatraemia	2 (2.3)	1 (1.1)	0	0	1 (1.1)
Metabolic acidosis	2 (2.3)	0	0	2 (2.3)	0
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Hyperammonaemia	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypercalcaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperglycaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperkalaemia	1 (1.1)	0	0	1 (1.1)	0
Hyperphosphataemia	1 (1.1)	1 (1.1)	0	0	0
Hyperuricaemia	1 (1.1)	0	1 (1.1)	0	0
Hypervolaemia	1 (1.1)	0	0	1 (1.1)	0
Malnutrition	1 (1.1)	0	1 (1.1)	0	0
Vitamin a deficiency	1 (1.1)	0	1 (1.1)	0	0
Vitamin b1 deficiency	1 (1.1)	1 (1.1)	0	0	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (18.4)	6 (6.9)	6 (6.9)	4 (4.6)	0
Arthralgia	6 (6.9)	4 (4.6)	2 (2.3)	0	0
Pain in extremity	6 (6.9)	1 (1.1)	3 (3.4)	2 (2.3)	0
Back pain	4 (4.6)	1 (1.1)	2 (2.3)	1 (1.1)	0
Bone pain	1 (1.1)	0	1 (1.1)	0	0
Joint effusion	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Pain in jaw	1 (1.1)	0	0	1 (1.1)	0
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.1)	0	0	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	0	0	1 (1.1)
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Nervous system disorders					
-Total	18 (20.7)	7 (8.0)	5 (5.7)	5 (5.7)	1 (1.1)
Headache	7 (8.0)	3 (3.4)	2 (2.3)	2 (2.3)	0
Neuropathy peripheral	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Paraesthesia	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Cognitive disorder	1 (1.1)	0	0	1 (1.1)	0
Dizziness	1 (1.1)	1 (1.1)	0	0	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	0	0	1 (1.1)
Intraventricular haemorrhage	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Peripheral motor neuropathy	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	8 (9.2)	2 (2.3)	3 (3.4)	3 (3.4)	0
Anxiety	3 (3.4)	2 (2.3)	0	1 (1.1)	0
Mental status changes	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Depression	1 (1.1)	0	1 (1.1)	0	0
Insomnia	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					
-Total	5 (5.7)	2 (2.3)	2 (2.3)	1 (1.1)	0
Acute kidney injury	2 (2.3)	2 (2.3)	0	0	0
Haematuria	1 (1.1)	0	1 (1.1)	0	0
Micturition disorder	1 (1.1)	1 (1.1)	0	0	0
Renal tubular necrosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Reproductive system and breast disorders					
-Total	1 (1.1)	0	0	1 (1.1)	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (20.7)	4 (4.6)	4 (4.6)	5 (5.7)	5 (5.7)
Epistaxis	4 (4.6)	2 (2.3)	0	2 (2.3)	0
Hypoxia	4 (4.6)	0	3 (3.4)	1 (1.1)	0
Respiratory failure	4 (4.6)	0	0	0	4 (4.6)
Cough	2 (2.3)	2 (2.3)	0	0	0
Dyspnoea	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Oropharyngeal pain	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Tachypnoea	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Acute respiratory distress syndrome	1 (1.1)	0	0	0	1 (1.1)
Atelectasis	1 (1.1)	0	0	1 (1.1)	0
Haemothorax	1 (1.1)	0	0	0	1 (1.1)
Nasal congestion	1 (1.1)	1 (1.1)	0	0	0
Pneumothorax	1 (1.1)	0	0	0	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (1.1)	0	0	0	1 (1.1)
Rhinorrhoea	1 (1.1)	1 (1.1)	0	0	0
Throat irritation	1 (1.1)	0	1 (1.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (14.9)	8 (9.2)	3 (3.4)	2 (2.3)	0
Skin ulcer	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Pain of skin	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Pruritus	2 (2.3)	0	2 (2.3)	0	0
Rash	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Blister	1 (1.1)	1 (1.1)	0	0	0
Dermatitis exfoliative generalised	1 (1.1)	1 (1.1)	0	0	0
Dry skin	1 (1.1)	1 (1.1)	0	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Ingrowing nail	1 (1.1)	1 (1.1)	0	0	0
Petechiae	1 (1.1)	1 (1.1)	0	0	0
Rash maculo-papular	1 (1.1)	1 (1.1)	0	0	0
Vascular disorders					

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	13 (14.9)	4 (4.6)	4 (4.6)	3 (3.4)	2 (2.3)
Hypertension	6 (6.9)	2 (2.3)	4 (4.6)	0	0
Hypotension	6 (6.9)	1 (1.1)	0	3 (3.4)	2 (2.3)
Haematoma	1 (1.1)	1 (1.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205p
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Blood and lymphatic system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypothyroidism	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Constipation	1 (14.3)	0	1 (14.3)	0	0
Duodenal perforation	1 (14.3)	0	0	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastritis	1 (14.3)	0	1 (14.3)	0	0
Hypoaesthesia oral	1 (14.3)	0	1 (14.3)	0	0
Oral pain	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Complication associated with device	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Decreased appetite	1 (14.3)	1 (14.3)	0	0	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0	0	0
Hypocalcaemia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	0	0	1 (14.3)
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Haemorrhage intracranial	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Atelectasis	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	1 (14.3)	1 (14.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205p
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	84 (92.3)	3 (3.3)	10 (11.0)	31 (34.1)	40 (44.0)
Blood and lymphatic system disorders					
-Total	48 (52.7)	1 (1.1)	2 (2.2)	28 (30.8)	17 (18.7)
Anaemia	23 (25.3)	2 (2.2)	4 (4.4)	16 (17.6)	1 (1.1)
Febrile neutropenia	22 (24.2)	0	0	21 (23.1)	1 (1.1)
Neutropenia	10 (11.0)	0	0	1 (1.1)	9 (9.9)
Thrombocytopenia	9 (9.9)	1 (1.1)	1 (1.1)	3 (3.3)	4 (4.4)
Pancytopenia	4 (4.4)	0	1 (1.1)	1 (1.1)	2 (2.2)
Leukopenia	3 (3.3)	0	0	0	3 (3.3)
Haemolytic anaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	0	0	1 (1.1)	0
Lymphadenitis	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.1)	0	0	0	1 (1.1)
Cardiac disorders					
-Total	10 (11.0)	3 (3.3)	1 (1.1)	6 (6.6)	0
Tachycardia	6 (6.6)	2 (2.2)	1 (1.1)	3 (3.3)	0
Bradycardia	1 (1.1)	1 (1.1)	0	0	0
Cardiac failure	1 (1.1)	0	0	1 (1.1)	0
Left ventricular dysfunction	1 (1.1)	0	0	1 (1.1)	0
Pericardial effusion	1 (1.1)	0	0	1 (1.1)	0
Ear and labyrinth disorders					
-Total	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Vertigo	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Endocrine disorders					
-Total	6 (6.6)	0	4 (4.4)	1 (1.1)	1 (1.1)
Adrenal insufficiency	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Addison's disease	1 (1.1)	0	1 (1.1)	0	0
Hypercalcaemia of malignancy	1 (1.1)	0	0	0	1 (1.1)
Hypothyroidism	1 (1.1)	0	1 (1.1)	0	0
Eye disorders					

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.2)	2 (2.2)	0	0	0
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eyelid oedema	1 (1.1)	1 (1.1)	0	0	0
Gastrointestinal disorders					
-Total	37 (40.7)	6 (6.6)	12 (13.2)	18 (19.8)	1 (1.1)
Abdominal pain	8 (8.8)	2 (2.2)	4 (4.4)	2 (2.2)	0
Nausea	7 (7.7)	1 (1.1)	5 (5.5)	1 (1.1)	0
Constipation	6 (6.6)	3 (3.3)	3 (3.3)	0	0
Stomatitis	6 (6.6)	0	0	6 (6.6)	0
Diarrhoea	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Neutropenic colitis	3 (3.3)	0	0	3 (3.3)	0
Abdominal pain upper	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Haematemesis	2 (2.2)	2 (2.2)	0	0	0
Oral disorder	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Vomiting	2 (2.2)	2 (2.2)	0	0	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
Anal fissure	1 (1.1)	0	1 (1.1)	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0
Colitis	1 (1.1)	0	0	1 (1.1)	0
Dry mouth	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Gastrooesophageal reflux disease	1 (1.1)	1 (1.1)	0	0	0
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
Haemoperitoneum	1 (1.1)	0	0	0	1 (1.1)
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Ileus	1 (1.1)	0	0	1 (1.1)	0
Ileus paralytic	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Mouth haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Oral mucosal blistering	1 (1.1)	1 (1.1)	0	0	0
Oral pain	1 (1.1)	0	0	1 (1.1)	0
Tongue blistering	1 (1.1)	1 (1.1)	0	0	0
Tooth pulp haemorrhage	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	24 (26.4)	3 (3.3)	17 (18.7)	4 (4.4)	0
Pyrexia	14 (15.4)	3 (3.3)	9 (9.9)	2 (2.2)	0
Catheter site pain	5 (5.5)	2 (2.2)	3 (3.3)	0	0
Fatigue	5 (5.5)	1 (1.1)	4 (4.4)	0	0
Pain	5 (5.5)	0	4 (4.4)	1 (1.1)	0
Chills	2 (2.2)	0	2 (2.2)	0	0
Non-cardiac chest pain	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Oedema peripheral	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Asthenia	1 (1.1)	0	1 (1.1)	0	0
Face oedema	1 (1.1)	1 (1.1)	0	0	0
Mucosal inflammation	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	10 (11.0)	3 (3.3)	2 (2.2)	5 (5.5)	0
Hyperbilirubinaemia	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Hepatic cytolysis	2 (2.2)	1 (1.1)	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatomegaly	1 (1.1)	1 (1.1)	0	0	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Immune system disorders					
-Total	12 (13.2)	0	8 (8.8)	4 (4.4)	0
Hypogammaglobulinaemia	7 (7.7)	0	6 (6.6)	1 (1.1)	0
Immunodeficiency	2 (2.2)	0	0	2 (2.2)	0
Graft versus host disease	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	0	1 (1.1)	0	0
Immune system disorder	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	48 (52.7)	2 (2.2)	6 (6.6)	28 (30.8)	12 (13.2)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Oral herpes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Pneumonia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Sinusitis	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Staphylococcal bacteraemia	3 (3.3)	0	0	3 (3.3)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Clostridium difficile colitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Device related infection	2 (2.2)	0	0	2 (2.2)	0
Herpes zoster	2 (2.2)	0	0	2 (2.2)	0
Localised infection	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Parainfluenzae virus infection	2 (2.2)	0	0	2 (2.2)	0
Pneumonia fungal	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	0	0	2 (2.2)	0
Septic shock	2 (2.2)	0	0	0	2 (2.2)
Sialoadenitis	2 (2.2)	0	0	2 (2.2)	0
Staphylococcal infection	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Staphylococcal sepsis	2 (2.2)	0	0	0	2 (2.2)
Urinary tract infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Abscess limb	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Bacterial sepsis	1 (1.1)	0	0	0	1 (1.1)
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (1.1)	0	1 (1.1)	0	0
Bronchopulmonary aspergillosis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cytomegalovirus infection reactivation	1 (1.1)	0	1 (1.1)	0	0
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Epstein-barr virus infection reactivation	1 (1.1)	1 (1.1)	0	0	0
Escherichia bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Fungal infection	1 (1.1)	0	1 (1.1)	0	0
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	0	0	1 (1.1)
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (1.1)	1 (1.1)	0	0	0
Haemophilus bacteraemia	1 (1.1)	0	0	0	1 (1.1)
Herpes simplex	1 (1.1)	0	1 (1.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Paronychia	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pseudomonal bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Sepsis	1 (1.1)	0	0	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Staphylococcal skin infection	1 (1.1)	0	0	1 (1.1)	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Tonsillitis	1 (1.1)	0	1 (1.1)	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	12 (13.2)	1 (1.1)	6 (6.6)	4 (4.4)	1 (1.1)
Procedural pain	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Fall	1 (1.1)	0	1 (1.1)	0	0
Infusion related reaction	1 (1.1)	0	0	1 (1.1)	0
Post procedural haemorrhage	1 (1.1)	0	0	1 (1.1)	0
Radius fracture	1 (1.1)	0	1 (1.1)	0	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Wound	1 (1.1)	1 (1.1)	0	0	0
Investigations					
-Total	28 (30.8)	0	1 (1.1)	11 (12.1)	16 (17.6)
Neutrophil count decreased	11 (12.1)	1 (1.1)	0	2 (2.2)	8 (8.8)
Alanine aminotransferase increased	8 (8.8)	2 (2.2)	2 (2.2)	4 (4.4)	0
Platelet count decreased	8 (8.8)	0	0	0	8 (8.8)
C-reactive protein increased	7 (7.7)	2 (2.2)	2 (2.2)	2 (2.2)	1 (1.1)
White blood cell count decreased	7 (7.7)	1 (1.1)	0	0	6 (6.6)
Aspartate aminotransferase increased	5 (5.5)	0	1 (1.1)	3 (3.3)	1 (1.1)

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	5 (5.5)	1 (1.1)	1 (1.1)	2 (2.2)	1 (1.1)
Lymphocyte count decreased	4 (4.4)	1 (1.1)	0	1 (1.1)	2 (2.2)
Blood lactate dehydrogenase increased	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Weight decreased	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Blood creatinine increased	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Blood fibrinogen increased	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Blood glucose increased	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Blood potassium decreased	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Activated partial thromboplastin time shortened	1 (1.1)	0	1 (1.1)	0	0
Amylase increased	1 (1.1)	0	0	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	0	0	1 (1.1)	0
Blood calcium increased	1 (1.1)	0	0	1 (1.1)	0
Blood fibrinogen decreased	1 (1.1)	0	0	1 (1.1)	0
Blood immunoglobulin g decreased	1 (1.1)	0	1 (1.1)	0	0
Blood immunoglobulin m decreased	1 (1.1)	0	1 (1.1)	0	0
Blood magnesium decreased	1 (1.1)	0	1 (1.1)	0	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (1.1)	1 (1.1)	0	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Fibrin d dimer increased	1 (1.1)	0	0	0	1 (1.1)
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
International normalised ratio increased	1 (1.1)	0	1 (1.1)	0	0
Protein total decreased	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Weight increased	1 (1.1)	0	1 (1.1)	0	0
Metabolism and nutrition disorders					
-Total	23 (25.3)	0	7 (7.7)	12 (13.2)	4 (4.4)
Hypokalaemia	6 (6.6)	2 (2.2)	1 (1.1)	3 (3.3)	0
Decreased appetite	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Hypomagnesaemia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Tumour lysis syndrome	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Hypervolaemia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Hypoalbuminaemia	2 (2.2)	0	2 (2.2)	0	0
Hypocalcaemia	2 (2.2)	0	2 (2.2)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Metabolic acidosis	2 (2.2)	0	0	2 (2.2)	0
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Hyperammonaemia	1 (1.1)	0	0	1 (1.1)	0
Hypercalcaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperglycaemia	1 (1.1)	0	0	0	1 (1.1)
Hyperkalaemia	1 (1.1)	0	0	1 (1.1)	0
Hyperuricaemia	1 (1.1)	0	1 (1.1)	0	0
Hypophagia	1 (1.1)	0	0	1 (1.1)	0
Hypophosphataemia	1 (1.1)	0	1 (1.1)	0	0
Malnutrition	1 (1.1)	0	1 (1.1)	0	0
Vitamin a deficiency	1 (1.1)	0	1 (1.1)	0	0
Vitamin b1 deficiency	1 (1.1)	1 (1.1)	0	0	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (19.8)	7 (7.7)	7 (7.7)	4 (4.4)	0
Arthralgia	6 (6.6)	4 (4.4)	2 (2.2)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	6 (6.6)	1 (1.1)	3 (3.3)	2 (2.2)	0
Back pain	5 (5.5)	1 (1.1)	3 (3.3)	1 (1.1)	0
Bone pain	1 (1.1)	0	1 (1.1)	0	0
Groin pain	1 (1.1)	1 (1.1)	0	0	0
Joint effusion	1 (1.1)	0	0	1 (1.1)	0
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0
Pain in jaw	1 (1.1)	0	0	1 (1.1)	0
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.1)	0	0	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	0	0	1 (1.1)
Skin papilloma	1 (1.1)	1 (1.1)	0	0	0
Nervous system disorders					
-Total	18 (19.8)	6 (6.6)	6 (6.6)	6 (6.6)	0
Headache	8 (8.8)	3 (3.3)	3 (3.3)	2 (2.2)	0
Neuropathy peripheral	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paraesthesia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Cognitive disorder	1 (1.1)	0	0	1 (1.1)	0
Encephalopathy	1 (1.1)	0	0	1 (1.1)	0
Intraventricular haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Lethargy	1 (1.1)	1 (1.1)	0	0	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Peripheral motor neuropathy	1 (1.1)	0	1 (1.1)	0	0
Post herpetic neuralgia	1 (1.1)	0	0	1 (1.1)	0
Seizure	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	10 (11.0)	2 (2.2)	5 (5.5)	3 (3.3)	0
Anxiety	4 (4.4)	2 (2.2)	1 (1.1)	1 (1.1)	0
Mental status changes	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Insomnia	2 (2.2)	0	2 (2.2)	0	0
Agitation	1 (1.1)	1 (1.1)	0	0	0
Depression	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					
-Total	5 (5.5)	2 (2.2)	2 (2.2)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (2.2)	2 (2.2)	0	0	0
Haematuria	1 (1.1)	0	1 (1.1)	0	0
Micturition disorder	1 (1.1)	1 (1.1)	0	0	0
Renal tubular necrosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0
Reproductive system and breast disorders					
-Total	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Heavy menstrual bleeding	1 (1.1)	0	1 (1.1)	0	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (18.7)	5 (5.5)	3 (3.3)	4 (4.4)	5 (5.5)
Epistaxis	4 (4.4)	2 (2.2)	0	2 (2.2)	0
Hypoxia	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Respiratory failure	4 (4.4)	0	0	0	4 (4.4)
Cough	2 (2.2)	2 (2.2)	0	0	0
Dyspnoea	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Nasal congestion	2 (2.2)	2 (2.2)	0	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Acute respiratory distress syndrome	1 (1.1)	0	0	0	1 (1.1)
Haemothorax	1 (1.1)	0	0	0	1 (1.1)
Oropharyngeal pain	1 (1.1)	1 (1.1)	0	0	0
Pneumothorax	1 (1.1)	0	0	0	1 (1.1)
Pulmonary oedema	1 (1.1)	0	0	0	1 (1.1)
Rhinorrhoea	1 (1.1)	1 (1.1)	0	0	0
Throat irritation	1 (1.1)	0	1 (1.1)	0	0
Wheezing	1 (1.1)	1 (1.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (15.4)	9 (9.9)	3 (3.3)	2 (2.2)	0
Pruritus	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Skin ulcer	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Pain of skin	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Rash	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Blister	1 (1.1)	1 (1.1)	0	0	0
Dermatitis exfoliative generalised	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Ingrowing nail	1 (1.1)	1 (1.1)	0	0	0
Petechiae	1 (1.1)	1 (1.1)	0	0	0
Rash maculo-papular	1 (1.1)	1 (1.1)	0	0	0
Vascular disorders					
-Total	14 (15.4)	4 (4.4)	5 (5.5)	3 (3.3)	2 (2.2)
Hypertension	7 (7.7)	2 (2.2)	5 (5.5)	0	0
Hypotension	6 (6.6)	1 (1.1)	0	3 (3.3)	2 (2.2)
Haematoma	1 (1.1)	1 (1.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205q
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	1 (2.5)	2 (5.0)	14 (35.0)	18 (45.0)
Blood and lymphatic system disorders					
-Total	22 (55.0)	0	0	12 (30.0)	10 (25.0)
Febrile neutropenia	10 (25.0)	0	0	10 (25.0)	0
Anaemia	9 (22.5)	0	1 (2.5)	8 (20.0)	0
Neutropenia	9 (22.5)	0	0	0	9 (22.5)
Leukopenia	3 (7.5)	0	0	0	3 (7.5)
Thrombocytopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Lymphadenitis	1 (2.5)	0	1 (2.5)	0	0
Lymphopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	0	0	1 (2.5)	0
Tachycardia	1 (2.5)	0	0	1 (2.5)	0
Ear and labyrinth disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Vertigo	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Adrenal insufficiency	1 (2.5)	0	0	1 (2.5)	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal disorders					
-Total	12 (30.0)	0	3 (7.5)	9 (22.5)	0
Stomatitis	3 (7.5)	0	0	3 (7.5)	0
Constipation	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Nausea	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Neutropenic colitis	2 (5.0)	0	0	2 (5.0)	0
Abdominal pain	1 (2.5)	1 (2.5)	0	0	0
Abdominal pain upper	1 (2.5)	0	1 (2.5)	0	0
Anal fistula	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal inflammation	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Haemorrhoids	1 (2.5)	0	1 (2.5)	0	0
Ileus	1 (2.5)	0	0	1 (2.5)	0
Oral disorder	1 (2.5)	1 (2.5)	0	0	0
Oral mucosal blistering	1 (2.5)	1 (2.5)	0	0	0
Tongue blistering	1 (2.5)	1 (2.5)	0	0	0
Vomiting	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Pyrexia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Chills	2 (5.0)	0	2 (5.0)	0	0
Asthenia	1 (2.5)	0	1 (2.5)	0	0
Fatigue	1 (2.5)	0	1 (2.5)	0	0
Mucosal inflammation	1 (2.5)	0	0	1 (2.5)	0
Non-cardiac chest pain	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	1 (2.5)	0	1 (2.5)	0	0
Thirst	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	5 (12.5)	2 (5.0)	1 (2.5)	2 (5.0)	0
Hepatic cytolysis	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Drug-induced liver injury	1 (2.5)	0	0	1 (2.5)	0
Hepatomegaly	1 (2.5)	1 (2.5)	0	0	0
Hepatosplenomegaly	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	8 (20.0)	0	5 (12.5)	3 (7.5)	0
Hypogammaglobulinaemia	6 (15.0)	0	5 (12.5)	1 (2.5)	0
Immunodeficiency	2 (5.0)	0	0	2 (5.0)	0
Infections and infestations					
-Total	20 (50.0)	1 (2.5)	3 (7.5)	13 (32.5)	3 (7.5)
Catheter site infection	2 (5.0)	0	0	2 (5.0)	0
Herpes zoster	2 (5.0)	0	0	2 (5.0)	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Respiratory tract infection	2 (5.0)	0	0	2 (5.0)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (2.5)	0	0	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Cytomegalovirus infection reactivation	1 (2.5)	0	1 (2.5)	0	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis adenovirus	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Haemophilus bacteraemia	1 (2.5)	0	0	0	1 (2.5)
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Paronychia	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Staphylococcal skin infection	1 (2.5)	0	0	1 (2.5)	0
Stomatococcal infection	1 (2.5)	0	0	0	1 (2.5)
Tonsillitis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0
Vascular device infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	4 (10.0)	0	4 (10.0)	0	0
Extradural haematoma	1 (2.5)	0	1 (2.5)	0	0
Procedural pain	1 (2.5)	0	1 (2.5)	0	0
Radius fracture	1 (2.5)	0	1 (2.5)	0	0
Transfusion reaction	1 (2.5)	0	1 (2.5)	0	0
Traumatic haematoma	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (2.5)	1 (2.5)	0	0	0
Investigations					
-Total	14 (35.0)	0	0	5 (12.5)	9 (22.5)
Neutrophil count decreased	7 (17.5)	0	0	2 (5.0)	5 (12.5)
Platelet count decreased	5 (12.5)	0	0	0	5 (12.5)
White blood cell count decreased	5 (12.5)	0	0	0	5 (12.5)
Alanine aminotransferase increased	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
C-reactive protein increased	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Aspartate aminotransferase increased	2 (5.0)	0	0	2 (5.0)	0
Blood glucose increased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Lymphocyte count decreased	2 (5.0)	0	0	0	2 (5.0)
Activated partial thromboplastin time shortened	1 (2.5)	0	1 (2.5)	0	0
Amylase increased	1 (2.5)	0	0	0	1 (2.5)
Blood bilirubin increased	1 (2.5)	0	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	0	0	1 (2.5)	0
Blood fibrinogen increased	1 (2.5)	1 (2.5)	0	0	0
Blood phosphorus decreased	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (2.5)	0	0	0	1 (2.5)
Eosinophil count decreased	1 (2.5)	1 (2.5)	0	0	0
Haematocrit decreased	1 (2.5)	1 (2.5)	0	0	0
Red blood cell count decreased	1 (2.5)	1 (2.5)	0	0	0
Serum ferritin increased	1 (2.5)	1 (2.5)	0	0	0
Weight decreased	1 (2.5)	0	0	1 (2.5)	0
Weight increased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	4 (10.0)	0	0	3 (7.5)	1 (2.5)
Hypokalaemia	1 (2.5)	0	0	1 (2.5)	0
Hyponatraemia	1 (2.5)	0	0	0	1 (2.5)
Hypophagia	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (20.0)	3 (7.5)	2 (5.0)	3 (7.5)	0
Pain in extremity	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Arthralgia	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Bone pain	1 (2.5)	0	1 (2.5)	0	0
Joint effusion	1 (2.5)	0	0	1 (2.5)	0
Myopathy	1 (2.5)	0	0	1 (2.5)	0
Pain in jaw	1 (2.5)	0	0	1 (2.5)	0
Spinal pain	1 (2.5)	0	0	1 (2.5)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	0	0	1 (2.5)
Acute lymphocytic leukaemia	1 (2.5)	0	0	0	1 (2.5)
Skin papilloma	1 (2.5)	1 (2.5)	0	0	0
Nervous system disorders					
-Total	7 (17.5)	2 (5.0)	2 (5.0)	3 (7.5)	0
Headache	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Neuropathy peripheral	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Neuralgia	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	0	1 (2.5)	0	0
Post herpetic neuralgia	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Anxiety	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Renal and urinary disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Micturition disorder	1 (2.5)	1 (2.5)	0	0	0
Renal tubular necrosis	1 (2.5)	0	0	1 (2.5)	0
Urinary tract disorder	1 (2.5)	0	1 (2.5)	0	0
Reproductive system and breast disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Heavy menstrual bleeding	1 (2.5)	0	1 (2.5)	0	0
Prostatitis	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Epistaxis	2 (5.0)	2 (5.0)	0	0	0
Hypoxia	2 (5.0)	0	2 (5.0)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (2.5)	1 (2.5)	0	0	0
Oropharyngeal pain	1 (2.5)	1 (2.5)	0	0	0
Throat irritation	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (17.5)	5 (12.5)	1 (2.5)	1 (2.5)	0
Blister	1 (2.5)	1 (2.5)	0	0	0
Dermatitis exfoliative generalised	1 (2.5)	1 (2.5)	0	0	0
Erythema nodosum	1 (2.5)	1 (2.5)	0	0	0
Ingrowing nail	1 (2.5)	1 (2.5)	0	0	0
Pain of skin	1 (2.5)	0	0	1 (2.5)	0
Pruritus	1 (2.5)	0	1 (2.5)	0	0
Rash maculo-papular	1 (2.5)	1 (2.5)	0	0	0
Skin ulcer	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	1 (2.5)	0	0	0	1 (2.5)
Hypotension	1 (2.5)	0	0	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205q
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (90.0)	2 (5.0)	7 (17.5)	15 (37.5)	12 (30.0)
Blood and lymphatic system disorders					
-Total	18 (45.0)	1 (2.5)	2 (5.0)	11 (27.5)	4 (10.0)
Anaemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	1 (2.5)	2 (5.0)	2 (5.0)
Neutropenia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Haemolytic anaemia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Tachycardia	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pericardial effusion	1 (2.5)	0	0	1 (2.5)	0
Ear and labyrinth disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Vertigo	1 (2.5)	0	1 (2.5)	0	0
Endocrine disorders					
-Total	3 (7.5)	0	3 (7.5)	0	0
Addison's disease	1 (2.5)	0	1 (2.5)	0	0
Adrenal insufficiency	1 (2.5)	0	1 (2.5)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Dry eye	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	18 (45.0)	4 (10.0)	9 (22.5)	5 (12.5)	0
Abdominal pain	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Constipation	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Nausea	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Stomatitis	3 (7.5)	0	1 (2.5)	2 (5.0)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Anal fissure	1 (2.5)	0	1 (2.5)	0	0
Diarrhoea	1 (2.5)	1 (2.5)	0	0	0
Dry mouth	1 (2.5)	0	1 (2.5)	0	0
Gastrooesophageal reflux disease	1 (2.5)	1 (2.5)	0	0	0
Haematemesis	1 (2.5)	1 (2.5)	0	0	0
Hypoaesthesia oral	1 (2.5)	0	1 (2.5)	0	0
Ileus paralytic	1 (2.5)	1 (2.5)	0	0	0
Lip ulceration	1 (2.5)	0	1 (2.5)	0	0
Mouth haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Neutropenic colitis	1 (2.5)	0	0	1 (2.5)	0
Oral disorder	1 (2.5)	0	0	1 (2.5)	0
Tooth pulp haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Vomiting	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	12 (30.0)	2 (5.0)	10 (25.0)	0	0
Pyrexia	7 (17.5)	2 (5.0)	5 (12.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Catheter site pain	2 (5.0)	0	2 (5.0)	0	0
Pain	2 (5.0)	0	2 (5.0)	0	0
Complication associated with device	1 (2.5)	1 (2.5)	0	0	0
Face oedema	1 (2.5)	1 (2.5)	0	0	0
Non-cardiac chest pain	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Hypertransaminasaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hyperbilirubinaemia	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	2 (5.0)	0	2 (5.0)	0	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Immune system disorder	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	17 (42.5)	1 (2.5)	3 (7.5)	11 (27.5)	2 (5.0)
Sinusitis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Pneumonia	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Catheter site infection	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Epstein-barr virus infection reactivation	1 (2.5)	1 (2.5)	0	0	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pseudomonal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	6 (15.0)	0	2 (5.0)	3 (7.5)	1 (2.5)
Transfusion reaction	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Fall	1 (2.5)	0	1 (2.5)	0	0
Infusion related reaction	1 (2.5)	0	0	1 (2.5)	0
Procedural pain	1 (2.5)	0	0	1 (2.5)	0
Tracheal obstruction	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	13 (32.5)	2 (5.0)	1 (2.5)	4 (10.0)	6 (15.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Alanine aminotransferase increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Blood lactate dehydrogenase increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Serum ferritin increased	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Aspartate aminotransferase increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
C-reactive protein increased	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Fibrin d dimer increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
Weight decreased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
White blood cell count decreased	2 (5.0)	0	0	0	2 (5.0)
Activated partial thromboplastin time prolonged	1 (2.5)	1 (2.5)	0	0	0
Blood calcium increased	1 (2.5)	0	0	1 (2.5)	0
Blood fibrinogen decreased	1 (2.5)	0	0	1 (2.5)	0
Blood fibrinogen increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	1 (2.5)	0	0
Blood uric acid increased	1 (2.5)	1 (2.5)	0	0	0
Electrocardiogram qt prolonged	1 (2.5)	1 (2.5)	0	0	0
International normalised ratio increased	1 (2.5)	0	1 (2.5)	0	0
Lymphocyte count decreased	1 (2.5)	0	0	1 (2.5)	0
Protein total decreased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (35.0)	2 (5.0)	6 (15.0)	5 (12.5)	1 (2.5)
Hypokalaemia	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Decreased appetite	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Hypervolaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hypomagnesaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Eating disorder symptom	1 (2.5)	0	1 (2.5)	0	0
Hypercalcaemia	1 (2.5)	0	0	0	1 (2.5)
Hyperphosphataemia	1 (2.5)	1 (2.5)	0	0	0
Hypoalbuminaemia	1 (2.5)	0	1 (2.5)	0	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0	0	0
Hyponatraemia	1 (2.5)	1 (2.5)	0	0	0
Hypophosphataemia	1 (2.5)	0	1 (2.5)	0	0
Malnutrition	1 (2.5)	0	1 (2.5)	0	0
Vitamin a deficiency	1 (2.5)	0	1 (2.5)	0	0
Vitamin b1 deficiency	1 (2.5)	1 (2.5)	0	0	0
Vitamin d deficiency	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal and connective tissue disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (20.0)	3 (7.5)	4 (10.0)	1 (2.5)	0
Arthralgia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Pain in extremity	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Back pain	2 (5.0)	0	2 (5.0)	0	0
Groin pain	1 (2.5)	1 (2.5)	0	0	0
Osteopenia	1 (2.5)	1 (2.5)	0	0	0
Nervous system disorders					
-Total	8 (20.0)	3 (7.5)	4 (10.0)	1 (2.5)	0
Headache	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Lethargy	1 (2.5)	1 (2.5)	0	0	0
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Peripheral motor neuropathy	1 (2.5)	0	1 (2.5)	0	0
Seizure	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Anxiety	2 (5.0)	1 (2.5)	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	2 (5.0)	0	2 (5.0)	0	0
Depression	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Haematuria	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (22.5)	3 (7.5)	1 (2.5)	4 (10.0)	1 (2.5)
Dyspnoea	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Epistaxis	2 (5.0)	0	0	2 (5.0)	0
Nasal congestion	2 (5.0)	2 (5.0)	0	0	0
Atelectasis	1 (2.5)	0	0	1 (2.5)	0
Cough	1 (2.5)	1 (2.5)	0	0	0
Haemothorax	1 (2.5)	0	0	0	1 (2.5)
Hypoxia	1 (2.5)	0	0	1 (2.5)	0
Oropharyngeal pain	1 (2.5)	0	1 (2.5)	0	0
Pneumothorax	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Rhinorrhoea	1 (2.5)	1 (2.5)	0	0	0
Wheezing	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0
Petechiae	1 (2.5)	1 (2.5)	0	0	0
Rash	1 (2.5)	0	1 (2.5)	0	0
Skin ulcer	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	6 (15.0)	3 (7.5)	3 (7.5)	0	0
Hypertension	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Haematoma	1 (2.5)	1 (2.5)	0	0	0
Hypotension	1 (2.5)	1 (2.5)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to

any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205q
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders					
-Total	9 (50.0)	0	0	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	0	0	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Tachycardia	3 (16.7)	0	1 (5.6)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (5.6)	1 (5.6)	0	0	0
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Adrenal insufficiency	1 (5.6)	0	1 (5.6)	0	0
Hypercalcaemia of malignancy	1 (5.6)	0	0	0	1 (5.6)
Eye disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Eyelid oedema	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	9 (50.0)	2 (11.1)	1 (5.6)	5 (27.8)	1 (5.6)
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain upper	1 (5.6)	1 (5.6)	0	0	0
Colitis	1 (5.6)	0	0	1 (5.6)	0
Duodenal perforation	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastritis	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Haemoperitoneum	1 (5.6)	0	0	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	7 (38.9)	1 (5.6)	3 (16.7)	3 (16.7)	0
Pyrexia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Immune system disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Hypersensitivity	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	14 (77.8)	0	1 (5.6)	6 (33.3)	7 (38.9)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0
Peritonitis	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
Blood magnesium decreased	1 (5.6)	0	1 (5.6)	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (5.6)	0	0	1 (5.6)	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (38.9)	0	1 (5.6)	4 (22.2)	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Hyperammonaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperuricaemia	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	5 (27.8)	2 (11.1)	0	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	0	0	1 (5.6)
Headache	1 (5.6)	1 (5.6)	0	0	0
Intraventricular haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Paraesthesia	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.1)	2 (11.1)	0	0	0
Acute kidney injury	2 (11.1)	2 (11.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (33.3)	0	1 (5.6)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute respiratory distress syndrome	1 (5.6)	0	0	0	1 (5.6)
Hypoxia	1 (5.6)	0	1 (5.6)	0	0
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain of skin	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Skin ulcer	1 (5.6)	0	1 (5.6)	0	0
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	5 (62.5)	3 (37.5)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Tachycardia	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Gastrointestinal disorders					
-Total	4 (50.0)	1 (12.5)	0	2 (25.0)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
Tooth pulp haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Pyrexia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0	0	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood creatinine increased	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Hypocalcaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0
Nervous system disorders					

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Acute kidney injury	2 (25.0)	2 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (37.5)	1 (12.5)	0	0	2 (25.0)
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Hypotension	2 (25.0)	0	0	2 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (90.0)	1 (3.3)	4 (13.3)	11 (36.7)	11 (36.7)
Blood and lymphatic system disorders					
-Total	12 (40.0)	1 (3.3)	0	6 (20.0)	5 (16.7)
Anaemia	7 (23.3)	1 (3.3)	1 (3.3)	5 (16.7)	0
Thrombocytopenia	4 (13.3)	0	0	2 (6.7)	2 (6.7)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Neutropenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Hyperleukocytosis	1 (3.3)	0	0	1 (3.3)	0
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	0	1 (3.3)	0
Cardiac disorders					
-Total	2 (6.7)	1 (3.3)	0	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (3.3)	1 (3.3)	0	0	0
Left ventricular dysfunction	1 (3.3)	0	0	1 (3.3)	0
Endocrine disorders					
-Total	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Hypercalcaemia of malignancy	1 (3.3)	0	0	0	1 (3.3)
Hypothyroidism	1 (3.3)	0	1 (3.3)	0	0
Eye disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Eyelid oedema	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	13 (43.3)	2 (6.7)	5 (16.7)	6 (20.0)	0
Constipation	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Nausea	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Stomatitis	2 (6.7)	0	0	2 (6.7)	0
Abdominal pain	1 (3.3)	0	0	1 (3.3)	0
Abdominal pain upper	1 (3.3)	1 (3.3)	0	0	0
Anal fissure	1 (3.3)	0	1 (3.3)	0	0
Diarrhoea	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Ileus	1 (3.3)	0	0	1 (3.3)	0
Lip ulceration	1 (3.3)	0	1 (3.3)	0	0
Vomiting	1 (3.3)	1 (3.3)	0	0	0
General disorders and administration site conditions					
-Total	8 (26.7)	2 (6.7)	5 (16.7)	1 (3.3)	0
Pyrexia	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Catheter site pain	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Pain	2 (6.7)	0	2 (6.7)	0	0
Face oedema	1 (3.3)	1 (3.3)	0	0	0
Fatigue	1 (3.3)	0	1 (3.3)	0	0
Oedema peripheral	1 (3.3)	0	1 (3.3)	0	0
Hepatobiliary disorders					
-Total	1 (3.3)	0	0	1 (3.3)	0
Hyperbilirubinaemia	1 (3.3)	0	0	1 (3.3)	0
Immune system disorders					

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Hypersensitivity	1 (3.3)	0	1 (3.3)	0	0
Immune system disorder	1 (3.3)	0	1 (3.3)	0	0
Immunodeficiency	1 (3.3)	0	0	1 (3.3)	0
Infections and infestations					
-Total	11 (36.7)	0	0	8 (26.7)	3 (10.0)
Pneumonia fungal	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Acute sinusitis	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Fungal skin infection	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis adenovirus	1 (3.3)	0	0	1 (3.3)	0
Haemophilus bacteraemia	1 (3.3)	0	0	0	1 (3.3)
Klebsiella bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Oral herpes	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Systemic mycosis	1 (3.3)	0	0	1 (3.3)	0
Injury, poisoning and procedural complications					
-Total	2 (6.7)	0	0	2 (6.7)	0
Post procedural haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Transfusion reaction	1 (3.3)	0	0	1 (3.3)	0
Investigations					
-Total	10 (33.3)	1 (3.3)	1 (3.3)	5 (16.7)	3 (10.0)
C-reactive protein increased	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Serum ferritin increased	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Alanine aminotransferase increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Amylase increased	1 (3.3)	0	0	0	1 (3.3)
Aspartate aminotransferase increased	1 (3.3)	0	1 (3.3)	0	0
Blood fibrinogen increased	1 (3.3)	0	1 (3.3)	0	0
Blood lactate dehydrogenase increased	1 (3.3)	0	0	1 (3.3)	0
Blood magnesium decreased	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (3.3)	0	0	1 (3.3)	0
Blood uric acid increased	1 (3.3)	1 (3.3)	0	0	0
Fibrin d dimer increased	1 (3.3)	0	0	0	1 (3.3)
Lymphocyte count decreased	1 (3.3)	0	0	1 (3.3)	0
Neutrophil count decreased	1 (3.3)	0	0	1 (3.3)	0
Platelet count decreased	1 (3.3)	0	0	0	1 (3.3)
Protein total decreased	1 (3.3)	0	1 (3.3)	0	0
Weight decreased	1 (3.3)	0	1 (3.3)	0	0
White blood cell count decreased	1 (3.3)	0	0	0	1 (3.3)
Metabolism and nutrition disorders					
-Total	11 (36.7)	1 (3.3)	3 (10.0)	6 (20.0)	1 (3.3)
Decreased appetite	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Hypokalaemia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Tumour lysis syndrome	2 (6.7)	0	0	2 (6.7)	0
Hyperammonaemia	1 (3.3)	0	0	1 (3.3)	0
Hyperphosphataemia	1 (3.3)	1 (3.3)	0	0	0
Hyperuricaemia	1 (3.3)	0	1 (3.3)	0	0
Hypoalbuminaemia	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (3.3)	0	1 (3.3)	0	0
Hyponatraemia	1 (3.3)	0	0	0	1 (3.3)
Hypophagia	1 (3.3)	0	0	1 (3.3)	0
Vitamin d deficiency	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (16.7)	3 (10.0)	2 (6.7)	0	0
Pain in extremity	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Arthralgia	1 (3.3)	1 (3.3)	0	0	0
Back pain	1 (3.3)	1 (3.3)	0	0	0
Nervous system disorders					
-Total	3 (10.0)	3 (10.0)	0	0	0
Headache	1 (3.3)	1 (3.3)	0	0	0
Intraventricular haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Lethargy	1 (3.3)	1 (3.3)	0	0	0
Paraesthesia	1 (3.3)	1 (3.3)	0	0	0
Psychiatric disorders					
-Total	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Anxiety	1 (3.3)	1 (3.3)	0	0	0
Insomnia	1 (3.3)	0	1 (3.3)	0	0
Renal and urinary disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Haematuria	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (16.7)	0	2 (6.7)	3 (10.0)	0
Epistaxis	2 (6.7)	0	0	2 (6.7)	0
Hypoxia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Oropharyngeal pain	1 (3.3)	0	1 (3.3)	0	0
Tachypnoea	1 (3.3)	0	0	1 (3.3)	0
Skin and subcutaneous tissue disorders					
-Total	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Skin ulcer	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Pain of skin	1 (3.3)	1 (3.3)	0	0	0
Petechiae	1 (3.3)	1 (3.3)	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Hypotension	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Hypertension	1 (3.3)	0	1 (3.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	1 (5.6)	2 (11.1)	7 (38.9)	7 (38.9)
Blood and lymphatic system disorders					
-Total	12 (66.7)	0	1 (5.6)	8 (44.4)	3 (16.7)
Febrile neutropenia	7 (38.9)	0	0	7 (38.9)	0
Anaemia	6 (33.3)	1 (5.6)	2 (11.1)	2 (11.1)	1 (5.6)
Neutropenia	3 (16.7)	1 (5.6)	0	0	2 (11.1)
Thrombocytopenia	3 (16.7)	1 (5.6)	0	1 (5.6)	1 (5.6)
Leukopenia	1 (5.6)	0	0	0	1 (5.6)
Lymphopenia	1 (5.6)	0	0	0	1 (5.6)
Pancytopenia	1 (5.6)	0	1 (5.6)	0	0
Eye disorders					

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	1 (5.6)	0	0	0
Dry eye	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	6 (33.3)	1 (5.6)	2 (11.1)	3 (16.7)	0
Abdominal pain	2 (11.1)	0	2 (11.1)	0	0
Oral pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Stomatitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Anal inflammation	1 (5.6)	0	0	1 (5.6)	0
Constipation	1 (5.6)	0	1 (5.6)	0	0
Gastrooesophageal reflux disease	1 (5.6)	1 (5.6)	0	0	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Hypoaesthesia oral	1 (5.6)	0	1 (5.6)	0	0
Nausea	1 (5.6)	0	1 (5.6)	0	0
Neutropenic colitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	3 (16.7)	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Complication associated with device	1 (5.6)	1 (5.6)	0	0	0
Fatigue	1 (5.6)	0	1 (5.6)	0	0
Non-cardiac chest pain	1 (5.6)	1 (5.6)	0	0	0
Hepatobiliary disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Hyperbilirubinaemia	1 (5.6)	0	1 (5.6)	0	0
Hypertransaminasaemia	1 (5.6)	1 (5.6)	0	0	0
Infections and infestations					
-Total	10 (55.6)	0	2 (11.1)	7 (38.9)	1 (5.6)
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Pneumonia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Sinusitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute sinusitis	1 (5.6)	0	1 (5.6)	0	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bronchitis	1 (5.6)	0	1 (5.6)	0	0
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	1 (5.6)	0	0
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal infection	1 (5.6)	0	0	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	1 (5.6)	0	1 (5.6)	0	0
Transfusion reaction	1 (5.6)	0	1 (5.6)	0	0
Investigations					
-Total	7 (38.9)	1 (5.6)	0	4 (22.2)	2 (11.1)
Alanine aminotransferase increased	3 (16.7)	1 (5.6)	0	2 (11.1)	0
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Serum ferritin increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Activated partial thromboplastin time prolonged	1 (5.6)	1 (5.6)	0	0	0
Aspartate aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Blood calcium increased	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (5.6)	0	0	1 (5.6)	0
Blood glucose increased	1 (5.6)	1 (5.6)	0	0	0
Blood lactate dehydrogenase increased	1 (5.6)	0	0	1 (5.6)	0
Electrocardiogram qt prolonged	1 (5.6)	1 (5.6)	0	0	0
Eosinophil count decreased	1 (5.6)	1 (5.6)	0	0	0
Fibrin d dimer increased	1 (5.6)	1 (5.6)	0	0	0
Haematocrit decreased	1 (5.6)	1 (5.6)	0	0	0
International normalised ratio increased	1 (5.6)	0	1 (5.6)	0	0
Neutrophil count decreased	1 (5.6)	0	0	1 (5.6)	0
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Red blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Weight decreased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	0	0	0	1 (5.6)
Metabolism and nutrition disorders					
-Total	3 (16.7)	1 (5.6)	0	1 (5.6)	1 (5.6)
Hypercalcaemia	1 (5.6)	0	0	0	1 (5.6)
Hypocalcaemia	1 (5.6)	1 (5.6)	0	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (22.2)	3 (16.7)	0	1 (5.6)	0
Arthralgia	2 (11.1)	2 (11.1)	0	0	0
Back pain	1 (5.6)	0	1 (5.6)	0	0
Osteopenia	1 (5.6)	1 (5.6)	0	0	0
Pain in extremity	1 (5.6)	0	0	1 (5.6)	0
Nervous system disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Headache	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Neuralgia	1 (5.6)	0	1 (5.6)	0	0
Psychiatric disorders					
-Total	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Anxiety	1 (5.6)	0	0	1 (5.6)	0
Depression	1 (5.6)	0	1 (5.6)	0	0
Mental status changes	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Atelectasis	1 (5.6)	0	0	1 (5.6)	0
Cough	1 (5.6)	1 (5.6)	0	0	0
Dyspnoea	1 (5.6)	0	0	1 (5.6)	0
Nasal congestion	1 (5.6)	1 (5.6)	0	0	0
Rhinorrhoea	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	2 (11.1)	0	0	0
Dry skin	1 (5.6)	1 (5.6)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Hypertension	1 (5.6)	0	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to

any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 205r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (88.1)	1 (2.4)	4 (9.5)	11 (26.2)	21 (50.0)
Blood and lymphatic system disorders					
-Total	21 (50.0)	0	1 (2.4)	12 (28.6)	8 (19.0)
Febrile neutropenia	11 (26.2)	0	0	10 (23.8)	1 (2.4)
Anaemia	8 (19.0)	0	1 (2.4)	7 (16.7)	0
Neutropenia	5 (11.9)	0	0	0	5 (11.9)
Pancytopenia	2 (4.8)	0	0	0	2 (4.8)
Haemolytic anaemia	1 (2.4)	0	0	0	1 (2.4)
Leukopenia	1 (2.4)	0	0	0	1 (2.4)
Lymphadenitis	1 (2.4)	0	1 (2.4)	0	0
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	5 (11.9)	1 (2.4)	1 (2.4)	3 (7.1)	0
Tachycardia	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Cardiac failure	1 (2.4)	0	0	1 (2.4)	0
Pericardial effusion	1 (2.4)	0	0	1 (2.4)	0
Ear and labyrinth disorders					
-Total	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Vertigo	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Endocrine disorders					
-Total	5 (11.9)	0	4 (9.5)	1 (2.4)	0
Adrenal insufficiency	3 (7.1)	0	2 (4.8)	1 (2.4)	0
Addison's disease	1 (2.4)	0	1 (2.4)	0	0
Hypothyroidism	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	16 (38.1)	2 (4.8)	6 (14.3)	8 (19.0)	0
Abdominal pain	4 (9.5)	2 (4.8)	2 (4.8)	0	0
Constipation	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Diarrhoea	3 (7.1)	1 (2.4)	2 (4.8)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (7.1)	0	3 (7.1)	0	0
Neutropenic colitis	2 (4.8)	0	0	2 (4.8)	0
Oral disorder	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Stomatitis	2 (4.8)	0	0	2 (4.8)	0
Abdominal pain upper	1 (2.4)	0	1 (2.4)	0	0
Anal fistula	1 (2.4)	0	0	1 (2.4)	0
Colitis	1 (2.4)	0	0	1 (2.4)	0
Duodenal perforation	1 (2.4)	0	0	1 (2.4)	0
Gastritis	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal sounds abnormal	1 (2.4)	1 (2.4)	0	0	0
Haemorrhoids	1 (2.4)	0	1 (2.4)	0	0
Ileus paralytic	1 (2.4)	1 (2.4)	0	0	0
Mouth haemorrhage	1 (2.4)	0	1 (2.4)	0	0
Oral mucosal blistering	1 (2.4)	1 (2.4)	0	0	0
Tongue blistering	1 (2.4)	1 (2.4)	0	0	0
Vomiting	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (21.4)	1 (2.4)	6 (14.3)	2 (4.8)	0
Pyrexia	4 (9.5)	0	4 (9.5)	0	0
Fatigue	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Catheter site pain	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Pain	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Asthenia	1 (2.4)	0	1 (2.4)	0	0
Chills	1 (2.4)	0	1 (2.4)	0	0
Mucosal inflammation	1 (2.4)	0	0	1 (2.4)	0
Non-cardiac chest pain	1 (2.4)	0	1 (2.4)	0	0
Oedema peripheral	1 (2.4)	1 (2.4)	0	0	0
Thirst	1 (2.4)	1 (2.4)	0	0	0
Hepatobiliary disorders					
-Total	7 (16.7)	2 (4.8)	1 (2.4)	4 (9.5)	0
Hepatic cytolysis	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Drug-induced liver injury	1 (2.4)	0	0	1 (2.4)	0
Hepatomegaly	1 (2.4)	1 (2.4)	0	0	0
Hepatosplenomegaly	1 (2.4)	0	1 (2.4)	0	0
Hyperbilirubinaemia	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertransaminasaemia	1 (2.4)	0	0	1 (2.4)	0
Immune system disorders					
-Total	8 (19.0)	0	5 (11.9)	3 (7.1)	0
Hypogammaglobulinaemia	6 (14.3)	0	5 (11.9)	1 (2.4)	0
Graft versus host disease	1 (2.4)	0	0	1 (2.4)	0
Immunodeficiency	1 (2.4)	0	0	1 (2.4)	0
Infections and infestations					
-Total	24 (57.1)	2 (4.8)	5 (11.9)	11 (26.2)	6 (14.3)
Bacteraemia	2 (4.8)	0	0	2 (4.8)	0
Catheter site infection	2 (4.8)	0	0	2 (4.8)	0
Herpes zoster	2 (4.8)	0	0	2 (4.8)	0
Parainfluenzae virus infection	2 (4.8)	0	0	2 (4.8)	0
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Septic shock	2 (4.8)	0	0	0	2 (4.8)
Staphylococcal sepsis	2 (4.8)	0	0	0	2 (4.8)
Abscess limb	1 (2.4)	0	0	1 (2.4)	0
Bacterial sepsis	1 (2.4)	0	0	0	1 (2.4)
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	0	1 (2.4)	0	0
Cytomegalovirus infection reactivation	1 (2.4)	0	1 (2.4)	0	0
Device related bacteraemia	1 (2.4)	0	1 (2.4)	0	0
Device related infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection	1 (2.4)	0	1 (2.4)	0	0
Epstein-barr virus infection reactivation	1 (2.4)	1 (2.4)	0	0	0
Fungal infection	1 (2.4)	0	1 (2.4)	0	0
Fungal pharyngitis	1 (2.4)	0	0	1 (2.4)	0
Fungal sepsis	1 (2.4)	0	0	0	1 (2.4)
Gastroenteritis	1 (2.4)	0	1 (2.4)	0	0
Gingivitis	1 (2.4)	1 (2.4)	0	0	0
Herpes simplex	1 (2.4)	0	1 (2.4)	0	0
Paronychia	1 (2.4)	0	0	1 (2.4)	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal skin infection	1 (2.4)	0	0	1 (2.4)	0
Stomatococcal infection	1 (2.4)	0	0	0	1 (2.4)
Tonsillitis	1 (2.4)	0	1 (2.4)	0	0
Urinary tract infection	1 (2.4)	0	1 (2.4)	0	0
Vascular device infection	1 (2.4)	0	0	1 (2.4)	0
Injury, poisoning and procedural complications					
-Total	8 (19.0)	1 (2.4)	4 (9.5)	2 (4.8)	1 (2.4)
Procedural pain	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Extradural haematoma	1 (2.4)	0	1 (2.4)	0	0
Fall	1 (2.4)	0	1 (2.4)	0	0
Infusion related reaction	1 (2.4)	0	0	1 (2.4)	0
Tracheal obstruction	1 (2.4)	0	0	0	1 (2.4)
Transfusion reaction	1 (2.4)	0	1 (2.4)	0	0
Traumatic haematoma	1 (2.4)	0	1 (2.4)	0	0
Wound	1 (2.4)	1 (2.4)	0	0	0
Investigations					

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (28.6)	0	0	2 (4.8)	10 (23.8)
Neutrophil count decreased	9 (21.4)	1 (2.4)	0	1 (2.4)	7 (16.7)
Platelet count decreased	6 (14.3)	0	0	0	6 (14.3)
White blood cell count decreased	5 (11.9)	0	0	0	5 (11.9)
Aspartate aminotransferase increased	2 (4.8)	0	0	2 (4.8)	0
C-reactive protein increased	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Lymphocyte count decreased	2 (4.8)	0	0	0	2 (4.8)
Activated partial thromboplastin time shortened	1 (2.4)	0	1 (2.4)	0	0
Alanine aminotransferase increased	1 (2.4)	0	1 (2.4)	0	0
Blood bilirubin increased	1 (2.4)	0	0	1 (2.4)	0
Blood creatinine increased	1 (2.4)	0	0	1 (2.4)	0
Blood fibrinogen increased	1 (2.4)	1 (2.4)	0	0	0
Blood glucose increased	1 (2.4)	0	1 (2.4)	0	0
Blood lactate dehydrogenase increased	1 (2.4)	0	1 (2.4)	0	0
Blood phosphorus decreased	1 (2.4)	0	0	1 (2.4)	0
Blood potassium decreased	1 (2.4)	0	0	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (2.4)	1 (2.4)	0	0	0
Weight increased	1 (2.4)	0	1 (2.4)	0	0
Metabolism and nutrition disorders					
-Total	8 (19.0)	0	4 (9.5)	2 (4.8)	2 (4.8)
Hypervolaemia	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Hypokalaemia	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Decreased appetite	1 (2.4)	0	1 (2.4)	0	0
Eating disorder symptom	1 (2.4)	0	1 (2.4)	0	0
Hyperglycaemia	1 (2.4)	0	0	0	1 (2.4)
Hypomagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Hyponatraemia	1 (2.4)	1 (2.4)	0	0	0
Hypophosphataemia	1 (2.4)	0	1 (2.4)	0	0
Malnutrition	1 (2.4)	0	1 (2.4)	0	0
Tumour lysis syndrome	1 (2.4)	0	0	0	1 (2.4)
Vitamin a deficiency	1 (2.4)	0	1 (2.4)	0	0
Vitamin b1 deficiency	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal and connective tissue disorders					

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (19.0)	1 (2.4)	5 (11.9)	2 (4.8)	0
Arthralgia	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Back pain	3 (7.1)	0	2 (4.8)	1 (2.4)	0
Bone pain	1 (2.4)	0	1 (2.4)	0	0
Groin pain	1 (2.4)	1 (2.4)	0	0	0
Joint effusion	1 (2.4)	0	0	1 (2.4)	0
Myopathy	1 (2.4)	0	0	1 (2.4)	0
Pain in extremity	1 (2.4)	0	1 (2.4)	0	0
Pain in jaw	1 (2.4)	0	0	1 (2.4)	0
Spinal pain	1 (2.4)	0	0	1 (2.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.4)	0	0	0	1 (2.4)
Acute lymphocytic leukaemia	1 (2.4)	0	0	0	1 (2.4)
Skin papilloma	1 (2.4)	1 (2.4)	0	0	0
Nervous system disorders					
-Total	11 (26.2)	2 (4.8)	4 (9.5)	4 (9.5)	1 (2.4)
Headache	5 (11.9)	1 (2.4)	3 (7.1)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Paraesthesia	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Encephalopathy	1 (2.4)	0	0	1 (2.4)	0
Haemorrhage intracranial	1 (2.4)	0	0	0	1 (2.4)
Peripheral motor neuropathy	1 (2.4)	0	1 (2.4)	0	0
Post herpetic neuralgia	1 (2.4)	0	0	1 (2.4)	0
Seizure	1 (2.4)	0	1 (2.4)	0	0
Psychiatric disorders					
-Total	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Anxiety	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Agitation	1 (2.4)	1 (2.4)	0	0	0
Insomnia	1 (2.4)	0	1 (2.4)	0	0
Renal and urinary disorders					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Micturition disorder	1 (2.4)	1 (2.4)	0	0	0
Renal tubular necrosis	1 (2.4)	0	0	1 (2.4)	0
Urinary tract disorder	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Heavy menstrual bleeding	1 (2.4)	0	1 (2.4)	0	0
Prostatitis	1 (2.4)	0	0	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (19.0)	3 (7.1)	2 (4.8)	0	3 (7.1)
Epistaxis	2 (4.8)	2 (4.8)	0	0	0
Hypoxia	2 (4.8)	0	2 (4.8)	0	0
Respiratory failure	2 (4.8)	0	0	0	2 (4.8)
Acute respiratory distress syndrome	1 (2.4)	0	0	0	1 (2.4)
Cough	1 (2.4)	1 (2.4)	0	0	0
Dyspnoea	1 (2.4)	1 (2.4)	0	0	0
Haemothorax	1 (2.4)	0	0	0	1 (2.4)
Nasal congestion	1 (2.4)	1 (2.4)	0	0	0
Pneumothorax	1 (2.4)	0	0	0	1 (2.4)
Tachypnoea	1 (2.4)	0	1 (2.4)	0	0
Throat irritation	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (2.4)	1 (2.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (21.4)	6 (14.3)	2 (4.8)	1 (2.4)	0
Pruritus	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Rash	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Blister	1 (2.4)	1 (2.4)	0	0	0
Dermatitis exfoliative generalised	1 (2.4)	1 (2.4)	0	0	0
Erythema nodosum	1 (2.4)	1 (2.4)	0	0	0
Pain of skin	1 (2.4)	0	0	1 (2.4)	0
Rash maculo-papular	1 (2.4)	1 (2.4)	0	0	0
Skin ulcer	1 (2.4)	1 (2.4)	0	0	0
Vascular disorders					
-Total	8 (19.0)	4 (9.5)	3 (7.1)	0	1 (2.4)
Hypertension	5 (11.9)	2 (4.8)	3 (7.1)	0	0
Hypotension	2 (4.8)	1 (2.4)	0	0	1 (2.4)
Haematoma	1 (2.4)	1 (2.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility. -Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. -MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206a
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (79.4)	6 (17.6)	5 (14.7)	3 (8.8)	13 (38.2)
Blood and lymphatic system disorders					
-Total	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)
Anaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Lymphopenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	0	1 (2.9)
Cardiac disorders					
-Total	2 (5.9)	2 (5.9)	0	0	0
Tachycardia	2 (5.9)	2 (5.9)	0	0	0
Eye disorders					
-Total	3 (8.8)	2 (5.9)	1 (2.9)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye pain	1 (2.9)	1 (2.9)	0	0	0
Eyelid oedema	1 (2.9)	0	1 (2.9)	0	0
Vision blurred	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	10 (29.4)	6 (17.6)	4 (11.8)	0	0
Nausea	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Diarrhoea	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Vomiting	3 (8.8)	3 (8.8)	0	0	0
Abdominal pain	2 (5.9)	2 (5.9)	0	0	0
Stomatitis	2 (5.9)	0	2 (5.9)	0	0
Gingival bleeding	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
Pyrexia	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Catheter site dermatitis	1 (2.9)	1 (2.9)	0	0	0
Chills	1 (2.9)	1 (2.9)	0	0	0
Generalised oedema	1 (2.9)	0	0	1 (2.9)	0

Age: <10 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised oedema	1 (2.9)	0	1 (2.9)	0	0
Infections and infestations					
-Total	5 (14.7)	1 (2.9)	2 (5.9)	1 (2.9)	1 (2.9)
Conjunctivitis	1 (2.9)	1 (2.9)	0	0	0
Device related infection	1 (2.9)	0	1 (2.9)	0	0
Fungaemia	1 (2.9)	0	0	0	1 (2.9)
Nasopharyngitis	1 (2.9)	1 (2.9)	0	0	0
Upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Vulval cellulitis	1 (2.9)	0	0	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Fall	1 (2.9)	1 (2.9)	0	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Investigations					
-Total	13 (38.2)	0	1 (2.9)	1 (2.9)	11 (32.4)
White blood cell count decreased	7 (20.6)	0	1 (2.9)	1 (2.9)	5 (14.7)
Lymphocyte count decreased	5 (14.7)	0	0	0	5 (14.7)

Age: <10 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (14.7)	0	0	1 (2.9)	4 (11.8)
Neutrophil count decreased	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Alanine aminotransferase increased	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0	0	0
Blood phosphorus increased	1 (2.9)	0	1 (2.9)	0	0
C-reactive protein increased	1 (2.9)	0	0	1 (2.9)	0
Weight increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (20.6)	5 (14.7)	2 (5.9)	0	0
Decreased appetite	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Hyperphosphataemia	2 (5.9)	2 (5.9)	0	0	0
Hypoalbuminaemia	2 (5.9)	2 (5.9)	0	0	0
Hypocalcaemia	1 (2.9)	1 (2.9)	0	0	0
Hyponatraemia	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Bone pain	1 (2.9)	0	1 (2.9)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	1 (2.9)	1 (2.9)	0	0	0
Nervous system disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Headache	1 (2.9)	1 (2.9)	0	0	0
Somnolence	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Irritability	1 (2.9)	0	0	1 (2.9)	0
Renal and urinary disorders					
-Total	2 (5.9)	2 (5.9)	0	0	0
Acute kidney injury	1 (2.9)	1 (2.9)	0	0	0
Dysuria	1 (2.9)	1 (2.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (14.7)	3 (8.8)	0	1 (2.9)	1 (2.9)
Cough	2 (5.9)	2 (5.9)	0	0	0
Epistaxis	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Oropharyngeal pain	1 (2.9)	1 (2.9)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary haemorrhage	1 (2.9)	0	0	0	1 (2.9)
Pulmonary oedema	1 (2.9)	1 (2.9)	0	0	0
Respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Skin and subcutaneous tissue disorders					
-Total	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Rash	2 (5.9)	2 (5.9)	0	0	0
Rash papular	2 (5.9)	2 (5.9)	0	0	0
Petechiae	1 (2.9)	1 (2.9)	0	0	0
Pruritus	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Hypotension	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Hypertension	1 (2.9)	0	1 (2.9)	0	0
Peripheral ischaemia	1 (2.9)	0	1 (2.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between

the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206a
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (87.1)	9 (29.0)	7 (22.6)	4 (12.9)	7 (22.6)
Blood and lymphatic system disorders					
-Total	5 (16.1)	1 (3.2)	0	2 (6.5)	2 (6.5)
Anaemia	4 (12.9)	1 (3.2)	0	3 (9.7)	0
Febrile neutropenia	2 (6.5)	0	0	2 (6.5)	0
Leukopenia	1 (3.2)	0	0	0	1 (3.2)
Neutropenia	1 (3.2)	0	0	0	1 (3.2)
Gastrointestinal disorders					
-Total	10 (32.3)	4 (12.9)	4 (12.9)	2 (6.5)	0
Nausea	5 (16.1)	1 (3.2)	3 (9.7)	1 (3.2)	0
Vomiting	3 (9.7)	1 (3.2)	1 (3.2)	1 (3.2)	0

Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (3.2)	1 (3.2)	0	0	0
Constipation	1 (3.2)	1 (3.2)	0	0	0
Gingival bleeding	1 (3.2)	1 (3.2)	0	0	0
Haematemesis	1 (3.2)	1 (3.2)	0	0	0
Lip pain	1 (3.2)	1 (3.2)	0	0	0
Stomatitis	1 (3.2)	0	0	1 (3.2)	0
General disorders and administration site conditions					
-Total	6 (19.4)	3 (9.7)	3 (9.7)	0	0
Catheter site pain	1 (3.2)	0	1 (3.2)	0	0
Chills	1 (3.2)	0	1 (3.2)	0	0
Fatigue	1 (3.2)	1 (3.2)	0	0	0
Oedema peripheral	1 (3.2)	1 (3.2)	0	0	0
Pyrexia	1 (3.2)	0	1 (3.2)	0	0
Vascular device occlusion	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Hypogammaglobulinaemia	2 (6.5)	0	1 (3.2)	1 (3.2)	0

Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Paronychia	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Tinea pedis	1 (3.2)	1 (3.2)	0	0	0
Investigations					
-Total	10 (32.3)	3 (9.7)	1 (3.2)	2 (6.5)	4 (12.9)
White blood cell count decreased	4 (12.9)	0	0	1 (3.2)	3 (9.7)
Neutrophil count decreased	3 (9.7)	0	1 (3.2)	0	2 (6.5)
Blood fibrinogen decreased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0	0	0
Aspartate aminotransferase increased	1 (3.2)	1 (3.2)	0	0	0
Blood alkaline phosphatase decreased	1 (3.2)	1 (3.2)	0	0	0
Blood fibrinogen increased	1 (3.2)	1 (3.2)	0	0	0
International normalised ratio increased	1 (3.2)	1 (3.2)	0	0	0
Lymphocyte count decreased	1 (3.2)	0	0	0	1 (3.2)
Platelet count decreased	1 (3.2)	0	0	0	1 (3.2)

Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (3.2)	0	1 (3.2)	0	0
Metabolism and nutrition disorders					
-Total	6 (19.4)	2 (6.5)	1 (3.2)	2 (6.5)	1 (3.2)
Decreased appetite	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Hypokalaemia	3 (9.7)	0	0	2 (6.5)	1 (3.2)
Hypomagnesaemia	1 (3.2)	1 (3.2)	0	0	0
Hypophosphataemia	1 (3.2)	0	0	1 (3.2)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Muscular weakness	1 (3.2)	0	1 (3.2)	0	0
Nervous system disorders					
-Total	2 (6.5)	0	2 (6.5)	0	0
Headache	1 (3.2)	0	1 (3.2)	0	0
Posterior reversible encephalopathy syndrome	1 (3.2)	0	1 (3.2)	0	0
Seizure	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal pain	1 (3.2)	1 (3.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Cough	1 (3.2)	1 (3.2)	0	0	0
Pleural effusion	1 (3.2)	0	1 (3.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.9)	2 (6.5)	2 (6.5)	0	0
Acne	1 (3.2)	1 (3.2)	0	0	0
Drug eruption	1 (3.2)	0	1 (3.2)	0	0
Erythema	1 (3.2)	1 (3.2)	0	0	0
Ingrowing nail	1 (3.2)	0	1 (3.2)	0	0
Pruritus	1 (3.2)	1 (3.2)	0	0	0
Vascular disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Hypotension	1 (3.2)	0	1 (3.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis

product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206a
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (61.5)	3 (23.1)	2 (15.4)	2 (15.4)	1 (7.7)
Blood and lymphatic system disorders					
-Total	2 (15.4)	0	0	2 (15.4)	0
Febrile neutropenia	2 (15.4)	0	0	2 (15.4)	0
Endocrine disorders					
-Total	1 (7.7)	0	1 (7.7)	0	0
Adrenal insufficiency	1 (7.7)	0	1 (7.7)	0	0
Gastrointestinal disorders					
-Total	5 (38.5)	2 (15.4)	3 (23.1)	0	0
Nausea	3 (23.1)	1 (7.7)	2 (15.4)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal erythema	1 (7.7)	1 (7.7)	0	0	0
Constipation	1 (7.7)	0	1 (7.7)	0	0
Stomatitis	1 (7.7)	0	1 (7.7)	0	0
Vomiting	1 (7.7)	1 (7.7)	0	0	0
General disorders and administration site conditions					
-Total	1 (7.7)	0	1 (7.7)	0	0
Pyrexia	1 (7.7)	0	1 (7.7)	0	0
Immune system disorders					
-Total	1 (7.7)	0	1 (7.7)	0	0
Seasonal allergy	1 (7.7)	0	1 (7.7)	0	0
Infections and infestations					
-Total	3 (23.1)	0	0	2 (15.4)	1 (7.7)
Bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Escherichia bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Oral herpes	1 (7.7)	0	0	1 (7.7)	0
Staphylococcal bacteraemia	1 (7.7)	0	0	1 (7.7)	0

Age: >=18

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	1 (7.7)	1 (7.7)	0	0	0
International normalised ratio increased	1 (7.7)	1 (7.7)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Hypocalcaemia	1 (7.7)	0	0	1 (7.7)	0
Hypomagnesaemia	1 (7.7)	0	1 (7.7)	0	0
Hypophosphataemia	1 (7.7)	0	1 (7.7)	0	0
Vitamin d deficiency	1 (7.7)	1 (7.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (7.7)	0	0	1 (7.7)	0
Pain in jaw	1 (7.7)	0	0	1 (7.7)	0
Nervous system disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Headache	1 (7.7)	1 (7.7)	0	0	0
Skin and subcutaneous tissue disorders					

Age: >=18

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Pruritus	2 (15.4)	1 (7.7)	1 (7.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206b
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (78.3)	11 (23.9)	7 (15.2)	4 (8.7)	14 (30.4)
Blood and lymphatic system disorders					
-Total	8 (17.4)	0	0	4 (8.7)	4 (8.7)
Anaemia	5 (10.9)	0	0	5 (10.9)	0
Febrile neutropenia	1 (2.2)	0	0	1 (2.2)	0
Leukopenia	1 (2.2)	0	0	0	1 (2.2)
Lymphopenia	1 (2.2)	0	0	0	1 (2.2)
Neutropenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Cardiac disorders					
-Total	2 (4.3)	2 (4.3)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	2 (4.3)	2 (4.3)	0	0	0
Gastrointestinal disorders					
-Total	11 (23.9)	8 (17.4)	2 (4.3)	1 (2.2)	0
Nausea	5 (10.9)	2 (4.3)	2 (4.3)	1 (2.2)	0
Vomiting	3 (6.5)	3 (6.5)	0	0	0
Diarrhoea	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Abdominal pain	1 (2.2)	1 (2.2)	0	0	0
Constipation	1 (2.2)	1 (2.2)	0	0	0
Gingival bleeding	1 (2.2)	1 (2.2)	0	0	0
Stomatitis	1 (2.2)	0	0	1 (2.2)	0
General disorders and administration site conditions					
-Total	11 (23.9)	7 (15.2)	3 (6.5)	1 (2.2)	0
Pyrexia	7 (15.2)	4 (8.7)	3 (6.5)	0	0
Catheter site dermatitis	1 (2.2)	1 (2.2)	0	0	0
Chills	1 (2.2)	1 (2.2)	0	0	0
Generalised oedema	1 (2.2)	0	0	1 (2.2)	0
Oedema peripheral	1 (2.2)	1 (2.2)	0	0	0

Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device occlusion	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Hypogammaglobulinaemia	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Infections and infestations					
-Total	4 (8.7)	2 (4.3)	1 (2.2)	0	1 (2.2)
Conjunctivitis	1 (2.2)	1 (2.2)	0	0	0
Fungaemia	1 (2.2)	0	0	0	1 (2.2)
Nasopharyngitis	1 (2.2)	1 (2.2)	0	0	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Upper respiratory tract infection	1 (2.2)	0	1 (2.2)	0	0
Injury, poisoning and procedural complications					
-Total	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Fall	1 (2.2)	1 (2.2)	0	0	0
Infusion related reaction	1 (2.2)	0	1 (2.2)	0	0
Investigations					
-Total	15 (32.6)	3 (6.5)	2 (4.3)	1 (2.2)	9 (19.6)

Gender: Male

Primary system organ class Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	6 (13.0)	0	1 (2.2)	1 (2.2)	4 (8.7)
Lymphocyte count decreased	4 (8.7)	0	0	0	4 (8.7)
Platelet count decreased	4 (8.7)	0	0	1 (2.2)	3 (6.5)
Neutrophil count decreased	3 (6.5)	0	0	0	3 (6.5)
Alanine aminotransferase increased	1 (2.2)	0	1 (2.2)	0	0
Blood alkaline phosphatase decreased	1 (2.2)	1 (2.2)	0	0	0
Blood fibrinogen increased	1 (2.2)	1 (2.2)	0	0	0
Blood phosphorus increased	1 (2.2)	0	1 (2.2)	0	0
C-reactive protein increased	1 (2.2)	0	0	1 (2.2)	0
International normalised ratio increased	1 (2.2)	1 (2.2)	0	0	0
Serum ferritin increased	1 (2.2)	0	1 (2.2)	0	0
Weight increased	1 (2.2)	1 (2.2)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (17.4)	5 (10.9)	1 (2.2)	1 (2.2)	1 (2.2)
Decreased appetite	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Hyperphosphataemia	2 (4.3)	2 (4.3)	0	0	0
Hypokalaemia	2 (4.3)	0	0	1 (2.2)	1 (2.2)

Gender: Male

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (2.2)	1 (2.2)	0	0	0
Hypocalcaemia	1 (2.2)	1 (2.2)	0	0	0
Nervous system disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Headache	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	2 (4.3)	2 (4.3)	0	0	0
Acute kidney injury	1 (2.2)	1 (2.2)	0	0	0
Renal pain	1 (2.2)	1 (2.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (13.0)	4 (8.7)	1 (2.2)	0	1 (2.2)
Cough	2 (4.3)	2 (4.3)	0	0	0
Epistaxis	1 (2.2)	1 (2.2)	0	0	0
Oropharyngeal pain	1 (2.2)	1 (2.2)	0	0	0
Pleural effusion	1 (2.2)	0	1 (2.2)	0	0
Pulmonary haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Pulmonary oedema	1 (2.2)	1 (2.2)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (2.2)	0	0	0	1 (2.2)
Skin and subcutaneous tissue disorders					
-Total	4 (8.7)	3 (6.5)	1 (2.2)	0	0
Acne	1 (2.2)	1 (2.2)	0	0	0
Drug eruption	1 (2.2)	0	1 (2.2)	0	0
Rash	1 (2.2)	1 (2.2)	0	0	0
Rash papular	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Hypotension	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Flushing	1 (2.2)	1 (2.2)	0	0	0
Hypertension	1 (2.2)	0	1 (2.2)	0	0
Peripheral ischaemia	1 (2.2)	0	1 (2.2)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted

only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206b
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (81.3)	7 (21.9)	7 (21.9)	5 (15.6)	7 (21.9)
Blood and lymphatic system disorders					
-Total	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Anaemia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Febrile neutropenia	3 (9.4)	0	0	3 (9.4)	0
Endocrine disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Adrenal insufficiency	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Eye pain	1 (3.1)	1 (3.1)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eyelid oedema	1 (3.1)	0	1 (3.1)	0	0
Vision blurred	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	14 (43.8)	4 (12.5)	9 (28.1)	1 (3.1)	0
Nausea	8 (25.0)	3 (9.4)	5 (15.6)	0	0
Vomiting	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Stomatitis	3 (9.4)	0	3 (9.4)	0	0
Abdominal pain	2 (6.3)	2 (6.3)	0	0	0
Anal erythema	1 (3.1)	1 (3.1)	0	0	0
Constipation	1 (3.1)	0	1 (3.1)	0	0
Diarrhoea	1 (3.1)	1 (3.1)	0	0	0
Gingival bleeding	1 (3.1)	1 (3.1)	0	0	0
Haematemesis	1 (3.1)	1 (3.1)	0	0	0
Lip pain	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Catheter site pain	1 (3.1)	0	1 (3.1)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Chills	1 (3.1)	0	1 (3.1)	0	0
Fatigue	1 (3.1)	1 (3.1)	0	0	0
Localised oedema	1 (3.1)	0	1 (3.1)	0	0
Pyrexia	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Seasonal allergy	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	7 (21.9)	1 (3.1)	2 (6.3)	3 (9.4)	1 (3.1)
Paronychia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Device related infection	1 (3.1)	0	1 (3.1)	0	0
Escherichia bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Oral herpes	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Vulval cellulitis	1 (3.1)	0	0	1 (3.1)	0
Investigations					

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (28.1)	1 (3.1)	0	2 (6.3)	6 (18.8)
White blood cell count decreased	5 (15.6)	0	0	1 (3.1)	4 (12.5)
Neutrophil count decreased	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
Alanine aminotransferase increased	2 (6.3)	2 (6.3)	0	0	0
Aspartate aminotransferase increased	2 (6.3)	2 (6.3)	0	0	0
Blood fibrinogen decreased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Lymphocyte count decreased	2 (6.3)	0	0	0	2 (6.3)
Platelet count decreased	2 (6.3)	0	0	0	2 (6.3)
International normalised ratio increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (25.0)	3 (9.4)	3 (9.4)	2 (6.3)	0
Decreased appetite	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Hypomagnesaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hypophosphataemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Hypoalbuminaemia	1 (3.1)	1 (3.1)	0	0	0
Hypocalcaemia	1 (3.1)	0	0	1 (3.1)	0
Hypokalaemia	1 (3.1)	0	0	1 (3.1)	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyponatraemia	1 (3.1)	1 (3.1)	0	0	0
Vitamin d deficiency	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Bone pain	1 (3.1)	0	1 (3.1)	0	0
Muscular weakness	1 (3.1)	0	1 (3.1)	0	0
Pain in extremity	1 (3.1)	1 (3.1)	0	0	0
Pain in jaw	1 (3.1)	0	0	1 (3.1)	0
Nervous system disorders					
-Total	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Headache	2 (6.3)	2 (6.3)	0	0	0
Posterior reversible encephalopathy syndrome	1 (3.1)	0	1 (3.1)	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	1 (3.1)	0	0	1 (3.1)	0
Irritability	1 (3.1)	0	0	1 (3.1)	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Dysuria	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.1)	0	0	1 (3.1)	0
Cough	1 (3.1)	1 (3.1)	0	0	0
Epistaxis	1 (3.1)	0	0	1 (3.1)	0
Skin and subcutaneous tissue disorders					
-Total	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Pruritus	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Erythema	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Petechiae	1 (3.1)	1 (3.1)	0	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (3.1)	1 (3.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206c
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (78.9)	11 (19.3)	12 (21.1)	7 (12.3)	15 (26.3)
Blood and lymphatic system disorders					
-Total	10 (17.5)	1 (1.8)	0	5 (8.8)	4 (7.0)
Anaemia	6 (10.5)	1 (1.8)	0	5 (8.8)	0
Febrile neutropenia	2 (3.5)	0	0	2 (3.5)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)
Neutropenia	1 (1.8)	0	0	0	1 (1.8)
Thrombocytopenia	1 (1.8)	0	0	0	1 (1.8)
Cardiac disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	1 (1.8)	1 (1.8)	0	0	0
Eye disorders					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Eye pain	1 (1.8)	1 (1.8)	0	0	0
Eyelid oedema	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal disorders					
-Total	16 (28.1)	9 (15.8)	6 (10.5)	1 (1.8)	0
Nausea	9 (15.8)	4 (7.0)	4 (7.0)	1 (1.8)	0
Vomiting	5 (8.8)	5 (8.8)	0	0	0
Diarrhoea	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Stomatitis	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Abdominal pain	2 (3.5)	2 (3.5)	0	0	0
Gingival bleeding	2 (3.5)	2 (3.5)	0	0	0
General disorders and administration site conditions					
-Total	11 (19.3)	6 (10.5)	5 (8.8)	0	0
Pyrexia	7 (12.3)	3 (5.3)	4 (7.0)	0	0
Catheter site dermatitis	1 (1.8)	1 (1.8)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site pain	1 (1.8)	0	1 (1.8)	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Fatigue	1 (1.8)	1 (1.8)	0	0	0
Localised oedema	1 (1.8)	0	1 (1.8)	0	0
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypogammaglobulinaemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Infections and infestations					
-Total	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Paronychia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Conjunctivitis	1 (1.8)	1 (1.8)	0	0	0
Device related infection	1 (1.8)	0	1 (1.8)	0	0
Nasopharyngitis	1 (1.8)	1 (1.8)	0	0	0
Upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Vulval cellulitis	1 (1.8)	0	0	1 (1.8)	0

Race: White

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Fall	1 (1.8)	1 (1.8)	0	0	0
Infusion related reaction	1 (1.8)	0	1 (1.8)	0	0
Investigations					
-Total	19 (33.3)	4 (7.0)	2 (3.5)	2 (3.5)	11 (19.3)
White blood cell count decreased	9 (15.8)	0	1 (1.8)	2 (3.5)	6 (10.5)
Neutrophil count decreased	6 (10.5)	0	1 (1.8)	1 (1.8)	4 (7.0)
Lymphocyte count decreased	4 (7.0)	0	0	0	4 (7.0)
Platelet count decreased	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Alanine aminotransferase increased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Aspartate aminotransferase increased	1 (1.8)	1 (1.8)	0	0	0
Blood alkaline phosphatase decreased	1 (1.8)	1 (1.8)	0	0	0
Blood fibrinogen decreased	1 (1.8)	1 (1.8)	0	0	0
Blood fibrinogen increased	1 (1.8)	1 (1.8)	0	0	0
Blood phosphorus increased	1 (1.8)	0	1 (1.8)	0	0

Race: White

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
C-reactive protein increased	1 (1.8)	0	0	1 (1.8)	0
International normalised ratio increased	1 (1.8)	1 (1.8)	0	0	0
Serum ferritin increased	1 (1.8)	0	1 (1.8)	0	0
Weight increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (17.5)	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)
Decreased appetite	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Hyperphosphataemia	2 (3.5)	2 (3.5)	0	0	0
Hypokalaemia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Hypoalbuminaemia	1 (1.8)	1 (1.8)	0	0	0
Hypocalcaemia	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Pain in extremity	1 (1.8)	1 (1.8)	0	0	0
Nervous system disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Headache	1 (1.8)	1 (1.8)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Somnolence	1 (1.8)	1 (1.8)	0	0	0
Psychiatric disorders					
-Total	1 (1.8)	0	0	1 (1.8)	0
Irritability	1 (1.8)	0	0	1 (1.8)	0
Renal and urinary disorders					
-Total	2 (3.5)	2 (3.5)	0	0	0
Dysuria	1 (1.8)	1 (1.8)	0	0	0
Renal pain	1 (1.8)	1 (1.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Cough	2 (3.5)	2 (3.5)	0	0	0
Epistaxis	1 (1.8)	1 (1.8)	0	0	0
Oropharyngeal pain	1 (1.8)	1 (1.8)	0	0	0
Pleural effusion	1 (1.8)	0	1 (1.8)	0	0
Pulmonary oedema	1 (1.8)	1 (1.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (12.3)	4 (7.0)	3 (5.3)	0	0

Race: White

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	2 (3.5)	2 (3.5)	0	0	0
Rash papular	2 (3.5)	2 (3.5)	0	0	0
Acne	1 (1.8)	1 (1.8)	0	0	0
Drug eruption	1 (1.8)	0	1 (1.8)	0	0
Erythema	1 (1.8)	1 (1.8)	0	0	0
Ingrowing nail	1 (1.8)	0	1 (1.8)	0	0
Petechiae	1 (1.8)	1 (1.8)	0	0	0
Pruritus	1 (1.8)	0	1 (1.8)	0	0
Vascular disorders					
-Total	5 (8.8)	2 (3.5)	2 (3.5)	1 (1.8)	0
Hypotension	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Flushing	1 (1.8)	1 (1.8)	0	0	0
Hypertension	1 (1.8)	0	1 (1.8)	0	0
Peripheral ischaemia	1 (1.8)	0	1 (1.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted

only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206c
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (70.0)	5 (50.0)	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders					
-Total	5 (50.0)	3 (30.0)	1 (10.0)	1 (10.0)	0
Nausea	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Abdominal pain	1 (10.0)	1 (10.0)	0	0	0
Constipation	1 (10.0)	1 (10.0)	0	0	0
Haematemesis	1 (10.0)	1 (10.0)	0	0	0
Vomiting	1 (10.0)	0	0	1 (10.0)	0
Immune system disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Seasonal allergy	1 (10.0)	0	1 (10.0)	0	0

Race: Asian

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (10.0)	1 (10.0)	0	0	0
Tinea pedis	1 (10.0)	1 (10.0)	0	0	0
Investigations					
-Total	1 (10.0)	0	0	1 (10.0)	0
Blood fibrinogen decreased	1 (10.0)	0	0	1 (10.0)	0
International normalised ratio increased	1 (10.0)	1 (10.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (20.0)	2 (20.0)	0	0	0
Decreased appetite	1 (10.0)	1 (10.0)	0	0	0
Vitamin d deficiency	1 (10.0)	1 (10.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Headache	1 (10.0)	1 (10.0)	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Posterior reversible encephalopathy syndrome	1 (10.0)	0	1 (10.0)	0	0
Seizure	1 (10.0)	0	1 (10.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (20.0)	2 (20.0)	0	0	0
Pruritus	2 (20.0)	2 (20.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206c
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	2 (18.2)	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Anaemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Cardiac disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Tachycardia	1 (9.1)	1 (9.1)	0	0	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Vision blurred	1 (9.1)	1 (9.1)	0	0	0
Gastrointestinal disorders					
-Total	4 (36.4)	0	4 (36.4)	0	0
Nausea	2 (18.2)	0	2 (18.2)	0	0
Anal erythema	1 (9.1)	1 (9.1)	0	0	0
Constipation	1 (9.1)	0	1 (9.1)	0	0
Lip pain	1 (9.1)	1 (9.1)	0	0	0
Stomatitis	1 (9.1)	0	1 (9.1)	0	0
Vomiting	1 (9.1)	0	1 (9.1)	0	0
General disorders and administration site conditions					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	0	1 (9.1)	0	0
Generalised oedema	1 (9.1)	0	0	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device occlusion	1 (9.1)	1 (9.1)	0	0	0
Infections and infestations					
-Total	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Escherichia bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Fungaemia	1 (9.1)	0	0	0	1 (9.1)
Gastroenteritis	1 (9.1)	0	1 (9.1)	0	0
Oral herpes	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Platelet count decreased	2 (18.2)	0	0	0	2 (18.2)
White blood cell count decreased	2 (18.2)	0	0	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Neutrophil count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					

Race: Other

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (36.4)	1 (9.1)	1 (9.1)	2 (18.2)	0
Hypomagnesaemia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Hypophosphataemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	1 (9.1)	0	0	0
Hypocalcaemia	1 (9.1)	0	0	1 (9.1)	0
Hypokalaemia	1 (9.1)	0	0	1 (9.1)	0
Hyponatraemia	1 (9.1)	1 (9.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Bone pain	1 (9.1)	0	1 (9.1)	0	0
Pain in jaw	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Acute kidney injury	1 (9.1)	1 (9.1)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0	0	0
Epistaxis	1 (9.1)	0	0	1 (9.1)	0
Pulmonary haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Pruritus	1 (9.1)	0	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206d
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	2 (14.3)	3 (21.4)	3 (21.4)	5 (35.7)
Blood and lymphatic system disorders					
-Total	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Anaemia	3 (21.4)	1 (7.1)	0	2 (14.3)	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Endocrine disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Adrenal insufficiency	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	6 (42.9)	2 (14.3)	4 (28.6)	0	0
Vomiting	3 (21.4)	2 (14.3)	1 (7.1)	0	0

Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (14.3)	0	2 (14.3)	0	0
Anal erythema	1 (7.1)	1 (7.1)	0	0	0
Constipation	1 (7.1)	0	1 (7.1)	0	0
Lip pain	1 (7.1)	1 (7.1)	0	0	0
Stomatitis	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Chills	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pyrexia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Vascular device occlusion	1 (7.1)	1 (7.1)	0	0	0
Infections and infestations					
-Total	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Conjunctivitis	1 (7.1)	1 (7.1)	0	0	0
Escherichia bacteraemia	1 (7.1)	0	0	0	1 (7.1)
Gastroenteritis	1 (7.1)	0	1 (7.1)	0	0
Oral herpes	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0

Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	5 (35.7)	0	0	1 (7.1)	4 (28.6)
Neutrophil count decreased	3 (21.4)	0	1 (7.1)	0	2 (14.3)
White blood cell count decreased	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Platelet count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0	0	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hyperphosphataemia	1 (7.1)	1 (7.1)	0	0	0
Hypocalcaemia	1 (7.1)	0	0	1 (7.1)	0
Hypokalaemia	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					

Ethnicity: Hispanic or Latino

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	0	1 (7.1)	0
Pain in jaw	1 (7.1)	0	0	1 (7.1)	0
Nervous system disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Headache	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Pulmonary oedema	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Drug eruption	1 (7.1)	0	1 (7.1)	0	0
Pruritus	1 (7.1)	0	1 (7.1)	0	0
Vascular disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Flushing	1 (7.1)	1 (7.1)	0	0	0
Hypotension	1 (7.1)	0	0	1 (7.1)	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peripheral ischaemia	1 (7.1)	0	1 (7.1)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206d
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (76.6)	16 (25.0)	11 (17.2)	6 (9.4)	16 (25.0)
Blood and lymphatic system disorders					
-Total	9 (14.1)	0	1 (1.6)	4 (6.3)	4 (6.3)
Anaemia	5 (7.8)	0	1 (1.6)	4 (6.3)	0
Febrile neutropenia	2 (3.1)	0	0	2 (3.1)	0
Leukopenia	1 (1.6)	0	0	0	1 (1.6)
Lymphopenia	1 (1.6)	0	0	0	1 (1.6)
Neutropenia	1 (1.6)	0	0	0	1 (1.6)
Thrombocytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	2 (3.1)	2 (3.1)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	2 (3.1)	2 (3.1)	0	0	0
Eye disorders					
-Total	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Eye pain	1 (1.6)	1 (1.6)	0	0	0
Eyelid oedema	1 (1.6)	0	1 (1.6)	0	0
Vision blurred	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal disorders					
-Total	19 (29.7)	10 (15.6)	7 (10.9)	2 (3.1)	0
Nausea	11 (17.2)	5 (7.8)	5 (7.8)	1 (1.6)	0
Vomiting	4 (6.3)	3 (4.7)	0	1 (1.6)	0
Abdominal pain	3 (4.7)	3 (4.7)	0	0	0
Diarrhoea	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Stomatitis	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Gingival bleeding	2 (3.1)	2 (3.1)	0	0	0
Constipation	1 (1.6)	1 (1.6)	0	0	0
Haematemesis	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (17.2)	6 (9.4)	4 (6.3)	1 (1.6)	0
Pyrexia	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Catheter site dermatitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site pain	1 (1.6)	0	1 (1.6)	0	0
Fatigue	1 (1.6)	1 (1.6)	0	0	0
Generalised oedema	1 (1.6)	0	0	1 (1.6)	0
Localised oedema	1 (1.6)	0	1 (1.6)	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Hypogammaglobulinaemia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Seasonal allergy	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	8 (12.5)	3 (4.7)	2 (3.1)	2 (3.1)	1 (1.6)
Paronychia	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Device related infection	1 (1.6)	0	1 (1.6)	0	0
Fungaemia	1 (1.6)	0	0	0	1 (1.6)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasopharyngitis	1 (1.6)	1 (1.6)	0	0	0
Tinea pedis	1 (1.6)	1 (1.6)	0	0	0
Vulval cellulitis	1 (1.6)	0	0	1 (1.6)	0
Injury, poisoning and procedural complications					
-Total	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Fall	1 (1.6)	1 (1.6)	0	0	0
Infusion related reaction	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	19 (29.7)	4 (6.3)	2 (3.1)	2 (3.1)	11 (17.2)
White blood cell count decreased	8 (12.5)	0	1 (1.6)	1 (1.6)	6 (9.4)
Lymphocyte count decreased	5 (7.8)	0	0	0	5 (7.8)
Neutrophil count decreased	4 (6.3)	0	0	1 (1.6)	3 (4.7)
Platelet count decreased	4 (6.3)	0	0	0	4 (6.3)
Alanine aminotransferase increased	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Blood fibrinogen decreased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
International normalised ratio increased	2 (3.1)	2 (3.1)	0	0	0

Ethnicity: Other

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (1.6)	1 (1.6)	0	0	0
Blood alkaline phosphatase decreased	1 (1.6)	1 (1.6)	0	0	0
Blood fibrinogen increased	1 (1.6)	1 (1.6)	0	0	0
Blood phosphorus increased	1 (1.6)	0	1 (1.6)	0	0
C-reactive protein increased	1 (1.6)	0	0	1 (1.6)	0
Serum ferritin increased	1 (1.6)	0	1 (1.6)	0	0
Weight increased	1 (1.6)	1 (1.6)	0	0	0
Metabolism and nutrition disorders					
-Total	12 (18.8)	7 (10.9)	3 (4.7)	1 (1.6)	1 (1.6)
Decreased appetite	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Hypoalbuminaemia	2 (3.1)	2 (3.1)	0	0	0
Hypokalaemia	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Hyperphosphataemia	1 (1.6)	1 (1.6)	0	0	0
Hypocalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyponatraemia	1 (1.6)	1 (1.6)	0	0	0
Vitamin d deficiency	1 (1.6)	1 (1.6)	0	0	0

Ethnicity: Other

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Bone pain	1 (1.6)	0	1 (1.6)	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Pain in extremity	1 (1.6)	1 (1.6)	0	0	0
Nervous system disorders					
-Total	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Headache	2 (3.1)	2 (3.1)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.6)	0	1 (1.6)	0	0
Seizure	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	1 (1.6)	0	0	1 (1.6)	0
Irritability	1 (1.6)	0	0	1 (1.6)	0
Renal and urinary disorders					
-Total	3 (4.7)	3 (4.7)	0	0	0
Acute kidney injury	1 (1.6)	1 (1.6)	0	0	0

Ethnicity: Other

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	1 (1.6)	1 (1.6)	0	0	0
Renal pain	1 (1.6)	1 (1.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (9.4)	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)
Cough	2 (3.1)	2 (3.1)	0	0	0
Epistaxis	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Oropharyngeal pain	1 (1.6)	1 (1.6)	0	0	0
Pleural effusion	1 (1.6)	0	1 (1.6)	0	0
Pulmonary haemorrhage	1 (1.6)	0	0	0	1 (1.6)
Respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Skin and subcutaneous tissue disorders					
-Total	8 (12.5)	6 (9.4)	2 (3.1)	0	0
Pruritus	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Rash	2 (3.1)	2 (3.1)	0	0	0
Rash papular	2 (3.1)	2 (3.1)	0	0	0
Acne	1 (1.6)	1 (1.6)	0	0	0
Erythema	1 (1.6)	1 (1.6)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (1.6)	0	1 (1.6)	0	0
Petechiae	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Hypotension	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Hypertension	1 (1.6)	0	1 (1.6)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206e
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	1 (16.7)	2 (33.3)	0
Blood and lymphatic system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Anaemia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Eyelid oedema	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Abdominal pain	2 (33.3)	2 (33.3)	0	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0

Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vulval cellulitis	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)	0	0
White blood cell count decreased	1 (16.7)	0	0	1 (16.7)	0
Metabolism and nutrition disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Decreased appetite	2 (33.3)	2 (33.3)	0	0	0
Musculoskeletal and connective tissue disorders					

Response status at study entry: Primary refractory

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	1 (16.7)	0	0	0
Pain in extremity	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0
Somnolence	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Irritability	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Dysuria	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Petechiae	1 (16.7)	1 (16.7)	0	0	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Rash	1 (16.7)	1 (16.7)	0	0	0

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Hypotension	1 (16.7)	1 (16.7)	0	0	0

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Table 206e
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (79.2)	16 (22.2)	13 (18.1)	7 (9.7)	21 (29.2)
Blood and lymphatic system disorders					
-Total	12 (16.7)	0	1 (1.4)	7 (9.7)	4 (5.6)
Anaemia	7 (9.7)	0	1 (1.4)	6 (8.3)	0
Febrile neutropenia	4 (5.6)	0	0	4 (5.6)	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Neutropenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Cardiac disorders					
-Total	2 (2.8)	2 (2.8)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.8)	2 (2.8)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.8)	2 (2.8)	0	0	0
Eye pain	1 (1.4)	1 (1.4)	0	0	0
Vision blurred	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	23 (31.9)	11 (15.3)	10 (13.9)	2 (2.8)	0
Nausea	12 (16.7)	4 (5.6)	7 (9.7)	1 (1.4)	0
Vomiting	7 (9.7)	5 (6.9)	1 (1.4)	1 (1.4)	0
Diarrhoea	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Stomatitis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Constipation	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Gingival bleeding	2 (2.8)	2 (2.8)	0	0	0
Abdominal pain	1 (1.4)	1 (1.4)	0	0	0
Anal erythema	1 (1.4)	1 (1.4)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Lip pain	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	15 (20.8)	8 (11.1)	6 (8.3)	1 (1.4)	0
Pyrexia	8 (11.1)	4 (5.6)	4 (5.6)	0	0
Chills	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Catheter site dermatitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site pain	1 (1.4)	0	1 (1.4)	0	0
Fatigue	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	0	0	1 (1.4)	0
Localised oedema	1 (1.4)	0	1 (1.4)	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hypogammaglobulinaemia	1 (1.4)	0	0	1 (1.4)	0
Seasonal allergy	1 (1.4)	0	1 (1.4)	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	10 (13.9)	3 (4.2)	3 (4.2)	2 (2.8)	2 (2.8)
Paronychia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	1 (1.4)	0	0	0
Device related infection	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Nasopharyngitis	1 (1.4)	1 (1.4)	0	0	0
Oral herpes	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					
-Total	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Fall	1 (1.4)	1 (1.4)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	23 (31.9)	4 (5.6)	2 (2.8)	2 (2.8)	15 (20.8)
White blood cell count decreased	10 (13.9)	0	1 (1.4)	1 (1.4)	8 (11.1)
Lymphocyte count decreased	6 (8.3)	0	0	0	6 (8.3)
Neutrophil count decreased	6 (8.3)	0	0	1 (1.4)	5 (6.9)
Platelet count decreased	6 (8.3)	0	0	1 (1.4)	5 (6.9)
Alanine aminotransferase increased	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Blood fibrinogen decreased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
International normalised ratio increased	2 (2.8)	2 (2.8)	0	0	0
Aspartate aminotransferase increased	1 (1.4)	1 (1.4)	0	0	0
Blood alkaline phosphatase decreased	1 (1.4)	1 (1.4)	0	0	0
Blood fibrinogen increased	1 (1.4)	1 (1.4)	0	0	0
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
C-reactive protein increased	1 (1.4)	0	0	1 (1.4)	0
Serum ferritin increased	1 (1.4)	0	1 (1.4)	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (19.4)	6 (8.3)	4 (5.6)	3 (4.2)	1 (1.4)
Decreased appetite	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Hypokalaemia	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Hyperphosphataemia	2 (2.8)	2 (2.8)	0	0	0
Hypoalbuminaemia	2 (2.8)	2 (2.8)	0	0	0
Hypocalcaemia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Hypomagnesaemia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Hypophosphataemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	1 (1.4)	1 (1.4)	0	0	0
Vitamin d deficiency	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Muscular weakness	1 (1.4)	0	1 (1.4)	0	0
Pain in jaw	1 (1.4)	0	0	1 (1.4)	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Headache	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Posterior reversible encephalopathy syndrome	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	2 (2.8)	2 (2.8)	0	0	0
Acute kidney injury	1 (1.4)	1 (1.4)	0	0	0
Renal pain	1 (1.4)	1 (1.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (9.7)	4 (5.6)	1 (1.4)	1 (1.4)	1 (1.4)
Cough	3 (4.2)	3 (4.2)	0	0	0
Epistaxis	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Oropharyngeal pain	1 (1.4)	1 (1.4)	0	0	0
Pleural effusion	1 (1.4)	0	1 (1.4)	0	0
Pulmonary haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Skin and subcutaneous tissue disorders					
-Total	9 (12.5)	6 (8.3)	3 (4.2)	0	0
Pruritus	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Drug eruption	1 (1.4)	0	1 (1.4)	0	0
Erythema	1 (1.4)	1 (1.4)	0	0	0
Ingrowing nail	1 (1.4)	0	1 (1.4)	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	4 (5.6)	1 (1.4)	2 (2.8)	1 (1.4)	0
Hypotension	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hypertension	1 (1.4)	0	1 (1.4)	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206f
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Immune system disorders					
-Total	1 (100)	0	0	1 (100)	0
Hypogammaglobulinaemia	1 (100)	0	0	1 (100)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Pleural effusion	1 (100)	0	1 (100)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206f
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (79.2)	18 (23.4)	14 (18.2)	8 (10.4)	21 (27.3)
Blood and lymphatic system disorders					
-Total	13 (16.9)	1 (1.3)	1 (1.3)	7 (9.1)	4 (5.2)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Cardiac disorders					
-Total	2 (2.6)	2 (2.6)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.6)	2 (2.6)	0	0	0
Endocrine disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Adrenal insufficiency	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Eyelid oedema	1 (1.3)	0	1 (1.3)	0	0
Vision blurred	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	25 (32.5)	12 (15.6)	11 (14.3)	2 (2.6)	0
Nausea	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Vomiting	7 (9.1)	5 (6.5)	1 (1.3)	1 (1.3)	0
Stomatitis	4 (5.2)	0	3 (3.9)	1 (1.3)	0
Abdominal pain	3 (3.9)	3 (3.9)	0	0	0
Diarrhoea	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Constipation	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gingival bleeding	2 (2.6)	2 (2.6)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal erythema	1 (1.3)	1 (1.3)	0	0	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Lip pain	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	15 (19.5)	8 (10.4)	6 (7.8)	1 (1.3)	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Chills	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Catheter site dermatitis	1 (1.3)	1 (1.3)	0	0	0
Catheter site pain	1 (1.3)	0	1 (1.3)	0	0
Fatigue	1 (1.3)	1 (1.3)	0	0	0
Generalised oedema	1 (1.3)	0	0	1 (1.3)	0
Localised oedema	1 (1.3)	0	1 (1.3)	0	0
Oedema peripheral	1 (1.3)	1 (1.3)	0	0	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	2 (2.6)	0	2 (2.6)	0	0
Hypogammaglobulinaemia	1 (1.3)	0	1 (1.3)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Fall	1 (1.3)	1 (1.3)	0	0	0
Infusion related reaction	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	24 (31.2)	4 (5.2)	2 (2.6)	3 (3.9)	15 (19.5)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
Neutrophil count decreased	7 (9.1)	0	1 (1.3)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	6 (7.8)	0	0	0	6 (7.8)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Alanine aminotransferase increased	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Aspartate aminotransferase increased	2 (2.6)	2 (2.6)	0	0	0
Blood fibrinogen decreased	2 (2.6)	1 (1.3)	0	1 (1.3)	0
International normalised ratio increased	2 (2.6)	2 (2.6)	0	0	0
Blood alkaline phosphatase decreased	1 (1.3)	1 (1.3)	0	0	0
Blood fibrinogen increased	1 (1.3)	1 (1.3)	0	0	0
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.3)	0	0	1 (1.3)	0
Serum ferritin increased	1 (1.3)	0	1 (1.3)	0	0
Weight increased	1 (1.3)	1 (1.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (20.8)	8 (10.4)	4 (5.2)	3 (3.9)	1 (1.3)
Decreased appetite	6 (7.8)	3 (3.9)	3 (3.9)	0	0
Hypokalaemia	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Hyperphosphataemia	2 (2.6)	2 (2.6)	0	0	0
Hypoalbuminaemia	2 (2.6)	2 (2.6)	0	0	0
Hypocalcaemia	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Hypomagnesaemia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Hypophosphataemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hyponatraemia	1 (1.3)	1 (1.3)	0	0	0
Vitamin d deficiency	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (5.2)	1 (1.3)	2 (2.6)	1 (1.3)	0
Bone pain	1 (1.3)	0	1 (1.3)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Pain in extremity	1 (1.3)	1 (1.3)	0	0	0
Pain in jaw	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Headache	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	1 (1.3)	0	0	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Renal and urinary disorders					
-Total	3 (3.9)	3 (3.9)	0	0	0
Acute kidney injury	1 (1.3)	1 (1.3)	0	0	0
Dysuria	1 (1.3)	1 (1.3)	0	0	0
Renal pain	1 (1.3)	1 (1.3)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	6 (7.8)	4 (5.2)	0	1 (1.3)	1 (1.3)
Cough	3 (3.9)	3 (3.9)	0	0	0
Epistaxis	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Oropharyngeal pain	1 (1.3)	1 (1.3)	0	0	0
Pulmonary haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0	0	0
Respiratory failure	1 (1.3)	0	0	0	1 (1.3)
Skin and subcutaneous tissue disorders					
-Total	10 (13.0)	6 (7.8)	4 (5.2)	0	0
Pruritus	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Rash	2 (2.6)	2 (2.6)	0	0	0
Rash papular	2 (2.6)	2 (2.6)	0	0	0
Acne	1 (1.3)	1 (1.3)	0	0	0
Drug eruption	1 (1.3)	0	1 (1.3)	0	0
Erythema	1 (1.3)	1 (1.3)	0	0	0
Ingrowing nail	1 (1.3)	0	1 (1.3)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Petechiae	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	5 (6.5)	2 (2.6)	2 (2.6)	1 (1.3)	0
Hypotension	4 (5.2)	2 (2.6)	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hypertension	1 (1.3)	0	1 (1.3)	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206g
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades

column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206g
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (79.2)	17 (22.1)	14 (18.2)	9 (11.7)	21 (27.3)
Blood and lymphatic system disorders					
-Total	13 (16.9)	1 (1.3)	1 (1.3)	7 (9.1)	4 (5.2)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Cardiac disorders					
-Total	2 (2.6)	2 (2.6)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.6)	2 (2.6)	0	0	0
Endocrine disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Adrenal insufficiency	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Eyelid oedema	1 (1.3)	0	1 (1.3)	0	0
Vision blurred	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	24 (31.2)	11 (14.3)	11 (14.3)	2 (2.6)	0
Nausea	12 (15.6)	4 (5.2)	7 (9.1)	1 (1.3)	0
Vomiting	7 (9.1)	5 (6.5)	1 (1.3)	1 (1.3)	0
Stomatitis	4 (5.2)	0	3 (3.9)	1 (1.3)	0
Diarrhoea	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Abdominal pain	2 (2.6)	2 (2.6)	0	0	0
Constipation	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gingival bleeding	2 (2.6)	2 (2.6)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal erythema	1 (1.3)	1 (1.3)	0	0	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Lip pain	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	15 (19.5)	8 (10.4)	6 (7.8)	1 (1.3)	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Chills	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Catheter site dermatitis	1 (1.3)	1 (1.3)	0	0	0
Catheter site pain	1 (1.3)	0	1 (1.3)	0	0
Fatigue	1 (1.3)	1 (1.3)	0	0	0
Generalised oedema	1 (1.3)	0	0	1 (1.3)	0
Localised oedema	1 (1.3)	0	1 (1.3)	0	0
Oedema peripheral	1 (1.3)	1 (1.3)	0	0	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	3 (3.9)	0	2 (2.6)	1 (1.3)	0
Hypogammaglobulinaemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Fall	1 (1.3)	1 (1.3)	0	0	0
Infusion related reaction	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	24 (31.2)	4 (5.2)	2 (2.6)	3 (3.9)	15 (19.5)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
Neutrophil count decreased	7 (9.1)	0	1 (1.3)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	6 (7.8)	0	0	0	6 (7.8)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Alanine aminotransferase increased	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Aspartate aminotransferase increased	2 (2.6)	2 (2.6)	0	0	0
Blood fibrinogen decreased	2 (2.6)	1 (1.3)	0	1 (1.3)	0
International normalised ratio increased	2 (2.6)	2 (2.6)	0	0	0
Blood alkaline phosphatase decreased	1 (1.3)	1 (1.3)	0	0	0
Blood fibrinogen increased	1 (1.3)	1 (1.3)	0	0	0
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.3)	0	0	1 (1.3)	0
Serum ferritin increased	1 (1.3)	0	1 (1.3)	0	0
Weight increased	1 (1.3)	1 (1.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (20.8)	8 (10.4)	4 (5.2)	3 (3.9)	1 (1.3)
Decreased appetite	6 (7.8)	3 (3.9)	3 (3.9)	0	0
Hypokalaemia	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Hyperphosphataemia	2 (2.6)	2 (2.6)	0	0	0
Hypoalbuminaemia	2 (2.6)	2 (2.6)	0	0	0
Hypocalcaemia	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Hypomagnesaemia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Hypophosphataemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hyponatraemia	1 (1.3)	1 (1.3)	0	0	0
Vitamin d deficiency	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (5.2)	1 (1.3)	2 (2.6)	1 (1.3)	0
Bone pain	1 (1.3)	0	1 (1.3)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Pain in extremity	1 (1.3)	1 (1.3)	0	0	0
Pain in jaw	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Headache	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	1 (1.3)	0	0	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Renal and urinary disorders					
-Total	3 (3.9)	3 (3.9)	0	0	0
Acute kidney injury	1 (1.3)	1 (1.3)	0	0	0
Dysuria	1 (1.3)	1 (1.3)	0	0	0
Renal pain	1 (1.3)	1 (1.3)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	7 (9.1)	4 (5.2)	1 (1.3)	1 (1.3)	1 (1.3)
Cough	3 (3.9)	3 (3.9)	0	0	0
Epistaxis	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Oropharyngeal pain	1 (1.3)	1 (1.3)	0	0	0
Pleural effusion	1 (1.3)	0	1 (1.3)	0	0
Pulmonary haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0	0	0
Respiratory failure	1 (1.3)	0	0	0	1 (1.3)
Skin and subcutaneous tissue disorders					
-Total	10 (13.0)	6 (7.8)	4 (5.2)	0	0
Pruritus	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Rash	2 (2.6)	2 (2.6)	0	0	0
Rash papular	2 (2.6)	2 (2.6)	0	0	0
Acne	1 (1.3)	1 (1.3)	0	0	0
Drug eruption	1 (1.3)	0	1 (1.3)	0	0
Erythema	1 (1.3)	1 (1.3)	0	0	0

Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (1.3)	0	1 (1.3)	0	0
Petechiae	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	5 (6.5)	2 (2.6)	2 (2.6)	1 (1.3)	0
Hypotension	4 (5.2)	2 (2.6)	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hypertension	1 (1.3)	0	1 (1.3)	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206h
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	0	1 (100)
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only

once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206h
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (79.2)	18 (23.4)	14 (18.2)	9 (11.7)	20 (26.0)
Blood and lymphatic system disorders					
-Total	13 (16.9)	1 (1.3)	1 (1.3)	7 (9.1)	4 (5.2)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Cardiac disorders					
-Total	2 (2.6)	2 (2.6)	0	0	0

Hypodiploidy: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.6)	2 (2.6)	0	0	0
Endocrine disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Adrenal insufficiency	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Eyelid oedema	1 (1.3)	0	1 (1.3)	0	0
Vision blurred	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	25 (32.5)	12 (15.6)	11 (14.3)	2 (2.6)	0
Nausea	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Vomiting	7 (9.1)	5 (6.5)	1 (1.3)	1 (1.3)	0
Stomatitis	4 (5.2)	0	3 (3.9)	1 (1.3)	0
Abdominal pain	3 (3.9)	3 (3.9)	0	0	0
Diarrhoea	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Constipation	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gingival bleeding	2 (2.6)	2 (2.6)	0	0	0

Hypodiploidy: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal erythema	1 (1.3)	1 (1.3)	0	0	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Lip pain	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	15 (19.5)	8 (10.4)	6 (7.8)	1 (1.3)	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Chills	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Catheter site dermatitis	1 (1.3)	1 (1.3)	0	0	0
Catheter site pain	1 (1.3)	0	1 (1.3)	0	0
Fatigue	1 (1.3)	1 (1.3)	0	0	0
Generalised oedema	1 (1.3)	0	0	1 (1.3)	0
Localised oedema	1 (1.3)	0	1 (1.3)	0	0
Oedema peripheral	1 (1.3)	1 (1.3)	0	0	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	3 (3.9)	0	2 (2.6)	1 (1.3)	0
Hypogammaglobulinaemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0

Hypodiploidy: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Fall	1 (1.3)	1 (1.3)	0	0	0
Infusion related reaction	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	23 (29.9)	4 (5.2)	2 (2.6)	3 (3.9)	14 (18.2)
White blood cell count decreased	10 (13.0)	0	1 (1.3)	2 (2.6)	7 (9.1)
Neutrophil count decreased	6 (7.8)	0	1 (1.3)	0	5 (6.5)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Lymphocyte count decreased	5 (6.5)	0	0	0	5 (6.5)
Alanine aminotransferase increased	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Aspartate aminotransferase increased	2 (2.6)	2 (2.6)	0	0	0
Blood fibrinogen decreased	2 (2.6)	1 (1.3)	0	1 (1.3)	0
International normalised ratio increased	2 (2.6)	2 (2.6)	0	0	0
Blood alkaline phosphatase decreased	1 (1.3)	1 (1.3)	0	0	0
Blood fibrinogen increased	1 (1.3)	1 (1.3)	0	0	0
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0

Hypodiploidy: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.3)	0	0	1 (1.3)	0
Serum ferritin increased	1 (1.3)	0	1 (1.3)	0	0
Weight increased	1 (1.3)	1 (1.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (20.8)	8 (10.4)	4 (5.2)	3 (3.9)	1 (1.3)
Decreased appetite	6 (7.8)	3 (3.9)	3 (3.9)	0	0
Hypokalaemia	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Hyperphosphataemia	2 (2.6)	2 (2.6)	0	0	0
Hypoalbuminaemia	2 (2.6)	2 (2.6)	0	0	0
Hypocalcaemia	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Hypomagnesaemia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Hypophosphataemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hyponatraemia	1 (1.3)	1 (1.3)	0	0	0
Vitamin d deficiency	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (5.2)	1 (1.3)	2 (2.6)	1 (1.3)	0
Bone pain	1 (1.3)	0	1 (1.3)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Pain in extremity	1 (1.3)	1 (1.3)	0	0	0
Pain in jaw	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Headache	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	1 (1.3)	0	0	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Renal and urinary disorders					
-Total	3 (3.9)	3 (3.9)	0	0	0
Acute kidney injury	1 (1.3)	1 (1.3)	0	0	0
Dysuria	1 (1.3)	1 (1.3)	0	0	0
Renal pain	1 (1.3)	1 (1.3)	0	0	0

Hypodiploidy: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	7 (9.1)	4 (5.2)	1 (1.3)	1 (1.3)	1 (1.3)
Cough	3 (3.9)	3 (3.9)	0	0	0
Epistaxis	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Oropharyngeal pain	1 (1.3)	1 (1.3)	0	0	0
Pleural effusion	1 (1.3)	0	1 (1.3)	0	0
Pulmonary haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0	0	0
Respiratory failure	1 (1.3)	0	0	0	1 (1.3)
Skin and subcutaneous tissue disorders					
-Total	10 (13.0)	6 (7.8)	4 (5.2)	0	0
Pruritus	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Rash	2 (2.6)	2 (2.6)	0	0	0
Rash papular	2 (2.6)	2 (2.6)	0	0	0
Acne	1 (1.3)	1 (1.3)	0	0	0
Drug eruption	1 (1.3)	0	1 (1.3)	0	0
Erythema	1 (1.3)	1 (1.3)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (1.3)	0	1 (1.3)	0	0
Petechiae	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	5 (6.5)	2 (2.6)	2 (2.6)	1 (1.3)	0
Hypotension	4 (5.2)	2 (2.6)	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hypertension	1 (1.3)	0	1 (1.3)	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206i
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (80.5)	18 (23.4)	14 (18.2)	9 (11.7)	21 (27.3)
Blood and lymphatic system disorders					
-Total	13 (16.9)	1 (1.3)	1 (1.3)	7 (9.1)	4 (5.2)
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Febrile neutropenia	4 (5.2)	0	0	4 (5.2)	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Neutropenia	1 (1.3)	0	0	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	0	0	1 (1.3)
Cardiac disorders					
-Total	2 (2.6)	2 (2.6)	0	0	0

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.6)	2 (2.6)	0	0	0
Endocrine disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Adrenal insufficiency	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Eye pain	1 (1.3)	1 (1.3)	0	0	0
Eyelid oedema	1 (1.3)	0	1 (1.3)	0	0
Vision blurred	1 (1.3)	1 (1.3)	0	0	0
Gastrointestinal disorders					
-Total	25 (32.5)	12 (15.6)	11 (14.3)	2 (2.6)	0
Nausea	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Vomiting	7 (9.1)	5 (6.5)	1 (1.3)	1 (1.3)	0
Stomatitis	4 (5.2)	0	3 (3.9)	1 (1.3)	0
Abdominal pain	3 (3.9)	3 (3.9)	0	0	0
Diarrhoea	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Constipation	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Gingival bleeding	2 (2.6)	2 (2.6)	0	0	0

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal erythema	1 (1.3)	1 (1.3)	0	0	0
Haematemesis	1 (1.3)	1 (1.3)	0	0	0
Lip pain	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	15 (19.5)	8 (10.4)	6 (7.8)	1 (1.3)	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Chills	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Catheter site dermatitis	1 (1.3)	1 (1.3)	0	0	0
Catheter site pain	1 (1.3)	0	1 (1.3)	0	0
Fatigue	1 (1.3)	1 (1.3)	0	0	0
Generalised oedema	1 (1.3)	0	0	1 (1.3)	0
Localised oedema	1 (1.3)	0	1 (1.3)	0	0
Oedema peripheral	1 (1.3)	1 (1.3)	0	0	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	3 (3.9)	0	2 (2.6)	1 (1.3)	0
Hypogammaglobulinaemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	11 (14.3)	3 (3.9)	3 (3.9)	3 (3.9)	2 (2.6)
Paronychia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	1 (1.3)	0	0	0
Device related infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	0	1 (1.3)
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Gastroenteritis	1 (1.3)	0	1 (1.3)	0	0
Nasopharyngitis	1 (1.3)	1 (1.3)	0	0	0
Oral herpes	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Tinea pedis	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract infection	1 (1.3)	0	1 (1.3)	0	0
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Fall	1 (1.3)	1 (1.3)	0	0	0
Infusion related reaction	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	24 (31.2)	4 (5.2)	2 (2.6)	3 (3.9)	15 (19.5)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
Neutrophil count decreased	7 (9.1)	0	1 (1.3)	1 (1.3)	5 (6.5)
Lymphocyte count decreased	6 (7.8)	0	0	0	6 (7.8)
Platelet count decreased	6 (7.8)	0	0	1 (1.3)	5 (6.5)
Alanine aminotransferase increased	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Aspartate aminotransferase increased	2 (2.6)	2 (2.6)	0	0	0
Blood fibrinogen decreased	2 (2.6)	1 (1.3)	0	1 (1.3)	0
International normalised ratio increased	2 (2.6)	2 (2.6)	0	0	0
Blood alkaline phosphatase decreased	1 (1.3)	1 (1.3)	0	0	0
Blood fibrinogen increased	1 (1.3)	1 (1.3)	0	0	0
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.3)	0	0	1 (1.3)	0
Serum ferritin increased	1 (1.3)	0	1 (1.3)	0	0
Weight increased	1 (1.3)	1 (1.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (20.8)	8 (10.4)	4 (5.2)	3 (3.9)	1 (1.3)
Decreased appetite	6 (7.8)	3 (3.9)	3 (3.9)	0	0
Hypokalaemia	3 (3.9)	0	0	2 (2.6)	1 (1.3)
Hyperphosphataemia	2 (2.6)	2 (2.6)	0	0	0
Hypoalbuminaemia	2 (2.6)	2 (2.6)	0	0	0
Hypocalcaemia	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Hypomagnesaemia	2 (2.6)	1 (1.3)	1 (1.3)	0	0
Hypophosphataemia	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Hyponatraemia	1 (1.3)	1 (1.3)	0	0	0
Vitamin d deficiency	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (5.2)	1 (1.3)	2 (2.6)	1 (1.3)	0
Bone pain	1 (1.3)	0	1 (1.3)	0	0

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (1.3)	0	1 (1.3)	0	0
Pain in extremity	1 (1.3)	1 (1.3)	0	0	0
Pain in jaw	1 (1.3)	0	0	1 (1.3)	0
Nervous system disorders					
-Total	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Headache	3 (3.9)	2 (2.6)	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Seizure	1 (1.3)	0	1 (1.3)	0	0
Somnolence	1 (1.3)	1 (1.3)	0	0	0
Psychiatric disorders					
-Total	1 (1.3)	0	0	1 (1.3)	0
Irritability	1 (1.3)	0	0	1 (1.3)	0
Renal and urinary disorders					
-Total	3 (3.9)	3 (3.9)	0	0	0
Acute kidney injury	1 (1.3)	1 (1.3)	0	0	0
Dysuria	1 (1.3)	1 (1.3)	0	0	0
Renal pain	1 (1.3)	1 (1.3)	0	0	0

BCR-ABL1-like: No

	All patients N=77				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	7 (9.1)	4 (5.2)	1 (1.3)	1 (1.3)	1 (1.3)
Cough	3 (3.9)	3 (3.9)	0	0	0
Epistaxis	2 (2.6)	1 (1.3)	0	1 (1.3)	0
Oropharyngeal pain	1 (1.3)	1 (1.3)	0	0	0
Pleural effusion	1 (1.3)	0	1 (1.3)	0	0
Pulmonary haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0	0	0
Respiratory failure	1 (1.3)	0	0	0	1 (1.3)
Skin and subcutaneous tissue disorders					
-Total	10 (13.0)	6 (7.8)	4 (5.2)	0	0
Pruritus	4 (5.2)	2 (2.6)	2 (2.6)	0	0
Rash	2 (2.6)	2 (2.6)	0	0	0
Rash papular	2 (2.6)	2 (2.6)	0	0	0
Acne	1 (1.3)	1 (1.3)	0	0	0
Drug eruption	1 (1.3)	0	1 (1.3)	0	0
Erythema	1 (1.3)	1 (1.3)	0	0	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (1.3)	0	1 (1.3)	0	0
Petechiae	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	5 (6.5)	2 (2.6)	2 (2.6)	1 (1.3)	0
Hypotension	4 (5.2)	2 (2.6)	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Hypertension	1 (1.3)	0	1 (1.3)	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206j
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (74.1)	7 (25.9)	5 (18.5)	4 (14.8)	4 (14.8)
Blood and lymphatic system disorders					
-Total	3 (11.1)	0	0	1 (3.7)	2 (7.4)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Anaemia	1 (3.7)	0	0	1 (3.7)	0
Neutropenia	1 (3.7)	0	0	0	1 (3.7)
Thrombocytopenia	1 (3.7)	0	0	0	1 (3.7)
Cardiac disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Tachycardia	1 (3.7)	1 (3.7)	0	0	0
Eye disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eyelid oedema	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal disorders					
-Total	10 (37.0)	6 (22.2)	3 (11.1)	1 (3.7)	0
Nausea	6 (22.2)	3 (11.1)	2 (7.4)	1 (3.7)	0
Vomiting	3 (11.1)	3 (11.1)	0	0	0
Abdominal pain	2 (7.4)	2 (7.4)	0	0	0
Diarrhoea	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Stomatitis	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Constipation	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	6 (22.2)	3 (11.1)	2 (7.4)	1 (3.7)	0
Pyrexia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Catheter site pain	1 (3.7)	0	1 (3.7)	0	0
Fatigue	1 (3.7)	1 (3.7)	0	0	0
Generalised oedema	1 (3.7)	0	0	1 (3.7)	0
Oedema peripheral	1 (3.7)	1 (3.7)	0	0	0
Infections and infestations					
-Total	5 (18.5)	2 (7.4)	0	2 (7.4)	1 (3.7)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Fungaemia	1 (3.7)	0	0	0	1 (3.7)
Nasopharyngitis	1 (3.7)	1 (3.7)	0	0	0
Paronychia	1 (3.7)	1 (3.7)	0	0	0
Vulval cellulitis	1 (3.7)	0	0	1 (3.7)	0
Injury, poisoning and procedural complications					
-Total	1 (3.7)	0	1 (3.7)	0	0
Infusion related reaction	1 (3.7)	0	1 (3.7)	0	0
Investigations					
-Total	6 (22.2)	2 (7.4)	2 (7.4)	1 (3.7)	1 (3.7)
Blood alkaline phosphatase decreased	1 (3.7)	1 (3.7)	0	0	0
Blood fibrinogen decreased	1 (3.7)	1 (3.7)	0	0	0
Blood phosphorus increased	1 (3.7)	0	1 (3.7)	0	0
C-reactive protein increased	1 (3.7)	0	0	1 (3.7)	0
Neutrophil count decreased	1 (3.7)	0	0	0	1 (3.7)
Serum ferritin increased	1 (3.7)	0	1 (3.7)	0	0
White blood cell count decreased	1 (3.7)	0	1 (3.7)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Decreased appetite	1 (3.7)	1 (3.7)	0	0	0
Hypokalaemia	1 (3.7)	0	0	1 (3.7)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Pain in extremity	1 (3.7)	1 (3.7)	0	0	0
Nervous system disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Headache	1 (3.7)	1 (3.7)	0	0	0
Somnolence	1 (3.7)	1 (3.7)	0	0	0
Psychiatric disorders					
-Total	1 (3.7)	0	0	1 (3.7)	0
Irritability	1 (3.7)	0	0	1 (3.7)	0
Renal and urinary disorders					
-Total	3 (11.1)	3 (11.1)	0	0	0
Acute kidney injury	1 (3.7)	1 (3.7)	0	0	0
Dysuria	1 (3.7)	1 (3.7)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal pain	1 (3.7)	1 (3.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (7.4)	1 (3.7)	0	0	1 (3.7)
Oropharyngeal pain	1 (3.7)	1 (3.7)	0	0	0
Pulmonary haemorrhage	1 (3.7)	0	0	0	1 (3.7)
Respiratory failure	1 (3.7)	0	0	0	1 (3.7)
Skin and subcutaneous tissue disorders					
-Total	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Pruritus	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Erythema	1 (3.7)	1 (3.7)	0	0	0
Ingrowing nail	1 (3.7)	0	1 (3.7)	0	0
Petechiae	1 (3.7)	1 (3.7)	0	0	0
Rash	1 (3.7)	1 (3.7)	0	0	0
Vascular disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Hypertension	1 (3.7)	0	1 (3.7)	0	0
Hypotension	1 (3.7)	1 (3.7)	0	0	0

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Table 206j
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (82.4)	11 (21.6)	9 (17.6)	5 (9.8)	17 (33.3)
Blood and lymphatic system disorders					
-Total	10 (19.6)	1 (2.0)	1 (2.0)	6 (11.8)	2 (3.9)
Anaemia	7 (13.7)	1 (2.0)	1 (2.0)	5 (9.8)	0
Febrile neutropenia	2 (3.9)	0	0	2 (3.9)	0
Leukopenia	1 (2.0)	0	0	0	1 (2.0)
Lymphopenia	1 (2.0)	0	0	0	1 (2.0)
Cardiac disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Tachycardia	1 (2.0)	1 (2.0)	0	0	0
Endocrine disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	0	1 (2.0)	0	0
Adrenal insufficiency	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	2 (3.9)	2 (3.9)	0	0	0
Eye pain	1 (2.0)	1 (2.0)	0	0	0
Vision blurred	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					
-Total	15 (29.4)	6 (11.8)	8 (15.7)	1 (2.0)	0
Nausea	7 (13.7)	2 (3.9)	5 (9.8)	0	0
Vomiting	4 (7.8)	2 (3.9)	1 (2.0)	1 (2.0)	0
Gingival bleeding	2 (3.9)	2 (3.9)	0	0	0
Stomatitis	2 (3.9)	0	2 (3.9)	0	0
Abdominal pain	1 (2.0)	1 (2.0)	0	0	0
Anal erythema	1 (2.0)	1 (2.0)	0	0	0
Constipation	1 (2.0)	0	1 (2.0)	0	0
Diarrhoea	1 (2.0)	1 (2.0)	0	0	0
Haematemesis	1 (2.0)	1 (2.0)	0	0	0
Lip pain	1 (2.0)	1 (2.0)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	9 (17.6)	5 (9.8)	4 (7.8)	0	0
Pyrexia	6 (11.8)	3 (5.9)	3 (5.9)	0	0
Chills	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Catheter site dermatitis	1 (2.0)	1 (2.0)	0	0	0
Localised oedema	1 (2.0)	0	1 (2.0)	0	0
Vascular device occlusion	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	3 (5.9)	0	2 (3.9)	1 (2.0)	0
Hypogammaglobulinaemia	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Seasonal allergy	1 (2.0)	0	1 (2.0)	0	0
Infections and infestations					
-Total	6 (11.8)	1 (2.0)	3 (5.9)	1 (2.0)	1 (2.0)
Conjunctivitis	1 (2.0)	1 (2.0)	0	0	0
Device related infection	1 (2.0)	0	1 (2.0)	0	0
Escherichia bacteraemia	1 (2.0)	0	0	0	1 (2.0)
Gastroenteritis	1 (2.0)	0	1 (2.0)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (2.0)	0	0	1 (2.0)	0
Paronychia	1 (2.0)	0	1 (2.0)	0	0
Staphylococcal bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Tinea pedis	1 (2.0)	1 (2.0)	0	0	0
Upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.0)	1 (2.0)	0	0	0
Fall	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	18 (35.3)	2 (3.9)	0	2 (3.9)	14 (27.5)
White blood cell count decreased	10 (19.6)	0	0	2 (3.9)	8 (15.7)
Lymphocyte count decreased	6 (11.8)	0	0	0	6 (11.8)
Neutrophil count decreased	6 (11.8)	0	1 (2.0)	1 (2.0)	4 (7.8)
Platelet count decreased	6 (11.8)	0	0	1 (2.0)	5 (9.8)
Alanine aminotransferase increased	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Aspartate aminotransferase increased	2 (3.9)	2 (3.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	2 (3.9)	2 (3.9)	0	0	0
Blood fibrinogen decreased	1 (2.0)	0	0	1 (2.0)	0
Blood fibrinogen increased	1 (2.0)	1 (2.0)	0	0	0
Weight increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (27.5)	7 (13.7)	4 (7.8)	2 (3.9)	1 (2.0)
Decreased appetite	5 (9.8)	2 (3.9)	3 (5.9)	0	0
Hyperphosphataemia	2 (3.9)	2 (3.9)	0	0	0
Hypoalbuminaemia	2 (3.9)	2 (3.9)	0	0	0
Hypocalcaemia	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Hypokalaemia	2 (3.9)	0	0	1 (2.0)	1 (2.0)
Hypomagnesaemia	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hypophosphataemia	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Hyponatraemia	1 (2.0)	1 (2.0)	0	0	0
Vitamin d deficiency	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (5.9)	0	2 (3.9)	1 (2.0)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	1 (2.0)	0	1 (2.0)	0	0
Muscular weakness	1 (2.0)	0	1 (2.0)	0	0
Pain in jaw	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					
-Total	3 (5.9)	1 (2.0)	2 (3.9)	0	0
Headache	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Posterior reversible encephalopathy syndrome	1 (2.0)	0	1 (2.0)	0	0
Seizure	1 (2.0)	0	1 (2.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (9.8)	3 (5.9)	1 (2.0)	1 (2.0)	0
Cough	3 (5.9)	3 (5.9)	0	0	0
Epistaxis	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Pulmonary oedema	1 (2.0)	1 (2.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (13.7)	5 (9.8)	2 (3.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Rash papular	2 (3.9)	2 (3.9)	0	0	0
Acne	1 (2.0)	1 (2.0)	0	0	0
Drug eruption	1 (2.0)	0	1 (2.0)	0	0
Rash	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	3 (5.9)	1 (2.0)	1 (2.0)	1 (2.0)	0
Hypotension	3 (5.9)	1 (2.0)	1 (2.0)	1 (2.0)	0
Flushing	1 (2.0)	1 (2.0)	0	0	0
Peripheral ischaemia	1 (2.0)	0	1 (2.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206k
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (70.4)	2 (7.4)	3 (11.1)	4 (14.8)	10 (37.0)
Blood and lymphatic system disorders					
-Total	5 (18.5)	0	0	4 (14.8)	1 (3.7)
Anaemia	2 (7.4)	0	0	2 (7.4)	0
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Thrombocytopenia	1 (3.7)	0	0	0	1 (3.7)
Endocrine disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Adrenal insufficiency	1 (3.7)	0	1 (3.7)	0	0
Eye disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye pain	1 (3.7)	1 (3.7)	0	0	0
Gastrointestinal disorders					
-Total	6 (22.2)	2 (7.4)	4 (14.8)	0	0
Diarrhoea	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Nausea	2 (7.4)	0	2 (7.4)	0	0
Stomatitis	2 (7.4)	0	2 (7.4)	0	0
Anal erythema	1 (3.7)	1 (3.7)	0	0	0
Vomiting	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Pyrexia	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Localised oedema	1 (3.7)	0	1 (3.7)	0	0
Immune system disorders					
-Total	1 (3.7)	0	0	1 (3.7)	0
Hypogammaglobulinaemia	1 (3.7)	0	0	1 (3.7)	0
Infections and infestations					
-Total	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)

Region: Europe

Primary system organ class Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Device related infection	1 (3.7)	0	1 (3.7)	0	0
Escherichia bacteraemia	1 (3.7)	0	0	0	1 (3.7)
Gastroenteritis	1 (3.7)	0	1 (3.7)	0	0
Nasopharyngitis	1 (3.7)	1 (3.7)	0	0	0
Oral herpes	1 (3.7)	0	0	1 (3.7)	0
Injury, poisoning and procedural complications					
-Total	1 (3.7)	0	1 (3.7)	0	0
Infusion related reaction	1 (3.7)	0	1 (3.7)	0	0
Investigations					
-Total	8 (29.6)	0	0	1 (3.7)	7 (25.9)
Lymphocyte count decreased	5 (18.5)	0	0	0	5 (18.5)
White blood cell count decreased	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Neutrophil count decreased	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Platelet count decreased	2 (7.4)	0	0	0	2 (7.4)
C-reactive protein increased	1 (3.7)	0	0	1 (3.7)	0
Metabolism and nutrition disorders					

Region: Europe

Primary system organ class Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hypokalaemia	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Hypocalcaemia	1 (3.7)	0	0	1 (3.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Cough	1 (3.7)	1 (3.7)	0	0	0
Oropharyngeal pain	1 (3.7)	1 (3.7)	0	0	0
Pleural effusion	1 (3.7)	0	1 (3.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Acne	1 (3.7)	1 (3.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented

in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206k
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (88.6)	12 (27.3)	11 (25.0)	5 (11.4)	11 (25.0)
Blood and lymphatic system disorders					
-Total	8 (18.2)	1 (2.3)	1 (2.3)	3 (6.8)	3 (6.8)
Anaemia	6 (13.6)	1 (2.3)	1 (2.3)	4 (9.1)	0
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphopenia	1 (2.3)	0	0	0	1 (2.3)
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Cardiac disorders					
-Total	2 (4.5)	2 (4.5)	0	0	0
Tachycardia	2 (4.5)	2 (4.5)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Eyelid oedema	1 (2.3)	0	1 (2.3)	0	0
Vision blurred	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	17 (38.6)	8 (18.2)	7 (15.9)	2 (4.5)	0
Nausea	10 (22.7)	4 (9.1)	5 (11.4)	1 (2.3)	0
Vomiting	6 (13.6)	4 (9.1)	1 (2.3)	1 (2.3)	0
Abdominal pain	3 (6.8)	3 (6.8)	0	0	0
Gingival bleeding	2 (4.5)	2 (4.5)	0	0	0
Stomatitis	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Constipation	1 (2.3)	0	1 (2.3)	0	0
Diarrhoea	1 (2.3)	1 (2.3)	0	0	0
Haematemesis	1 (2.3)	1 (2.3)	0	0	0
Lip pain	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					
-Total	10 (22.7)	6 (13.6)	3 (6.8)	1 (2.3)	0

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Chills	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Catheter site dermatitis	1 (2.3)	1 (2.3)	0	0	0
Catheter site pain	1 (2.3)	0	1 (2.3)	0	0
Fatigue	1 (2.3)	1 (2.3)	0	0	0
Generalised oedema	1 (2.3)	0	0	1 (2.3)	0
Oedema peripheral	1 (2.3)	1 (2.3)	0	0	0
Vascular device occlusion	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	2 (4.5)	0	2 (4.5)	0	0
Hypogammaglobulinaemia	1 (2.3)	0	1 (2.3)	0	0
Seasonal allergy	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	6 (13.6)	1 (2.3)	2 (4.5)	2 (4.5)	1 (2.3)
Paronychia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Conjunctivitis	1 (2.3)	1 (2.3)	0	0	0
Fungaemia	1 (2.3)	0	0	0	1 (2.3)
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Vulval cellulitis	1 (2.3)	0	0	1 (2.3)	0
Injury, poisoning and procedural complications					
-Total	1 (2.3)	1 (2.3)	0	0	0
Fall	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	16 (36.4)	4 (9.1)	2 (4.5)	2 (4.5)	8 (18.2)
White blood cell count decreased	7 (15.9)	0	1 (2.3)	1 (2.3)	5 (11.4)
Neutrophil count decreased	5 (11.4)	0	1 (2.3)	0	4 (9.1)
Platelet count decreased	4 (9.1)	0	0	1 (2.3)	3 (6.8)
Alanine aminotransferase increased	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Aspartate aminotransferase increased	2 (4.5)	2 (4.5)	0	0	0
Blood fibrinogen decreased	2 (4.5)	1 (2.3)	0	1 (2.3)	0
International normalised ratio increased	2 (4.5)	2 (4.5)	0	0	0
Blood alkaline phosphatase decreased	1 (2.3)	1 (2.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood fibrinogen increased	1 (2.3)	1 (2.3)	0	0	0
Blood phosphorus increased	1 (2.3)	0	1 (2.3)	0	0
Lymphocyte count decreased	1 (2.3)	0	0	0	1 (2.3)
Serum ferritin increased	1 (2.3)	0	1 (2.3)	0	0
Weight increased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (29.5)	8 (18.2)	4 (9.1)	1 (2.3)	0
Decreased appetite	6 (13.6)	3 (6.8)	3 (6.8)	0	0
Hyperphosphataemia	2 (4.5)	2 (4.5)	0	0	0
Hypoalbuminaemia	2 (4.5)	2 (4.5)	0	0	0
Hypomagnesaemia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hypophosphataemia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Hypocalcaemia	1 (2.3)	1 (2.3)	0	0	0
Hypokalaemia	1 (2.3)	0	0	1 (2.3)	0
Hyponatraemia	1 (2.3)	1 (2.3)	0	0	0
Vitamin d deficiency	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (9.1)	1 (2.3)	2 (4.5)	1 (2.3)	0
Bone pain	1 (2.3)	0	1 (2.3)	0	0
Muscular weakness	1 (2.3)	0	1 (2.3)	0	0
Pain in extremity	1 (2.3)	1 (2.3)	0	0	0
Pain in jaw	1 (2.3)	0	0	1 (2.3)	0
Nervous system disorders					
-Total	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Headache	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Posterior reversible encephalopathy syndrome	1 (2.3)	0	1 (2.3)	0	0
Seizure	1 (2.3)	0	1 (2.3)	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Psychiatric disorders					
-Total	1 (2.3)	0	0	1 (2.3)	0
Irritability	1 (2.3)	0	0	1 (2.3)	0
Renal and urinary disorders					
-Total	3 (6.8)	3 (6.8)	0	0	0
Acute kidney injury	1 (2.3)	1 (2.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysuria	1 (2.3)	1 (2.3)	0	0	0
Renal pain	1 (2.3)	1 (2.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (9.1)	2 (4.5)	0	1 (2.3)	1 (2.3)
Cough	2 (4.5)	2 (4.5)	0	0	0
Epistaxis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Pulmonary haemorrhage	1 (2.3)	0	0	0	1 (2.3)
Pulmonary oedema	1 (2.3)	1 (2.3)	0	0	0
Respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Skin and subcutaneous tissue disorders					
-Total	8 (18.2)	4 (9.1)	4 (9.1)	0	0
Pruritus	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Rash	2 (4.5)	2 (4.5)	0	0	0
Rash papular	2 (4.5)	2 (4.5)	0	0	0
Drug eruption	1 (2.3)	0	1 (2.3)	0	0
Erythema	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	0	1 (2.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Petechiae	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	5 (11.4)	2 (4.5)	2 (4.5)	1 (2.3)	0
Hypotension	4 (9.1)	2 (4.5)	1 (2.3)	1 (2.3)	0
Flushing	1 (2.3)	1 (2.3)	0	0	0
Hypertension	1 (2.3)	0	1 (2.3)	0	0
Peripheral ischaemia	1 (2.3)	0	1 (2.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206k
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Rest of World

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	4 (57.1)	0	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Nausea	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	1 (14.3)	1 (14.3)	0	0	0
Tinea pedis	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0

Region: Rest of World

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206l
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (78.3)	9 (19.6)	7 (15.2)	5 (10.9)	15 (32.6)
Blood and lymphatic system disorders					
-Total	9 (19.6)	0	1 (2.2)	5 (10.9)	3 (6.5)
Anaemia	4 (8.7)	0	1 (2.2)	3 (6.5)	0
Febrile neutropenia	2 (4.3)	0	0	2 (4.3)	0
Leukopenia	1 (2.2)	0	0	0	1 (2.2)
Lymphopenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	0	0	1 (2.2)
Cardiac disorders					
-Total	2 (4.3)	2 (4.3)	0	0	0
Tachycardia	2 (4.3)	2 (4.3)	0	0	0

Prior SCT therapy: Yes

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Adrenal insufficiency	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	2 (4.3)	2 (4.3)	0	0	0
Eye pain	1 (2.2)	1 (2.2)	0	0	0
Vision blurred	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal disorders					
-Total	13 (28.3)	7 (15.2)	6 (13.0)	0	0
Nausea	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Vomiting	4 (8.7)	4 (8.7)	0	0	0
Diarrhoea	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Stomatitis	2 (4.3)	0	2 (4.3)	0	0
Abdominal pain	1 (2.2)	1 (2.2)	0	0	0
Anal erythema	1 (2.2)	1 (2.2)	0	0	0
Constipation	1 (2.2)	1 (2.2)	0	0	0
Gingival bleeding	1 (2.2)	1 (2.2)	0	0	0

Prior SCT therapy: Yes

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	7 (15.2)	3 (6.5)	3 (6.5)	1 (2.2)	0
Pyrexia	6 (13.0)	3 (6.5)	3 (6.5)	0	0
Chills	1 (2.2)	1 (2.2)	0	0	0
Generalised oedema	1 (2.2)	0	0	1 (2.2)	0
Localised oedema	1 (2.2)	0	1 (2.2)	0	0
Immune system disorders					
-Total	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Hypogammaglobulinaemia	1 (2.2)	0	0	1 (2.2)	0
Seasonal allergy	1 (2.2)	0	1 (2.2)	0	0
Infections and infestations					
-Total	8 (17.4)	2 (4.3)	3 (6.5)	1 (2.2)	2 (4.3)
Bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Conjunctivitis	1 (2.2)	1 (2.2)	0	0	0
Device related infection	1 (2.2)	0	1 (2.2)	0	0
Escherichia bacteraemia	1 (2.2)	0	0	0	1 (2.2)
Fungaemia	1 (2.2)	0	0	0	1 (2.2)

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (2.2)	0	1 (2.2)	0	0
Nasopharyngitis	1 (2.2)	1 (2.2)	0	0	0
Oral herpes	1 (2.2)	0	0	1 (2.2)	0
Paronychia	1 (2.2)	0	1 (2.2)	0	0
Tinea pedis	1 (2.2)	1 (2.2)	0	0	0
Upper respiratory tract infection	1 (2.2)	0	1 (2.2)	0	0
Injury, poisoning and procedural complications					
-Total	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Fall	1 (2.2)	1 (2.2)	0	0	0
Infusion related reaction	1 (2.2)	0	1 (2.2)	0	0
Investigations					
-Total	15 (32.6)	3 (6.5)	1 (2.2)	1 (2.2)	10 (21.7)
White blood cell count decreased	8 (17.4)	0	0	1 (2.2)	7 (15.2)
Neutrophil count decreased	5 (10.9)	0	0	1 (2.2)	4 (8.7)
Lymphocyte count decreased	4 (8.7)	0	0	0	4 (8.7)
Platelet count decreased	4 (8.7)	0	0	1 (2.2)	3 (6.5)
Alanine aminotransferase increased	2 (4.3)	1 (2.2)	1 (2.2)	0	0

Prior SCT therapy: Yes

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (2.2)	1 (2.2)	0	0	0
Blood alkaline phosphatase decreased	1 (2.2)	1 (2.2)	0	0	0
Blood fibrinogen increased	1 (2.2)	1 (2.2)	0	0	0
C-reactive protein increased	1 (2.2)	0	0	1 (2.2)	0
International normalised ratio increased	1 (2.2)	1 (2.2)	0	0	0
Serum ferritin increased	1 (2.2)	0	1 (2.2)	0	0
Metabolism and nutrition disorders					
-Total	10 (21.7)	4 (8.7)	3 (6.5)	2 (4.3)	1 (2.2)
Decreased appetite	3 (6.5)	0	3 (6.5)	0	0
Hypoalbuminaemia	2 (4.3)	2 (4.3)	0	0	0
Hypocalcaemia	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Hypokalaemia	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Hyperphosphataemia	1 (2.2)	1 (2.2)	0	0	0
Hyponatraemia	1 (2.2)	1 (2.2)	0	0	0
Vitamin d deficiency	1 (2.2)	1 (2.2)	0	0	0

Prior SCT therapy: Yes

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Bone pain	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	1 (2.2)	1 (2.2)	0	0	0
Acute kidney injury	1 (2.2)	1 (2.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (15.2)	4 (8.7)	1 (2.2)	1 (2.2)	1 (2.2)
Cough	3 (6.5)	3 (6.5)	0	0	0
Epistaxis	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Oropharyngeal pain	1 (2.2)	1 (2.2)	0	0	0
Pleural effusion	1 (2.2)	0	1 (2.2)	0	0
Pulmonary haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Pulmonary oedema	1 (2.2)	1 (2.2)	0	0	0
Respiratory failure	1 (2.2)	0	0	0	1 (2.2)
Skin and subcutaneous tissue disorders					

Prior SCT therapy: Yes

	All patients N=46				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.9)	5 (10.9)	0	0	0
Rash papular	2 (4.3)	2 (4.3)	0	0	0
Acne	1 (2.2)	1 (2.2)	0	0	0
Pruritus	1 (2.2)	1 (2.2)	0	0	0
Rash	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Hypotension	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)	0
Flushing	1 (2.2)	1 (2.2)	0	0	0
Peripheral ischaemia	1 (2.2)	0	1 (2.2)	0	0

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Table 206l
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (81.3)	9 (28.1)	7 (21.9)	4 (12.5)	6 (18.8)
Blood and lymphatic system disorders					
-Total	4 (12.5)	1 (3.1)	0	2 (6.3)	1 (3.1)
Anaemia	4 (12.5)	1 (3.1)	0	3 (9.4)	0
Febrile neutropenia	2 (6.3)	0	0	2 (6.3)	0
Neutropenia	1 (3.1)	0	0	0	1 (3.1)
Eye disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Eyelid oedema	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	12 (37.5)	5 (15.6)	5 (15.6)	2 (6.3)	0

Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Vomiting	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Abdominal pain	2 (6.3)	2 (6.3)	0	0	0
Stomatitis	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Constipation	1 (3.1)	0	1 (3.1)	0	0
Diarrhoea	1 (3.1)	1 (3.1)	0	0	0
Gingival bleeding	1 (3.1)	1 (3.1)	0	0	0
Haematemesis	1 (3.1)	1 (3.1)	0	0	0
Lip pain	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	8 (25.0)	5 (15.6)	3 (9.4)	0	0
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Catheter site dermatitis	1 (3.1)	1 (3.1)	0	0	0
Catheter site pain	1 (3.1)	0	1 (3.1)	0	0
Chills	1 (3.1)	0	1 (3.1)	0	0
Fatigue	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device occlusion	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Hypogammaglobulinaemia	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Paronychia	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Vulval cellulitis	1 (3.1)	0	0	1 (3.1)	0
Investigations					
-Total	9 (28.1)	1 (3.1)	1 (3.1)	2 (6.3)	5 (15.6)
White blood cell count decreased	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Blood fibrinogen decreased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Lymphocyte count decreased	2 (6.3)	0	0	0	2 (6.3)
Neutrophil count decreased	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Platelet count decreased	2 (6.3)	0	0	0	2 (6.3)
Alanine aminotransferase increased	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.1)	1 (3.1)	0	0	0
Blood phosphorus increased	1 (3.1)	0	1 (3.1)	0	0
International normalised ratio increased	1 (3.1)	1 (3.1)	0	0	0
Weight increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Decreased appetite	3 (9.4)	3 (9.4)	0	0	0
Hypomagnesaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hypophosphataemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Hyperphosphataemia	1 (3.1)	1 (3.1)	0	0	0
Hypokalaemia	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Muscular weakness	1 (3.1)	0	1 (3.1)	0	0
Pain in extremity	1 (3.1)	1 (3.1)	0	0	0
Pain in jaw	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: No

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Headache	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Posterior reversible encephalopathy syndrome	1 (3.1)	0	1 (3.1)	0	0
Seizure	1 (3.1)	0	1 (3.1)	0	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	1 (3.1)	0	0	1 (3.1)	0
Irritability	1 (3.1)	0	0	1 (3.1)	0
Renal and urinary disorders					
-Total	2 (6.3)	2 (6.3)	0	0	0
Dysuria	1 (3.1)	1 (3.1)	0	0	0
Renal pain	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.6)	1 (3.1)	4 (12.5)	0	0
Pruritus	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Drug eruption	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Petechiae	1 (3.1)	1 (3.1)	0	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hypertension	1 (3.1)	0	1 (3.1)	0	0
Hypotension	1 (3.1)	1 (3.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206m
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (92.3)	9 (69.2)	3 (23.1)	0	0
Eye disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Vision blurred	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	7 (53.8)	5 (38.5)	2 (15.4)	0	0
Nausea	6 (46.2)	4 (30.8)	2 (15.4)	0	0
Vomiting	2 (15.4)	2 (15.4)	0	0	0
Abdominal pain	1 (7.7)	1 (7.7)	0	0	0
Constipation	1 (7.7)	1 (7.7)	0	0	0
Gingival bleeding	1 (7.7)	1 (7.7)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	2 (15.4)	2 (15.4)	0	0	0
Catheter site dermatitis	1 (7.7)	1 (7.7)	0	0	0
Fatigue	1 (7.7)	1 (7.7)	0	0	0
Infections and infestations					
-Total	1 (7.7)	1 (7.7)	0	0	0
Tinea pedis	1 (7.7)	1 (7.7)	0	0	0
Investigations					
-Total	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Blood fibrinogen decreased	1 (7.7)	1 (7.7)	0	0	0
International normalised ratio increased	1 (7.7)	1 (7.7)	0	0	0
Serum ferritin increased	1 (7.7)	0	1 (7.7)	0	0
Metabolism and nutrition disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Decreased appetite	1 (7.7)	0	1 (7.7)	0	0
Hyperphosphataemia	1 (7.7)	1 (7.7)	0	0	0
Nervous system disorders					

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (7.7)	1 (7.7)	0	0	0
Headache	1 (7.7)	1 (7.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Rash papular	2 (15.4)	2 (15.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206m
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (76.9)	9 (13.8)	11 (16.9)	9 (13.8)	21 (32.3)
Blood and lymphatic system disorders					
-Total	13 (20.0)	1 (1.5)	1 (1.5)	7 (10.8)	4 (6.2)
Anaemia	8 (12.3)	1 (1.5)	1 (1.5)	6 (9.2)	0
Febrile neutropenia	4 (6.2)	0	0	4 (6.2)	0
Leukopenia	1 (1.5)	0	0	0	1 (1.5)
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)
Neutropenia	1 (1.5)	0	0	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Cardiac disorders					
-Total	2 (3.1)	2 (3.1)	0	0	0

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (3.1)	2 (3.1)	0	0	0
Endocrine disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Eye pain	1 (1.5)	1 (1.5)	0	0	0
Eyelid oedema	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	18 (27.7)	7 (10.8)	9 (13.8)	2 (3.1)	0
Nausea	7 (10.8)	1 (1.5)	5 (7.7)	1 (1.5)	0
Vomiting	5 (7.7)	3 (4.6)	1 (1.5)	1 (1.5)	0
Stomatitis	4 (6.2)	0	3 (4.6)	1 (1.5)	0
Diarrhoea	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Abdominal pain	2 (3.1)	2 (3.1)	0	0	0
Anal erythema	1 (1.5)	1 (1.5)	0	0	0
Constipation	1 (1.5)	0	1 (1.5)	0	0
Gingival bleeding	1 (1.5)	1 (1.5)	0	0	0

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (1.5)	1 (1.5)	0	0	0
Lip pain	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	13 (20.0)	6 (9.2)	6 (9.2)	1 (1.5)	0
Pyrexia	8 (12.3)	4 (6.2)	4 (6.2)	0	0
Chills	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Catheter site pain	1 (1.5)	0	1 (1.5)	0	0
Generalised oedema	1 (1.5)	0	0	1 (1.5)	0
Localised oedema	1 (1.5)	0	1 (1.5)	0	0
Oedema peripheral	1 (1.5)	1 (1.5)	0	0	0
Vascular device occlusion	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Hypogammaglobulinaemia	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Seasonal allergy	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	10 (15.4)	2 (3.1)	3 (4.6)	3 (4.6)	2 (3.1)

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Conjunctivitis	1 (1.5)	1 (1.5)	0	0	0
Device related infection	1 (1.5)	0	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Fungaemia	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Nasopharyngitis	1 (1.5)	1 (1.5)	0	0	0
Oral herpes	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Upper respiratory tract infection	1 (1.5)	0	1 (1.5)	0	0
Vulval cellulitis	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Fall	1 (1.5)	1 (1.5)	0	0	0
Infusion related reaction	1 (1.5)	0	1 (1.5)	0	0
Investigations					

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (32.3)	2 (3.1)	1 (1.5)	3 (4.6)	15 (23.1)
White blood cell count decreased	11 (16.9)	0	1 (1.5)	2 (3.1)	8 (12.3)
Neutrophil count decreased	7 (10.8)	0	1 (1.5)	1 (1.5)	5 (7.7)
Lymphocyte count decreased	6 (9.2)	0	0	0	6 (9.2)
Platelet count decreased	6 (9.2)	0	0	1 (1.5)	5 (7.7)
Alanine aminotransferase increased	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Aspartate aminotransferase increased	2 (3.1)	2 (3.1)	0	0	0
Blood alkaline phosphatase decreased	1 (1.5)	1 (1.5)	0	0	0
Blood fibrinogen decreased	1 (1.5)	0	0	1 (1.5)	0
Blood fibrinogen increased	1 (1.5)	1 (1.5)	0	0	0
Blood phosphorus increased	1 (1.5)	0	1 (1.5)	0	0
C-reactive protein increased	1 (1.5)	0	0	1 (1.5)	0
International normalised ratio increased	1 (1.5)	1 (1.5)	0	0	0
Weight increased	1 (1.5)	1 (1.5)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (21.5)	7 (10.8)	3 (4.6)	3 (4.6)	1 (1.5)

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	5 (7.7)	3 (4.6)	2 (3.1)	0	0
Hypokalaemia	3 (4.6)	0	0	2 (3.1)	1 (1.5)
Hypoalbuminaemia	2 (3.1)	2 (3.1)	0	0	0
Hypocalcaemia	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Hypomagnesaemia	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Hypophosphataemia	2 (3.1)	0	1 (1.5)	1 (1.5)	0
Hyperphosphataemia	1 (1.5)	1 (1.5)	0	0	0
Hyponatraemia	1 (1.5)	1 (1.5)	0	0	0
Vitamin d deficiency	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Bone pain	1 (1.5)	0	1 (1.5)	0	0
Muscular weakness	1 (1.5)	0	1 (1.5)	0	0
Pain in extremity	1 (1.5)	1 (1.5)	0	0	0
Pain in jaw	1 (1.5)	0	0	1 (1.5)	0
Nervous system disorders					
-Total	3 (4.6)	1 (1.5)	2 (3.1)	0	0

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (3.1)	1 (1.5)	1 (1.5)	0	0
Posterior reversible encephalopathy syndrome	1 (1.5)	0	1 (1.5)	0	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Somnolence	1 (1.5)	1 (1.5)	0	0	0
Psychiatric disorders					
-Total	1 (1.5)	0	0	1 (1.5)	0
Irritability	1 (1.5)	0	0	1 (1.5)	0
Renal and urinary disorders					
-Total	3 (4.6)	3 (4.6)	0	0	0
Acute kidney injury	1 (1.5)	1 (1.5)	0	0	0
Dysuria	1 (1.5)	1 (1.5)	0	0	0
Renal pain	1 (1.5)	1 (1.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (10.8)	4 (6.2)	1 (1.5)	1 (1.5)	1 (1.5)
Cough	3 (4.6)	3 (4.6)	0	0	0
Epistaxis	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Oropharyngeal pain	1 (1.5)	1 (1.5)	0	0	0

Eligibility for SCT: No

	All patients N=65				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (1.5)	0	1 (1.5)	0	0
Pulmonary haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Pulmonary oedema	1 (1.5)	1 (1.5)	0	0	0
Respiratory failure	1 (1.5)	0	0	0	1 (1.5)
Skin and subcutaneous tissue disorders					
-Total	8 (12.3)	4 (6.2)	4 (6.2)	0	0
Pruritus	4 (6.2)	2 (3.1)	2 (3.1)	0	0
Rash	2 (3.1)	2 (3.1)	0	0	0
Acne	1 (1.5)	1 (1.5)	0	0	0
Drug eruption	1 (1.5)	0	1 (1.5)	0	0
Erythema	1 (1.5)	1 (1.5)	0	0	0
Ingrowing nail	1 (1.5)	0	1 (1.5)	0	0
Petechiae	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	5 (7.7)	2 (3.1)	2 (3.1)	1 (1.5)	0
Hypotension	4 (6.2)	2 (3.1)	1 (1.5)	1 (1.5)	0
Flushing	1 (1.5)	1 (1.5)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (1.5)	0	1 (1.5)	0	0
Peripheral ischaemia	1 (1.5)	0	1 (1.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206n
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (84.0)	5 (20.0)	6 (24.0)	3 (12.0)	7 (28.0)
Blood and lymphatic system disorders					
-Total	4 (16.0)	0	0	2 (8.0)	2 (8.0)
Anaemia	3 (12.0)	0	0	3 (12.0)	0
Febrile neutropenia	2 (8.0)	0	0	2 (8.0)	0
Leukopenia	1 (4.0)	0	0	0	1 (4.0)
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Eye disorders					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Eye pain	1 (4.0)	1 (4.0)	0	0	0
Eyelid oedema	1 (4.0)	0	1 (4.0)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	10 (40.0)	4 (16.0)	5 (20.0)	1 (4.0)	0
Nausea	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Stomatitis	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Vomiting	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Abdominal pain	2 (8.0)	2 (8.0)	0	0	0
Diarrhoea	2 (8.0)	2 (8.0)	0	0	0
Gingival bleeding	1 (4.0)	1 (4.0)	0	0	0
Lip pain	1 (4.0)	1 (4.0)	0	0	0
General disorders and administration site conditions					
-Total	5 (20.0)	3 (12.0)	2 (8.0)	0	0
Chills	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Pyrexia	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Catheter site dermatitis	1 (4.0)	1 (4.0)	0	0	0
Localised oedema	1 (4.0)	0	1 (4.0)	0	0
Oedema peripheral	1 (4.0)	1 (4.0)	0	0	0
Immune system disorders					

Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Hypogammaglobulinaemia	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Seasonal allergy	1 (4.0)	0	1 (4.0)	0	0
Infections and infestations					
-Total	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Conjunctivitis	1 (4.0)	1 (4.0)	0	0	0
Device related infection	1 (4.0)	0	1 (4.0)	0	0
Tinea pedis	1 (4.0)	1 (4.0)	0	0	0
Upper respiratory tract infection	1 (4.0)	0	1 (4.0)	0	0
Vulval cellulitis	1 (4.0)	0	0	1 (4.0)	0
Investigations					
-Total	7 (28.0)	1 (4.0)	1 (4.0)	0	5 (20.0)
White blood cell count decreased	3 (12.0)	0	1 (4.0)	0	2 (8.0)
Lymphocyte count decreased	2 (8.0)	0	0	0	2 (8.0)
Neutrophil count decreased	2 (8.0)	0	0	0	2 (8.0)
Platelet count decreased	2 (8.0)	0	0	1 (4.0)	1 (4.0)
Blood fibrinogen increased	1 (4.0)	1 (4.0)	0	0	0
Blood phosphorus increased	1 (4.0)	0	1 (4.0)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (24.0)	4 (16.0)	1 (4.0)	1 (4.0)	0
Decreased appetite	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Hypokalaemia	1 (4.0)	0	0	1 (4.0)	0
Hypomagnesaemia	1 (4.0)	1 (4.0)	0	0	0
Hypophosphataemia	1 (4.0)	0	0	1 (4.0)	0
Vitamin d deficiency	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Pain in extremity	1 (4.0)	1 (4.0)	0	0	0
Nervous system disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Headache	1 (4.0)	1 (4.0)	0	0	0
Somnolence	1 (4.0)	1 (4.0)	0	0	0
Psychiatric disorders					
-Total	1 (4.0)	0	0	1 (4.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (4.0)	0	0	1 (4.0)	0
Renal and urinary disorders					
-Total	2 (8.0)	2 (8.0)	0	0	0
Dysuria	1 (4.0)	1 (4.0)	0	0	0
Renal pain	1 (4.0)	1 (4.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Cough	1 (4.0)	1 (4.0)	0	0	0
Pleural effusion	1 (4.0)	0	1 (4.0)	0	0
Pulmonary oedema	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Pruritus	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Acne	1 (4.0)	1 (4.0)	0	0	0
Petechiae	1 (4.0)	1 (4.0)	0	0	0
Rash	1 (4.0)	1 (4.0)	0	0	0
Rash papular	1 (4.0)	1 (4.0)	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Hypotension	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0
Flushing	1 (4.0)	1 (4.0)	0	0	0
Hypertension	1 (4.0)	0	1 (4.0)	0	0
Peripheral ischaemia	1 (4.0)	0	1 (4.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206n
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (77.4)	13 (24.5)	8 (15.1)	6 (11.3)	14 (26.4)
Blood and lymphatic system disorders					
-Total	9 (17.0)	1 (1.9)	1 (1.9)	5 (9.4)	2 (3.8)
Anaemia	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Febrile neutropenia	2 (3.8)	0	0	2 (3.8)	0
Lymphopenia	1 (1.9)	0	0	0	1 (1.9)
Thrombocytopenia	1 (1.9)	0	0	0	1 (1.9)
Cardiac disorders					
-Total	2 (3.8)	2 (3.8)	0	0	0
Tachycardia	2 (3.8)	2 (3.8)	0	0	0
Endocrine disorders					

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	1 (1.9)	0	0
Adrenal insufficiency	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Vision blurred	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	15 (28.3)	8 (15.1)	6 (11.3)	1 (1.9)	0
Nausea	9 (17.0)	4 (7.5)	5 (9.4)	0	0
Vomiting	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Constipation	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal pain	1 (1.9)	1 (1.9)	0	0	0
Anal erythema	1 (1.9)	1 (1.9)	0	0	0
Diarrhoea	1 (1.9)	0	1 (1.9)	0	0
Gingival bleeding	1 (1.9)	1 (1.9)	0	0	0
Haematemesis	1 (1.9)	1 (1.9)	0	0	0
Stomatitis	1 (1.9)	0	1 (1.9)	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (18.9)	5 (9.4)	4 (7.5)	1 (1.9)	0
Pyrexia	6 (11.3)	3 (5.7)	3 (5.7)	0	0
Catheter site pain	1 (1.9)	0	1 (1.9)	0	0
Fatigue	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	0	0	1 (1.9)	0
Vascular device occlusion	1 (1.9)	1 (1.9)	0	0	0
Infections and infestations					
-Total	7 (13.2)	2 (3.8)	1 (1.9)	2 (3.8)	2 (3.8)
Paronychia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	0	1 (1.9)
Fungaemia	1 (1.9)	0	0	0	1 (1.9)
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Nasopharyngitis	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Fall	1 (1.9)	1 (1.9)	0	0	0
Infusion related reaction	1 (1.9)	0	1 (1.9)	0	0
Investigations					
-Total	17 (32.1)	3 (5.7)	1 (1.9)	3 (5.7)	10 (18.9)
White blood cell count decreased	8 (15.1)	0	0	2 (3.8)	6 (11.3)
Neutrophil count decreased	5 (9.4)	0	1 (1.9)	1 (1.9)	3 (5.7)
Lymphocyte count decreased	4 (7.5)	0	0	0	4 (7.5)
Platelet count decreased	4 (7.5)	0	0	0	4 (7.5)
Alanine aminotransferase increased	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Aspartate aminotransferase increased	2 (3.8)	2 (3.8)	0	0	0
Blood fibrinogen decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
International normalised ratio increased	2 (3.8)	2 (3.8)	0	0	0
Blood alkaline phosphatase decreased	1 (1.9)	1 (1.9)	0	0	0
C-reactive protein increased	1 (1.9)	0	0	1 (1.9)	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	10 (18.9)	4 (7.5)	3 (5.7)	2 (3.8)	1 (1.9)
Decreased appetite	2 (3.8)	0	2 (3.8)	0	0
Hyperphosphataemia	2 (3.8)	2 (3.8)	0	0	0
Hypoalbuminaemia	2 (3.8)	2 (3.8)	0	0	0
Hypocalcaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hypokalaemia	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Hypomagnesaemia	1 (1.9)	0	1 (1.9)	0	0
Hyponatraemia	1 (1.9)	1 (1.9)	0	0	0
Hypophosphataemia	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Bone pain	1 (1.9)	0	1 (1.9)	0	0
Muscular weakness	1 (1.9)	0	1 (1.9)	0	0
Pain in jaw	1 (1.9)	0	0	1 (1.9)	0
Nervous system disorders					
-Total	3 (5.7)	1 (1.9)	2 (3.8)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Posterior reversible encephalopathy syndrome	1 (1.9)	0	1 (1.9)	0	0
Seizure	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Acute kidney injury	1 (1.9)	1 (1.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (9.4)	3 (5.7)	0	1 (1.9)	1 (1.9)
Cough	2 (3.8)	2 (3.8)	0	0	0
Epistaxis	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Oropharyngeal pain	1 (1.9)	1 (1.9)	0	0	0
Pulmonary haemorrhage	1 (1.9)	0	0	0	1 (1.9)
Respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Skin and subcutaneous tissue disorders					
-Total	6 (11.3)	3 (5.7)	3 (5.7)	0	0
Pruritus	2 (3.8)	1 (1.9)	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Drug eruption	1 (1.9)	0	1 (1.9)	0	0
Erythema	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	0	1 (1.9)	0	0
Rash	1 (1.9)	1 (1.9)	0	0	0
Rash papular	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Hypotension	1 (1.9)	1 (1.9)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206o
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	3 (27.3)	1 (9.1)	1 (9.1)	2 (18.2)
Blood and lymphatic system disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Leukopenia	1 (9.1)	0	0	0	1 (9.1)
Gastrointestinal disorders					
-Total	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Nausea	2 (18.2)	0	2 (18.2)	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	1 (9.1)	1 (9.1)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (9.1)	1 (9.1)	0	0	0
Immune system disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hypogammaglobulinaemia	1 (9.1)	0	0	1 (9.1)	0
Seasonal allergy	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Blood fibrinogen increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Vitamin d deficiency	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Pleural effusion	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acne	1 (9.1)	1 (9.1)	0	0	0
Pruritus	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypotension	1 (9.1)	0	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206o
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (82.1)	15 (22.4)	13 (19.4)	8 (11.9)	19 (28.4)
Blood and lymphatic system disorders					
-Total	12 (17.9)	1 (1.5)	1 (1.5)	7 (10.4)	3 (4.5)
Anaemia	8 (11.9)	1 (1.5)	1 (1.5)	6 (9.0)	0
Febrile neutropenia	4 (6.0)	0	0	4 (6.0)	0
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)
Neutropenia	1 (1.5)	0	0	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	0	0	1 (1.5)
Cardiac disorders					
-Total	2 (3.0)	2 (3.0)	0	0	0
Tachycardia	2 (3.0)	2 (3.0)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Endocrine disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Eye pain	1 (1.5)	1 (1.5)	0	0	0
Eyelid oedema	1 (1.5)	0	1 (1.5)	0	0
Vision blurred	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	22 (32.8)	11 (16.4)	9 (13.4)	2 (3.0)	0
Nausea	11 (16.4)	5 (7.5)	5 (7.5)	1 (1.5)	0
Vomiting	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Stomatitis	4 (6.0)	0	3 (4.5)	1 (1.5)	0
Abdominal pain	3 (4.5)	3 (4.5)	0	0	0
Diarrhoea	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Constipation	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Gingival bleeding	2 (3.0)	2 (3.0)	0	0	0
Anal erythema	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (1.5)	1 (1.5)	0	0	0
Lip pain	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	14 (20.9)	7 (10.4)	6 (9.0)	1 (1.5)	0
Pyrexia	7 (10.4)	3 (4.5)	4 (6.0)	0	0
Chills	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Catheter site dermatitis	1 (1.5)	1 (1.5)	0	0	0
Catheter site pain	1 (1.5)	0	1 (1.5)	0	0
Fatigue	1 (1.5)	1 (1.5)	0	0	0
Generalised oedema	1 (1.5)	0	0	1 (1.5)	0
Localised oedema	1 (1.5)	0	1 (1.5)	0	0
Oedema peripheral	1 (1.5)	1 (1.5)	0	0	0
Vascular device occlusion	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Hypogammaglobulinaemia	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (16.4)	3 (4.5)	3 (4.5)	3 (4.5)	2 (3.0)
Paronychia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Conjunctivitis	1 (1.5)	1 (1.5)	0	0	0
Device related infection	1 (1.5)	0	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	0	1 (1.5)
Fungaemia	1 (1.5)	0	0	0	1 (1.5)
Gastroenteritis	1 (1.5)	0	1 (1.5)	0	0
Nasopharyngitis	1 (1.5)	1 (1.5)	0	0	0
Oral herpes	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Tinea pedis	1 (1.5)	1 (1.5)	0	0	0
Upper respiratory tract infection	1 (1.5)	0	1 (1.5)	0	0
Vulval cellulitis	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Fall	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infusion related reaction	1 (1.5)	0	1 (1.5)	0	0
Investigations					
-Total	22 (32.8)	3 (4.5)	2 (3.0)	3 (4.5)	14 (20.9)
White blood cell count decreased	10 (14.9)	0	1 (1.5)	2 (3.0)	7 (10.4)
Neutrophil count decreased	7 (10.4)	0	1 (1.5)	1 (1.5)	5 (7.5)
Lymphocyte count decreased	6 (9.0)	0	0	0	6 (9.0)
Platelet count decreased	6 (9.0)	0	0	1 (1.5)	5 (7.5)
Alanine aminotransferase increased	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Aspartate aminotransferase increased	2 (3.0)	2 (3.0)	0	0	0
Blood fibrinogen decreased	2 (3.0)	1 (1.5)	0	1 (1.5)	0
International normalised ratio increased	2 (3.0)	2 (3.0)	0	0	0
Blood alkaline phosphatase decreased	1 (1.5)	1 (1.5)	0	0	0
Blood phosphorus increased	1 (1.5)	0	1 (1.5)	0	0
C-reactive protein increased	1 (1.5)	0	0	1 (1.5)	0
Serum ferritin increased	1 (1.5)	0	1 (1.5)	0	0
Weight increased	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders					
-Total	15 (22.4)	7 (10.4)	4 (6.0)	3 (4.5)	1 (1.5)
Decreased appetite	6 (9.0)	3 (4.5)	3 (4.5)	0	0
Hypokalaemia	3 (4.5)	0	0	2 (3.0)	1 (1.5)
Hyperphosphataemia	2 (3.0)	2 (3.0)	0	0	0
Hypoalbuminaemia	2 (3.0)	2 (3.0)	0	0	0
Hypocalcaemia	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Hypomagnesaemia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Hypophosphataemia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Hyponatraemia	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Bone pain	1 (1.5)	0	1 (1.5)	0	0
Muscular weakness	1 (1.5)	0	1 (1.5)	0	0
Pain in extremity	1 (1.5)	1 (1.5)	0	0	0
Pain in jaw	1 (1.5)	0	0	1 (1.5)	0
Nervous system disorders					

Baseline extramedullary disease presence: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Headache	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Posterior reversible encephalopathy syndrome	1 (1.5)	0	1 (1.5)	0	0
Seizure	1 (1.5)	0	1 (1.5)	0	0
Somnolence	1 (1.5)	1 (1.5)	0	0	0
Psychiatric disorders					
-Total	1 (1.5)	0	0	1 (1.5)	0
Irritability	1 (1.5)	0	0	1 (1.5)	0
Renal and urinary disorders					
-Total	3 (4.5)	3 (4.5)	0	0	0
Acute kidney injury	1 (1.5)	1 (1.5)	0	0	0
Dysuria	1 (1.5)	1 (1.5)	0	0	0
Renal pain	1 (1.5)	1 (1.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (9.0)	4 (6.0)	0	1 (1.5)	1 (1.5)
Cough	3 (4.5)	3 (4.5)	0	0	0
Epistaxis	2 (3.0)	1 (1.5)	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (1.5)	1 (1.5)	0	0	0
Pulmonary haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Pulmonary oedema	1 (1.5)	1 (1.5)	0	0	0
Respiratory failure	1 (1.5)	0	0	0	1 (1.5)
Skin and subcutaneous tissue disorders					
-Total	8 (11.9)	4 (6.0)	4 (6.0)	0	0
Pruritus	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Rash	2 (3.0)	2 (3.0)	0	0	0
Rash papular	2 (3.0)	2 (3.0)	0	0	0
Drug eruption	1 (1.5)	0	1 (1.5)	0	0
Erythema	1 (1.5)	1 (1.5)	0	0	0
Ingrowing nail	1 (1.5)	0	1 (1.5)	0	0
Petechiae	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Hypotension	3 (4.5)	2 (3.0)	0	1 (1.5)	0
Flushing	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (1.5)	0	1 (1.5)	0	0
Peripheral ischaemia	1 (1.5)	0	1 (1.5)	0	0

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Table 206p
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Blood and lymphatic system disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Anaemia	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	1 (16.7)	0	1 (16.7)	0	0
Catheter site pain	1 (16.7)	0	1 (16.7)	0	0

Down syndrome: Yes

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (16.7)	1 (16.7)	0	0	0
Paronychia	1 (16.7)	1 (16.7)	0	0	0
Investigations					
-Total	3 (50.0)	0	0	0	3 (50.0)
Platelet count decreased	2 (33.3)	0	0	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)	0	0
Lymphocyte count decreased	1 (16.7)	0	0	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	1 (16.7)	0	0	0
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Hyperphosphataemia	1 (16.7)	1 (16.7)	0	0	0
Hypoalbuminaemia	1 (16.7)	1 (16.7)	0	0	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Ingrowing nail	1 (16.7)	0	1 (16.7)	0	0
Rash	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206p
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (77.8)	16 (22.2)	13 (18.1)	9 (12.5)	18 (25.0)
Blood and lymphatic system disorders					
-Total	12 (16.7)	1 (1.4)	1 (1.4)	6 (8.3)	4 (5.6)
Anaemia	7 (9.7)	1 (1.4)	1 (1.4)	5 (6.9)	0
Febrile neutropenia	4 (5.6)	0	0	4 (5.6)	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Neutropenia	1 (1.4)	0	0	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	0	0	1 (1.4)
Cardiac disorders					
-Total	2 (2.8)	2 (2.8)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	2 (2.8)	2 (2.8)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Eye pain	1 (1.4)	1 (1.4)	0	0	0
Eyelid oedema	1 (1.4)	0	1 (1.4)	0	0
Vision blurred	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	24 (33.3)	11 (15.3)	11 (15.3)	2 (2.8)	0
Nausea	13 (18.1)	5 (6.9)	7 (9.7)	1 (1.4)	0
Vomiting	7 (9.7)	5 (6.9)	1 (1.4)	1 (1.4)	0
Stomatitis	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Abdominal pain	3 (4.2)	3 (4.2)	0	0	0
Diarrhoea	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Gingival bleeding	2 (2.8)	2 (2.8)	0	0	0
Anal erythema	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (1.4)	0	1 (1.4)	0	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Lip pain	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	14 (19.4)	8 (11.1)	5 (6.9)	1 (1.4)	0
Pyrexia	8 (11.1)	4 (5.6)	4 (5.6)	0	0
Chills	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Catheter site dermatitis	1 (1.4)	1 (1.4)	0	0	0
Fatigue	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	0	0	1 (1.4)	0
Localised oedema	1 (1.4)	0	1 (1.4)	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Hypogammaglobulinaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Seasonal allergy	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	10 (13.9)	2 (2.8)	3 (4.2)	3 (4.2)	2 (2.8)
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	1 (1.4)	0	0	0
Device related infection	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	0	1 (1.4)
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Gastroenteritis	1 (1.4)	0	1 (1.4)	0	0
Nasopharyngitis	1 (1.4)	1 (1.4)	0	0	0
Oral herpes	1 (1.4)	0	0	1 (1.4)	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract infection	1 (1.4)	0	1 (1.4)	0	0
Vulval cellulitis	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	2 (2.8)	1 (1.4)	1 (1.4)	0	0

Down syndrome: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fall	1 (1.4)	1 (1.4)	0	0	0
Infusion related reaction	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	21 (29.2)	4 (5.6)	2 (2.8)	3 (4.2)	12 (16.7)
White blood cell count decreased	10 (13.9)	0	1 (1.4)	2 (2.8)	7 (9.7)
Neutrophil count decreased	6 (8.3)	0	1 (1.4)	1 (1.4)	4 (5.6)
Lymphocyte count decreased	5 (6.9)	0	0	0	5 (6.9)
Platelet count decreased	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Alanine aminotransferase increased	2 (2.8)	2 (2.8)	0	0	0
Aspartate aminotransferase increased	2 (2.8)	2 (2.8)	0	0	0
Blood fibrinogen decreased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
International normalised ratio increased	2 (2.8)	2 (2.8)	0	0	0
Blood alkaline phosphatase decreased	1 (1.4)	1 (1.4)	0	0	0
Blood fibrinogen increased	1 (1.4)	1 (1.4)	0	0	0
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
C-reactive protein increased	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serum ferritin increased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	14 (19.4)	6 (8.3)	4 (5.6)	3 (4.2)	1 (1.4)
Decreased appetite	6 (8.3)	3 (4.2)	3 (4.2)	0	0
Hypokalaemia	3 (4.2)	0	0	2 (2.8)	1 (1.4)
Hypomagnesaemia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Hypophosphataemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyperphosphataemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	1 (1.4)	0	0	0
Hypocalcaemia	1 (1.4)	0	0	1 (1.4)	0
Hyponatraemia	1 (1.4)	1 (1.4)	0	0	0
Vitamin d deficiency	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (5.6)	1 (1.4)	2 (2.8)	1 (1.4)	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Muscular weakness	1 (1.4)	0	1 (1.4)	0	0
Pain in extremity	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in jaw	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Headache	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Posterior reversible encephalopathy syndrome	1 (1.4)	0	1 (1.4)	0	0
Seizure	1 (1.4)	0	1 (1.4)	0	0
Somnolence	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	0	0	1 (1.4)	0
Renal and urinary disorders					
-Total	3 (4.2)	3 (4.2)	0	0	0
Acute kidney injury	1 (1.4)	1 (1.4)	0	0	0
Dysuria	1 (1.4)	1 (1.4)	0	0	0
Renal pain	1 (1.4)	1 (1.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (9.7)	4 (5.6)	1 (1.4)	1 (1.4)	1 (1.4)

Down syndrome: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	3 (4.2)	3 (4.2)	0	0	0
Epistaxis	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Oropharyngeal pain	1 (1.4)	1 (1.4)	0	0	0
Pleural effusion	1 (1.4)	0	1 (1.4)	0	0
Pulmonary haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0	0	0
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Skin and subcutaneous tissue disorders					
-Total	8 (11.1)	5 (6.9)	3 (4.2)	0	0
Pruritus	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Drug eruption	1 (1.4)	0	1 (1.4)	0	0
Petechiae	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	5 (6.9)	2 (2.8)	2 (2.8)	1 (1.4)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Flushing	1 (1.4)	1 (1.4)	0	0	0
Hypertension	1 (1.4)	0	1 (1.4)	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206q
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (65.8)	6 (15.8)	3 (7.9)	3 (7.9)	13 (34.2)
Blood and lymphatic system disorders					
-Total	9 (23.7)	1 (2.6)	1 (2.6)	5 (13.2)	2 (5.3)
Anaemia	5 (13.2)	1 (2.6)	1 (2.6)	3 (7.9)	0
Febrile neutropenia	2 (5.3)	0	0	2 (5.3)	0
Lymphopenia	1 (2.6)	0	0	0	1 (2.6)
Thrombocytopenia	1 (2.6)	0	0	0	1 (2.6)
Cardiac disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Tachycardia	1 (2.6)	1 (2.6)	0	0	0
Endocrine disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.6)	0	1 (2.6)	0	0
Adrenal insufficiency	1 (2.6)	0	1 (2.6)	0	0
Eye disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Eye pain	1 (2.6)	1 (2.6)	0	0	0
Gastrointestinal disorders					
-Total	7 (18.4)	4 (10.5)	3 (7.9)	0	0
Nausea	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Stomatitis	2 (5.3)	0	2 (5.3)	0	0
Anal erythema	1 (2.6)	1 (2.6)	0	0	0
Constipation	1 (2.6)	1 (2.6)	0	0	0
Diarrhoea	1 (2.6)	1 (2.6)	0	0	0
Vomiting	1 (2.6)	1 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	4 (10.5)	2 (5.3)	2 (5.3)	0	0
Pyrexia	4 (10.5)	2 (5.3)	2 (5.3)	0	0
Localised oedema	1 (2.6)	0	1 (2.6)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	1 (2.6)	0	0	1 (2.6)	0
Hypogammaglobulinaemia	1 (2.6)	0	0	1 (2.6)	0
Infections and infestations					
-Total	4 (10.5)	1 (2.6)	1 (2.6)	1 (2.6)	1 (2.6)
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Device related infection	1 (2.6)	0	1 (2.6)	0	0
Escherichia bacteraemia	1 (2.6)	0	0	0	1 (2.6)
Gastroenteritis	1 (2.6)	0	1 (2.6)	0	0
Oral herpes	1 (2.6)	0	0	1 (2.6)	0
Tinea pedis	1 (2.6)	1 (2.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.6)	1 (2.6)	0	0	0
Fall	1 (2.6)	1 (2.6)	0	0	0
Investigations					
-Total	13 (34.2)	1 (2.6)	1 (2.6)	1 (2.6)	10 (26.3)
White blood cell count decreased	8 (21.1)	0	0	2 (5.3)	6 (15.8)

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	5 (13.2)	0	0	0	5 (13.2)
Neutrophil count decreased	4 (10.5)	0	1 (2.6)	1 (2.6)	2 (5.3)
Platelet count decreased	4 (10.5)	0	0	0	4 (10.5)
Alanine aminotransferase increased	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Aspartate aminotransferase increased	2 (5.3)	2 (5.3)	0	0	0
International normalised ratio increased	1 (2.6)	1 (2.6)	0	0	0
Serum ferritin increased	1 (2.6)	0	1 (2.6)	0	0
Metabolism and nutrition disorders					
-Total	5 (13.2)	2 (5.3)	1 (2.6)	1 (2.6)	1 (2.6)
Hypoalbuminaemia	2 (5.3)	2 (5.3)	0	0	0
Hypocalcaemia	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Decreased appetite	1 (2.6)	0	1 (2.6)	0	0
Hypokalaemia	1 (2.6)	0	0	0	1 (2.6)
Hyponatraemia	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	1 (2.6)	0	1 (2.6)	0	0
Nervous system disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Headache	1 (2.6)	1 (2.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (10.5)	2 (5.3)	1 (2.6)	1 (2.6)	0
Cough	2 (5.3)	2 (5.3)	0	0	0
Epistaxis	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Pleural effusion	1 (2.6)	0	1 (2.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (7.9)	3 (7.9)	0	0	0
Acne	1 (2.6)	1 (2.6)	0	0	0
Pruritus	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Hypotension	1 (2.6)	1 (2.6)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206q
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (92.3)	12 (30.8)	11 (28.2)	6 (15.4)	7 (17.9)
Blood and lymphatic system disorders					
-Total	4 (10.3)	0	0	2 (5.1)	2 (5.1)
Anaemia	3 (7.7)	0	0	3 (7.7)	0
Febrile neutropenia	2 (5.1)	0	0	2 (5.1)	0
Leukopenia	1 (2.6)	0	0	0	1 (2.6)
Neutropenia	1 (2.6)	0	0	0	1 (2.6)
Eye disorders					
-Total	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Eyelid oedema	1 (2.6)	0	1 (2.6)	0	0
Vision blurred	1 (2.6)	1 (2.6)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	18 (46.2)	8 (20.5)	8 (20.5)	2 (5.1)	0
Nausea	10 (25.6)	3 (7.7)	6 (15.4)	1 (2.6)	0
Vomiting	6 (15.4)	4 (10.3)	1 (2.6)	1 (2.6)	0
Abdominal pain	3 (7.7)	3 (7.7)	0	0	0
Diarrhoea	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Gingival bleeding	2 (5.1)	2 (5.1)	0	0	0
Stomatitis	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Constipation	1 (2.6)	0	1 (2.6)	0	0
Haematemesis	1 (2.6)	1 (2.6)	0	0	0
Lip pain	1 (2.6)	1 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	10 (25.6)	6 (15.4)	4 (10.3)	0	0
Pyrexia	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Chills	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Catheter site dermatitis	1 (2.6)	1 (2.6)	0	0	0
Catheter site pain	1 (2.6)	0	1 (2.6)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	1 (2.6)	1 (2.6)	0	0	0
Oedema peripheral	1 (2.6)	1 (2.6)	0	0	0
Vascular device occlusion	1 (2.6)	1 (2.6)	0	0	0
Immune system disorders					
-Total	2 (5.1)	0	2 (5.1)	0	0
Hypogammaglobulinaemia	1 (2.6)	0	1 (2.6)	0	0
Seasonal allergy	1 (2.6)	0	1 (2.6)	0	0
Infections and infestations					
-Total	6 (15.4)	2 (5.1)	2 (5.1)	2 (5.1)	0
Paronychia	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Conjunctivitis	1 (2.6)	1 (2.6)	0	0	0
Nasopharyngitis	1 (2.6)	1 (2.6)	0	0	0
Staphylococcal bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Vulval cellulitis	1 (2.6)	0	0	1 (2.6)	0
Injury, poisoning and procedural complications					
-Total	1 (2.6)	0	1 (2.6)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (2.6)	0	1 (2.6)	0	0
Investigations					
-Total	11 (28.2)	3 (7.7)	1 (2.6)	2 (5.1)	5 (12.8)
Neutrophil count decreased	3 (7.7)	0	0	0	3 (7.7)
White blood cell count decreased	3 (7.7)	0	1 (2.6)	0	2 (5.1)
Blood fibrinogen decreased	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Platelet count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Blood alkaline phosphatase decreased	1 (2.6)	1 (2.6)	0	0	0
Blood fibrinogen increased	1 (2.6)	1 (2.6)	0	0	0
Blood phosphorus increased	1 (2.6)	0	1 (2.6)	0	0
C-reactive protein increased	1 (2.6)	0	0	1 (2.6)	0
International normalised ratio increased	1 (2.6)	1 (2.6)	0	0	0
Lymphocyte count decreased	1 (2.6)	0	0	0	1 (2.6)
Weight increased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	11 (28.2)	6 (15.4)	3 (7.7)	2 (5.1)	0
Decreased appetite	5 (12.8)	3 (7.7)	2 (5.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (5.1)	2 (5.1)	0	0	0
Hypokalaemia	2 (5.1)	0	0	2 (5.1)	0
Hypomagnesaemia	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Hypophosphataemia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Vitamin d deficiency	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Muscular weakness	1 (2.6)	0	1 (2.6)	0	0
Pain in extremity	1 (2.6)	1 (2.6)	0	0	0
Pain in jaw	1 (2.6)	0	0	1 (2.6)	0
Nervous system disorders					
-Total	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Headache	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Posterior reversible encephalopathy syndrome	1 (2.6)	0	1 (2.6)	0	0
Seizure	1 (2.6)	0	1 (2.6)	0	0
Somnolence	1 (2.6)	1 (2.6)	0	0	0
Psychiatric disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.6)	0	0	1 (2.6)	0
Irritability	1 (2.6)	0	0	1 (2.6)	0
Renal and urinary disorders					
-Total	2 (5.1)	2 (5.1)	0	0	0
Dysuria	1 (2.6)	1 (2.6)	0	0	0
Renal pain	1 (2.6)	1 (2.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (5.1)	2 (5.1)	0	0	0
Cough	1 (2.6)	1 (2.6)	0	0	0
Oropharyngeal pain	1 (2.6)	1 (2.6)	0	0	0
Pulmonary oedema	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (17.9)	3 (7.7)	4 (10.3)	0	0
Pruritus	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Rash papular	2 (5.1)	2 (5.1)	0	0	0
Drug eruption	1 (2.6)	0	1 (2.6)	0	0
Erythema	1 (2.6)	1 (2.6)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (2.6)	0	1 (2.6)	0	0
Petechiae	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0
Hypotension	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Flushing	1 (2.6)	1 (2.6)	0	0	0
Hypertension	1 (2.6)	0	1 (2.6)	0	0
Peripheral ischaemia	1 (2.6)	0	1 (2.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized. -A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206q
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Cardiac disorders					
-Total	1 (100)	1 (100)	0	0	0
Tachycardia	1 (100)	1 (100)	0	0	0
General disorders and administration site conditions					
-Total	1 (100)	0	0	1 (100)	0
Generalised oedema	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Fungaemia	1 (100)	0	0	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (100)	1 (100)	0	0	0
Acute kidney injury	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	0	1 (100)
Pulmonary haemorrhage	1 (100)	0	0	0	1 (100)
Respiratory failure	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	1 (16.7)	2 (33.3)	0
Blood and lymphatic system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Anaemia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Eyelid oedema	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Abdominal pain	2 (33.3)	2 (33.3)	0	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0

Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vulval cellulitis	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)	0	0
White blood cell count decreased	1 (16.7)	0	0	1 (16.7)	0
Metabolism and nutrition disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Decreased appetite	2 (33.3)	2 (33.3)	0	0	0
Musculoskeletal and connective tissue disorders					

Number of previous relapses: 0

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	1 (16.7)	0	0	0
Pain in extremity	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0
Somnolence	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Irritability	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Dysuria	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Petechiae	1 (16.7)	1 (16.7)	0	0	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Rash	1 (16.7)	1 (16.7)	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Hypotension	1 (16.7)	1 (16.7)	0	0	0

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Table 206r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (86.4)	8 (36.4)	2 (9.1)	2 (9.1)	7 (31.8)
Blood and lymphatic system disorders					
-Total	3 (13.6)	0	0	2 (9.1)	1 (4.5)
Anaemia	3 (13.6)	0	0	3 (13.6)	0
Febrile neutropenia	2 (9.1)	0	0	2 (9.1)	0
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Gastrointestinal disorders					
-Total	8 (36.4)	5 (22.7)	2 (9.1)	1 (4.5)	0
Nausea	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Vomiting	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Abdominal pain	1 (4.5)	1 (4.5)	0	0	0

Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (4.5)	0	1 (4.5)	0	0
Diarrhoea	1 (4.5)	1 (4.5)	0	0	0
Gingival bleeding	1 (4.5)	1 (4.5)	0	0	0
Lip pain	1 (4.5)	1 (4.5)	0	0	0
Stomatitis	1 (4.5)	0	0	1 (4.5)	0
General disorders and administration site conditions					
-Total	6 (27.3)	4 (18.2)	2 (9.1)	0	0
Pyrexia	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Chills	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Catheter site dermatitis	1 (4.5)	1 (4.5)	0	0	0
Oedema peripheral	1 (4.5)	1 (4.5)	0	0	0
Infections and infestations					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Conjunctivitis	1 (4.5)	1 (4.5)	0	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Tinea pedis	1 (4.5)	1 (4.5)	0	0	0
Upper respiratory tract infection	1 (4.5)	0	1 (4.5)	0	0

Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	8 (36.4)	1 (4.5)	1 (4.5)	0	6 (27.3)
Lymphocyte count decreased	3 (13.6)	0	0	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Neutrophil count decreased	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Platelet count decreased	2 (9.1)	0	0	0	2 (9.1)
Blood alkaline phosphatase decreased	1 (4.5)	1 (4.5)	0	0	0
Blood phosphorus increased	1 (4.5)	0	1 (4.5)	0	0
Weight increased	1 (4.5)	1 (4.5)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (22.7)	3 (13.6)	1 (4.5)	1 (4.5)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hypomagnesaemia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hypophosphataemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Decreased appetite	1 (4.5)	1 (4.5)	0	0	0
Hypokalaemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					

Number of previous relapses: 1

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	0	0	1 (4.5)	0
Pain in jaw	1 (4.5)	0	0	1 (4.5)	0
Renal and urinary disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Renal pain	1 (4.5)	1 (4.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Cough	1 (4.5)	1 (4.5)	0	0	0
Pulmonary oedema	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Pruritus	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Rash papular	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Flushing	1 (4.5)	1 (4.5)	0	0	0
Hypertension	1 (4.5)	0	1 (4.5)	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (4.5)	0	0	1 (4.5)	0
Peripheral ischaemia	1 (4.5)	0	1 (4.5)	0	0

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Table 206r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (73.3)	4 (26.7)	5 (33.3)	1 (6.7)	1 (6.7)
Blood and lymphatic system disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Eye disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Vision blurred	1 (6.7)	1 (6.7)	0	0	0
Gastrointestinal disorders					
-Total	6 (40.0)	2 (13.3)	3 (20.0)	1 (6.7)	0
Nausea	4 (26.7)	1 (6.7)	3 (20.0)	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vomiting	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Haematemesis	1 (6.7)	1 (6.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (26.7)	3 (20.0)	1 (6.7)	0	0
Catheter site pain	1 (6.7)	0	1 (6.7)	0	0
Fatigue	1 (6.7)	1 (6.7)	0	0	0
Pyrexia	1 (6.7)	1 (6.7)	0	0	0
Vascular device occlusion	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Seasonal allergy	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	1 (6.7)	1 (6.7)	0	0	0
Paronychia	1 (6.7)	1 (6.7)	0	0	0
Investigations					
-Total	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Blood fibrinogen decreased	1 (6.7)	0	0	1 (6.7)	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
International normalised ratio increased	1 (6.7)	1 (6.7)	0	0	0
Neutrophil count decreased	1 (6.7)	0	0	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	0	1 (6.7)	0
White blood cell count decreased	1 (6.7)	0	0	0	1 (6.7)
Metabolism and nutrition disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Vitamin d deficiency	1 (6.7)	1 (6.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Muscular weakness	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Headache	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Posterior reversible encephalopathy syndrome	1 (6.7)	0	1 (6.7)	0	0
Seizure	1 (6.7)	0	1 (6.7)	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Drug eruption	1 (6.7)	0	1 (6.7)	0	0
Erythema	1 (6.7)	1 (6.7)	0	0	0
Ingrowing nail	1 (6.7)	0	1 (6.7)	0	0
Pruritus	1 (6.7)	1 (6.7)	0	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 206r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (77.1)	4 (11.4)	6 (17.1)	4 (11.4)	13 (37.1)
Blood and lymphatic system disorders					
-Total	8 (22.9)	0	1 (2.9)	4 (11.4)	3 (8.6)
Anaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Febrile neutropenia	2 (5.7)	0	0	2 (5.7)	0
Leukopenia	1 (2.9)	0	0	0	1 (2.9)
Lymphopenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	0	0	0	1 (2.9)
Cardiac disorders					
-Total	2 (5.7)	2 (5.7)	0	0	0

Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (5.7)	2 (5.7)	0	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Eye pain	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	9 (25.7)	4 (11.4)	5 (14.3)	0	0
Nausea	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Vomiting	3 (8.6)	3 (8.6)	0	0	0
Diarrhoea	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Stomatitis	2 (5.7)	0	2 (5.7)	0	0
Anal erythema	1 (2.9)	1 (2.9)	0	0	0
Constipation	1 (2.9)	1 (2.9)	0	0	0
Gingival bleeding	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					

Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (14.3)	1 (2.9)	3 (8.6)	1 (2.9)	0
Pyrexia	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Generalised oedema	1 (2.9)	0	0	1 (2.9)	0
Localised oedema	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Hypogammaglobulinaemia	1 (2.9)	0	0	1 (2.9)	0
Infections and infestations					
-Total	6 (17.1)	1 (2.9)	2 (5.7)	1 (2.9)	2 (5.7)
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Device related infection	1 (2.9)	0	1 (2.9)	0	0
Escherichia bacteraemia	1 (2.9)	0	0	0	1 (2.9)
Fungaemia	1 (2.9)	0	0	0	1 (2.9)
Gastroenteritis	1 (2.9)	0	1 (2.9)	0	0
Nasopharyngitis	1 (2.9)	1 (2.9)	0	0	0
Oral herpes	1 (2.9)	0	0	1 (2.9)	0
Paronychia	1 (2.9)	0	1 (2.9)	0	0

Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Fall	1 (2.9)	1 (2.9)	0	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Investigations					
-Total	13 (37.1)	3 (8.6)	1 (2.9)	1 (2.9)	8 (22.9)
White blood cell count decreased	6 (17.1)	0	0	1 (2.9)	5 (14.3)
Lymphocyte count decreased	3 (8.6)	0	0	0	3 (8.6)
Neutrophil count decreased	3 (8.6)	0	0	0	3 (8.6)
Platelet count decreased	3 (8.6)	0	0	0	3 (8.6)
Alanine aminotransferase increased	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0	0	0
Blood fibrinogen decreased	1 (2.9)	1 (2.9)	0	0	0
Blood fibrinogen increased	1 (2.9)	1 (2.9)	0	0	0
C-reactive protein increased	1 (2.9)	0	0	1 (2.9)	0
International normalised ratio increased	1 (2.9)	1 (2.9)	0	0	0

Number of previous relapses: >=3

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (2.9)	0	1 (2.9)	0	0
Metabolism and nutrition disorders					
-Total	8 (22.9)	2 (5.7)	3 (8.6)	2 (5.7)	1 (2.9)
Decreased appetite	3 (8.6)	0	3 (8.6)	0	0
Hypoalbuminaemia	2 (5.7)	2 (5.7)	0	0	0
Hypocalcaemia	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Hypokalaemia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Hyponatraemia	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Bone pain	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Acute kidney injury	1 (2.9)	1 (2.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (17.1)	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)
Cough	2 (5.7)	2 (5.7)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Oropharyngeal pain	1 (2.9)	1 (2.9)	0	0	0
Pleural effusion	1 (2.9)	0	1 (2.9)	0	0
Pulmonary haemorrhage	1 (2.9)	0	0	0	1 (2.9)
Respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Skin and subcutaneous tissue disorders					
-Total	3 (8.6)	3 (8.6)	0	0	0
Acne	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0
Rash papular	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hypotension	2 (5.7)	1 (2.9)	1 (2.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility -Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted

only once in the total row. -A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade. -System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column. - MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207a
Adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	2 (25.0)	6 (75.0)
Blood and lymphatic system disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Anaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	0	0	1 (12.5)	0
Cardiac disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Tachycardia	1 (12.5)	0	1 (12.5)	0	0
Endocrine disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	0	0	1 (12.5)

Age: <10 years

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Abdominal pain	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Diarrhoea	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Duodenal perforation	1 (12.5)	0	0	1 (12.5)	0
Gastritis	1 (12.5)	0	1 (12.5)	0	0
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Catheter site pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Oedema peripheral	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Generalised oedema	1 (12.5)	0	0	1 (12.5)	0
Pain	1 (12.5)	0	0	1 (12.5)	0
Pyrexia	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	0	0	1 (12.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypersensitivity	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Acute sinusitis	1 (12.5)	0	0	1 (12.5)	0
Aspergillus infection	1 (12.5)	0	0	0	1 (12.5)
Device related infection	1 (12.5)	0	0	1 (12.5)	0
Fungaemia	1 (12.5)	0	0	0	1 (12.5)
Fungal skin infection	1 (12.5)	0	0	1 (12.5)	0
Peritonitis	1 (12.5)	0	0	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	0	0	1 (12.5)
Systemic mycosis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					
-Total	1 (12.5)	1 (12.5)	0	0	0
Procedural pain	1 (12.5)	1 (12.5)	0	0	0
Investigations					

Age: <10 years

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
C-reactive protein increased	1 (12.5)	0	0	1 (12.5)	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Tumour lysis syndrome	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hyperuricaemia	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Haemorrhage intracranial	1 (12.5)	0	0	0	1 (12.5)
Psychiatric disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Mental status changes	1 (12.5)	0	0	1 (12.5)	0
Renal and urinary disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Acute kidney injury	1 (12.5)	1 (12.5)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	0	1 (12.5)	0	0
Pulmonary haemorrhage	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Tachypnoea	1 (12.5)	0	1 (12.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Pain of skin	1 (12.5)	1 (12.5)	0	0	0
Skin ulcer	1 (12.5)	0	1 (12.5)	0	0
Vascular disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Hypertension	2 (25.0)	0	2 (25.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207a
Adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	2 (28.6)	4 (57.1)
Blood and lymphatic system disorders					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Anaemia	2 (28.6)	0	0	2 (28.6)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	0	0	3 (42.9)	0
Tachycardia	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal disorders					
-Total	4 (57.1)	1 (14.3)	0	2 (28.6)	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	0	0	1 (14.3)

Age: >=10 years to <18 years

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (14.3)	0	0	1 (14.3)	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Haematemesis	1 (14.3)	1 (14.3)	0	0	0
Haemoperitoneum	1 (14.3)	0	0	0	1 (14.3)
General disorders and administration site conditions					
-Total	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Pyrexia	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Pain	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	0	0	1 (14.3)	0
Immune system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Graft versus host disease	1 (14.3)	0	0	1 (14.3)	0
Infections and infestations					
-Total	6 (85.7)	0	1 (14.3)	2 (28.6)	3 (42.9)

Age: >=10 years to <18 years

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Disseminated trichosporonosis	1 (14.3)	0	0	0	1 (14.3)
Epstein-barr virus infection	1 (14.3)	0	1 (14.3)	0	0
Klebsiella bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Oral herpes	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Serratia sepsis	1 (14.3)	0	0	0	1 (14.3)
Staphylococcal infection	1 (14.3)	0	0	0	1 (14.3)
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	0	1 (14.3)	0
Post procedural haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Alanine aminotransferase increased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	1 (14.3)	0	0	0
Blood magnesium decreased	1 (14.3)	0	1 (14.3)	0	0

Age: >=10 years to <18 years

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (14.3)	0	0	1 (14.3)	0
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0	0	0
Serum ferritin increased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (42.9)	0	0	3 (42.9)	0
Hypocalcaemia	2 (28.6)	0	2 (28.6)	0	0
Metabolic acidosis	2 (28.6)	0	0	2 (28.6)	0
Hyperammonaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Hypokalaemia	1 (14.3)	0	1 (14.3)	0	0
Hypomagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Myositis	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					

Age: >=10 years to <18 years

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Cognitive disorder	1 (14.3)	0	0	1 (14.3)	0
Intraventricular haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Acute kidney injury	2 (28.6)	2 (28.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Respiratory failure	2 (28.6)	0	0	0	2 (28.6)
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Vascular disorders					
-Total	5 (71.4)	1 (14.3)	0	3 (42.9)	1 (14.3)
Hypotension	4 (57.1)	0	0	3 (42.9)	1 (14.3)

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (14.3)	1 (14.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207a
Adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Pancytopenia	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Bradycardia	1 (33.3)	1 (33.3)	0	0	0
Cardiac failure	1 (33.3)	0	0	1 (33.3)	0
Endocrine disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Adrenal insufficiency	1 (33.3)	0	1 (33.3)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Eyelid oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Abdominal pain upper	1 (33.3)	1 (33.3)	0	0	0
Nausea	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Catheter site pain	1 (33.3)	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Bacterial sepsis	1 (33.3)	0	0	0	1 (33.3)
Clostridium difficile colitis	1 (33.3)	0	1 (33.3)	0	0
Device related sepsis	1 (33.3)	0	0	1 (33.3)	0
Fungal sepsis	1 (33.3)	0	0	0	1 (33.3)

Age: >=18

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (33.3)	0	0	0	1 (33.3)
Investigations					
-Total	1 (33.3)	0	0	1 (33.3)	0
C-reactive protein increased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Decreased appetite	1 (33.3)	0	1 (33.3)	0	0
Hyperglycaemia	1 (33.3)	0	0	0	1 (33.3)
Musculoskeletal and connective tissue disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Arthralgia	1 (33.3)	0	1 (33.3)	0	0
Back pain	1 (33.3)	1 (33.3)	0	0	0
Nervous system disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Headache	1 (33.3)	1 (33.3)	0	0	0
Paraesthesia	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					

Age: >=18

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (33.3)	0	0	0	1 (33.3)
Acute respiratory distress syndrome	1 (33.3)	0	0	0	1 (33.3)
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Rash	1 (33.3)	1 (33.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207b
Adverse events by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	0	2 (22.2)	7 (77.8)
Blood and lymphatic system disorders					
-Total	4 (44.4)	0	0	4 (44.4)	0
Anaemia	2 (22.2)	0	0	2 (22.2)	0
Febrile neutropenia	2 (22.2)	0	0	2 (22.2)	0
Hyperleukocytosis	1 (11.1)	0	0	1 (11.1)	0
Cardiac disorders					
-Total	4 (44.4)	0	1 (11.1)	3 (33.3)	0
Tachycardia	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Left ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)

Gender: Male

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypercalcaemia of malignancy	1 (11.1)	0	0	0	1 (11.1)
Gastrointestinal disorders					
-Total	6 (66.7)	1 (11.1)	0	4 (44.4)	1 (11.1)
Abdominal pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Diarrhoea	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Abdominal compartment syndrome	1 (11.1)	0	0	0	1 (11.1)
Duodenal perforation	1 (11.1)	0	0	1 (11.1)	0
Gastritis	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal haemorrhage	1 (11.1)	0	0	1 (11.1)	0
Haematemesis	1 (11.1)	1 (11.1)	0	0	0
Haemoperitoneum	1 (11.1)	0	0	0	1 (11.1)
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	6 (66.7)	0	2 (22.2)	4 (44.4)	0
Pyrexia	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Oedema peripheral	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0

Gender: Male

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site pain	1 (11.1)	1 (11.1)	0	0	0
Generalised oedema	1 (11.1)	0	0	1 (11.1)	0
Hepatobiliary disorders					
-Total	2 (22.2)	0	0	2 (22.2)	0
Hyperbilirubinaemia	2 (22.2)	0	0	2 (22.2)	0
Infections and infestations					
-Total	7 (77.8)	0	0	3 (33.3)	4 (44.4)
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Disseminated trichosporonosis	1 (11.1)	0	0	0	1 (11.1)
Fungaemia	1 (11.1)	0	0	0	1 (11.1)
Klebsiella bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Oral herpes	1 (11.1)	0	0	1 (11.1)	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Serratia sepsis	1 (11.1)	0	0	0	1 (11.1)
Staphylococcal infection	1 (11.1)	0	0	0	1 (11.1)
Injury, poisoning and procedural complications					

Gender: Male

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	0	0	1 (11.1)	0
Procedural pain	1 (11.1)	1 (11.1)	0	0	0
Investigations					
-Total	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Alanine aminotransferase increased	1 (11.1)	1 (11.1)	0	0	0
Aspartate aminotransferase increased	1 (11.1)	0	0	0	1 (11.1)
Blood creatinine increased	1 (11.1)	1 (11.1)	0	0	0
C-reactive protein increased	1 (11.1)	0	0	1 (11.1)	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0	0	0
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Platelet count decreased	1 (11.1)	0	0	0	1 (11.1)
White blood cell count decreased	1 (11.1)	1 (11.1)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (55.6)	0	0	4 (44.4)	1 (11.1)
Hypocalcaemia	2 (22.2)	0	2 (22.2)	0	0
Metabolic acidosis	2 (22.2)	0	0	2 (22.2)	0

Gender: Male

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Hyperammonaemia	1 (11.1)	0	0	1 (11.1)	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)	0	0
Hypokalaemia	1 (11.1)	0	1 (11.1)	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Myositis	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	4 (44.4)	1 (11.1)	0	2 (22.2)	1 (11.1)
Cognitive disorder	1 (11.1)	0	0	1 (11.1)	0
Encephalopathy	1 (11.1)	0	0	1 (11.1)	0
Haemorrhage intracranial	1 (11.1)	0	0	0	1 (11.1)
Intraventricular haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Psychiatric disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0

Gender: Male

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Renal and urinary disorders					
-Total	3 (33.3)	3 (33.3)	0	0	0
Acute kidney injury	3 (33.3)	3 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (55.6)	0	1 (11.1)	1 (11.1)	3 (33.3)
Respiratory failure	3 (33.3)	0	0	0	3 (33.3)
Tachypnoea	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hypoxia	1 (11.1)	0	1 (11.1)	0	0
Pulmonary haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	0	0	1 (11.1)
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Pain of skin	1 (11.1)	1 (11.1)	0	0	0
Skin ulcer	1 (11.1)	0	1 (11.1)	0	0
Vascular disorders					
-Total	6 (66.7)	0	2 (22.2)	3 (33.3)	1 (11.1)

Gender: Male

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (44.4)	0	0	3 (33.3)	1 (11.1)
Hypertension	2 (22.2)	0	2 (22.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207b
Adverse events by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Female

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	1 (11.1)	3 (33.3)	5 (55.6)
Blood and lymphatic system disorders					
-Total	5 (55.6)	0	0	2 (22.2)	3 (33.3)
Febrile neutropenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Anaemia	1 (11.1)	0	0	1 (11.1)	0
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Bradycardia	1 (11.1)	1 (11.1)	0	0	0
Cardiac failure	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					

Gender: Female

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Eye disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Eyelid oedema	1 (11.1)	1 (11.1)	0	0	0
Gastrointestinal disorders					
-Total	3 (33.3)	1 (11.1)	1 (11.1)	1 (11.1)	0
Abdominal pain upper	1 (11.1)	1 (11.1)	0	0	0
Colitis	1 (11.1)	0	0	1 (11.1)	0
Diarrhoea	1 (11.1)	0	1 (11.1)	0	0
Nausea	1 (11.1)	0	1 (11.1)	0	0
General disorders and administration site conditions					
-Total	3 (33.3)	1 (11.1)	2 (22.2)	0	0
Catheter site pain	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	1 (11.1)	0	0
Immune system disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0

Gender: Female

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Graft versus host disease	1 (11.1)	0	0	1 (11.1)	0
Hypersensitivity	1 (11.1)	0	1 (11.1)	0	0
Infections and infestations					
-Total	8 (88.9)	0	1 (11.1)	3 (33.3)	4 (44.4)
Acute sinusitis	1 (11.1)	0	0	1 (11.1)	0
Aspergillus infection	1 (11.1)	0	0	0	1 (11.1)
Bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Bacterial sepsis	1 (11.1)	0	0	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)	0	0
Device related sepsis	1 (11.1)	0	0	1 (11.1)	0
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Fungal sepsis	1 (11.1)	0	0	0	1 (11.1)
Fungal skin infection	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0	0	1 (11.1)
Systemic mycosis	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	2 (22.2)	0	0	2 (22.2)	0

Gender: Female

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	1 (11.1)	0	0	1 (11.1)	0
Blood magnesium decreased	1 (11.1)	0	1 (11.1)	0	0
Blood potassium decreased	1 (11.1)	0	0	1 (11.1)	0
C-reactive protein increased	1 (11.1)	0	0	1 (11.1)	0
Serum ferritin increased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Decreased appetite	1 (11.1)	0	1 (11.1)	0	0
Hyperglycaemia	1 (11.1)	0	0	0	1 (11.1)
Hyperuricaemia	1 (11.1)	0	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Arthralgia	1 (11.1)	0	1 (11.1)	0	0
Back pain	1 (11.1)	1 (11.1)	0	0	0
Nervous system disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Headache	1 (11.1)	1 (11.1)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paraesthesia	1 (11.1)	1 (11.1)	0	0	0
Psychiatric disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Acute respiratory distress syndrome	1 (11.1)	0	0	0	1 (11.1)
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Rash	1 (11.1)	1 (11.1)	0	0	0
Vascular disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Hypertension	1 (11.1)	1 (11.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207c
Adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	0	4 (36.4)	7 (63.6)
Blood and lymphatic system disorders					
-Total	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Pancytopenia	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Hyperleukocytosis	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	4 (36.4)	1 (9.1)	0	3 (27.3)	0
Tachycardia	2 (18.2)	0	0	2 (18.2)	0
Bradycardia	1 (9.1)	1 (9.1)	0	0	0
Cardiac failure	1 (9.1)	0	0	1 (9.1)	0

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Endocrine disorders					
-Total	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Hypercalcaemia of malignancy	1 (9.1)	0	0	0	1 (9.1)
Eye disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Eyelid oedema	1 (9.1)	1 (9.1)	0	0	0
Gastrointestinal disorders					
-Total	7 (63.6)	2 (18.2)	1 (9.1)	3 (27.3)	1 (9.1)
Diarrhoea	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Abdominal compartment syndrome	1 (9.1)	0	0	0	1 (9.1)
Abdominal pain	1 (9.1)	0	0	1 (9.1)	0
Abdominal pain upper	1 (9.1)	1 (9.1)	0	0	0
Colitis	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematemesis	1 (9.1)	1 (9.1)	0	0	0
Haemoperitoneum	1 (9.1)	0	0	0	1 (9.1)
Nausea	1 (9.1)	0	1 (9.1)	0	0

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	6 (54.5)	1 (9.1)	2 (18.2)	3 (27.3)	0
Pyrexia	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Catheter site pain	2 (18.2)	2 (18.2)	0	0	0
Oedema peripheral	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Hyperbilirubinaemia	1 (9.1)	0	0	1 (9.1)	0
Immune system disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Graft versus host disease	1 (9.1)	0	0	1 (9.1)	0
Hypersensitivity	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	9 (81.8)	0	0	4 (36.4)	5 (45.5)
Acute sinusitis	1 (9.1)	0	0	1 (9.1)	0
Aspergillus infection	1 (9.1)	0	0	0	1 (9.1)

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Bacterial sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	1 (9.1)	0	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Device related sepsis	1 (9.1)	0	0	1 (9.1)	0
Disseminated trichosporonosis	1 (9.1)	0	0	0	1 (9.1)
Fungal sepsis	1 (9.1)	0	0	0	1 (9.1)
Fungal skin infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Serratia sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Systemic mycosis	1 (9.1)	0	0	1 (9.1)	0
Injury, poisoning and procedural complications					
-Total	1 (9.1)	1 (9.1)	0	0	0
Procedural pain	1 (9.1)	1 (9.1)	0	0	0
Investigations					

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (27.3)	0	0	2 (18.2)	1 (9.1)
C-reactive protein increased	2 (18.2)	0	0	2 (18.2)	0
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood creatinine increased	1 (9.1)	1 (9.1)	0	0	0
Lymphocyte count decreased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	0	4 (36.4)	2 (18.2)
Hypocalcaemia	2 (18.2)	0	2 (18.2)	0	0
Metabolic acidosis	2 (18.2)	0	0	2 (18.2)	0
Tumour lysis syndrome	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Decreased appetite	1 (9.1)	0	1 (9.1)	0	0
Hyperammonaemia	1 (9.1)	0	0	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	0	0	1 (9.1)
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)	0	0

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Back pain	1 (9.1)	1 (9.1)	0	0	0
Nervous system disorders					
-Total	4 (36.4)	2 (18.2)	0	2 (18.2)	0
Cognitive disorder	1 (9.1)	0	0	1 (9.1)	0
Encephalopathy	1 (9.1)	0	0	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0	0	0
Intraventricular haemorrhage	1 (9.1)	1 (9.1)	0	0	0
Paraesthesia	1 (9.1)	1 (9.1)	0	0	0
Psychiatric disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Mental status changes	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (18.2)	2 (18.2)	0	0	0
Acute kidney injury	2 (18.2)	2 (18.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Respiratory failure	2 (18.2)	0	0	0	2 (18.2)
Acute respiratory distress syndrome	1 (9.1)	0	0	0	1 (9.1)
Hypoxia	1 (9.1)	0	1 (9.1)	0	0
Pulmonary oedema	1 (9.1)	0	0	0	1 (9.1)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Skin and subcutaneous tissue disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Pain of skin	1 (9.1)	1 (9.1)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Skin ulcer	1 (9.1)	0	1 (9.1)	0	0
Vascular disorders					
-Total	5 (45.5)	1 (9.1)	1 (9.1)	2 (18.2)	1 (9.1)
Hypotension	3 (27.3)	0	0	2 (18.2)	1 (9.1)

Race: White

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	2 (18.2)	1 (9.1)	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207c
Adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Anaemia	1 (20.0)	0	0	1 (20.0)	0
Thrombocytopenia	1 (20.0)	0	0	0	1 (20.0)
Cardiac disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Left ventricular dysfunction	1 (20.0)	0	0	1 (20.0)	0
Tachycardia	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Duodenal perforation	1 (20.0)	0	0	1 (20.0)	0
Gastritis	1 (20.0)	0	1 (20.0)	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	2 (40.0)	0	2 (40.0)	0	0
Catheter site pain	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	0	1 (20.0)	2 (40.0)	1 (20.0)
Epstein-barr virus infection	1 (20.0)	0	1 (20.0)	0	0
Klebsiella bacteraemia	1 (20.0)	0	0	1 (20.0)	0
Peritonitis	1 (20.0)	0	0	1 (20.0)	0
Pneumonia fungal	1 (20.0)	0	0	0	1 (20.0)
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	0	1 (20.0)	0
Post procedural haemorrhage	1 (20.0)	0	0	1 (20.0)	0
Investigations					
-Total	1 (20.0)	0	0	1 (20.0)	0
Alanine aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood magnesium decreased	1 (20.0)	0	1 (20.0)	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood potassium decreased	1 (20.0)	0	0	1 (20.0)	0
Serum ferritin increased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hyperuricaemia	1 (20.0)	0	1 (20.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Myositis	1 (20.0)	0	1 (20.0)	0	0
Nervous system disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Haemorrhage intracranial	1 (20.0)	0	0	0	1 (20.0)
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hypotension	1 (20.0)	0	0	1 (20.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207c
Adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Febrile neutropenia	2 (100)	0	0	1 (50.0)	1 (50.0)
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Tachycardia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Abdominal pain	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Generalised oedema	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hyperbilirubinaemia	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	2 (100)	0	0	0	2 (100)
Fungaemia	1 (50.0)	0	0	0	1 (50.0)
Pneumonia	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	0	0	1 (50.0)
Platelet count decreased	1 (50.0)	0	0	0	1 (50.0)
Renal and urinary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (50.0)	1 (50.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Pulmonary haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Respiratory failure	1 (50.0)	0	0	0	1 (50.0)
Tachypnoea	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypertension	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207d
Adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Cardiac disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Colitis	1 (33.3)	0	0	1 (33.3)	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Haematemesis	1 (33.3)	1 (33.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Pyrexia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Graft versus host disease	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Aspergillus infection	1 (33.3)	0	0	0	1 (33.3)
Bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Disseminated trichosporonosis	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hyperkalaemia	1 (33.3)	0	0	1 (33.3)	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Hypomagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0

Ethnicity: Hispanic or Latino

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Mental status changes	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Acute kidney injury	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypertension	1 (33.3)	1 (33.3)	0	0	0
Hypotension	1 (33.3)	0	0	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207d
Adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	1 (6.7)	4 (26.7)	10 (66.7)
Blood and lymphatic system disorders					
-Total	8 (53.3)	0	0	5 (33.3)	3 (20.0)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Febrile neutropenia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Pancytopenia	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hyperleukocytosis	1 (6.7)	0	0	1 (6.7)	0
Thrombocytopenia	1 (6.7)	0	0	0	1 (6.7)
Cardiac disorders					
-Total	5 (33.3)	1 (6.7)	1 (6.7)	3 (20.0)	0
Tachycardia	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Bradycardia	1 (6.7)	1 (6.7)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	1 (6.7)	0	0	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	0	0	1 (6.7)	0
Endocrine disorders					
-Total	2 (13.3)	0	1 (6.7)	0	1 (6.7)
Adrenal insufficiency	1 (6.7)	0	1 (6.7)	0	0
Hypercalcaemia of malignancy	1 (6.7)	0	0	0	1 (6.7)
Eye disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Eyelid oedema	1 (6.7)	1 (6.7)	0	0	0
Gastrointestinal disorders					
-Total	7 (46.7)	1 (6.7)	1 (6.7)	4 (26.7)	1 (6.7)
Abdominal pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Diarrhoea	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Abdominal compartment syndrome	1 (6.7)	0	0	0	1 (6.7)
Abdominal pain upper	1 (6.7)	1 (6.7)	0	0	0
Duodenal perforation	1 (6.7)	0	0	1 (6.7)	0
Gastritis	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal haemorrhage	1 (6.7)	0	0	1 (6.7)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoperitoneum	1 (6.7)	0	0	0	1 (6.7)
Nausea	1 (6.7)	0	1 (6.7)	0	0
Stomatitis	1 (6.7)	0	0	1 (6.7)	0
General disorders and administration site conditions					
-Total	8 (53.3)	1 (6.7)	4 (26.7)	3 (20.0)	0
Pyrexia	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Catheter site pain	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Oedema peripheral	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Generalised oedema	1 (6.7)	0	0	1 (6.7)	0
Hepatobiliary disorders					
-Total	2 (13.3)	0	0	2 (13.3)	0
Hyperbilirubinaemia	2 (13.3)	0	0	2 (13.3)	0
Immune system disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Hypersensitivity	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	12 (80.0)	0	1 (6.7)	5 (33.3)	6 (40.0)
Acute sinusitis	1 (6.7)	0	0	1 (6.7)	0
Bacterial sepsis	1 (6.7)	0	0	0	1 (6.7)
Clostridium difficile colitis	1 (6.7)	0	1 (6.7)	0	0
Device related infection	1 (6.7)	0	0	1 (6.7)	0
Device related sepsis	1 (6.7)	0	0	1 (6.7)	0
Epstein-barr virus infection	1 (6.7)	0	1 (6.7)	0	0
Fungaemia	1 (6.7)	0	0	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	0	0	1 (6.7)
Fungal skin infection	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Oral herpes	1 (6.7)	0	0	1 (6.7)	0
Peritonitis	1 (6.7)	0	0	1 (6.7)	0
Pneumonia	1 (6.7)	0	0	0	1 (6.7)
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Sepsis	1 (6.7)	0	0	0	1 (6.7)
Serratia sepsis	1 (6.7)	0	0	0	1 (6.7)
Staphylococcal infection	1 (6.7)	0	0	0	1 (6.7)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (6.7)	0	0	1 (6.7)	0
Injury, poisoning and procedural complications					
-Total	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	0	0	1 (6.7)	0
Procedural pain	1 (6.7)	1 (6.7)	0	0	0
Investigations					
-Total	5 (33.3)	0	0	3 (20.0)	2 (13.3)
Alanine aminotransferase increased	2 (13.3)	1 (6.7)	0	1 (6.7)	0
C-reactive protein increased	2 (13.3)	0	0	2 (13.3)	0
Aspartate aminotransferase increased	1 (6.7)	0	0	0	1 (6.7)
Blood creatinine increased	1 (6.7)	1 (6.7)	0	0	0
Blood magnesium decreased	1 (6.7)	0	1 (6.7)	0	0
Blood potassium decreased	1 (6.7)	0	0	1 (6.7)	0
Lymphocyte count decreased	1 (6.7)	1 (6.7)	0	0	0
Neutrophil count decreased	1 (6.7)	0	0	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	0	0	1 (6.7)
Serum ferritin increased	1 (6.7)	0	0	1 (6.7)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	1 (6.7)	1 (6.7)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (40.0)	0	1 (6.7)	3 (20.0)	2 (13.3)
Tumour lysis syndrome	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Decreased appetite	1 (6.7)	0	1 (6.7)	0	0
Hyperammonaemia	1 (6.7)	0	0	1 (6.7)	0
Hyperglycaemia	1 (6.7)	0	0	0	1 (6.7)
Hyperuricaemia	1 (6.7)	0	1 (6.7)	0	0
Hypoalbuminaemia	1 (6.7)	0	1 (6.7)	0	0
Hypocalcaemia	1 (6.7)	0	1 (6.7)	0	0
Hypokalaemia	1 (6.7)	0	1 (6.7)	0	0
Metabolic acidosis	1 (6.7)	0	0	1 (6.7)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Arthralgia	1 (6.7)	0	1 (6.7)	0	0
Back pain	1 (6.7)	1 (6.7)	0	0	0
Myositis	1 (6.7)	0	1 (6.7)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	5 (33.3)	2 (13.3)	0	2 (13.3)	1 (6.7)
Cognitive disorder	1 (6.7)	0	0	1 (6.7)	0
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	0	0	1 (6.7)
Headache	1 (6.7)	1 (6.7)	0	0	0
Intraventricular haemorrhage	1 (6.7)	1 (6.7)	0	0	0
Paraesthesia	1 (6.7)	1 (6.7)	0	0	0
Psychiatric disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Mental status changes	1 (6.7)	0	0	1 (6.7)	0
Renal and urinary disorders					
-Total	2 (13.3)	2 (13.3)	0	0	0
Acute kidney injury	2 (13.3)	2 (13.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (33.3)	0	1 (6.7)	1 (6.7)	3 (20.0)
Respiratory failure	2 (13.3)	0	0	0	2 (13.3)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Acute respiratory distress syndrome	1 (6.7)	0	0	0	1 (6.7)
Hypoxia	1 (6.7)	0	1 (6.7)	0	0
Pulmonary haemorrhage	1 (6.7)	0	0	0	1 (6.7)
Pulmonary oedema	1 (6.7)	0	0	0	1 (6.7)
Skin and subcutaneous tissue disorders					
-Total	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pain of skin	1 (6.7)	1 (6.7)	0	0	0
Rash	1 (6.7)	1 (6.7)	0	0	0
Skin ulcer	1 (6.7)	0	1 (6.7)	0	0
Vascular disorders					
-Total	5 (33.3)	0	2 (13.3)	2 (13.3)	1 (6.7)
Hypotension	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Hypertension	2 (13.3)	0	2 (13.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207e
Adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	2 (100)	0	0	2 (100)	0
Tachycardia	2 (100)	0	0	2 (100)	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	0	0	1 (50.0)
Haematemesis	1 (50.0)	1 (50.0)	0	0	0

Response status at study entry: Primary refractory

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (50.0)	0	0	0	1 (50.0)
General disorders and administration site conditions					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Pyrexia	2 (100)	0	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	0	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	0	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood creatinine increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0	0	0

Response status at study entry: Primary refractory

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypocalcaemia	2 (100)	0	2 (100)	0	0
Metabolic acidosis	2 (100)	0	0	2 (100)	0
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypomagnesaemia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	2 (100)	2 (100)	0	0	0
Acute kidney injury	2 (100)	2 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	0	0	2 (100)
Respiratory failure	2 (100)	0	0	0	2 (100)
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypotension	2 (100)	0	0	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207e
Adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

		All patients N=16			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	0	1 (6.3)	5 (31.3)	10 (62.5)
Blood and lymphatic system disorders					
-Total	7 (43.8)	0	0	4 (25.0)	3 (18.8)
Febrile neutropenia	3 (18.8)	0	0	2 (12.5)	1 (6.3)
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Pancytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	0	0	1 (6.3)	0
Thrombocytopenia	1 (6.3)	0	0	0	1 (6.3)
Cardiac disorders					
-Total	4 (25.0)	1 (6.3)	1 (6.3)	2 (12.5)	0
Tachycardia	2 (12.5)	0	2 (12.5)	0	0
Bradycardia	1 (6.3)	1 (6.3)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (6.3)	0	0	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	0	0	1 (6.3)	0
Endocrine disorders					
-Total	2 (12.5)	0	1 (6.3)	0	1 (6.3)
Adrenal insufficiency	1 (6.3)	0	1 (6.3)	0	0
Hypercalcaemia of malignancy	1 (6.3)	0	0	0	1 (6.3)
Eye disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Eyelid oedema	1 (6.3)	1 (6.3)	0	0	0
Gastrointestinal disorders					
-Total	7 (43.8)	1 (6.3)	1 (6.3)	5 (31.3)	0
Diarrhoea	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Abdominal pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Abdominal pain upper	1 (6.3)	1 (6.3)	0	0	0
Colitis	1 (6.3)	0	0	1 (6.3)	0
Duodenal perforation	1 (6.3)	0	0	1 (6.3)	0
Gastritis	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	0	0	1 (6.3)	0

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (6.3)	0	1 (6.3)	0	0
Stomatitis	1 (6.3)	0	0	1 (6.3)	0
General disorders and administration site conditions					
-Total	7 (43.8)	1 (6.3)	3 (18.8)	3 (18.8)	0
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Pyrexia	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Generalised oedema	1 (6.3)	0	0	1 (6.3)	0
Pain	1 (6.3)	0	0	1 (6.3)	0
Hepatobiliary disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	0	0	2 (12.5)	0
Immune system disorders					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Graft versus host disease	1 (6.3)	0	0	1 (6.3)	0
Hypersensitivity	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (81.3)	0	1 (6.3)	6 (37.5)	6 (37.5)
Acute sinusitis	1 (6.3)	0	0	1 (6.3)	0
Aspergillus infection	1 (6.3)	0	0	0	1 (6.3)
Bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	0	0	1 (6.3)
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Device related infection	1 (6.3)	0	0	1 (6.3)	0
Device related sepsis	1 (6.3)	0	0	1 (6.3)	0
Epstein-barr virus infection	1 (6.3)	0	1 (6.3)	0	0
Fungaemia	1 (6.3)	0	0	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	0	0	1 (6.3)
Fungal skin infection	1 (6.3)	0	0	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Oral herpes	1 (6.3)	0	0	1 (6.3)	0
Peritonitis	1 (6.3)	0	0	1 (6.3)	0
Pneumonia	1 (6.3)	0	0	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	0	0	1 (6.3)
Sepsis	1 (6.3)	0	0	0	1 (6.3)

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (6.3)	0	0	1 (6.3)	0
Injury, poisoning and procedural complications					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	0	0	1 (6.3)	0
Procedural pain	1 (6.3)	1 (6.3)	0	0	0
Investigations					
-Total	4 (25.0)	0	0	3 (18.8)	1 (6.3)
C-reactive protein increased	2 (12.5)	0	0	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	0	0	1 (6.3)	0
Blood magnesium decreased	1 (6.3)	0	1 (6.3)	0	0
Blood potassium decreased	1 (6.3)	0	0	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	0	0	1 (6.3)
Platelet count decreased	1 (6.3)	0	0	0	1 (6.3)
Serum ferritin increased	1 (6.3)	0	0	1 (6.3)	0
Metabolism and nutrition disorders					
-Total	5 (31.3)	0	1 (6.3)	2 (12.5)	2 (12.5)
Tumour lysis syndrome	2 (12.5)	0	0	1 (6.3)	1 (6.3)

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (6.3)	0	1 (6.3)	0	0
Hyperammonaemia	1 (6.3)	0	0	1 (6.3)	0
Hyperglycaemia	1 (6.3)	0	0	0	1 (6.3)
Hyperuricaemia	1 (6.3)	0	1 (6.3)	0	0
Hypokalaemia	1 (6.3)	0	1 (6.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Arthralgia	1 (6.3)	0	1 (6.3)	0	0
Back pain	1 (6.3)	1 (6.3)	0	0	0
Myositis	1 (6.3)	0	1 (6.3)	0	0
Nervous system disorders					
-Total	4 (25.0)	2 (12.5)	0	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	0	0	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	0	0	1 (6.3)
Headache	1 (6.3)	1 (6.3)	0	0	0
Intraventricular haemorrhage	1 (6.3)	1 (6.3)	0	0	0
Paraesthesia	1 (6.3)	1 (6.3)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Mental status changes	2 (12.5)	0	0	2 (12.5)	0
Renal and urinary disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Acute kidney injury	1 (6.3)	1 (6.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (25.0)	0	1 (6.3)	1 (6.3)	2 (12.5)
Tachypnoea	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Acute respiratory distress syndrome	1 (6.3)	0	0	0	1 (6.3)
Hypoxia	1 (6.3)	0	1 (6.3)	0	0
Pulmonary haemorrhage	1 (6.3)	0	0	0	1 (6.3)
Respiratory failure	1 (6.3)	0	0	0	1 (6.3)
Skin and subcutaneous tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain of skin	1 (6.3)	1 (6.3)	0	0	0
Rash	1 (6.3)	1 (6.3)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin ulcer	1 (6.3)	0	1 (6.3)	0	0
Vascular disorders					
-Total	5 (31.3)	1 (6.3)	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Hypotension	2 (12.5)	0	0	1 (6.3)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207f
Adverse events by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders					
-Total	9 (50.0)	0	0	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	0	0	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Bradycardia	1 (5.6)	1 (5.6)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Adrenal insufficiency	1 (5.6)	0	1 (5.6)	0	0
Hypercalcaemia of malignancy	1 (5.6)	0	0	0	1 (5.6)
Eye disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Eyelid oedema	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	9 (50.0)	2 (11.1)	1 (5.6)	5 (27.8)	1 (5.6)
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain upper	1 (5.6)	1 (5.6)	0	0	0
Colitis	1 (5.6)	0	0	1 (5.6)	0
Duodenal perforation	1 (5.6)	0	0	1 (5.6)	0
Gastritis	1 (5.6)	0	1 (5.6)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Haemoperitoneum	1 (5.6)	0	0	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	9 (50.0)	1 (5.6)	4 (22.2)	4 (22.2)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Generalised oedema	1 (5.6)	0	0	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Immune system disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Hypersensitivity	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	15 (83.3)	0	1 (5.6)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood magnesium decreased	1 (5.6)	0	1 (5.6)	0	0
Blood potassium decreased	1 (5.6)	0	0	1 (5.6)	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (38.9)	0	1 (5.6)	4 (22.2)	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Hyperammonaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperuricaemia	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Myositis	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	5 (27.8)	2 (11.1)	0	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	0	0	1 (5.6)
Headache	1 (5.6)	1 (5.6)	0	0	0
Intraventricular haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Paraesthesia	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (33.3)	0	1 (5.6)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute respiratory distress syndrome	1 (5.6)	0	0	0	1 (5.6)
Hypoxia	1 (5.6)	0	1 (5.6)	0	0
Pulmonary haemorrhage	1 (5.6)	0	0	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain of skin	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Skin ulcer	1 (5.6)	0	1 (5.6)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207g
Adverse events by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders					
-Total	9 (50.0)	0	0	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	0	0	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Bradycardia	1 (5.6)	1 (5.6)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Adrenal insufficiency	1 (5.6)	0	1 (5.6)	0	0
Hypercalcaemia of malignancy	1 (5.6)	0	0	0	1 (5.6)
Eye disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Eyelid oedema	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	9 (50.0)	2 (11.1)	1 (5.6)	5 (27.8)	1 (5.6)
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain upper	1 (5.6)	1 (5.6)	0	0	0
Colitis	1 (5.6)	0	0	1 (5.6)	0
Duodenal perforation	1 (5.6)	0	0	1 (5.6)	0
Gastritis	1 (5.6)	0	1 (5.6)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Haemoperitoneum	1 (5.6)	0	0	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	9 (50.0)	1 (5.6)	4 (22.2)	4 (22.2)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Generalised oedema	1 (5.6)	0	0	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Immune system disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Hypersensitivity	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	15 (83.3)	0	1 (5.6)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood magnesium decreased	1 (5.6)	0	1 (5.6)	0	0
Blood potassium decreased	1 (5.6)	0	0	1 (5.6)	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (38.9)	0	1 (5.6)	4 (22.2)	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Hyperammonaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperuricaemia	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Myositis	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	5 (27.8)	2 (11.1)	0	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	0	0	1 (5.6)
Headache	1 (5.6)	1 (5.6)	0	0	0
Intraventricular haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Paraesthesia	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (33.3)	0	1 (5.6)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute respiratory distress syndrome	1 (5.6)	0	0	0	1 (5.6)
Hypoxia	1 (5.6)	0	1 (5.6)	0	0
Pulmonary haemorrhage	1 (5.6)	0	0	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain of skin	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Skin ulcer	1 (5.6)	0	1 (5.6)	0	0

Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207h
Adverse events by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Yes

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	2 (100)	0	0	2 (100)	0
Tachycardia	2 (100)	0	1 (50.0)	1 (50.0)	0
Left ventricular dysfunction	1 (50.0)	0	0	1 (50.0)	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	0	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	0	0	1 (50.0)

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	2 (100)	0	2 (100)	0	0
Pyrexia	2 (100)	0	2 (100)	0	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Klebsiella bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Serratia sepsis	1 (50.0)	0	0	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Injury, poisoning and procedural complications					
-Total	1 (50.0)	0	0	1 (50.0)	0
Post procedural haemorrhage	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatinine increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypocalcaemia	1 (50.0)	0	1 (50.0)	0	0
Metabolic acidosis	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Myositis	1 (50.0)	0	1 (50.0)	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Acute kidney injury	1 (50.0)	1 (50.0)	0	0	0

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Respiratory failure	1 (50.0)	0	0	0	1 (50.0)
Vascular disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypotension	2 (100)	0	0	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207h
Adverse events by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	0	1 (6.3)	4 (25.0)	11 (68.8)
Blood and lymphatic system disorders					
-Total	8 (50.0)	0	0	5 (31.3)	3 (18.8)
Febrile neutropenia	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Pancytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	0	0	1 (6.3)	0
Thrombocytopenia	1 (6.3)	0	0	0	1 (6.3)
Cardiac disorders					
-Total	4 (25.0)	1 (6.3)	1 (6.3)	2 (12.5)	0
Tachycardia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Bradycardia	1 (6.3)	1 (6.3)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	1 (6.3)	0	0	1 (6.3)	0
Endocrine disorders					
-Total	2 (12.5)	0	1 (6.3)	0	1 (6.3)
Adrenal insufficiency	1 (6.3)	0	1 (6.3)	0	0
Hypercalcaemia of malignancy	1 (6.3)	0	0	0	1 (6.3)
Eye disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Eyelid oedema	1 (6.3)	1 (6.3)	0	0	0
Gastrointestinal disorders					
-Total	8 (50.0)	2 (12.5)	1 (6.3)	5 (31.3)	0
Diarrhoea	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Abdominal pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Abdominal pain upper	1 (6.3)	1 (6.3)	0	0	0
Colitis	1 (6.3)	0	0	1 (6.3)	0
Duodenal perforation	1 (6.3)	0	0	1 (6.3)	0
Gastritis	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	0	0	1 (6.3)	0
Haematemesis	1 (6.3)	1 (6.3)	0	0	0

Hypodiploidy: No

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (6.3)	0	1 (6.3)	0	0
Stomatitis	1 (6.3)	0	0	1 (6.3)	0
General disorders and administration site conditions					
-Total	7 (43.8)	1 (6.3)	2 (12.5)	4 (25.0)	0
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Pyrexia	3 (18.8)	0	1 (6.3)	2 (12.5)	0
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Generalised oedema	1 (6.3)	0	0	1 (6.3)	0
Pain	1 (6.3)	0	0	1 (6.3)	0
Hepatobiliary disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	0	0	2 (12.5)	0
Immune system disorders					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Graft versus host disease	1 (6.3)	0	0	1 (6.3)	0
Hypersensitivity	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	13 (81.3)	0	1 (6.3)	5 (31.3)	7 (43.8)
Acute sinusitis	1 (6.3)	0	0	1 (6.3)	0
Aspergillus infection	1 (6.3)	0	0	0	1 (6.3)
Bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	0	0	1 (6.3)
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Device related infection	1 (6.3)	0	0	1 (6.3)	0
Device related sepsis	1 (6.3)	0	0	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	0	0	1 (6.3)
Epstein-barr virus infection	1 (6.3)	0	1 (6.3)	0	0
Fungaemia	1 (6.3)	0	0	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	0	0	1 (6.3)
Fungal skin infection	1 (6.3)	0	0	1 (6.3)	0
Oral herpes	1 (6.3)	0	0	1 (6.3)	0
Peritonitis	1 (6.3)	0	0	1 (6.3)	0
Pneumonia	1 (6.3)	0	0	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	0	0	1 (6.3)
Sepsis	1 (6.3)	0	0	0	1 (6.3)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (6.3)	0	0	1 (6.3)	0
Injury, poisoning and procedural complications					
-Total	1 (6.3)	1 (6.3)	0	0	0
Procedural pain	1 (6.3)	1 (6.3)	0	0	0
Investigations					
-Total	4 (25.0)	0	0	3 (18.8)	1 (6.3)
C-reactive protein increased	2 (12.5)	0	0	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	0	0	1 (6.3)	0
Blood magnesium decreased	1 (6.3)	0	1 (6.3)	0	0
Blood potassium decreased	1 (6.3)	0	0	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	0	0	1 (6.3)
Platelet count decreased	1 (6.3)	0	0	0	1 (6.3)
Serum ferritin increased	1 (6.3)	0	0	1 (6.3)	0
Metabolism and nutrition disorders					
-Total	6 (37.5)	0	1 (6.3)	3 (18.8)	2 (12.5)
Tumour lysis syndrome	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Decreased appetite	1 (6.3)	0	1 (6.3)	0	0

Hypodiploidy: No

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperammonaemia	1 (6.3)	0	0	1 (6.3)	0
Hyperglycaemia	1 (6.3)	0	0	0	1 (6.3)
Hyperkalaemia	1 (6.3)	0	0	1 (6.3)	0
Hyperuricaemia	1 (6.3)	0	1 (6.3)	0	0
Hypocalcaemia	1 (6.3)	0	1 (6.3)	0	0
Hypokalaemia	1 (6.3)	0	1 (6.3)	0	0
Hypomagnesaemia	1 (6.3)	1 (6.3)	0	0	0
Metabolic acidosis	1 (6.3)	0	0	1 (6.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Arthralgia	1 (6.3)	0	1 (6.3)	0	0
Back pain	1 (6.3)	1 (6.3)	0	0	0
Nervous system disorders					
-Total	4 (25.0)	2 (12.5)	0	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	0	0	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	0	0	1 (6.3)
Headache	1 (6.3)	1 (6.3)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Intraventricular haemorrhage	1 (6.3)	1 (6.3)	0	0	0
Paraesthesia	1 (6.3)	1 (6.3)	0	0	0
Psychiatric disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Mental status changes	2 (12.5)	0	0	2 (12.5)	0
Renal and urinary disorders					
-Total	2 (12.5)	2 (12.5)	0	0	0
Acute kidney injury	2 (12.5)	2 (12.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (31.3)	0	1 (6.3)	1 (6.3)	3 (18.8)
Respiratory failure	2 (12.5)	0	0	0	2 (12.5)
Tachypnoea	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Acute respiratory distress syndrome	1 (6.3)	0	0	0	1 (6.3)
Hypoxia	1 (6.3)	0	1 (6.3)	0	0
Pulmonary haemorrhage	1 (6.3)	0	0	0	1 (6.3)
Skin and subcutaneous tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain of skin	1 (6.3)	1 (6.3)	0	0	0
Rash	1 (6.3)	1 (6.3)	0	0	0
Skin ulcer	1 (6.3)	0	1 (6.3)	0	0
Vascular disorders					
-Total	5 (31.3)	1 (6.3)	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Hypotension	2 (12.5)	0	0	1 (6.3)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207i
Adverse events by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypersensitivity	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Acute sinusitis	1 (100)	0	0	1 (100)	0
Fungal skin infection	1 (100)	0	0	1 (100)	0
Systemic mycosis	1 (100)	0	0	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207i
Adverse events by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	1 (5.9)	4 (23.5)	12 (70.6)
Blood and lymphatic system disorders					
-Total	8 (47.1)	0	0	5 (29.4)	3 (17.6)
Anaemia	3 (17.6)	0	0	3 (17.6)	0
Febrile neutropenia	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Hyperleukocytosis	1 (5.9)	0	0	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Cardiac disorders					
-Total	6 (35.3)	1 (5.9)	1 (5.9)	4 (23.5)	0
Tachycardia	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Bradycardia	1 (5.9)	1 (5.9)	0	0	0

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.9)	0	0	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	0	0	1 (5.9)	0
Endocrine disorders					
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Adrenal insufficiency	1 (5.9)	0	1 (5.9)	0	0
Hypercalcaemia of malignancy	1 (5.9)	0	0	0	1 (5.9)
Eye disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Eyelid oedema	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	9 (52.9)	2 (11.8)	1 (5.9)	5 (29.4)	1 (5.9)
Diarrhoea	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Abdominal pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Abdominal compartment syndrome	1 (5.9)	0	0	0	1 (5.9)
Abdominal pain upper	1 (5.9)	1 (5.9)	0	0	0
Colitis	1 (5.9)	0	0	1 (5.9)	0
Duodenal perforation	1 (5.9)	0	0	1 (5.9)	0
Gastritis	1 (5.9)	0	1 (5.9)	0	0

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.9)	0	0	1 (5.9)	0
Haematemesis	1 (5.9)	1 (5.9)	0	0	0
Haemoperitoneum	1 (5.9)	0	0	0	1 (5.9)
Nausea	1 (5.9)	0	1 (5.9)	0	0
Stomatitis	1 (5.9)	0	0	1 (5.9)	0
General disorders and administration site conditions					
-Total	9 (52.9)	1 (5.9)	4 (23.5)	4 (23.5)	0
Pyrexia	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Catheter site pain	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Oedema peripheral	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Generalised oedema	1 (5.9)	0	0	1 (5.9)	0
Hepatobiliary disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Hyperbilirubinaemia	2 (11.8)	0	0	2 (11.8)	0
Immune system disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (5.9)	0	0	1 (5.9)	0
Infections and infestations					
-Total	14 (82.4)	0	1 (5.9)	5 (29.4)	8 (47.1)
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)
Bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Clostridium difficile colitis	1 (5.9)	0	1 (5.9)	0	0
Device related infection	1 (5.9)	0	0	1 (5.9)	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	0	0	1 (5.9)
Epstein-barr virus infection	1 (5.9)	0	1 (5.9)	0	0
Fungaemia	1 (5.9)	0	0	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)
Klebsiella bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Oral herpes	1 (5.9)	0	0	1 (5.9)	0
Peritonitis	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	0	0	1 (5.9)

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (5.9)	0	0	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	0	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	0	0	1 (5.9)
Injury, poisoning and procedural complications					
-Total	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	0	0	1 (5.9)	0
Procedural pain	1 (5.9)	1 (5.9)	0	0	0
Investigations					
-Total	5 (29.4)	0	0	3 (17.6)	2 (11.8)
Alanine aminotransferase increased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
C-reactive protein increased	2 (11.8)	0	0	2 (11.8)	0
Aspartate aminotransferase increased	1 (5.9)	0	0	0	1 (5.9)
Blood creatinine increased	1 (5.9)	1 (5.9)	0	0	0
Blood magnesium decreased	1 (5.9)	0	1 (5.9)	0	0
Blood potassium decreased	1 (5.9)	0	0	1 (5.9)	0
Lymphocyte count decreased	1 (5.9)	1 (5.9)	0	0	0
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (5.9)	0	0	0	1 (5.9)
Serum ferritin increased	1 (5.9)	0	0	1 (5.9)	0
White blood cell count decreased	1 (5.9)	1 (5.9)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (41.2)	0	1 (5.9)	4 (23.5)	2 (11.8)
Hypocalcaemia	2 (11.8)	0	2 (11.8)	0	0
Metabolic acidosis	2 (11.8)	0	0	2 (11.8)	0
Tumour lysis syndrome	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Decreased appetite	1 (5.9)	0	1 (5.9)	0	0
Hyperammonaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	0	0	1 (5.9)
Hyperkalaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperuricaemia	1 (5.9)	0	1 (5.9)	0	0
Hypoalbuminaemia	1 (5.9)	0	1 (5.9)	0	0
Hypokalaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Musculoskeletal and connective tissue disorders					

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Arthralgia	1 (5.9)	0	1 (5.9)	0	0
Back pain	1 (5.9)	1 (5.9)	0	0	0
Myositis	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					
-Total	5 (29.4)	2 (11.8)	0	2 (11.8)	1 (5.9)
Cognitive disorder	1 (5.9)	0	0	1 (5.9)	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Haemorrhage intracranial	1 (5.9)	0	0	0	1 (5.9)
Headache	1 (5.9)	1 (5.9)	0	0	0
Intraventricular haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Paraesthesia	1 (5.9)	1 (5.9)	0	0	0
Psychiatric disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Mental status changes	2 (11.8)	0	0	2 (11.8)	0
Renal and urinary disorders					
-Total	3 (17.6)	3 (17.6)	0	0	0
Acute kidney injury	3 (17.6)	3 (17.6)	0	0	0

BCR-ABL1-like: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	6 (35.3)	0	1 (5.9)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	0	0	3 (17.6)
Tachypnoea	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Acute respiratory distress syndrome	1 (5.9)	0	0	0	1 (5.9)
Hypoxia	1 (5.9)	0	1 (5.9)	0	0
Pulmonary haemorrhage	1 (5.9)	0	0	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	0	0	1 (5.9)
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain of skin	1 (5.9)	1 (5.9)	0	0	0
Rash	1 (5.9)	1 (5.9)	0	0	0
Skin ulcer	1 (5.9)	0	1 (5.9)	0	0
Vascular disorders					
-Total	7 (41.2)	1 (5.9)	2 (11.8)	3 (17.6)	1 (5.9)
Hypotension	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Hypertension	3 (17.6)	1 (5.9)	2 (11.8)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207j
Adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	0	3 (100)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Tachycardia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	0	0	1 (33.3)
Abdominal pain	1 (33.3)	0	1 (33.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Haemoperitoneum	1 (33.3)	0	0	0	1 (33.3)
Stomatitis	1 (33.3)	0	0	1 (33.3)	0
General disorders and administration site conditions					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Generalised oedema	1 (33.3)	0	0	1 (33.3)	0
Pain	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Hepatobiliary disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	3 (100)	0	0	0	3 (100)
Aspergillus infection	1 (33.3)	0	0	0	1 (33.3)
Fungaemia	1 (33.3)	0	0	0	1 (33.3)
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Investigations					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (66.7)	0	0	0	2 (66.7)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Aspartate aminotransferase increased	1 (33.3)	0	0	0	1 (33.3)
Blood creatinine increased	1 (33.3)	1 (33.3)	0	0	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	0	0	0	1 (33.3)
White blood cell count decreased	1 (33.3)	1 (33.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0
Psychiatric disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	2 (66.7)	2 (66.7)	0	0	0
Acute kidney injury	2 (66.7)	2 (66.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Respiratory failure	2 (66.7)	0	0	0	2 (66.7)
Pulmonary haemorrhage	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Tachypnoea	1 (33.3)	0	1 (33.3)	0	0
Vascular disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hypertension	1 (33.3)	0	1 (33.3)	0	0
Hypotension	1 (33.3)	0	0	1 (33.3)	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207j
Adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	1 (6.7)	5 (33.3)	9 (60.0)
Blood and lymphatic system disorders					
-Total	7 (46.7)	0	0	4 (26.7)	3 (20.0)
Febrile neutropenia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Pancytopenia	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Hyperleukocytosis	1 (6.7)	0	0	1 (6.7)	0
Thrombocytopenia	1 (6.7)	0	0	0	1 (6.7)
Cardiac disorders					
-Total	4 (26.7)	1 (6.7)	0	3 (20.0)	0
Tachycardia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Bradycardia	1 (6.7)	1 (6.7)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (6.7)	0	0	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	0	0	1 (6.7)	0
Endocrine disorders					
-Total	2 (13.3)	0	1 (6.7)	0	1 (6.7)
Adrenal insufficiency	1 (6.7)	0	1 (6.7)	0	0
Hypercalcaemia of malignancy	1 (6.7)	0	0	0	1 (6.7)
Eye disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Eyelid oedema	1 (6.7)	1 (6.7)	0	0	0
Gastrointestinal disorders					
-Total	7 (46.7)	2 (13.3)	1 (6.7)	4 (26.7)	0
Diarrhoea	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Abdominal pain	1 (6.7)	0	0	1 (6.7)	0
Abdominal pain upper	1 (6.7)	1 (6.7)	0	0	0
Colitis	1 (6.7)	0	0	1 (6.7)	0
Duodenal perforation	1 (6.7)	0	0	1 (6.7)	0
Gastritis	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal haemorrhage	1 (6.7)	0	0	1 (6.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (6.7)	1 (6.7)	0	0	0
Nausea	1 (6.7)	0	1 (6.7)	0	0
General disorders and administration site conditions					
-Total	7 (46.7)	1 (6.7)	3 (20.0)	3 (20.0)	0
Pyrexia	4 (26.7)	0	2 (13.3)	2 (13.3)	0
Catheter site pain	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Oedema peripheral	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pain	1 (6.7)	0	0	1 (6.7)	0
Hepatobiliary disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Hyperbilirubinaemia	1 (6.7)	0	0	1 (6.7)	0
Immune system disorders					
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Graft versus host disease	1 (6.7)	0	0	1 (6.7)	0
Hypersensitivity	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	12 (80.0)	0	1 (6.7)	6 (40.0)	5 (33.3)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute sinusitis	1 (6.7)	0	0	1 (6.7)	0
Bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Bacterial sepsis	1 (6.7)	0	0	0	1 (6.7)
Clostridium difficile colitis	1 (6.7)	0	1 (6.7)	0	0
Device related infection	1 (6.7)	0	0	1 (6.7)	0
Device related sepsis	1 (6.7)	0	0	1 (6.7)	0
Disseminated trichosporonosis	1 (6.7)	0	0	0	1 (6.7)
Epstein-barr virus infection	1 (6.7)	0	1 (6.7)	0	0
Fungal sepsis	1 (6.7)	0	0	0	1 (6.7)
Fungal skin infection	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Oral herpes	1 (6.7)	0	0	1 (6.7)	0
Peritonitis	1 (6.7)	0	0	1 (6.7)	0
Pneumonia	1 (6.7)	0	0	0	1 (6.7)
Pneumonia fungal	1 (6.7)	0	0	0	1 (6.7)
Sepsis	1 (6.7)	0	0	0	1 (6.7)
Systemic mycosis	1 (6.7)	0	0	1 (6.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	0	0	1 (6.7)	0
Procedural pain	1 (6.7)	1 (6.7)	0	0	0
Investigations					
-Total	3 (20.0)	0	0	3 (20.0)	0
C-reactive protein increased	2 (13.3)	0	0	2 (13.3)	0
Alanine aminotransferase increased	1 (6.7)	0	0	1 (6.7)	0
Blood magnesium decreased	1 (6.7)	0	1 (6.7)	0	0
Blood potassium decreased	1 (6.7)	0	0	1 (6.7)	0
Serum ferritin increased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	6 (40.0)	0	1 (6.7)	3 (20.0)	2 (13.3)
Tumour lysis syndrome	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Decreased appetite	1 (6.7)	0	1 (6.7)	0	0
Hyperammonaemia	1 (6.7)	0	0	1 (6.7)	0
Hyperglycaemia	1 (6.7)	0	0	0	1 (6.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (6.7)	0	0	1 (6.7)	0
Hyperuricaemia	1 (6.7)	0	1 (6.7)	0	0
Hypocalcaemia	1 (6.7)	0	1 (6.7)	0	0
Hypokalaemia	1 (6.7)	0	1 (6.7)	0	0
Hypomagnesaemia	1 (6.7)	1 (6.7)	0	0	0
Metabolic acidosis	1 (6.7)	0	0	1 (6.7)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Arthralgia	1 (6.7)	0	1 (6.7)	0	0
Back pain	1 (6.7)	1 (6.7)	0	0	0
Myositis	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	4 (26.7)	2 (13.3)	0	1 (6.7)	1 (6.7)
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	0	0	1 (6.7)
Headache	1 (6.7)	1 (6.7)	0	0	0
Intraventricular haemorrhage	1 (6.7)	1 (6.7)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	1 (6.7)	1 (6.7)	0	0	0
Psychiatric disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Mental status changes	1 (6.7)	0	0	1 (6.7)	0
Renal and urinary disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Acute kidney injury	1 (6.7)	1 (6.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (26.7)	0	1 (6.7)	1 (6.7)	2 (13.3)
Acute respiratory distress syndrome	1 (6.7)	0	0	0	1 (6.7)
Hypoxia	1 (6.7)	0	1 (6.7)	0	0
Respiratory failure	1 (6.7)	0	0	0	1 (6.7)
Tachypnoea	1 (6.7)	0	0	1 (6.7)	0
Skin and subcutaneous tissue disorders					
-Total	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pain of skin	1 (6.7)	1 (6.7)	0	0	0
Rash	1 (6.7)	1 (6.7)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (6.7)	0	1 (6.7)	0	0
Vascular disorders					
-Total	5 (33.3)	1 (6.7)	1 (6.7)	2 (13.3)	1 (6.7)
Hypotension	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Hypertension	2 (13.3)	1 (6.7)	1 (6.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207k
Adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Europe

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	2 (50.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	0	1 (25.0)
Pancytopenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Bradycardia	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Eyelid oedema	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					

Region: Europe

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Abdominal pain upper	1 (25.0)	1 (25.0)	0	0	0
Diarrhoea	1 (25.0)	0	0	1 (25.0)	0
General disorders and administration site conditions					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Catheter site pain	2 (50.0)	2 (50.0)	0	0	0
Oedema peripheral	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Pain	1 (25.0)	0	0	1 (25.0)	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Device related infection	1 (25.0)	0	0	1 (25.0)	0
Device related sepsis	1 (25.0)	0	0	1 (25.0)	0
Pneumonia	1 (25.0)	0	0	0	1 (25.0)
Injury, poisoning and procedural complications					
-Total	1 (25.0)	1 (25.0)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Procedural pain	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	2 (50.0)	0	0	2 (50.0)	0
C-reactive protein increased	2 (50.0)	0	0	2 (50.0)	0
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Tumour lysis syndrome	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Back pain	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Encephalopathy	1 (25.0)	0	0	1 (25.0)	0
Headache	1 (25.0)	1 (25.0)	0	0	0
Paraesthesia	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pain of skin	1 (25.0)	1 (25.0)	0	0	0
Skin ulcer	1 (25.0)	0	1 (25.0)	0	0
Vascular disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypertension	1 (25.0)	0	1 (25.0)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207k
Adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=12				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (100)	0	0	3 (25.0)	9 (75.0)
Blood and lymphatic system disorders					
-Total	7 (58.3)	0	0	5 (41.7)	2 (16.7)
Anaemia	3 (25.0)	0	0	3 (25.0)	0
Febrile neutropenia	3 (25.0)	0	0	3 (25.0)	0
Hyperleukocytosis	1 (8.3)	0	0	1 (8.3)	0
Pancytopenia	1 (8.3)	0	0	0	1 (8.3)
Thrombocytopenia	1 (8.3)	0	0	0	1 (8.3)
Cardiac disorders					
-Total	5 (41.7)	0	1 (8.3)	4 (33.3)	0
Tachycardia	4 (33.3)	0	2 (16.7)	2 (16.7)	0
Cardiac failure	1 (8.3)	0	0	1 (8.3)	0

Region: US

Primary system organ class Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Left ventricular dysfunction	1 (8.3)	0	0	1 (8.3)	0
Endocrine disorders					
-Total	2 (16.7)	0	1 (8.3)	0	1 (8.3)
Adrenal insufficiency	1 (8.3)	0	1 (8.3)	0	0
Hypercalcaemia of malignancy	1 (8.3)	0	0	0	1 (8.3)
Gastrointestinal disorders					
-Total	6 (50.0)	1 (8.3)	1 (8.3)	3 (25.0)	1 (8.3)
Diarrhoea	2 (16.7)	0	2 (16.7)	0	0
Abdominal compartment syndrome	1 (8.3)	0	0	0	1 (8.3)
Abdominal pain	1 (8.3)	0	1 (8.3)	0	0
Colitis	1 (8.3)	0	0	1 (8.3)	0
Gastrointestinal haemorrhage	1 (8.3)	0	0	1 (8.3)	0
Haematemesis	1 (8.3)	1 (8.3)	0	0	0
Haemoperitoneum	1 (8.3)	0	0	0	1 (8.3)
Nausea	1 (8.3)	0	1 (8.3)	0	0
Stomatitis	1 (8.3)	0	0	1 (8.3)	0
General disorders and administration site conditions					

Region: US

Primary system organ class Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (50.0)	0	4 (33.3)	2 (16.7)	0
Pyrexia	4 (33.3)	0	3 (25.0)	1 (8.3)	0
Catheter site pain	1 (8.3)	0	1 (8.3)	0	0
Generalised oedema	1 (8.3)	0	0	1 (8.3)	0
Pain	1 (8.3)	0	1 (8.3)	0	0
Hepatobiliary disorders					
-Total	2 (16.7)	0	0	2 (16.7)	0
Hyperbilirubinaemia	2 (16.7)	0	0	2 (16.7)	0
Immune system disorders					
-Total	2 (16.7)	0	1 (8.3)	1 (8.3)	0
Graft versus host disease	1 (8.3)	0	0	1 (8.3)	0
Hypersensitivity	1 (8.3)	0	1 (8.3)	0	0
Infections and infestations					
-Total	10 (83.3)	0	0	3 (25.0)	7 (58.3)
Acute sinusitis	1 (8.3)	0	0	1 (8.3)	0
Aspergillus infection	1 (8.3)	0	0	0	1 (8.3)
Bacteraemia	1 (8.3)	0	0	1 (8.3)	0
Bacterial sepsis	1 (8.3)	0	0	0	1 (8.3)

Region: US

Primary system organ class Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	1 (8.3)	0	1 (8.3)	0	0
Disseminated trichosporonosis	1 (8.3)	0	0	0	1 (8.3)
Fungaemia	1 (8.3)	0	0	0	1 (8.3)
Fungal sepsis	1 (8.3)	0	0	0	1 (8.3)
Fungal skin infection	1 (8.3)	0	0	1 (8.3)	0
Klebsiella bacteraemia	1 (8.3)	0	0	1 (8.3)	0
Oral herpes	1 (8.3)	0	0	1 (8.3)	0
Pneumonia fungal	1 (8.3)	0	0	0	1 (8.3)
Sepsis	1 (8.3)	0	0	0	1 (8.3)
Serratia sepsis	1 (8.3)	0	0	0	1 (8.3)
Staphylococcal infection	1 (8.3)	0	0	0	1 (8.3)
Systemic mycosis	1 (8.3)	0	0	1 (8.3)	0
Injury, poisoning and procedural complications					
-Total	1 (8.3)	0	0	1 (8.3)	0
Post procedural haemorrhage	1 (8.3)	0	0	1 (8.3)	0
Investigations					
-Total	3 (25.0)	0	0	1 (8.3)	2 (16.7)

Region: US

Primary system organ class Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Aspartate aminotransferase increased	1 (8.3)	0	0	0	1 (8.3)
Blood creatinine increased	1 (8.3)	1 (8.3)	0	0	0
Blood magnesium decreased	1 (8.3)	0	1 (8.3)	0	0
Blood potassium decreased	1 (8.3)	0	0	1 (8.3)	0
Lymphocyte count decreased	1 (8.3)	1 (8.3)	0	0	0
Neutrophil count decreased	1 (8.3)	0	0	0	1 (8.3)
Platelet count decreased	1 (8.3)	0	0	0	1 (8.3)
Serum ferritin increased	1 (8.3)	0	0	1 (8.3)	0
White blood cell count decreased	1 (8.3)	1 (8.3)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (41.7)	0	1 (8.3)	3 (25.0)	1 (8.3)
Hypocalcaemia	2 (16.7)	0	2 (16.7)	0	0
Metabolic acidosis	2 (16.7)	0	0	2 (16.7)	0
Decreased appetite	1 (8.3)	0	1 (8.3)	0	0
Hyperammonaemia	1 (8.3)	0	0	1 (8.3)	0
Hyperglycaemia	1 (8.3)	0	0	0	1 (8.3)

Region: US

Primary system organ class Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	1 (8.3)	0	0	1 (8.3)	0
Hyperuricaemia	1 (8.3)	0	1 (8.3)	0	0
Hypoalbuminaemia	1 (8.3)	0	1 (8.3)	0	0
Hypokalaemia	1 (8.3)	0	1 (8.3)	0	0
Hypomagnesaemia	1 (8.3)	1 (8.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (16.7)	0	2 (16.7)	0	0
Arthralgia	1 (8.3)	0	1 (8.3)	0	0
Myositis	1 (8.3)	0	1 (8.3)	0	0
Nervous system disorders					
-Total	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Cognitive disorder	1 (8.3)	0	0	1 (8.3)	0
Intraventricular haemorrhage	1 (8.3)	1 (8.3)	0	0	0
Psychiatric disorders					
-Total	2 (16.7)	0	0	2 (16.7)	0
Mental status changes	2 (16.7)	0	0	2 (16.7)	0
Renal and urinary disorders					

Region: US

Primary system organ class Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (25.0)	3 (25.0)	0	0	0
Acute kidney injury	3 (25.0)	3 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (41.7)	0	0	1 (8.3)	4 (33.3)
Respiratory failure	3 (25.0)	0	0	0	3 (25.0)
Tachypnoea	2 (16.7)	0	1 (8.3)	1 (8.3)	0
Acute respiratory distress syndrome	1 (8.3)	0	0	0	1 (8.3)
Pulmonary haemorrhage	1 (8.3)	0	0	0	1 (8.3)
Pulmonary oedema	1 (8.3)	0	0	0	1 (8.3)
Skin and subcutaneous tissue disorders					
-Total	1 (8.3)	1 (8.3)	0	0	0
Rash	1 (8.3)	1 (8.3)	0	0	0
Vascular disorders					
-Total	6 (50.0)	1 (8.3)	1 (8.3)	3 (25.0)	1 (8.3)
Hypotension	4 (33.3)	0	0	3 (25.0)	1 (8.3)
Hypertension	2 (16.7)	1 (8.3)	1 (8.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207k
Adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Rest of World

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Duodenal perforation	1 (50.0)	0	0	1 (50.0)	0
Gastritis	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Epstein-barr virus infection	1 (50.0)	0	1 (50.0)	0	0
Peritonitis	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)

Region: Rest of World

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemorrhage intracranial	1 (50.0)	0	0	0	1 (50.0)

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207l
Adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	4 (40.0)	5 (50.0)
Blood and lymphatic system disorders					
-Total	4 (40.0)	0	0	2 (20.0)	2 (20.0)
Febrile neutropenia	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Pancytopenia	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Anaemia	1 (10.0)	0	0	1 (10.0)	0
Cardiac disorders					
-Total	4 (40.0)	1 (10.0)	1 (10.0)	2 (20.0)	0
Tachycardia	2 (20.0)	0	2 (20.0)	0	0
Bradycardia	1 (10.0)	1 (10.0)	0	0	0
Cardiac failure	1 (10.0)	0	0	1 (10.0)	0
Left ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Adrenal insufficiency	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0
Eyelid oedema	1 (10.0)	1 (10.0)	0	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	1 (10.0)	1 (10.0)	4 (40.0)	0
Diarrhoea	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal pain	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Abdominal pain upper	1 (10.0)	1 (10.0)	0	0	0
Colitis	1 (10.0)	0	0	1 (10.0)	0
Duodenal perforation	1 (10.0)	0	0	1 (10.0)	0
Gastritis	1 (10.0)	0	1 (10.0)	0	0
Nausea	1 (10.0)	0	1 (10.0)	0	0
Stomatitis	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (60.0)	1 (10.0)	2 (20.0)	3 (30.0)	0
Pyrexia	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Catheter site pain	2 (20.0)	2 (20.0)	0	0	0
Oedema peripheral	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Generalised oedema	1 (10.0)	0	0	1 (10.0)	0
Pain	1 (10.0)	0	0	1 (10.0)	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Hyperbilirubinaemia	1 (10.0)	0	0	1 (10.0)	0
Immune system disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Graft versus host disease	1 (10.0)	0	0	1 (10.0)	0
Infections and infestations					
-Total	9 (90.0)	0	1 (10.0)	5 (50.0)	3 (30.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	0	1 (10.0)	0	0
Device related infection	1 (10.0)	0	0	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (10.0)	0	0	1 (10.0)	0
Epstein-barr virus infection	1 (10.0)	0	1 (10.0)	0	0
Fungaemia	1 (10.0)	0	0	0	1 (10.0)
Fungal sepsis	1 (10.0)	0	0	0	1 (10.0)
Klebsiella bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Peritonitis	1 (10.0)	0	0	1 (10.0)	0
Pneumonia	1 (10.0)	0	0	0	1 (10.0)
Injury, poisoning and procedural complications					
-Total	2 (20.0)	1 (10.0)	0	1 (10.0)	0
Post procedural haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Procedural pain	1 (10.0)	1 (10.0)	0	0	0
Investigations					
-Total	3 (30.0)	0	0	2 (20.0)	1 (10.0)
C-reactive protein increased	2 (20.0)	0	0	2 (20.0)	0
Neutrophil count decreased	1 (10.0)	0	0	0	1 (10.0)
Platelet count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					

Prior SCT therapy: Yes

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Tumour lysis syndrome	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Decreased appetite	1 (10.0)	0	1 (10.0)	0	0
Hyperglycaemia	1 (10.0)	0	0	0	1 (10.0)
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	1 (10.0)	2 (20.0)	0	0
Arthralgia	1 (10.0)	0	1 (10.0)	0	0
Back pain	1 (10.0)	1 (10.0)	0	0	0
Myositis	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	3 (30.0)	1 (10.0)	0	1 (10.0)	1 (10.0)
Encephalopathy	1 (10.0)	0	0	1 (10.0)	0
Haemorrhage intracranial	1 (10.0)	0	0	0	1 (10.0)
Headache	1 (10.0)	1 (10.0)	0	0	0
Paraesthesia	1 (10.0)	1 (10.0)	0	0	0
Renal and urinary disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0

Prior SCT therapy: Yes

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (10.0)	1 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (30.0)	0	1 (10.0)	0	2 (20.0)
Acute respiratory distress syndrome	1 (10.0)	0	0	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)	0	0
Pulmonary haemorrhage	1 (10.0)	0	0	0	1 (10.0)
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Tachypnoea	1 (10.0)	0	1 (10.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Pain of skin	1 (10.0)	1 (10.0)	0	0	0
Rash	1 (10.0)	1 (10.0)	0	0	0
Skin ulcer	1 (10.0)	0	1 (10.0)	0	0
Vascular disorders					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Hypertension	3 (30.0)	1 (10.0)	2 (20.0)	0	0
Hypotension	1 (10.0)	0	0	1 (10.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207l
Adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders					
-Total	5 (62.5)	0	0	4 (50.0)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Hyperleukocytosis	1 (12.5)	0	0	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Tachycardia	2 (25.0)	0	0	2 (25.0)	0
Endocrine disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypercalcaemia of malignancy	1 (12.5)	0	0	0	1 (12.5)
Gastrointestinal disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Gastrointestinal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
General disorders and administration site conditions					
-Total	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Pyrexia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Catheter site pain	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0

Prior SCT therapy: No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	1 (12.5)	5 (62.5)
Acute sinusitis	1 (12.5)	0	0	1 (12.5)	0
Aspergillus infection	1 (12.5)	0	0	0	1 (12.5)
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Fungal skin infection	1 (12.5)	0	0	1 (12.5)	0
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	0	0	1 (12.5)
Sepsis	1 (12.5)	0	0	0	1 (12.5)
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Systemic mycosis	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatinine increased	1 (12.5)	1 (12.5)	0	0	0
Blood magnesium decreased	1 (12.5)	0	1 (12.5)	0	0
Blood potassium decreased	1 (12.5)	0	0	1 (12.5)	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Serum ferritin increased	1 (12.5)	0	0	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Hypocalcaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Hyperammonaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperuricaemia	1 (12.5)	0	1 (12.5)	0	0
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	1 (12.5)	0	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Nervous system disorders					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Prior SCT therapy: No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Intraventricular haemorrhage	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Mental status changes	2 (25.0)	0	0	2 (25.0)	0
Renal and urinary disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Acute kidney injury	2 (25.0)	2 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Tachypnoea	1 (12.5)	0	0	1 (12.5)	0
Vascular disorders					
-Total	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Hypotension	3 (37.5)	0	0	2 (25.0)	1 (12.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207m
Adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Gastrointestinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Duodenal perforation	1 (25.0)	0	0	1 (25.0)	0
Gastritis	1 (25.0)	0	1 (25.0)	0	0
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypersensitivity	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					

Eligibility for SCT: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (100)	0	1 (25.0)	2 (50.0)	1 (25.0)
Acute sinusitis	1 (25.0)	0	0	1 (25.0)	0
Aspergillus infection	1 (25.0)	0	0	0	1 (25.0)
Epstein-barr virus infection	1 (25.0)	0	1 (25.0)	0	0
Fungal skin infection	1 (25.0)	0	0	1 (25.0)	0
Peritonitis	1 (25.0)	0	0	1 (25.0)	0
Systemic mycosis	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Haemorrhage intracranial	1 (25.0)	0	0	0	1 (25.0)
Psychiatric disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Mental status changes	1 (25.0)	0	0	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207m
Adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	0	4 (28.6)	10 (71.4)
Blood and lymphatic system disorders					
-Total	8 (57.1)	0	0	5 (35.7)	3 (21.4)
Anaemia	3 (21.4)	0	0	3 (21.4)	0
Febrile neutropenia	3 (21.4)	0	0	2 (14.3)	1 (7.1)
Pancytopenia	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Hyperleukocytosis	1 (7.1)	0	0	1 (7.1)	0
Thrombocytopenia	1 (7.1)	0	0	0	1 (7.1)
Cardiac disorders					
-Total	6 (42.9)	1 (7.1)	1 (7.1)	4 (28.6)	0
Tachycardia	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Bradycardia	1 (7.1)	1 (7.1)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	1 (7.1)	0	0	1 (7.1)	0
Left ventricular dysfunction	1 (7.1)	0	0	1 (7.1)	0
Endocrine disorders					
-Total	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Adrenal insufficiency	1 (7.1)	0	1 (7.1)	0	0
Hypercalcaemia of malignancy	1 (7.1)	0	0	0	1 (7.1)
Eye disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Eyelid oedema	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	8 (57.1)	2 (14.3)	1 (7.1)	4 (28.6)	1 (7.1)
Diarrhoea	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Abdominal pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Abdominal compartment syndrome	1 (7.1)	0	0	0	1 (7.1)
Abdominal pain upper	1 (7.1)	1 (7.1)	0	0	0
Colitis	1 (7.1)	0	0	1 (7.1)	0
Gastrointestinal haemorrhage	1 (7.1)	0	0	1 (7.1)	0
Haematemesis	1 (7.1)	1 (7.1)	0	0	0

Eligibility for SCT: No

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (7.1)	0	0	0	1 (7.1)
Nausea	1 (7.1)	0	1 (7.1)	0	0
Stomatitis	1 (7.1)	0	0	1 (7.1)	0
General disorders and administration site conditions					
-Total	9 (64.3)	1 (7.1)	4 (28.6)	4 (28.6)	0
Pyrexia	5 (35.7)	0	3 (21.4)	2 (14.3)	0
Catheter site pain	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Oedema peripheral	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Generalised oedema	1 (7.1)	0	0	1 (7.1)	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	0	0	2 (14.3)	0
Immune system disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Graft versus host disease	1 (7.1)	0	0	1 (7.1)	0
Infections and infestations					

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (78.6)	0	0	4 (28.6)	7 (50.0)
Bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Clostridium difficile colitis	1 (7.1)	0	1 (7.1)	0	0
Device related infection	1 (7.1)	0	0	1 (7.1)	0
Device related sepsis	1 (7.1)	0	0	1 (7.1)	0
Disseminated trichosporonosis	1 (7.1)	0	0	0	1 (7.1)
Fungaemia	1 (7.1)	0	0	0	1 (7.1)
Fungal sepsis	1 (7.1)	0	0	0	1 (7.1)
Klebsiella bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Oral herpes	1 (7.1)	0	0	1 (7.1)	0
Pneumonia	1 (7.1)	0	0	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	0	0	1 (7.1)
Sepsis	1 (7.1)	0	0	0	1 (7.1)
Serratia sepsis	1 (7.1)	0	0	0	1 (7.1)
Staphylococcal infection	1 (7.1)	0	0	0	1 (7.1)
Injury, poisoning and procedural complications					

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Post procedural haemorrhage	1 (7.1)	0	0	1 (7.1)	0
Procedural pain	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	5 (35.7)	0	0	3 (21.4)	2 (14.3)
Alanine aminotransferase increased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
C-reactive protein increased	2 (14.3)	0	0	2 (14.3)	0
Aspartate aminotransferase increased	1 (7.1)	0	0	0	1 (7.1)
Blood creatinine increased	1 (7.1)	1 (7.1)	0	0	0
Blood magnesium decreased	1 (7.1)	0	1 (7.1)	0	0
Blood potassium decreased	1 (7.1)	0	0	1 (7.1)	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Serum ferritin increased	1 (7.1)	0	0	1 (7.1)	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					

Eligibility for SCT: No

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (50.0)	0	1 (7.1)	4 (28.6)	2 (14.3)
Hypocalcaemia	2 (14.3)	0	2 (14.3)	0	0
Metabolic acidosis	2 (14.3)	0	0	2 (14.3)	0
Tumour lysis syndrome	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Decreased appetite	1 (7.1)	0	1 (7.1)	0	0
Hyperammonaemia	1 (7.1)	0	0	1 (7.1)	0
Hyperglycaemia	1 (7.1)	0	0	0	1 (7.1)
Hyperkalaemia	1 (7.1)	0	0	1 (7.1)	0
Hyperuricaemia	1 (7.1)	0	1 (7.1)	0	0
Hypoalbuminaemia	1 (7.1)	0	1 (7.1)	0	0
Hypokalaemia	1 (7.1)	0	1 (7.1)	0	0
Hypomagnesaemia	1 (7.1)	1 (7.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Arthralgia	1 (7.1)	0	1 (7.1)	0	0
Back pain	1 (7.1)	1 (7.1)	0	0	0
Myositis	1 (7.1)	0	1 (7.1)	0	0

Eligibility for SCT: No

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	4 (28.6)	2 (14.3)	0	2 (14.3)	0
Cognitive disorder	1 (7.1)	0	0	1 (7.1)	0
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Headache	1 (7.1)	1 (7.1)	0	0	0
Intraventricular haemorrhage	1 (7.1)	1 (7.1)	0	0	0
Paraesthesia	1 (7.1)	1 (7.1)	0	0	0
Psychiatric disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Mental status changes	1 (7.1)	0	0	1 (7.1)	0
Renal and urinary disorders					
-Total	3 (21.4)	3 (21.4)	0	0	0
Acute kidney injury	3 (21.4)	3 (21.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (42.9)	0	1 (7.1)	1 (7.1)	4 (28.6)
Respiratory failure	3 (21.4)	0	0	0	3 (21.4)
Tachypnoea	2 (14.3)	0	1 (7.1)	1 (7.1)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute respiratory distress syndrome	1 (7.1)	0	0	0	1 (7.1)
Hypoxia	1 (7.1)	0	1 (7.1)	0	0
Pulmonary haemorrhage	1 (7.1)	0	0	0	1 (7.1)
Pulmonary oedema	1 (7.1)	0	0	0	1 (7.1)
Skin and subcutaneous tissue disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pain of skin	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Skin ulcer	1 (7.1)	0	1 (7.1)	0	0
Vascular disorders					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	3 (21.4)	1 (7.1)
Hypotension	4 (28.6)	0	0	3 (21.4)	1 (7.1)
Hypertension	3 (21.4)	1 (7.1)	2 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207n
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Thrombocytopenia	1 (50.0)	0	0	0	1 (50.0)
Infections and infestations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Epstein-barr virus infection	1 (50.0)	0	1 (50.0)	0	0
Investigations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Blood magnesium decreased	1 (50.0)	0	1 (50.0)	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood potassium decreased	1 (50.0)	0	0	1 (50.0)	0
Serum ferritin increased	1 (50.0)	0	0	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207n
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	0	0	5 (31.3)	11 (68.8)
Blood and lymphatic system disorders					
-Total	8 (50.0)	0	0	6 (37.5)	2 (12.5)
Febrile neutropenia	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Pancytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	0	0	1 (6.3)	0
Cardiac disorders					
-Total	6 (37.5)	1 (6.3)	1 (6.3)	4 (25.0)	0
Tachycardia	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Bradycardia	1 (6.3)	1 (6.3)	0	0	0
Cardiac failure	1 (6.3)	0	0	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (6.3)	0	0	1 (6.3)	0
Endocrine disorders					
-Total	2 (12.5)	0	1 (6.3)	0	1 (6.3)
Adrenal insufficiency	1 (6.3)	0	1 (6.3)	0	0
Hypercalcaemia of malignancy	1 (6.3)	0	0	0	1 (6.3)
Eye disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Eyelid oedema	1 (6.3)	1 (6.3)	0	0	0
Gastrointestinal disorders					
-Total	9 (56.3)	2 (12.5)	1 (6.3)	5 (31.3)	1 (6.3)
Diarrhoea	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Abdominal pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Abdominal compartment syndrome	1 (6.3)	0	0	0	1 (6.3)
Abdominal pain upper	1 (6.3)	1 (6.3)	0	0	0
Colitis	1 (6.3)	0	0	1 (6.3)	0
Duodenal perforation	1 (6.3)	0	0	1 (6.3)	0
Gastritis	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	0	0	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (6.3)	1 (6.3)	0	0	0
Haemoperitoneum	1 (6.3)	0	0	0	1 (6.3)
Nausea	1 (6.3)	0	1 (6.3)	0	0
Stomatitis	1 (6.3)	0	0	1 (6.3)	0
General disorders and administration site conditions					
-Total	9 (56.3)	1 (6.3)	4 (25.0)	4 (25.0)	0
Pyrexia	5 (31.3)	0	3 (18.8)	2 (12.5)	0
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Generalised oedema	1 (6.3)	0	0	1 (6.3)	0
Hepatobiliary disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	0	0	2 (12.5)	0
Immune system disorders					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Graft versus host disease	1 (6.3)	0	0	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					
-Total	14 (87.5)	0	0	6 (37.5)	8 (50.0)
Acute sinusitis	1 (6.3)	0	0	1 (6.3)	0
Aspergillus infection	1 (6.3)	0	0	0	1 (6.3)
Bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	0	0	1 (6.3)
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Device related infection	1 (6.3)	0	0	1 (6.3)	0
Device related sepsis	1 (6.3)	0	0	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	0	0	1 (6.3)
Fungaemia	1 (6.3)	0	0	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	0	0	1 (6.3)
Fungal skin infection	1 (6.3)	0	0	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Oral herpes	1 (6.3)	0	0	1 (6.3)	0
Peritonitis	1 (6.3)	0	0	1 (6.3)	0
Pneumonia	1 (6.3)	0	0	0	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (6.3)	0	0	0	1 (6.3)
Sepsis	1 (6.3)	0	0	0	1 (6.3)
Serratia sepsis	1 (6.3)	0	0	0	1 (6.3)
Staphylococcal infection	1 (6.3)	0	0	0	1 (6.3)
Systemic mycosis	1 (6.3)	0	0	1 (6.3)	0
Injury, poisoning and procedural complications					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	0	0	1 (6.3)	0
Procedural pain	1 (6.3)	1 (6.3)	0	0	0
Investigations					
-Total	4 (25.0)	0	0	2 (12.5)	2 (12.5)
C-reactive protein increased	2 (12.5)	0	0	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	1 (6.3)	0	0	0
Aspartate aminotransferase increased	1 (6.3)	0	0	0	1 (6.3)
Blood creatinine increased	1 (6.3)	1 (6.3)	0	0	0
Lymphocyte count decreased	1 (6.3)	1 (6.3)	0	0	0
Neutrophil count decreased	1 (6.3)	0	0	0	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (6.3)	0	0	0	1 (6.3)
White blood cell count decreased	1 (6.3)	1 (6.3)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (43.8)	0	1 (6.3)	4 (25.0)	2 (12.5)
Hypocalcaemia	2 (12.5)	0	2 (12.5)	0	0
Metabolic acidosis	2 (12.5)	0	0	2 (12.5)	0
Tumour lysis syndrome	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Decreased appetite	1 (6.3)	0	1 (6.3)	0	0
Hyperammonaemia	1 (6.3)	0	0	1 (6.3)	0
Hyperglycaemia	1 (6.3)	0	0	0	1 (6.3)
Hyperkalaemia	1 (6.3)	0	0	1 (6.3)	0
Hyperuricaemia	1 (6.3)	0	1 (6.3)	0	0
Hypoalbuminaemia	1 (6.3)	0	1 (6.3)	0	0
Hypokalaemia	1 (6.3)	0	1 (6.3)	0	0
Hypomagnesaemia	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (18.8)	1 (6.3)	2 (12.5)	0	0

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (6.3)	0	1 (6.3)	0	0
Back pain	1 (6.3)	1 (6.3)	0	0	0
Myositis	1 (6.3)	0	1 (6.3)	0	0
Nervous system disorders					
-Total	5 (31.3)	2 (12.5)	0	2 (12.5)	1 (6.3)
Cognitive disorder	1 (6.3)	0	0	1 (6.3)	0
Encephalopathy	1 (6.3)	0	0	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	0	0	1 (6.3)
Headache	1 (6.3)	1 (6.3)	0	0	0
Intraventricular haemorrhage	1 (6.3)	1 (6.3)	0	0	0
Paraesthesia	1 (6.3)	1 (6.3)	0	0	0
Psychiatric disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Mental status changes	2 (12.5)	0	0	2 (12.5)	0
Renal and urinary disorders					
-Total	3 (18.8)	3 (18.8)	0	0	0
Acute kidney injury	3 (18.8)	3 (18.8)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	6 (37.5)	0	1 (6.3)	1 (6.3)	4 (25.0)
Respiratory failure	3 (18.8)	0	0	0	3 (18.8)
Tachypnoea	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Acute respiratory distress syndrome	1 (6.3)	0	0	0	1 (6.3)
Hypoxia	1 (6.3)	0	1 (6.3)	0	0
Pulmonary haemorrhage	1 (6.3)	0	0	0	1 (6.3)
Pulmonary oedema	1 (6.3)	0	0	0	1 (6.3)
Skin and subcutaneous tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain of skin	1 (6.3)	1 (6.3)	0	0	0
Rash	1 (6.3)	1 (6.3)	0	0	0
Skin ulcer	1 (6.3)	0	1 (6.3)	0	0
Vascular disorders					
-Total	7 (43.8)	1 (6.3)	2 (12.5)	3 (18.8)	1 (6.3)
Hypotension	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207o
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders					
-Total	9 (50.0)	0	0	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	0	0	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Bradycardia	1 (5.6)	1 (5.6)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Adrenal insufficiency	1 (5.6)	0	1 (5.6)	0	0
Hypercalcaemia of malignancy	1 (5.6)	0	0	0	1 (5.6)
Eye disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Eyelid oedema	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	9 (50.0)	2 (11.1)	1 (5.6)	5 (27.8)	1 (5.6)
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain upper	1 (5.6)	1 (5.6)	0	0	0
Colitis	1 (5.6)	0	0	1 (5.6)	0
Duodenal perforation	1 (5.6)	0	0	1 (5.6)	0
Gastritis	1 (5.6)	0	1 (5.6)	0	0

Baseline extramedullary disease presence: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Haemoperitoneum	1 (5.6)	0	0	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	9 (50.0)	1 (5.6)	4 (22.2)	4 (22.2)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Generalised oedema	1 (5.6)	0	0	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Immune system disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Baseline extramedullary disease presence: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Hypersensitivity	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	15 (83.3)	0	1 (5.6)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0

Baseline extramedullary disease presence: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood magnesium decreased	1 (5.6)	0	1 (5.6)	0	0
Blood potassium decreased	1 (5.6)	0	0	1 (5.6)	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (38.9)	0	1 (5.6)	4 (22.2)	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Hyperammonaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperuricaemia	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0

Baseline extramedullary disease presence: No

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Myositis	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	5 (27.8)	2 (11.1)	0	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	0	0	1 (5.6)
Headache	1 (5.6)	1 (5.6)	0	0	0
Intraventricular haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Paraesthesia	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (33.3)	0	1 (5.6)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute respiratory distress syndrome	1 (5.6)	0	0	0	1 (5.6)
Hypoxia	1 (5.6)	0	1 (5.6)	0	0
Pulmonary haemorrhage	1 (5.6)	0	0	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain of skin	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Skin ulcer	1 (5.6)	0	1 (5.6)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207p
Adverse events by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Gastrointestinal disorders					
-Total	1 (100)	0	0	1 (100)	0
Duodenal perforation	1 (100)	0	0	1 (100)	0
Gastritis	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Peritonitis	1 (100)	0	0	1 (100)	0
Nervous system disorders					
-Total	1 (100)	0	0	0	1 (100)
Haemorrhage intracranial	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207p
Adverse events by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	1 (5.9)	5 (29.4)	11 (64.7)
Blood and lymphatic system disorders					
-Total	9 (52.9)	0	0	6 (35.3)	3 (17.6)
Febrile neutropenia	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Anaemia	3 (17.6)	0	0	3 (17.6)	0
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Hyperleukocytosis	1 (5.9)	0	0	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Cardiac disorders					
-Total	6 (35.3)	1 (5.9)	1 (5.9)	4 (23.5)	0
Tachycardia	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Bradycardia	1 (5.9)	1 (5.9)	0	0	0

Down syndrome: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.9)	0	0	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	0	0	1 (5.9)	0
Endocrine disorders					
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Adrenal insufficiency	1 (5.9)	0	1 (5.9)	0	0
Hypercalcaemia of malignancy	1 (5.9)	0	0	0	1 (5.9)
Eye disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Eyelid oedema	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	8 (47.1)	2 (11.8)	1 (5.9)	4 (23.5)	1 (5.9)
Diarrhoea	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Abdominal pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Abdominal compartment syndrome	1 (5.9)	0	0	0	1 (5.9)
Abdominal pain upper	1 (5.9)	1 (5.9)	0	0	0
Colitis	1 (5.9)	0	0	1 (5.9)	0
Gastrointestinal haemorrhage	1 (5.9)	0	0	1 (5.9)	0
Haematemesis	1 (5.9)	1 (5.9)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoperitoneum	1 (5.9)	0	0	0	1 (5.9)
Nausea	1 (5.9)	0	1 (5.9)	0	0
Stomatitis	1 (5.9)	0	0	1 (5.9)	0
General disorders and administration site conditions					
-Total	9 (52.9)	1 (5.9)	4 (23.5)	4 (23.5)	0
Pyrexia	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Catheter site pain	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Oedema peripheral	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Generalised oedema	1 (5.9)	0	0	1 (5.9)	0
Hepatobiliary disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Hyperbilirubinaemia	2 (11.8)	0	0	2 (11.8)	0
Immune system disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Graft versus host disease	1 (5.9)	0	0	1 (5.9)	0
Hypersensitivity	1 (5.9)	0	1 (5.9)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	14 (82.4)	0	1 (5.9)	5 (29.4)	8 (47.1)
Acute sinusitis	1 (5.9)	0	0	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)
Bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	0	0	1 (5.9)
Clostridium difficile colitis	1 (5.9)	0	1 (5.9)	0	0
Device related infection	1 (5.9)	0	0	1 (5.9)	0
Device related sepsis	1 (5.9)	0	0	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	0	0	1 (5.9)
Epstein-barr virus infection	1 (5.9)	0	1 (5.9)	0	0
Fungaemia	1 (5.9)	0	0	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	0	0	1 (5.9)
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0
Klebsiella bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Oral herpes	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	0	0	1 (5.9)

Down syndrome: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (5.9)	0	0	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	0	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	0	0	1 (5.9)
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	0	0	1 (5.9)	0
Procedural pain	1 (5.9)	1 (5.9)	0	0	0
Investigations					
-Total	5 (29.4)	0	0	3 (17.6)	2 (11.8)
Alanine aminotransferase increased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
C-reactive protein increased	2 (11.8)	0	0	2 (11.8)	0
Aspartate aminotransferase increased	1 (5.9)	0	0	0	1 (5.9)
Blood creatinine increased	1 (5.9)	1 (5.9)	0	0	0
Blood magnesium decreased	1 (5.9)	0	1 (5.9)	0	0
Blood potassium decreased	1 (5.9)	0	0	1 (5.9)	0
Lymphocyte count decreased	1 (5.9)	1 (5.9)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)
Platelet count decreased	1 (5.9)	0	0	0	1 (5.9)
Serum ferritin increased	1 (5.9)	0	0	1 (5.9)	0
White blood cell count decreased	1 (5.9)	1 (5.9)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (41.2)	0	1 (5.9)	4 (23.5)	2 (11.8)
Hypocalcaemia	2 (11.8)	0	2 (11.8)	0	0
Metabolic acidosis	2 (11.8)	0	0	2 (11.8)	0
Tumour lysis syndrome	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Decreased appetite	1 (5.9)	0	1 (5.9)	0	0
Hyperammonaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	0	0	1 (5.9)
Hyperkalaemia	1 (5.9)	0	0	1 (5.9)	0
Hyperuricaemia	1 (5.9)	0	1 (5.9)	0	0
Hypoalbuminaemia	1 (5.9)	0	1 (5.9)	0	0
Hypokalaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0

Down syndrome: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Arthralgia	1 (5.9)	0	1 (5.9)	0	0
Back pain	1 (5.9)	1 (5.9)	0	0	0
Myositis	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					
-Total	4 (23.5)	2 (11.8)	0	2 (11.8)	0
Cognitive disorder	1 (5.9)	0	0	1 (5.9)	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Headache	1 (5.9)	1 (5.9)	0	0	0
Intraventricular haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Paraesthesia	1 (5.9)	1 (5.9)	0	0	0
Psychiatric disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Mental status changes	2 (11.8)	0	0	2 (11.8)	0
Renal and urinary disorders					
-Total	3 (17.6)	3 (17.6)	0	0	0

Down syndrome: No

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	3 (17.6)	3 (17.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (35.3)	0	1 (5.9)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	0	0	3 (17.6)
Tachypnoea	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Acute respiratory distress syndrome	1 (5.9)	0	0	0	1 (5.9)
Hypoxia	1 (5.9)	0	1 (5.9)	0	0
Pulmonary haemorrhage	1 (5.9)	0	0	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	0	0	1 (5.9)
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain of skin	1 (5.9)	1 (5.9)	0	0	0
Rash	1 (5.9)	1 (5.9)	0	0	0
Skin ulcer	1 (5.9)	0	1 (5.9)	0	0
Vascular disorders					
-Total	7 (41.2)	1 (5.9)	2 (11.8)	3 (17.6)	1 (5.9)
Hypotension	4 (23.5)	0	0	3 (17.6)	1 (5.9)

Down syndrome: No

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	3 (17.6)	1 (5.9)	2 (11.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207q
Adverse events by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders					
-Total	9 (50.0)	0	0	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	0	0	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Bradycardia	1 (5.6)	1 (5.6)	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Adrenal insufficiency	1 (5.6)	0	1 (5.6)	0	0
Hypercalcaemia of malignancy	1 (5.6)	0	0	0	1 (5.6)
Eye disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Eyelid oedema	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	9 (50.0)	2 (11.1)	1 (5.6)	5 (27.8)	1 (5.6)
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain upper	1 (5.6)	1 (5.6)	0	0	0
Colitis	1 (5.6)	0	0	1 (5.6)	0
Duodenal perforation	1 (5.6)	0	0	1 (5.6)	0
Gastritis	1 (5.6)	0	1 (5.6)	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Haemoperitoneum	1 (5.6)	0	0	0	1 (5.6)
Nausea	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	9 (50.0)	1 (5.6)	4 (22.2)	4 (22.2)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Generalised oedema	1 (5.6)	0	0	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Immune system disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Hypersensitivity	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	15 (83.3)	0	1 (5.6)	6 (33.3)	8 (44.4)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Clostridium difficile colitis	1 (5.6)	0	1 (5.6)	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Oral herpes	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peritonitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood magnesium decreased	1 (5.6)	0	1 (5.6)	0	0
Blood potassium decreased	1 (5.6)	0	0	1 (5.6)	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (38.9)	0	1 (5.6)	4 (22.2)	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Hyperammonaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperuricaemia	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Myositis	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	5 (27.8)	2 (11.1)	0	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	0	0	1 (5.6)
Headache	1 (5.6)	1 (5.6)	0	0	0
Intraventricular haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Paraesthesia	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (33.3)	0	1 (5.6)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute respiratory distress syndrome	1 (5.6)	0	0	0	1 (5.6)
Hypoxia	1 (5.6)	0	1 (5.6)	0	0
Pulmonary haemorrhage	1 (5.6)	0	0	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain of skin	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Skin ulcer	1 (5.6)	0	1 (5.6)	0	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	2 (100)	0	0	2 (100)	0
Tachycardia	2 (100)	0	0	2 (100)	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	0	0	1 (50.0)
Haematemesis	1 (50.0)	1 (50.0)	0	0	0

Number of previous relapses: 0

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (50.0)	0	0	0	1 (50.0)
General disorders and administration site conditions					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Pyrexia	2 (100)	0	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	0	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	0	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood creatinine increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0	0	0

Number of previous relapses: 0

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypocalcaemia	2 (100)	0	2 (100)	0	0
Metabolic acidosis	2 (100)	0	0	2 (100)	0
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypomagnesaemia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	2 (100)	2 (100)	0	0	0
Acute kidney injury	2 (100)	2 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	0	0	2 (100)
Respiratory failure	2 (100)	0	0	0	2 (100)
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypotension	2 (100)	0	0	2 (100)	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	4 (50.0)	4 (50.0)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	1 (12.5)	0	0	1 (12.5)	0
Febrile neutropenia	1 (12.5)	0	0	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	0	0	1 (12.5)	0
Pancytopenia	1 (12.5)	0	0	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Bradycardia	1 (12.5)	1 (12.5)	0	0	0
Left ventricular dysfunction	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (12.5)	0	1 (12.5)	0	0
Endocrine disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	0	0	1 (12.5)
Eye disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Eyelid oedema	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Abdominal pain upper	1 (12.5)	1 (12.5)	0	0	0
Diarrhoea	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	1 (12.5)	2 (25.0)	1 (12.5)	0
Catheter site pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Pyrexia	2 (25.0)	0	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (12.5)	0	1 (12.5)	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypersensitivity	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Acute sinusitis	1 (12.5)	0	0	1 (12.5)	0
Device related infection	1 (12.5)	0	0	1 (12.5)	0
Device related sepsis	1 (12.5)	0	0	1 (12.5)	0
Fungal skin infection	1 (12.5)	0	0	1 (12.5)	0
Klebsiella bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	0	0	1 (12.5)
Sepsis	1 (12.5)	0	0	0	1 (12.5)
Systemic mycosis	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	1 (12.5)	0	0	1 (12.5)	0
Post procedural haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	3 (37.5)	0	0	3 (37.5)	0
C-reactive protein increased	2 (25.0)	0	0	2 (25.0)	0
Alanine aminotransferase increased	1 (12.5)	0	0	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	0	1 (12.5)	0	0
Blood potassium decreased	1 (12.5)	0	0	1 (12.5)	0
Serum ferritin increased	1 (12.5)	0	0	1 (12.5)	0
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Hyperammonaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperuricaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	1 (12.5)	0	0
Tumour lysis syndrome	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					

Number of previous relapses: 1

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Back pain	1 (12.5)	1 (12.5)	0	0	0
Myositis	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Headache	1 (12.5)	1 (12.5)	0	0	0
Intraventricular haemorrhage	1 (12.5)	1 (12.5)	0	0	0
Paraesthesia	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Mental status changes	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Hypoxia	1 (12.5)	0	1 (12.5)	0	0
Tachypnoea	1 (12.5)	0	0	1 (12.5)	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain of skin	1 (12.5)	1 (12.5)	0	0	0
Skin ulcer	1 (12.5)	0	1 (12.5)	0	0
Vascular disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	0	0	1 (12.5)	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Aspergillus infection	1 (100)	0	0	0	1 (100)
Psychiatric disorders					
-Total	1 (100)	0	0	1 (100)	0
Mental status changes	1 (100)	0	0	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 207r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	7 (100)	0	1 (14.3)	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Febrile neutropenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Pancytopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Cardiac failure	1 (14.3)	0	0	1 (14.3)	0
Tachycardia	1 (14.3)	0	1 (14.3)	0	0
Endocrine disorders					

Number of previous relapses: >=3

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	0	1 (14.3)	3 (42.9)	0
Diarrhoea	2 (28.6)	0	2 (28.6)	0	0
Abdominal pain	1 (14.3)	0	1 (14.3)	0	0
Colitis	1 (14.3)	0	0	1 (14.3)	0
Duodenal perforation	1 (14.3)	0	0	1 (14.3)	0
Gastritis	1 (14.3)	0	1 (14.3)	0	0
Nausea	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Catheter site pain	1 (14.3)	1 (14.3)	0	0	0
Generalised oedema	1 (14.3)	0	0	1 (14.3)	0
Oedema peripheral	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0

Number of previous relapses: >=3

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	0	0	1 (14.3)	0
Immune system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Graft versus host disease	1 (14.3)	0	0	1 (14.3)	0
Infections and infestations					
-Total	6 (85.7)	0	1 (14.3)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bacterial sepsis	1 (14.3)	0	0	0	1 (14.3)
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Epstein-barr virus infection	1 (14.3)	0	1 (14.3)	0	0
Fungaemia	1 (14.3)	0	0	0	1 (14.3)
Fungal sepsis	1 (14.3)	0	0	0	1 (14.3)
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	0	1 (14.3)

Number of previous relapses: >=3

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	1 (14.3)	0	0	0
Investigations					
-Total	1 (14.3)	0	0	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
Platelet count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Decreased appetite	1 (14.3)	0	1 (14.3)	0	0
Hyperglycaemia	1 (14.3)	0	0	0	1 (14.3)
Tumour lysis syndrome	1 (14.3)	0	0	0	1 (14.3)
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthralgia	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Number of previous relapses: >=3

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (14.3)	0	0	1 (14.3)	0
Haemorrhage intracranial	1 (14.3)	0	0	0	1 (14.3)
Renal and urinary disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Acute kidney injury	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Acute respiratory distress syndrome	1 (14.3)	0	0	0	1 (14.3)
Pulmonary haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Rash	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208a
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (95.1)	0	3 (7.3)	7 (17.1)	29 (70.7)
Blood and lymphatic system disorders					
-Total	29 (70.7)	1 (2.4)	5 (12.2)	18 (43.9)	5 (12.2)
Anaemia	20 (48.8)	3 (7.3)	5 (12.2)	12 (29.3)	0
Febrile neutropenia	17 (41.5)	0	0	17 (41.5)	0
Thrombocytopenia	7 (17.1)	0	0	2 (4.9)	5 (12.2)
Neutropenia	5 (12.2)	0	1 (2.4)	1 (2.4)	3 (7.3)
Disseminated intravascular coagulation	4 (9.8)	0	3 (7.3)	1 (2.4)	0
Leukopenia	3 (7.3)	0	0	1 (2.4)	2 (4.9)
Lymphadenopathy	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Lymphopenia	2 (4.9)	0	0	0	2 (4.9)

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
Coagulopathy	1 (2.4)	0	0	1 (2.4)	0
Eosinophilia	1 (2.4)	0	1 (2.4)	0	0
Hypercoagulation	1 (2.4)	0	1 (2.4)	0	0
Leukocytosis	1 (2.4)	0	1 (2.4)	0	0
Pancytopenia	1 (2.4)	0	0	1 (2.4)	0
Splenomegaly	1 (2.4)	1 (2.4)	0	0	0
Cardiac disorders					
-Total	12 (29.3)	4 (9.8)	3 (7.3)	3 (7.3)	2 (4.9)
Tachycardia	10 (24.4)	4 (9.8)	4 (9.8)	1 (2.4)	1 (2.4)
Left ventricular dysfunction	2 (4.9)	0	0	2 (4.9)	0
Cardiac arrest	1 (2.4)	0	0	0	1 (2.4)
Cardiac dysfunction	1 (2.4)	1 (2.4)	0	0	0
Cardiac failure congestive	1 (2.4)	0	1 (2.4)	0	0
Mitral valve incompetence	1 (2.4)	1 (2.4)	0	0	0
Right ventricular dysfunction	1 (2.4)	1 (2.4)	0	0	0
Tricuspid valve incompetence	1 (2.4)	1 (2.4)	0	0	0
Ear and labyrinth disorders					

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Ear pain	1 (2.4)	1 (2.4)	0	0	0
Vertigo	1 (2.4)	0	1 (2.4)	0	0
Endocrine disorders					
-Total	2 (4.9)	0	2 (4.9)	0	0
Adrenal insufficiency	1 (2.4)	0	1 (2.4)	0	0
Hypothyroidism	1 (2.4)	0	1 (2.4)	0	0
Eye disorders					
-Total	10 (24.4)	6 (14.6)	3 (7.3)	1 (2.4)	0
Eye pain	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Eyelid oedema	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Ocular hyperaemia	3 (7.3)	3 (7.3)	0	0	0
Cataract	1 (2.4)	1 (2.4)	0	0	0
Conjunctival haemorrhage	1 (2.4)	1 (2.4)	0	0	0
Hypermetropia	1 (2.4)	1 (2.4)	0	0	0
Mydriasis	1 (2.4)	0	1 (2.4)	0	0
Vision blurred	1 (2.4)	1 (2.4)	0	0	0
Visual impairment	1 (2.4)	1 (2.4)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders					
-Total	31 (75.6)	8 (19.5)	11 (26.8)	11 (26.8)	1 (2.4)
Vomiting	18 (43.9)	13 (31.7)	5 (12.2)	0	0
Diarrhoea	15 (36.6)	9 (22.0)	4 (9.8)	2 (4.9)	0
Nausea	15 (36.6)	7 (17.1)	7 (17.1)	1 (2.4)	0
Abdominal pain	9 (22.0)	3 (7.3)	4 (9.8)	2 (4.9)	0
Constipation	7 (17.1)	4 (9.8)	3 (7.3)	0	0
Stomatitis	5 (12.2)	0	2 (4.9)	3 (7.3)	0
Abdominal distension	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Ascites	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Abdominal pain upper	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Anal fissure	2 (4.9)	0	2 (4.9)	0	0
Gastrointestinal sounds abnormal	2 (4.9)	2 (4.9)	0	0	0
Haematemesis	2 (4.9)	2 (4.9)	0	0	0
Mouth haemorrhage	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Pancreatitis	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Abdominal compartment syndrome	1 (2.4)	0	0	0	1 (2.4)
Anal haemorrhage	1 (2.4)	1 (2.4)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal inflammation	1 (2.4)	0	0	1 (2.4)	0
Duodenal perforation	1 (2.4)	0	0	1 (2.4)	0
Dyspepsia	1 (2.4)	1 (2.4)	0	0	0
Gastritis	1 (2.4)	0	1 (2.4)	0	0
Gingival bleeding	1 (2.4)	1 (2.4)	0	0	0
Lip oedema	1 (2.4)	1 (2.4)	0	0	0
Melaena	1 (2.4)	0	0	1 (2.4)	0
Neutropenic colitis	1 (2.4)	0	0	1 (2.4)	0
Proctalgia	1 (2.4)	1 (2.4)	0	0	0
Upper gastrointestinal haemorrhage	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					
-Total	28 (68.3)	15 (36.6)	6 (14.6)	4 (9.8)	3 (7.3)
Pyrexia	19 (46.3)	10 (24.4)	5 (12.2)	3 (7.3)	1 (2.4)
Fatigue	11 (26.8)	9 (22.0)	2 (4.9)	0	0
Chills	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Generalised oedema	4 (9.8)	1 (2.4)	2 (4.9)	1 (2.4)	0
Face oedema	3 (7.3)	1 (2.4)	2 (4.9)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	2 (4.9)	0	0	0	2 (4.9)
Pain	2 (4.9)	0	0	2 (4.9)	0
Asthenia	1 (2.4)	1 (2.4)	0	0	0
Catheter site dermatitis	1 (2.4)	1 (2.4)	0	0	0
Catheter site erythema	1 (2.4)	1 (2.4)	0	0	0
Catheter site pain	1 (2.4)	1 (2.4)	0	0	0
Chest discomfort	1 (2.4)	0	0	1 (2.4)	0
Influenza like illness	1 (2.4)	0	1 (2.4)	0	0
Localised oedema	1 (2.4)	0	1 (2.4)	0	0
Systemic inflammatory response syndrome	1 (2.4)	0	0	1 (2.4)	0
Hepatobiliary disorders					
-Total	11 (26.8)	4 (9.8)	4 (9.8)	2 (4.9)	1 (2.4)
Hyperbilirubinaemia	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Cholelithiasis	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Cholestasis	1 (2.4)	0	0	0	1 (2.4)
Gallbladder enlargement	1 (2.4)	1 (2.4)	0	0	0
Hepatic function abnormal	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (2.4)	1 (2.4)	0	0	0
Hepatosplenomegaly	1 (2.4)	0	1 (2.4)	0	0
Hypertransaminasaemia	1 (2.4)	1 (2.4)	0	0	0
Liver disorder	1 (2.4)	0	1 (2.4)	0	0
Ocular icterus	1 (2.4)	1 (2.4)	0	0	0
Immune system disorders					
-Total	29 (70.7)	2 (4.9)	11 (26.8)	7 (17.1)	9 (22.0)
Cytokine release syndrome	24 (58.5)	3 (7.3)	10 (24.4)	3 (7.3)	8 (19.5)
Hypogammaglobulinaemia	14 (34.1)	1 (2.4)	11 (26.8)	2 (4.9)	0
Haemophagocytic lymphohistiocytosis	3 (7.3)	1 (2.4)	0	0	2 (4.9)
Chronic graft versus host disease	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Immunodeficiency	2 (4.9)	0	0	2 (4.9)	0
Allergy to immunoglobulin therapy	1 (2.4)	1 (2.4)	0	0	0
Drug hypersensitivity	1 (2.4)	0	1 (2.4)	0	0
Graft versus host disease	1 (2.4)	0	0	1 (2.4)	0
Infections and infestations					
-Total	30 (73.2)	4 (9.8)	7 (17.1)	10 (24.4)	9 (22.0)

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	7 (17.1)	4 (9.8)	3 (7.3)	0	0
Conjunctivitis	6 (14.6)	2 (4.9)	4 (9.8)	0	0
Nasopharyngitis	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Pneumonia	4 (9.8)	1 (2.4)	0	1 (2.4)	2 (4.9)
Gastroenteritis	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Otitis media	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Parainfluenzae virus infection	3 (7.3)	0	0	2 (4.9)	1 (2.4)
Rhinovirus infection	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Bronchopulmonary aspergillosis	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Candida infection	2 (4.9)	0	2 (4.9)	0	0
Clostridium difficile infection	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Cytomegalovirus infection reactivation	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Device related infection	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Escherichia bacteraemia	2 (4.9)	0	0	2 (4.9)	0
Metapneumovirus infection	2 (4.9)	0	0	2 (4.9)	0
Oral herpes	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Oral infection	2 (4.9)	0	2 (4.9)	0	0
Pneumocystis jirovecii pneumonia	2 (4.9)	0	0	1 (2.4)	1 (2.4)

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	2 (4.9)	0	0	2 (4.9)	0
Staphylococcal infection	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Viral infection	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Acute sinusitis	1 (2.4)	0	0	1 (2.4)	0
Aspergillus infection	1 (2.4)	0	0	0	1 (2.4)
Bk virus infection	1 (2.4)	1 (2.4)	0	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchitis	1 (2.4)	0	1 (2.4)	0	0
Cellulitis	1 (2.4)	0	1 (2.4)	0	0
Covid-19 pneumonia	1 (2.4)	0	0	0	1 (2.4)
Cystitis	1 (2.4)	0	1 (2.4)	0	0
Ear infection	1 (2.4)	0	1 (2.4)	0	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Enterobacter infection	1 (2.4)	0	0	1 (2.4)	0
Enterovirus infection	1 (2.4)	0	0	1 (2.4)	0
Fungaemia	1 (2.4)	0	0	0	1 (2.4)
Fungal infection	1 (2.4)	0	1 (2.4)	0	0
Fungal skin infection	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (2.4)	1 (2.4)	0	0	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Human herpesvirus 6 infection	1 (2.4)	0	0	1 (2.4)	0
Influenza	1 (2.4)	0	0	0	1 (2.4)
Klebsiella infection	1 (2.4)	0	0	1 (2.4)	0
Localised infection	1 (2.4)	1 (2.4)	0	0	0
Mastoiditis	1 (2.4)	0	0	1 (2.4)	0
Nail infection	1 (2.4)	1 (2.4)	0	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Oral candidiasis	1 (2.4)	0	1 (2.4)	0	0
Otitis externa	1 (2.4)	0	0	1 (2.4)	0
Otitis media acute	1 (2.4)	0	1 (2.4)	0	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Pneumonia viral	1 (2.4)	0	0	1 (2.4)	0
Respiratory syncytial virus infection	1 (2.4)	0	1 (2.4)	0	0
Respiratory tract infection viral	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinitis	1 (2.4)	0	1 (2.4)	0	0
Salmonellosis	1 (2.4)	0	1 (2.4)	0	0
Sepsis	1 (2.4)	0	0	0	1 (2.4)
Sialoadenitis	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Skin infection	1 (2.4)	0	1 (2.4)	0	0
Soft tissue infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal sepsis	1 (2.4)	0	0	0	1 (2.4)
Staphylococcal skin infection	1 (2.4)	0	1 (2.4)	0	0
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Systemic mycosis	1 (2.4)	0	0	1 (2.4)	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Vulval cellulitis	1 (2.4)	0	0	1 (2.4)	0
Injury, poisoning and procedural complications					
-Total	12 (29.3)	6 (14.6)	4 (9.8)	0	2 (4.9)
Infusion related reaction	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Fall	2 (4.9)	1 (2.4)	1 (2.4)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Transfusion reaction	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Abdominal injury	1 (2.4)	1 (2.4)	0	0	0
Contusion	1 (2.4)	1 (2.4)	0	0	0
Ligament sprain	1 (2.4)	1 (2.4)	0	0	0
Scratch	1 (2.4)	1 (2.4)	0	0	0
Skin abrasion	1 (2.4)	1 (2.4)	0	0	0
Skin injury	1 (2.4)	0	1 (2.4)	0	0
Skin wound	1 (2.4)	1 (2.4)	0	0	0
Tracheal obstruction	1 (2.4)	0	0	0	1 (2.4)
Vasoplegia syndrome	1 (2.4)	0	0	0	1 (2.4)
Wound	1 (2.4)	0	0	1 (2.4)	0
Investigations					
-Total	29 (70.7)	1 (2.4)	1 (2.4)	7 (17.1)	20 (48.8)
White blood cell count decreased	20 (48.8)	2 (4.9)	1 (2.4)	1 (2.4)	16 (39.0)
Neutrophil count decreased	18 (43.9)	0	1 (2.4)	2 (4.9)	15 (36.6)
Platelet count decreased	16 (39.0)	4 (9.8)	1 (2.4)	4 (9.8)	7 (17.1)
Lymphocyte count decreased	14 (34.1)	0	0	6 (14.6)	8 (19.5)
Alanine aminotransferase increased	11 (26.8)	2 (4.9)	5 (12.2)	4 (9.8)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	8 (19.5)	1 (2.4)	2 (4.9)	3 (7.3)	2 (4.9)
Blood immunoglobulin m decreased	6 (14.6)	4 (9.8)	1 (2.4)	1 (2.4)	0
Blood bilirubin increased	5 (12.2)	0	1 (2.4)	4 (9.8)	0
Blood immunoglobulin a decreased	5 (12.2)	4 (9.8)	1 (2.4)	0	0
C-reactive protein increased	4 (9.8)	2 (4.9)	0	2 (4.9)	0
International normalised ratio increased	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Serum ferritin increased	4 (9.8)	2 (4.9)	2 (4.9)	0	0
Activated partial thromboplastin time prolonged	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Blood fibrinogen decreased	3 (7.3)	2 (4.9)	0	0	1 (2.4)
Blood lactate dehydrogenase increased	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Blood uric acid increased	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Weight increased	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Blood immunoglobulin g decreased	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Fibrin d dimer increased	2 (4.9)	2 (4.9)	0	0	0
Gamma-glutamyltransferase increased	2 (4.9)	0	0	2 (4.9)	0

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oxygen saturation decreased	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Amylase increased	1 (2.4)	0	0	0	1 (2.4)
Blood creatine phosphokinase increased	1 (2.4)	0	0	0	1 (2.4)
Blood creatinine increased	1 (2.4)	0	0	1 (2.4)	0
Blood glucose increased	1 (2.4)	1 (2.4)	0	0	0
Blood phosphorus increased	1 (2.4)	0	1 (2.4)	0	0
Electrocardiogram qt prolonged	1 (2.4)	0	1 (2.4)	0	0
Eosinophil count decreased	1 (2.4)	1 (2.4)	0	0	0
Haematocrit decreased	1 (2.4)	1 (2.4)	0	0	0
Hepatitis b virus test positive	1 (2.4)	0	1 (2.4)	0	0
Immunoglobulins decreased	1 (2.4)	0	1 (2.4)	0	0
Lipase increased	1 (2.4)	0	0	0	1 (2.4)
Red blood cell count decreased	1 (2.4)	1 (2.4)	0	0	0
Urine output decreased	1 (2.4)	0	0	1 (2.4)	0
Metabolism and nutrition disorders					
-Total	24 (58.5)	5 (12.2)	5 (12.2)	7 (17.1)	7 (17.1)
Decreased appetite	12 (29.3)	4 (9.8)	3 (7.3)	4 (9.8)	1 (2.4)

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	10 (24.4)	2 (4.9)	4 (9.8)	3 (7.3)	1 (2.4)
Hypokalaemia	9 (22.0)	3 (7.3)	1 (2.4)	3 (7.3)	2 (4.9)
Hypocalcaemia	7 (17.1)	1 (2.4)	4 (9.8)	2 (4.9)	0
Hyperglycaemia	4 (9.8)	0	0	4 (9.8)	0
Hypoalbuminaemia	4 (9.8)	0	4 (9.8)	0	0
Hyperphosphataemia	3 (7.3)	3 (7.3)	0	0	0
Hyperkalaemia	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Hypernatraemia	2 (4.9)	1 (2.4)	0	0	1 (2.4)
Hyperuricaemia	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Hyponatraemia	2 (4.9)	1 (2.4)	0	0	1 (2.4)
Metabolic acidosis	2 (4.9)	1 (2.4)	0	0	1 (2.4)
Dehydration	1 (2.4)	0	1 (2.4)	0	0
Eating disorder symptom	1 (2.4)	0	1 (2.4)	0	0
Haemosiderosis	1 (2.4)	0	1 (2.4)	0	0
Hypercalcaemia	1 (2.4)	0	0	1 (2.4)	0
Hyperlactacidaemia	1 (2.4)	1 (2.4)	0	0	0
Hypermagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Hypertriglyceridaemia	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypervolaemia	1 (2.4)	0	1 (2.4)	0	0
Hypomagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Hypophagia	1 (2.4)	0	1 (2.4)	0	0
Iron overload	1 (2.4)	0	1 (2.4)	0	0
Malnutrition	1 (2.4)	0	0	1 (2.4)	0
Obesity	1 (2.4)	0	0	1 (2.4)	0
Tumour lysis syndrome	1 (2.4)	0	0	0	1 (2.4)
Musculoskeletal and connective tissue disorders					
-Total	19 (46.3)	7 (17.1)	8 (19.5)	3 (7.3)	1 (2.4)
Pain in extremity	13 (31.7)	6 (14.6)	6 (14.6)	1 (2.4)	0
Back pain	5 (12.2)	1 (2.4)	2 (4.9)	2 (4.9)	0
Arthralgia	4 (9.8)	1 (2.4)	3 (7.3)	0	0
Myalgia	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Bone pain	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Growth retardation	1 (2.4)	0	1 (2.4)	0	0
Muscular weakness	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal chest pain	1 (2.4)	1 (2.4)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myositis	1 (2.4)	0	1 (2.4)	0	0
Rhabdomyolysis	1 (2.4)	0	0	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (4.9)	0	0	2 (4.9)	0
Bone giant cell tumour benign	1 (2.4)	0	0	1 (2.4)	0
Myelodysplastic syndrome	1 (2.4)	0	0	1 (2.4)	0
Nervous system disorders					
-Total	21 (51.2)	8 (19.5)	4 (9.8)	6 (14.6)	3 (7.3)
Headache	10 (24.4)	7 (17.1)	1 (2.4)	2 (4.9)	0
Encephalopathy	5 (12.2)	0	2 (4.9)	3 (7.3)	0
Dysgeusia	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Lethargy	2 (4.9)	2 (4.9)	0	0	0
Somnolence	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Tremor	2 (4.9)	2 (4.9)	0	0	0
Cerebral haemorrhage	1 (2.4)	0	0	0	1 (2.4)
Depressed level of consciousness	1 (2.4)	0	0	1 (2.4)	0
Dizziness	1 (2.4)	1 (2.4)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemorrhage intracranial	1 (2.4)	0	0	0	1 (2.4)
Hydrocephalus	1 (2.4)	0	0	0	1 (2.4)
Monoparesis	1 (2.4)	0	1 (2.4)	0	0
Neuralgia	1 (2.4)	0	1 (2.4)	0	0
Seizure	1 (2.4)	0	0	1 (2.4)	0
Psychiatric disorders					
-Total	17 (41.5)	8 (19.5)	6 (14.6)	3 (7.3)	0
Anxiety	5 (12.2)	2 (4.9)	3 (7.3)	0	0
Confusional state	4 (9.8)	4 (9.8)	0	0	0
Delirium	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Insomnia	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Irritability	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Agitation	2 (4.9)	2 (4.9)	0	0	0
Hallucination	2 (4.9)	0	2 (4.9)	0	0
Mental status changes	2 (4.9)	0	0	2 (4.9)	0
Mood altered	1 (2.4)	1 (2.4)	0	0	0
Nightmare	1 (2.4)	1 (2.4)	0	0	0
Restlessness	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

	All patients N=41				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (2.4)	0	1 (2.4)	0	0
Tearfulness	1 (2.4)	1 (2.4)	0	0	0
Renal and urinary disorders					
-Total	10 (24.4)	5 (12.2)	2 (4.9)	0	3 (7.3)
Acute kidney injury	4 (9.8)	2 (4.9)	0	0	2 (4.9)
Dysuria	3 (7.3)	3 (7.3)	0	0	0
Haematuria	2 (4.9)	2 (4.9)	0	0	0
Anuria	1 (2.4)	0	0	0	1 (2.4)
Bladder dilatation	1 (2.4)	0	1 (2.4)	0	0
Incontinence	1 (2.4)	0	1 (2.4)	0	0
Proteinuria	1 (2.4)	1 (2.4)	0	0	0
Renal failure	1 (2.4)	0	1 (2.4)	0	0
Renal tubular dysfunction	1 (2.4)	1 (2.4)	0	0	0
Renal tubular necrosis	1 (2.4)	0	0	0	1 (2.4)
Urinary retention	1 (2.4)	0	1 (2.4)	0	0
Reproductive system and breast disorders					
-Total	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vaginal ulceration	1 (2.4)	0	0	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	25 (61.0)	9 (22.0)	3 (7.3)	6 (14.6)	7 (17.1)
Cough	13 (31.7)	12 (29.3)	1 (2.4)	0	0
Hypoxia	8 (19.5)	0	2 (4.9)	4 (9.8)	2 (4.9)
Tachypnoea	6 (14.6)	2 (4.9)	1 (2.4)	2 (4.9)	1 (2.4)
Epistaxis	5 (12.2)	3 (7.3)	0	2 (4.9)	0
Nasal congestion	5 (12.2)	4 (9.8)	1 (2.4)	0	0
Pulmonary oedema	5 (12.2)	1 (2.4)	1 (2.4)	3 (7.3)	0
Dyspnoea	3 (7.3)	0	0	1 (2.4)	2 (4.9)
Pleural effusion	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Respiratory failure	3 (7.3)	0	0	0	3 (7.3)
Rhinorrhoea	3 (7.3)	3 (7.3)	0	0	0
Oropharyngeal pain	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Rhinitis allergic	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Acute respiratory distress syndrome	1 (2.4)	0	0	0	1 (2.4)
Atelectasis	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchospasm	1 (2.4)	0	1 (2.4)	0	0
Dyspnoea exertional	1 (2.4)	1 (2.4)	0	0	0
Lung infiltration	1 (2.4)	0	0	1 (2.4)	0
Pharyngeal erythema	1 (2.4)	1 (2.4)	0	0	0
Productive cough	1 (2.4)	1 (2.4)	0	0	0
Pulmonary haemorrhage	1 (2.4)	0	0	0	1 (2.4)
Respiratory acidosis	1 (2.4)	0	0	1 (2.4)	0
Respiratory distress	1 (2.4)	0	1 (2.4)	0	0
Sleep apnoea syndrome	1 (2.4)	0	1 (2.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (48.8)	10 (24.4)	7 (17.1)	3 (7.3)	0
Rash	5 (12.2)	3 (7.3)	2 (4.9)	0	0
Pruritus	4 (9.8)	1 (2.4)	3 (7.3)	0	0
Dry skin	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Erythema	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Rash maculo-papular	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Rash papular	3 (7.3)	3 (7.3)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blister	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Dermatitis atopic	2 (4.9)	2 (4.9)	0	0	0
Skin ulcer	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Decubitus ulcer	1 (2.4)	0	1 (2.4)	0	0
Dermatitis	1 (2.4)	1 (2.4)	0	0	0
Dermatitis allergic	1 (2.4)	1 (2.4)	0	0	0
Eczema	1 (2.4)	1 (2.4)	0	0	0
Miliaria	1 (2.4)	1 (2.4)	0	0	0
Night sweats	1 (2.4)	1 (2.4)	0	0	0
Petechiae	1 (2.4)	0	0	1 (2.4)	0
Photosensitivity reaction	1 (2.4)	0	1 (2.4)	0	0
Pruritus allergic	1 (2.4)	0	1 (2.4)	0	0
Purpura	1 (2.4)	1 (2.4)	0	0	0
Rash pruritic	1 (2.4)	1 (2.4)	0	0	0
Rash vesicular	1 (2.4)	1 (2.4)	0	0	0
Scab	1 (2.4)	1 (2.4)	0	0	0
Skin discolouration	1 (2.4)	1 (2.4)	0	0	0
Skin necrosis	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urticaria	1 (2.4)	0	1 (2.4)	0	0
Vascular disorders					
-Total	17 (41.5)	2 (4.9)	6 (14.6)	6 (14.6)	3 (7.3)
Hypotension	11 (26.8)	1 (2.4)	3 (7.3)	4 (9.8)	3 (7.3)
Hypertension	8 (19.5)	2 (4.9)	3 (7.3)	3 (7.3)	0
Flushing	1 (2.4)	1 (2.4)	0	0	0
Haematoma	1 (2.4)	1 (2.4)	0	0	0
Peripheral ischaemia	1 (2.4)	0	1 (2.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208a
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (97.5)	0	2 (5.0)	9 (22.5)	28 (70.0)
Blood and lymphatic system disorders					
-Total	26 (65.0)	0	2 (5.0)	12 (30.0)	12 (30.0)
Febrile neutropenia	15 (37.5)	0	0	13 (32.5)	2 (5.0)
Anaemia	13 (32.5)	2 (5.0)	4 (10.0)	6 (15.0)	1 (2.5)
Neutropenia	8 (20.0)	1 (2.5)	0	1 (2.5)	6 (15.0)
Disseminated intravascular coagulation	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Thrombocytopenia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Splenomegaly	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Coagulopathy	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Leukopenia	2 (5.0)	0	0	0	2 (5.0)

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocytosis	1 (2.5)	0	1 (2.5)	0	0
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Cardiac disorders					
-Total	16 (40.0)	3 (7.5)	4 (10.0)	6 (15.0)	3 (7.5)
Tachycardia	8 (20.0)	2 (5.0)	3 (7.5)	3 (7.5)	0
Bradycardia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Left ventricular dysfunction	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Cardiac arrest	2 (5.0)	0	0	0	2 (5.0)
Cardiac failure	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pericardial effusion	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Atrioventricular block first degree	1 (2.5)	0	1 (2.5)	0	0
Sinus bradycardia	1 (2.5)	0	0	1 (2.5)	0
Sinus tachycardia	1 (2.5)	1 (2.5)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Ear pruritus	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	4 (10.0)	0	4 (10.0)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	2 (5.0)	0	2 (5.0)	0	0
Hypothyroidism	2 (5.0)	0	2 (5.0)	0	0
Delayed puberty	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Conjunctival haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Dry eye	1 (2.5)	1 (2.5)	0	0	0
Eye oedema	1 (2.5)	1 (2.5)	0	0	0
Periorbital oedema	1 (2.5)	1 (2.5)	0	0	0
Retinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Visual field defect	1 (2.5)	0	1 (2.5)	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	28 (70.0)	6 (15.0)	14 (35.0)	7 (17.5)	1 (2.5)
Nausea	12 (30.0)	4 (10.0)	6 (15.0)	2 (5.0)	0
Diarrhoea	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Constipation	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Abdominal pain	6 (15.0)	1 (2.5)	5 (12.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	6 (15.0)	3 (7.5)	1 (2.5)	2 (5.0)	0
Pancreatitis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Stomatitis	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Gingival erythema	2 (5.0)	2 (5.0)	0	0	0
Haematemesis	2 (5.0)	2 (5.0)	0	0	0
Mouth haemorrhage	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oral pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal compartment syndrome	1 (2.5)	0	0	0	1 (2.5)
Abdominal pain upper	1 (2.5)	1 (2.5)	0	0	0
Abdominal rigidity	1 (2.5)	0	1 (2.5)	0	0
Anal fistula	1 (2.5)	0	0	1 (2.5)	0
Dry mouth	1 (2.5)	0	1 (2.5)	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Enterocolitis	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal inflammation	1 (2.5)	0	1 (2.5)	0	0
Gastrooesophageal reflux disease	1 (2.5)	0	1 (2.5)	0	0
Gingival bleeding	1 (2.5)	1 (2.5)	0	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (2.5)	0	0	0	1 (2.5)
Ileus	1 (2.5)	0	0	1 (2.5)	0
Irritable bowel syndrome	1 (2.5)	0	1 (2.5)	0	0
Lip pain	1 (2.5)	1 (2.5)	0	0	0
Lip ulceration	1 (2.5)	0	1 (2.5)	0	0
Mouth swelling	1 (2.5)	1 (2.5)	0	0	0
Neutropenic colitis	1 (2.5)	0	1 (2.5)	0	0
Odynophagia	1 (2.5)	1 (2.5)	0	0	0
Oral disorder	1 (2.5)	1 (2.5)	0	0	0
Peritoneal haematoma	1 (2.5)	1 (2.5)	0	0	0
Proctalgia	1 (2.5)	0	0	1 (2.5)	0
Trichoglossia	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	24 (60.0)	9 (22.5)	7 (17.5)	7 (17.5)	1 (2.5)
Pyrexia	17 (42.5)	6 (15.0)	4 (10.0)	6 (15.0)	1 (2.5)
Fatigue	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Oedema peripheral	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Catheter site pain	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Chills	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Pain	3 (7.5)	0	3 (7.5)	0	0
Generalised oedema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Localised oedema	2 (5.0)	2 (5.0)	0	0	0
Asthenia	1 (2.5)	1 (2.5)	0	0	0
Catheter site haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Complication associated with device	1 (2.5)	1 (2.5)	0	0	0
Drug withdrawal syndrome	1 (2.5)	0	1 (2.5)	0	0
Malaise	1 (2.5)	1 (2.5)	0	0	0
Oedema due to hepatic disease	1 (2.5)	0	1 (2.5)	0	0
Vascular device occlusion	1 (2.5)	1 (2.5)	0	0	0
Xerosis	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	8 (20.0)	2 (5.0)	2 (5.0)	2 (5.0)	2 (5.0)
Hepatic cytolysis	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hepatic function abnormal	2 (5.0)	0	0	1 (2.5)	1 (2.5)

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatomegaly	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Hyperbilirubinaemia	2 (5.0)	0	2 (5.0)	0	0
Hypertransaminasaemia	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	31 (77.5)	0	9 (22.5)	13 (32.5)	9 (22.5)
Cytokine release syndrome	25 (62.5)	1 (2.5)	5 (12.5)	10 (25.0)	9 (22.5)
Hypogammaglobulinaemia	17 (42.5)	0	11 (27.5)	6 (15.0)	0
Seasonal allergy	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Graft versus host disease	2 (5.0)	0	0	2 (5.0)	0
Haemophagocytic lymphohistiocytosis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Drug hypersensitivity	1 (2.5)	0	0	1 (2.5)	0
Engraftment syndrome	1 (2.5)	0	0	1 (2.5)	0
Hypersensitivity	1 (2.5)	1 (2.5)	0	0	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	32 (80.0)	1 (2.5)	4 (10.0)	19 (47.5)	8 (20.0)

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Sinusitis	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Upper respiratory tract infection	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Pneumonia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Rhinovirus infection	4 (10.0)	0	4 (10.0)	0	0
Bacteraemia	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Gastroenteritis viral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Herpes zoster	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Sepsis	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Staphylococcal bacteraemia	3 (7.5)	0	0	3 (7.5)	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Bronchitis	2 (5.0)	0	2 (5.0)	0	0
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Covid-19	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Ear infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Gastroenteritis	2 (5.0)	2 (5.0)	0	0	0
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oral herpes	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Otitis externa	2 (5.0)	0	2 (5.0)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Respiratory tract infection	2 (5.0)	0	2 (5.0)	0	0
Rhinitis	2 (5.0)	2 (5.0)	0	0	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Skin infection	2 (5.0)	0	2 (5.0)	0	0
Tinea pedis	2 (5.0)	2 (5.0)	0	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	0	0	1 (2.5)	0
Catheter site infection	1 (2.5)	0	0	1 (2.5)	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	0	0	1 (2.5)
Epstein-barr virus infection	1 (2.5)	0	1 (2.5)	0	0
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection pseudomonal	1 (2.5)	0	1 (2.5)	0	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	11 (27.5)	3 (7.5)	6 (15.0)	2 (5.0)	0
Procedural pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Infusion related reaction	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Wound	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Contusion	1 (2.5)	1 (2.5)	0	0	0
Fibula fracture	1 (2.5)	0	1 (2.5)	0	0
Ligament sprain	1 (2.5)	1 (2.5)	0	0	0
Limb injury	1 (2.5)	0	1 (2.5)	0	0
Radius fracture	1 (2.5)	0	1 (2.5)	0	0
Skin abrasion	1 (2.5)	1 (2.5)	0	0	0
Transfusion reaction	1 (2.5)	0	1 (2.5)	0	0
Traumatic haematoma	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	26 (65.0)	0	4 (10.0)	9 (22.5)	13 (32.5)
White blood cell count decreased	10 (25.0)	1 (2.5)	2 (5.0)	0	7 (17.5)
Alanine aminotransferase increased	8 (20.0)	3 (7.5)	1 (2.5)	4 (10.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	8 (20.0)	0	3 (7.5)	3 (7.5)	2 (5.0)
Lymphocyte count decreased	8 (20.0)	1 (2.5)	1 (2.5)	3 (7.5)	3 (7.5)
Neutrophil count decreased	8 (20.0)	0	1 (2.5)	1 (2.5)	6 (15.0)
Platelet count decreased	7 (17.5)	1 (2.5)	1 (2.5)	1 (2.5)	4 (10.0)
Blood bilirubin increased	6 (15.0)	1 (2.5)	1 (2.5)	4 (10.0)	0
Serum ferritin increased	6 (15.0)	0	3 (7.5)	3 (7.5)	0
Blood creatinine increased	5 (12.5)	2 (5.0)	1 (2.5)	1 (2.5)	1 (2.5)
Blood fibrinogen decreased	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
C-reactive protein increased	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Electrocardiogram qt prolonged	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
International normalised ratio increased	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Weight decreased	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Activated partial thromboplastin time prolonged	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Blood lactate dehydrogenase increased	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Blood fibrinogen increased	2 (5.0)	2 (5.0)	0	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Amylase increased	1 (2.5)	1 (2.5)	0	0	0
Bacterial test positive	1 (2.5)	0	0	1 (2.5)	0
Blood alkaline phosphatase decreased	1 (2.5)	1 (2.5)	0	0	0
Blood alkaline phosphatase increased	1 (2.5)	1 (2.5)	0	0	0
Blood bicarbonate decreased	1 (2.5)	0	1 (2.5)	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	1 (2.5)	0
Blood immunoglobulin a decreased	1 (2.5)	0	0	1 (2.5)	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Blood phosphorus increased	1 (2.5)	0	1 (2.5)	0	0
Blood testosterone decreased	1 (2.5)	1 (2.5)	0	0	0
Blood thyroid stimulating hormone increased	1 (2.5)	1 (2.5)	0	0	0
Blood urea increased	1 (2.5)	0	0	1 (2.5)	0
Blood uric acid increased	1 (2.5)	0	0	0	1 (2.5)

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bone density decreased	1 (2.5)	1 (2.5)	0	0	0
Cardiac murmur	1 (2.5)	1 (2.5)	0	0	0
Coagulation test abnormal	1 (2.5)	1 (2.5)	0	0	0
Ejection fraction decreased	1 (2.5)	0	1 (2.5)	0	0
Electrocardiogram t wave abnormal	1 (2.5)	0	1 (2.5)	0	0
Enterovirus test positive	1 (2.5)	0	1 (2.5)	0	0
Fibrin d dimer increased	1 (2.5)	0	0	1 (2.5)	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Haptoglobin decreased	1 (2.5)	1 (2.5)	0	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Lipase increased	1 (2.5)	1 (2.5)	0	0	0
Oxygen saturation decreased	1 (2.5)	0	1 (2.5)	0	0
Prothrombin time prolonged	1 (2.5)	0	1 (2.5)	0	0
Troponin increased	1 (2.5)	0	0	1 (2.5)	0
Urine output decreased	1 (2.5)	0	0	0	1 (2.5)
Metabolism and nutrition disorders					
-Total	27 (67.5)	2 (5.0)	5 (12.5)	14 (35.0)	6 (15.0)
Decreased appetite	16 (40.0)	5 (12.5)	5 (12.5)	5 (12.5)	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	10 (25.0)	0	1 (2.5)	8 (20.0)	1 (2.5)
Hypophosphataemia	8 (20.0)	1 (2.5)	3 (7.5)	4 (10.0)	0
Hypocalcaemia	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Hyperuricaemia	6 (15.0)	5 (12.5)	0	1 (2.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hypervolaemia	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Hypomagnesaemia	5 (12.5)	5 (12.5)	0	0	0
Metabolic acidosis	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Tumour lysis syndrome	4 (10.0)	0	0	3 (7.5)	1 (2.5)
Hyperphosphataemia	3 (7.5)	2 (5.0)	0	0	1 (2.5)
Hypercalcaemia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Hyperchloraemia	2 (5.0)	2 (5.0)	0	0	0
Hyperglycaemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hyperkalaemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Hyponatraemia	2 (5.0)	2 (5.0)	0	0	0
Acidosis	1 (2.5)	0	0	1 (2.5)	0
Calcium deficiency	1 (2.5)	1 (2.5)	0	0	0
Haemochromatosis	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlipidaemia	1 (2.5)	0	1 (2.5)	0	0
Hypermagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Hypernatraemia	1 (2.5)	0	0	1 (2.5)	0
Hypertriglyceridaemia	1 (2.5)	0	0	0	1 (2.5)
Metabolic syndrome	1 (2.5)	0	1 (2.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	20 (50.0)	8 (20.0)	8 (20.0)	4 (10.0)	0
Pain in extremity	8 (20.0)	2 (5.0)	4 (10.0)	2 (5.0)	0
Arthralgia	5 (12.5)	3 (7.5)	1 (2.5)	1 (2.5)	0
Back pain	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Myalgia	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Bone pain	1 (2.5)	0	1 (2.5)	0	0
Groin pain	1 (2.5)	1 (2.5)	0	0	0
Growth retardation	1 (2.5)	0	1 (2.5)	0	0
Haemarthrosis	1 (2.5)	0	0	1 (2.5)	0
Muscle rigidity	1 (2.5)	1 (2.5)	0	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal pain	1 (2.5)	0	1 (2.5)	0	0
Osteonecrosis	1 (2.5)	1 (2.5)	0	0	0
Osteopenia	1 (2.5)	1 (2.5)	0	0	0
Pain in jaw	1 (2.5)	1 (2.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cancer pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	25 (62.5)	6 (15.0)	13 (32.5)	5 (12.5)	1 (2.5)
Headache	17 (42.5)	6 (15.0)	10 (25.0)	1 (2.5)	0
Seizure	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Dizziness	3 (7.5)	3 (7.5)	0	0	0
Encephalopathy	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Dysarthria	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Somnolence	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Autonomic neuropathy	1 (2.5)	0	0	1 (2.5)	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Hypoaesthesia	1 (2.5)	1 (2.5)	0	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorder	1 (2.5)	0	0	1 (2.5)	0
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Posterior reversible encephalopathy syndrome	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	17 (42.5)	4 (10.0)	8 (20.0)	5 (12.5)	0
Anxiety	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Agitation	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Confusional state	3 (7.5)	3 (7.5)	0	0	0
Delirium	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Mental status changes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Insomnia	2 (5.0)	0	2 (5.0)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	2 (5.0)	0	2 (5.0)	0	0
Automatism	1 (2.5)	1 (2.5)	0	0	0
Persistent depressive disorder	1 (2.5)	0	1 (2.5)	0	0
Tic	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	14 (35.0)	5 (12.5)	2 (5.0)	4 (10.0)	3 (7.5)
Acute kidney injury	9 (22.5)	3 (7.5)	1 (2.5)	2 (5.0)	3 (7.5)
Dysuria	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Anuria	1 (2.5)	1 (2.5)	0	0	0
Azotaemia	1 (2.5)	0	1 (2.5)	0	0
Haematuria	1 (2.5)	0	0	1 (2.5)	0
Kidney enlargement	1 (2.5)	0	1 (2.5)	0	0
Micturition urgency	1 (2.5)	0	1 (2.5)	0	0
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Renal mass	1 (2.5)	0	1 (2.5)	0	0
Renal pain	1 (2.5)	1 (2.5)	0	0	0
Renal tubular disorder	1 (2.5)	0	0	1 (2.5)	0
Urinary tract disorder	1 (2.5)	0	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Dysmenorrhoea	1 (2.5)	0	1 (2.5)	0	0
Perineal rash	1 (2.5)	0	1 (2.5)	0	0
Prostatitis	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	25 (62.5)	7 (17.5)	3 (7.5)	4 (10.0)	11 (27.5)
Cough	11 (27.5)	7 (17.5)	4 (10.0)	0	0
Hypoxia	9 (22.5)	0	2 (5.0)	3 (7.5)	4 (10.0)
Oropharyngeal pain	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Pleural effusion	6 (15.0)	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)
Nasal congestion	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Pulmonary oedema	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory failure	5 (12.5)	0	0	0	5 (12.5)
Epistaxis	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Dyspnoea	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Tachypnoea	3 (7.5)	1 (2.5)	0	2 (5.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	2 (5.0)	0	0	0	2 (5.0)
Respiratory distress	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Rhinorrhoea	2 (5.0)	0	2 (5.0)	0	0
Wheezing	2 (5.0)	0	2 (5.0)	0	0
Acute respiratory failure	1 (2.5)	0	0	1 (2.5)	0
Atelectasis	1 (2.5)	0	0	1 (2.5)	0
Bradypnoea	1 (2.5)	0	0	1 (2.5)	0
Haemoptysis	1 (2.5)	0	1 (2.5)	0	0
Lung disorder	1 (2.5)	1 (2.5)	0	0	0
Nasal discomfort	1 (2.5)	0	1 (2.5)	0	0
Painful respiration	1 (2.5)	1 (2.5)	0	0	0
Paranasal sinus inflammation	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Respiratory disorder	1 (2.5)	0	1 (2.5)	0	0
Sleep apnoea syndrome	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (42.5)	6 (15.0)	7 (17.5)	4 (10.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Rash	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Ingrowing nail	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Eczema	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Erythema	2 (5.0)	2 (5.0)	0	0	0
Skin ulcer	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Acne	1 (2.5)	1 (2.5)	0	0	0
Blister	1 (2.5)	1 (2.5)	0	0	0
Dermatitis atopic	1 (2.5)	0	0	1 (2.5)	0
Dermatitis diaper	1 (2.5)	0	1 (2.5)	0	0
Drug eruption	1 (2.5)	0	1 (2.5)	0	0
Hyperhidrosis	1 (2.5)	1 (2.5)	0	0	0
Papule	1 (2.5)	1 (2.5)	0	0	0
Petechiae	1 (2.5)	0	1 (2.5)	0	0
Rash erythematous	1 (2.5)	1 (2.5)	0	0	0
Rash macular	1 (2.5)	0	0	1 (2.5)	0
Skin discolouration	1 (2.5)	1 (2.5)	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin hypopigmentation	1 (2.5)	1 (2.5)	0	0	0
Skin swelling	1 (2.5)	1 (2.5)	0	0	0
Vancomycin infusion reaction	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	19 (47.5)	2 (5.0)	4 (10.0)	8 (20.0)	5 (12.5)
Hypotension	15 (37.5)	1 (2.5)	3 (7.5)	6 (15.0)	5 (12.5)
Hypertension	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Capillary leak syndrome	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Thrombosis	1 (2.5)	0	1 (2.5)	0	0
Venoocclusive disease	1 (2.5)	0	0	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208a
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	0	4 (23.5)	13 (76.5)
Blood and lymphatic system disorders					
-Total	12 (70.6)	0	2 (11.8)	7 (41.2)	3 (17.6)
Febrile neutropenia	7 (41.2)	0	0	6 (35.3)	1 (5.9)
Anaemia	5 (29.4)	0	2 (11.8)	3 (17.6)	0
Neutropenia	3 (17.6)	0	1 (5.9)	1 (5.9)	1 (5.9)
Coagulopathy	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Thrombocytopenia	2 (11.8)	0	0	2 (11.8)	0
B-cell aplasia	1 (5.9)	0	1 (5.9)	0	0
Hypofibrinogenaemia	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	7 (41.2)	3 (17.6)	1 (5.9)	2 (11.8)	1 (5.9)
Tachycardia	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Cardiac failure	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Sinus tachycardia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Cardiac dysfunction	1 (5.9)	1 (5.9)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Cerebral cavernous malformation	1 (5.9)	1 (5.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Deafness unilateral	1 (5.9)	0	1 (5.9)	0	0
Endocrine disorders					
-Total	3 (17.6)	0	3 (17.6)	0	0
Adrenal insufficiency	3 (17.6)	0	3 (17.6)	0	0
Eye disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cataract	1 (5.9)	1 (5.9)	0	0	0
Periorbital swelling	1 (5.9)	0	1 (5.9)	0	0
Gastrointestinal disorders					
-Total	13 (76.5)	6 (35.3)	5 (29.4)	2 (11.8)	0
Nausea	6 (35.3)	3 (17.6)	3 (17.6)	0	0
Vomiting	6 (35.3)	4 (23.5)	2 (11.8)	0	0
Constipation	5 (29.4)	2 (11.8)	3 (17.6)	0	0
Diarrhoea	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Stomatitis	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Abdominal pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Mouth haemorrhage	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Abdominal pain upper	1 (5.9)	1 (5.9)	0	0	0
Anal erythema	1 (5.9)	1 (5.9)	0	0	0
Dry mouth	1 (5.9)	0	1 (5.9)	0	0
Enteritis	1 (5.9)	0	1 (5.9)	0	0
Gastrointestinal haemorrhage	1 (5.9)	0	1 (5.9)	0	0
Gastrointestinal sounds abnormal	1 (5.9)	1 (5.9)	0	0	0
Gingival bleeding	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gingivitis ulcerative	1 (5.9)	0	0	1 (5.9)	0
Haemorrhoids	1 (5.9)	0	1 (5.9)	0	0
Ileus	1 (5.9)	0	1 (5.9)	0	0
Lip dry	1 (5.9)	0	1 (5.9)	0	0
Pancreatitis	1 (5.9)	1 (5.9)	0	0	0
Trichoglossia	1 (5.9)	1 (5.9)	0	0	0
General disorders and administration site conditions					
-Total	11 (64.7)	5 (29.4)	3 (17.6)	2 (11.8)	1 (5.9)
Pyrexia	7 (41.2)	2 (11.8)	3 (17.6)	2 (11.8)	0
Pain	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Asthenia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Chills	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Fatigue	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Non-cardiac chest pain	2 (11.8)	2 (11.8)	0	0	0
Oedema peripheral	2 (11.8)	2 (11.8)	0	0	0
Catheter site pain	1 (5.9)	0	0	1 (5.9)	0
Crying	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Drug withdrawal syndrome	1 (5.9)	0	1 (5.9)	0	0
Face oedema	1 (5.9)	1 (5.9)	0	0	0
Facial pain	1 (5.9)	0	1 (5.9)	0	0
Influenza like illness	1 (5.9)	1 (5.9)	0	0	0
Malaise	1 (5.9)	0	1 (5.9)	0	0
Multiple organ dysfunction syndrome	1 (5.9)	0	0	0	1 (5.9)
Sluggishness	1 (5.9)	0	1 (5.9)	0	0
Swelling face	1 (5.9)	1 (5.9)	0	0	0
Thirst	1 (5.9)	1 (5.9)	0	0	0
Vascular device occlusion	1 (5.9)	1 (5.9)	0	0	0
Hepatobiliary disorders					
-Total	5 (29.4)	1 (5.9)	2 (11.8)	2 (11.8)	0
Hepatic function abnormal	2 (11.8)	0	2 (11.8)	0	0
Biliary tract disorder	1 (5.9)	1 (5.9)	0	0	0
Drug-induced liver injury	1 (5.9)	0	0	1 (5.9)	0
Gallbladder enlargement	1 (5.9)	1 (5.9)	0	0	0
Hyperbilirubinaemia	1 (5.9)	0	0	1 (5.9)	0
Hypertransaminasaemia	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immune system disorders					
-Total	13 (76.5)	0	4 (23.5)	5 (29.4)	4 (23.5)
Cytokine release syndrome	12 (70.6)	1 (5.9)	3 (17.6)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	5 (29.4)	1 (5.9)	4 (23.5)	0	0
Allergy to immunoglobulin therapy	1 (5.9)	0	0	1 (5.9)	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	0	1 (5.9)	0
Immunodeficiency	1 (5.9)	0	0	1 (5.9)	0
Seasonal allergy	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	14 (82.4)	1 (5.9)	2 (11.8)	8 (47.1)	3 (17.6)
Parainfluenzae virus infection	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Sinusitis	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Acute sinusitis	2 (11.8)	0	2 (11.8)	0	0
Bacteraemia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Candida infection	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Catheter site infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Gastroenteritis	2 (11.8)	0	1 (5.9)	1 (5.9)	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasopharyngitis	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Oral herpes	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Pneumonia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Rhinovirus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Urinary tract infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Varicella zoster virus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Adenovirus infection	1 (5.9)	0	0	1 (5.9)	0
Atypical pneumonia	1 (5.9)	1 (5.9)	0	0	0
Clostridium difficile infection	1 (5.9)	0	0	1 (5.9)	0
Conjunctivitis	1 (5.9)	0	1 (5.9)	0	0
Ear, nose and throat infection	1 (5.9)	0	1 (5.9)	0	0
Encephalitis viral	1 (5.9)	0	0	1 (5.9)	0
Escherichia bacteraemia	1 (5.9)	0	0	0	1 (5.9)
Fungal skin infection	1 (5.9)	0	1 (5.9)	0	0
Gingivitis	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Granulicatella infection	1 (5.9)	0	0	1 (5.9)	0
Herpes simplex	1 (5.9)	0	0	1 (5.9)	0
Human herpesvirus 6 infection	1 (5.9)	0	0	1 (5.9)	0
Influenza	1 (5.9)	0	1 (5.9)	0	0
Klebsiella bacteraemia	1 (5.9)	0	1 (5.9)	0	0
Myringitis	1 (5.9)	1 (5.9)	0	0	0
Nail infection	1 (5.9)	1 (5.9)	0	0	0
Oral candidiasis	1 (5.9)	0	1 (5.9)	0	0
Pharyngitis streptococcal	1 (5.9)	0	0	1 (5.9)	0
Pneumonia fungal	1 (5.9)	0	0	1 (5.9)	0
Respiratory syncytial virus infection	1 (5.9)	0	0	1 (5.9)	0
Respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Septic shock	1 (5.9)	0	0	0	1 (5.9)
Staphylococcal abscess	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	0	0	1 (5.9)	0
Stomatococcal infection	1 (5.9)	0	0	0	1 (5.9)
Systemic candida	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Viral upper respiratory tract infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	4 (23.5)	0	2 (11.8)	1 (5.9)	1 (5.9)
Extradural haematoma	1 (5.9)	0	1 (5.9)	0	0
Fall	1 (5.9)	0	1 (5.9)	0	0
Post-traumatic neck syndrome	1 (5.9)	0	1 (5.9)	0	0
Transfusion reaction	1 (5.9)	0	0	1 (5.9)	0
Transplant failure	1 (5.9)	0	0	0	1 (5.9)
Investigations					
-Total	11 (64.7)	0	1 (5.9)	4 (23.5)	6 (35.3)
Aspartate aminotransferase increased	5 (29.4)	1 (5.9)	0	4 (23.5)	0
Platelet count decreased	5 (29.4)	1 (5.9)	0	1 (5.9)	3 (17.6)
Alanine aminotransferase increased	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Neutrophil count decreased	3 (17.6)	1 (5.9)	0	0	2 (11.8)
Blood bilirubin increased	2 (11.8)	0	0	2 (11.8)	0
C-reactive protein increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)	0	0
White blood cell count decreased	2 (11.8)	0	0	0	2 (11.8)
Blood creatinine increased	1 (5.9)	0	0	1 (5.9)	0
Blood fibrinogen increased	1 (5.9)	0	1 (5.9)	0	0
Blood glucose increased	1 (5.9)	0	0	0	1 (5.9)
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin g decreased	1 (5.9)	0	1 (5.9)	0	0
Blood lactate dehydrogenase increased	1 (5.9)	0	0	1 (5.9)	0
Blood phosphorus decreased	1 (5.9)	0	0	1 (5.9)	0
Blood potassium decreased	1 (5.9)	0	0	0	1 (5.9)
Breath sounds abnormal	1 (5.9)	0	1 (5.9)	0	0
Fibrin d dimer increased	1 (5.9)	0	0	0	1 (5.9)
Heart sounds abnormal	1 (5.9)	1 (5.9)	0	0	0
Lymphocyte count decreased	1 (5.9)	0	0	0	1 (5.9)
Serum ferritin increased	1 (5.9)	0	0	0	1 (5.9)
Staphylococcus test positive	1 (5.9)	1 (5.9)	0	0	0
Weight increased	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders					
-Total	8 (47.1)	1 (5.9)	1 (5.9)	5 (29.4)	1 (5.9)
Decreased appetite	6 (35.3)	3 (17.6)	0	3 (17.6)	0
Hypokalaemia	6 (35.3)	1 (5.9)	3 (17.6)	2 (11.8)	0
Hypocalcaemia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Hyperglycaemia	3 (17.6)	0	3 (17.6)	0	0
Hypervolaemia	3 (17.6)	0	0	3 (17.6)	0
Hypomagnesaemia	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Hypophosphataemia	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Hypoalbuminaemia	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Acidosis	1 (5.9)	0	0	0	1 (5.9)
Hypercholesterolaemia	1 (5.9)	0	1 (5.9)	0	0
Hypertriglyceridaemia	1 (5.9)	0	1 (5.9)	0	0
Hyperuricaemia	1 (5.9)	1 (5.9)	0	0	0
Hypoglycaemia	1 (5.9)	0	1 (5.9)	0	0
Iron overload	1 (5.9)	0	1 (5.9)	0	0
Malnutrition	1 (5.9)	0	0	1 (5.9)	0
Polydipsia	1 (5.9)	0	0	1 (5.9)	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0
Vitamin d deficiency	1 (5.9)	1 (5.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (52.9)	3 (17.6)	3 (17.6)	3 (17.6)	0
Arthralgia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Back pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Joint effusion	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Myalgia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Neck pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain in extremity	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain in jaw	2 (11.8)	0	0	2 (11.8)	0
Bone pain	1 (5.9)	0	1 (5.9)	0	0
Muscle spasms	1 (5.9)	0	1 (5.9)	0	0
Musculoskeletal chest pain	1 (5.9)	1 (5.9)	0	0	0
Myopathy	1 (5.9)	0	0	1 (5.9)	0
Spinal pain	1 (5.9)	0	0	1 (5.9)	0
Synovitis	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	9 (52.9)	3 (17.6)	3 (17.6)	2 (11.8)	1 (5.9)
Headache	5 (29.4)	3 (17.6)	2 (11.8)	0	0
Lethargy	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Neuropathy peripheral	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Paraesthesia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Somnolence	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Tremor	2 (11.8)	2 (11.8)	0	0	0
Amnesia	1 (5.9)	0	1 (5.9)	0	0
Aphasia	1 (5.9)	1 (5.9)	0	0	0
Cognitive disorder	1 (5.9)	0	0	1 (5.9)	0
Disturbance in attention	1 (5.9)	1 (5.9)	0	0	0
Dizziness	1 (5.9)	1 (5.9)	0	0	0
Dysgeusia	1 (5.9)	1 (5.9)	0	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Extrapyramidal disorder	1 (5.9)	0	1 (5.9)	0	0
Hyperaesthesia	1 (5.9)	1 (5.9)	0	0	0
Migraine	1 (5.9)	0	1 (5.9)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neurological decompensation	1 (5.9)	0	0	0	1 (5.9)
Psychiatric disorders					
-Total	7 (41.2)	1 (5.9)	4 (23.5)	2 (11.8)	0
Anxiety	4 (23.5)	1 (5.9)	3 (17.6)	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Delirium	2 (11.8)	0	0	2 (11.8)	0
Affect lability	1 (5.9)	0	1 (5.9)	0	0
Hallucination	1 (5.9)	1 (5.9)	0	0	0
Hallucination, visual	1 (5.9)	0	1 (5.9)	0	0
Insomnia	1 (5.9)	0	1 (5.9)	0	0
Irritability	1 (5.9)	1 (5.9)	0	0	0
Mental status changes	1 (5.9)	0	1 (5.9)	0	0
Social avoidant behaviour	1 (5.9)	0	1 (5.9)	0	0
Renal and urinary disorders					
-Total	6 (35.3)	0	3 (17.6)	2 (11.8)	1 (5.9)
Acute kidney injury	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Cystitis haemorrhagic	1 (5.9)	0	1 (5.9)	0	0
Haematuria	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pollakiuria	1 (5.9)	0	1 (5.9)	0	0
Renal failure	1 (5.9)	0	0	0	1 (5.9)
Renal tubular necrosis	1 (5.9)	0	0	1 (5.9)	0
Urinary incontinence	1 (5.9)	0	1 (5.9)	0	0
Urinary retention	1 (5.9)	0	1 (5.9)	0	0
Reproductive system and breast disorders					
-Total	4 (23.5)	1 (5.9)	2 (11.8)	1 (5.9)	0
Endometriosis	1 (5.9)	0	0	1 (5.9)	0
Female genital tract fistula	1 (5.9)	1 (5.9)	0	0	0
Heavy menstrual bleeding	1 (5.9)	0	1 (5.9)	0	0
Vaginal haemorrhage	1 (5.9)	0	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (70.6)	3 (17.6)	2 (11.8)	3 (17.6)	4 (23.5)
Hypoxia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Pulmonary oedema	4 (23.5)	1 (5.9)	0	2 (11.8)	1 (5.9)
Epistaxis	3 (17.6)	2 (11.8)	0	1 (5.9)	0
Cough	2 (11.8)	2 (11.8)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dyspnoea	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0	0	0
Respiratory failure	2 (11.8)	0	0	0	2 (11.8)
Acute respiratory distress syndrome	1 (5.9)	0	0	0	1 (5.9)
Atelectasis	1 (5.9)	0	1 (5.9)	0	0
Bronchial oedema	1 (5.9)	1 (5.9)	0	0	0
Laryngeal oedema	1 (5.9)	0	0	0	1 (5.9)
Nasal congestion	1 (5.9)	1 (5.9)	0	0	0
Nasal dryness	1 (5.9)	1 (5.9)	0	0	0
Oropharyngeal plaque	1 (5.9)	0	1 (5.9)	0	0
Paranasal sinus discomfort	1 (5.9)	0	1 (5.9)	0	0
Pharyngeal erythema	1 (5.9)	0	1 (5.9)	0	0
Pharyngeal exudate	1 (5.9)	0	1 (5.9)	0	0
Pharyngeal oedema	1 (5.9)	0	1 (5.9)	0	0
Pleural effusion	1 (5.9)	0	1 (5.9)	0	0
Pulmonary mass	1 (5.9)	0	1 (5.9)	0	0
Respiratory distress	1 (5.9)	0	0	0	1 (5.9)
Rhinorrhoea	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (5.9)	0	1 (5.9)	0	0
Upper respiratory tract inflammation	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (64.7)	6 (35.3)	4 (23.5)	1 (5.9)	0
Pruritus	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Hyperhidrosis	2 (11.8)	0	2 (11.8)	0	0
Decubitus ulcer	1 (5.9)	0	0	1 (5.9)	0
Dry skin	1 (5.9)	1 (5.9)	0	0	0
Erythema	1 (5.9)	1 (5.9)	0	0	0
Erythema nodosum	1 (5.9)	1 (5.9)	0	0	0
Hangnail	1 (5.9)	1 (5.9)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (5.9)	1 (5.9)	0	0	0
Petechiae	1 (5.9)	1 (5.9)	0	0	0
Rash maculo-papular	1 (5.9)	1 (5.9)	0	0	0
Rash papular	1 (5.9)	0	1 (5.9)	0	0
Skin lesion	1 (5.9)	0	1 (5.9)	0	0
Social circumstances					

Age: >=18

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	0	1 (5.9)	0	0
Patient uncooperative	1 (5.9)	0	1 (5.9)	0	0
Surgical and medical procedures					
-Total	1 (5.9)	0	0	1 (5.9)	0
Thrombolysis	1 (5.9)	0	0	1 (5.9)	0
Vascular disorders					
-Total	7 (41.2)	1 (5.9)	1 (5.9)	2 (11.8)	3 (17.6)
Hypertension	5 (29.4)	1 (5.9)	3 (17.6)	1 (5.9)	0
Hypotension	4 (23.5)	0	0	2 (11.8)	2 (11.8)
Flushing	1 (5.9)	1 (5.9)	0	0	0
Hot flush	1 (5.9)	1 (5.9)	0	0	0
Peripheral ischaemia	1 (5.9)	0	1 (5.9)	0	0
Venoocclusive disease	1 (5.9)	0	0	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208b
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (98.2)	0	3 (5.5)	10 (18.2)	41 (74.5)
Blood and lymphatic system disorders					
-Total	35 (63.6)	0	7 (12.7)	17 (30.9)	11 (20.0)
Anaemia	21 (38.2)	1 (1.8)	6 (10.9)	13 (23.6)	1 (1.8)
Febrile neutropenia	17 (30.9)	0	0	17 (30.9)	0
Thrombocytopenia	9 (16.4)	0	1 (1.8)	2 (3.6)	6 (10.9)
Neutropenia	8 (14.5)	0	1 (1.8)	1 (1.8)	6 (10.9)
Disseminated intravascular coagulation	6 (10.9)	0	5 (9.1)	1 (1.8)	0
Leukopenia	4 (7.3)	0	0	0	4 (7.3)
Coagulopathy	2 (3.6)	0	2 (3.6)	0	0
Lymphopenia	2 (3.6)	0	0	0	2 (3.6)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Agranulocytosis	1 (1.8)	0	0	1 (1.8)	0
Eosinophilia	1 (1.8)	0	1 (1.8)	0	0
Hypercoagulation	1 (1.8)	0	1 (1.8)	0	0
Leukocytosis	1 (1.8)	0	1 (1.8)	0	0
Lymphadenopathy	1 (1.8)	1 (1.8)	0	0	0
Lymphocytosis	1 (1.8)	0	1 (1.8)	0	0
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Cardiac disorders					
-Total	17 (30.9)	4 (7.3)	5 (9.1)	7 (12.7)	1 (1.8)
Tachycardia	12 (21.8)	3 (5.5)	5 (9.1)	4 (7.3)	0
Left ventricular dysfunction	4 (7.3)	0	1 (1.8)	3 (5.5)	0
Bradycardia	2 (3.6)	2 (3.6)	0	0	0
Atrioventricular block first degree	1 (1.8)	0	1 (1.8)	0	0
Cardiac arrest	1 (1.8)	0	0	0	1 (1.8)
Cardiac dysfunction	1 (1.8)	1 (1.8)	0	0	0
Cardiac failure	1 (1.8)	0	0	1 (1.8)	0
Cardiac failure congestive	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mitral valve incompetence	1 (1.8)	1 (1.8)	0	0	0
Pericardial effusion	1 (1.8)	1 (1.8)	0	0	0
Right ventricular dysfunction	1 (1.8)	1 (1.8)	0	0	0
Tricuspid valve incompetence	1 (1.8)	1 (1.8)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Cerebral cavernous malformation	1 (1.8)	1 (1.8)	0	0	0
Ear and labyrinth disorders					
-Total	3 (5.5)	1 (1.8)	2 (3.6)	0	0
Deafness unilateral	1 (1.8)	0	1 (1.8)	0	0
Ear pain	1 (1.8)	1 (1.8)	0	0	0
Vertigo	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	4 (7.3)	0	4 (7.3)	0	0
Adrenal insufficiency	2 (3.6)	0	2 (3.6)	0	0
Hypothyroidism	2 (3.6)	0	2 (3.6)	0	0
Delayed puberty	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders					
-Total	10 (18.2)	7 (12.7)	2 (3.6)	1 (1.8)	0
Cataract	2 (3.6)	2 (3.6)	0	0	0
Eye pain	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Eyelid oedema	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Ocular hyperaemia	2 (3.6)	2 (3.6)	0	0	0
Visual impairment	2 (3.6)	2 (3.6)	0	0	0
Conjunctival haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Dry eye	1 (1.8)	1 (1.8)	0	0	0
Eye oedema	1 (1.8)	1 (1.8)	0	0	0
Hypermetropia	1 (1.8)	1 (1.8)	0	0	0
Mydriasis	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal disorders					
-Total	44 (80.0)	13 (23.6)	16 (29.1)	13 (23.6)	2 (3.6)
Nausea	20 (36.4)	10 (18.2)	8 (14.5)	2 (3.6)	0
Vomiting	17 (30.9)	14 (25.5)	3 (5.5)	0	0
Diarrhoea	15 (27.3)	9 (16.4)	4 (7.3)	2 (3.6)	0
Constipation	10 (18.2)	5 (9.1)	5 (9.1)	0	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	9 (16.4)	2 (3.6)	5 (9.1)	2 (3.6)	0
Pancreatitis	4 (7.3)	0	2 (3.6)	2 (3.6)	0
Stomatitis	3 (5.5)	0	0	3 (5.5)	0
Abdominal compartment syndrome	2 (3.6)	0	0	0	2 (3.6)
Abdominal pain upper	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Dry mouth	2 (3.6)	0	2 (3.6)	0	0
Gastrointestinal haemorrhage	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Gastrointestinal sounds abnormal	2 (3.6)	2 (3.6)	0	0	0
Haematemesis	2 (3.6)	2 (3.6)	0	0	0
Mouth haemorrhage	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Trichoglossia	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Abdominal distension	1 (1.8)	0	1 (1.8)	0	0
Anal fissure	1 (1.8)	0	1 (1.8)	0	0
Anal fistula	1 (1.8)	0	0	1 (1.8)	0
Anal inflammation	1 (1.8)	0	0	1 (1.8)	0
Ascites	1 (1.8)	1 (1.8)	0	0	0
Duodenal perforation	1 (1.8)	0	0	1 (1.8)	0
Enteritis	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.8)	0	1 (1.8)	0	0
Gastritis	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal inflammation	1 (1.8)	0	1 (1.8)	0	0
Gastrooesophageal reflux disease	1 (1.8)	0	1 (1.8)	0	0
Gingival bleeding	1 (1.8)	1 (1.8)	0	0	0
Haemoperitoneum	1 (1.8)	0	0	0	1 (1.8)
Haemorrhoids	1 (1.8)	0	1 (1.8)	0	0
Ileus	1 (1.8)	0	0	1 (1.8)	0
Irritable bowel syndrome	1 (1.8)	0	1 (1.8)	0	0
Mouth swelling	1 (1.8)	1 (1.8)	0	0	0
Neutropenic colitis	1 (1.8)	0	0	1 (1.8)	0
Odynophagia	1 (1.8)	1 (1.8)	0	0	0
Oral disorder	1 (1.8)	1 (1.8)	0	0	0
Peritoneal haematoma	1 (1.8)	1 (1.8)	0	0	0
Proctalgia	1 (1.8)	0	0	1 (1.8)	0
Upper gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	38 (69.1)	16 (29.1)	11 (20.0)	8 (14.5)	3 (5.5)
Pyrexia	27 (49.1)	10 (18.2)	9 (16.4)	6 (10.9)	2 (3.6)
Fatigue	11 (20.0)	8 (14.5)	3 (5.5)	0	0
Pain	5 (9.1)	0	4 (7.3)	1 (1.8)	0
Chills	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Face oedema	4 (7.3)	3 (5.5)	0	1 (1.8)	0
Oedema peripheral	4 (7.3)	3 (5.5)	0	1 (1.8)	0
Catheter site pain	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Asthenia	2 (3.6)	2 (3.6)	0	0	0
Generalised oedema	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Vascular device occlusion	2 (3.6)	2 (3.6)	0	0	0
Catheter site dermatitis	1 (1.8)	1 (1.8)	0	0	0
Catheter site erythema	1 (1.8)	1 (1.8)	0	0	0
Chest discomfort	1 (1.8)	0	0	1 (1.8)	0
Localised oedema	1 (1.8)	1 (1.8)	0	0	0
Malaise	1 (1.8)	1 (1.8)	0	0	0
Multiple organ dysfunction syndrome	1 (1.8)	0	0	0	1 (1.8)
Non-cardiac chest pain	1 (1.8)	1 (1.8)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oedema due to hepatic disease	1 (1.8)	0	1 (1.8)	0	0
Xerosis	1 (1.8)	1 (1.8)	0	0	0
Hepatobiliary disorders					
-Total	15 (27.3)	6 (10.9)	4 (7.3)	4 (7.3)	1 (1.8)
Hyperbilirubinaemia	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Hepatic cytolysis	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Hepatic function abnormal	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Hepatomegaly	2 (3.6)	2 (3.6)	0	0	0
Hypertransaminasaemia	2 (3.6)	2 (3.6)	0	0	0
Biliary tract disorder	1 (1.8)	1 (1.8)	0	0	0
Drug-induced liver injury	1 (1.8)	0	0	1 (1.8)	0
Gallbladder enlargement	1 (1.8)	1 (1.8)	0	0	0
Hepatosplenomegaly	1 (1.8)	0	1 (1.8)	0	0
Liver disorder	1 (1.8)	0	1 (1.8)	0	0
Ocular icterus	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	40 (72.7)	1 (1.8)	14 (25.5)	13 (23.6)	12 (21.8)
Cytokine release syndrome	31 (56.4)	3 (5.5)	9 (16.4)	8 (14.5)	11 (20.0)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	20 (36.4)	1 (1.8)	15 (27.3)	4 (7.3)	0
Haemophagocytic lymphohistiocytosis	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Immunodeficiency	3 (5.5)	0	0	3 (5.5)	0
Chronic graft versus host disease	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Graft versus host disease	2 (3.6)	0	0	2 (3.6)	0
Seasonal allergy	2 (3.6)	2 (3.6)	0	0	0
Allergy to immunoglobulin therapy	1 (1.8)	1 (1.8)	0	0	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0
Engraftment syndrome	1 (1.8)	0	0	1 (1.8)	0
Hypersensitivity	1 (1.8)	1 (1.8)	0	0	0
Selective igg subclass deficiency	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	45 (81.8)	5 (9.1)	8 (14.5)	22 (40.0)	10 (18.2)
Upper respiratory tract infection	9 (16.4)	4 (7.3)	3 (5.5)	2 (3.6)	0
Conjunctivitis	7 (12.7)	3 (5.5)	4 (7.3)	0	0
Pneumonia	7 (12.7)	1 (1.8)	1 (1.8)	3 (5.5)	2 (3.6)
Nasopharyngitis	6 (10.9)	4 (7.3)	2 (3.6)	0	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	4 (7.3)	1 (1.8)	2 (3.6)	1 (1.8)	0
Parainfluenzae virus infection	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Rhinovirus infection	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Sinusitis	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Staphylococcal bacteraemia	4 (7.3)	0	0	4 (7.3)	0
Staphylococcal infection	4 (7.3)	0	2 (3.6)	1 (1.8)	1 (1.8)
Candida infection	3 (5.5)	0	3 (5.5)	0	0
Clostridium difficile infection	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Influenza	3 (5.5)	0	2 (3.6)	0	1 (1.8)
Metapneumovirus infection	3 (5.5)	0	0	3 (5.5)	0
Otitis media	3 (5.5)	0	3 (5.5)	0	0
Paronychia	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Sepsis	3 (5.5)	0	0	1 (1.8)	2 (3.6)
Bk virus infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Catheter site infection	2 (3.6)	0	0	2 (3.6)	0
Covid-19	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Cytomegalovirus infection reactivation	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Ear infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	2 (3.6)	0	0	2 (3.6)	0
Gastroenteritis	2 (3.6)	2 (3.6)	0	0	0
Gingivitis	2 (3.6)	2 (3.6)	0	0	0
Herpes zoster	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Klebsiella bacteraemia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Nail infection	2 (3.6)	2 (3.6)	0	0	0
Oral infection	2 (3.6)	0	2 (3.6)	0	0
Otitis externa	2 (3.6)	0	2 (3.6)	0	0
Pneumocystis jirovecii pneumonia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Pneumonia fungal	2 (3.6)	0	0	2 (3.6)	0
Respiratory syncytial virus infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Respiratory tract infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Rhinitis	2 (3.6)	2 (3.6)	0	0	0
Skin infection	2 (3.6)	0	2 (3.6)	0	0
Tinea pedis	2 (3.6)	2 (3.6)	0	0	0
Viral infection	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Adenovirus infection	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal abscess	1 (1.8)	0	0	1 (1.8)	0
Atypical pneumonia	1 (1.8)	1 (1.8)	0	0	0
Bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Cholecystitis infective	1 (1.8)	0	1 (1.8)	0	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Coronavirus infection	1 (1.8)	0	0	1 (1.8)	0
Covid-19 pneumonia	1 (1.8)	0	0	0	1 (1.8)
Device related bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Fungaemia	1 (1.8)	0	0	0	1 (1.8)
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis clostridial	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis escherichia coli	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis salmonella	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal infection	1 (1.8)	1 (1.8)	0	0	0
Herpes simplex	1 (1.8)	0	1 (1.8)	0	0
Herpes virus infection	1 (1.8)	0	1 (1.8)	0	0
Human herpesvirus 6 infection	1 (1.8)	0	0	1 (1.8)	0
Localised infection	1 (1.8)	0	0	1 (1.8)	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Ophthalmic herpes zoster	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Peritonitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Salmonellosis	1 (1.8)	0	1 (1.8)	0	0
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sialoadenitis	1 (1.8)	0	0	1 (1.8)	0
Sinusitis fungal	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Soft tissue infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal sepsis	1 (1.8)	0	1 (1.8)	0	0
Syphilis	1 (1.8)	0	1 (1.8)	0	0
Varicella zoster virus infection	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral haemorrhagic cystitis	1 (1.8)	0	0	1 (1.8)	0
Viral skin infection	1 (1.8)	1 (1.8)	0	0	0
Injury, poisoning and procedural complications					
-Total	12 (21.8)	5 (9.1)	5 (9.1)	1 (1.8)	1 (1.8)
Infusion related reaction	3 (5.5)	1 (1.8)	1 (1.8)	1 (1.8)	0
Fall	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Transfusion reaction	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Contusion	1 (1.8)	1 (1.8)	0	0	0
Fibula fracture	1 (1.8)	0	1 (1.8)	0	0
Ligament sprain	1 (1.8)	1 (1.8)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Scratch	1 (1.8)	1 (1.8)	0	0	0
Skin abrasion	1 (1.8)	1 (1.8)	0	0	0
Tracheal obstruction	1 (1.8)	0	0	0	1 (1.8)
Traumatic haematoma	1 (1.8)	0	1 (1.8)	0	0
Wound	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	35 (63.6)	0	4 (7.3)	11 (20.0)	20 (36.4)
Alanine aminotransferase increased	17 (30.9)	5 (9.1)	6 (10.9)	6 (10.9)	0
White blood cell count decreased	16 (29.1)	1 (1.8)	1 (1.8)	1 (1.8)	13 (23.6)
Neutrophil count decreased	15 (27.3)	1 (1.8)	0	2 (3.6)	12 (21.8)
Aspartate aminotransferase increased	14 (25.5)	1 (1.8)	4 (7.3)	6 (10.9)	3 (5.5)
Platelet count decreased	14 (25.5)	2 (3.6)	1 (1.8)	4 (7.3)	7 (12.7)
Lymphocyte count decreased	12 (21.8)	1 (1.8)	0	4 (7.3)	7 (12.7)
Blood bilirubin increased	9 (16.4)	0	1 (1.8)	8 (14.5)	0
Serum ferritin increased	7 (12.7)	2 (3.6)	4 (7.3)	1 (1.8)	0
C-reactive protein increased	6 (10.9)	3 (5.5)	1 (1.8)	2 (3.6)	0
Blood creatinine increased	5 (9.1)	1 (1.8)	1 (1.8)	3 (5.5)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Blood fibrinogen decreased	4 (7.3)	1 (1.8)	2 (3.6)	0	1 (1.8)
Blood immunoglobulin a decreased	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Blood lactate dehydrogenase increased	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Weight increased	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Blood immunoglobulin m decreased	3 (5.5)	1 (1.8)	0	2 (3.6)	0
International normalised ratio increased	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Oxygen saturation decreased	3 (5.5)	1 (1.8)	1 (1.8)	1 (1.8)	0
Amylase increased	2 (3.6)	1 (1.8)	0	0	1 (1.8)
Blood fibrinogen increased	2 (3.6)	2 (3.6)	0	0	0
Blood immunoglobulin g decreased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Blood uric acid increased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Electrocardiogram qt prolonged	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Fibrin d dimer increased	2 (3.6)	2 (3.6)	0	0	0
Gamma-glutamyltransferase increased	2 (3.6)	0	0	2 (3.6)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunoglobulins decreased	2 (3.6)	0	2 (3.6)	0	0
Weight decreased	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Bacterial test positive	1 (1.8)	0	0	1 (1.8)	0
Blood alkaline phosphatase decreased	1 (1.8)	1 (1.8)	0	0	0
Blood creatine phosphokinase increased	1 (1.8)	0	0	1 (1.8)	0
Blood glucose increased	1 (1.8)	1 (1.8)	0	0	0
Blood phosphorus increased	1 (1.8)	0	1 (1.8)	0	0
Blood testosterone decreased	1 (1.8)	1 (1.8)	0	0	0
Blood urea increased	1 (1.8)	0	0	1 (1.8)	0
Bone density decreased	1 (1.8)	1 (1.8)	0	0	0
Coagulation test abnormal	1 (1.8)	1 (1.8)	0	0	0
Ejection fraction decreased	1 (1.8)	0	1 (1.8)	0	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Haemoglobin decreased	1 (1.8)	0	0	1 (1.8)	0
Heart sounds abnormal	1 (1.8)	1 (1.8)	0	0	0
Hepatitis b virus test positive	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (1.8)	1 (1.8)	0	0	0
Prothrombin time prolonged	1 (1.8)	0	1 (1.8)	0	0
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Staphylococcus test positive	1 (1.8)	1 (1.8)	0	0	0
Urine output decreased	1 (1.8)	0	0	1 (1.8)	0
Metabolism and nutrition disorders					
-Total	35 (63.6)	5 (9.1)	8 (14.5)	13 (23.6)	9 (16.4)
Decreased appetite	18 (32.7)	6 (10.9)	5 (9.1)	5 (9.1)	2 (3.6)
Hypokalaemia	13 (23.6)	2 (3.6)	2 (3.6)	7 (12.7)	2 (3.6)
Hypocalcaemia	10 (18.2)	2 (3.6)	5 (9.1)	3 (5.5)	0
Hypophosphataemia	9 (16.4)	3 (5.5)	3 (5.5)	2 (3.6)	1 (1.8)
Hyperuricaemia	5 (9.1)	4 (7.3)	1 (1.8)	0	0
Hypoalbuminaemia	5 (9.1)	0	5 (9.1)	0	0
Hyperglycaemia	4 (7.3)	0	0	4 (7.3)	0
Hypervolaemia	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Hypomagnesaemia	4 (7.3)	4 (7.3)	0	0	0
Metabolic acidosis	4 (7.3)	1 (1.8)	0	2 (3.6)	1 (1.8)
Tumour lysis syndrome	4 (7.3)	0	0	3 (5.5)	1 (1.8)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	3 (5.5)	0	1 (1.8)	2 (3.6)	0
Hyperphosphataemia	3 (5.5)	3 (5.5)	0	0	0
Hypertriglyceridaemia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Dehydration	1 (1.8)	0	1 (1.8)	0	0
Eating disorder symptom	1 (1.8)	0	1 (1.8)	0	0
Haemochromatosis	1 (1.8)	0	0	1 (1.8)	0
Hypercalcaemia	1 (1.8)	0	0	1 (1.8)	0
Hypermagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Hypernatraemia	1 (1.8)	1 (1.8)	0	0	0
Hyponatraemia	1 (1.8)	0	0	0	1 (1.8)
Iron overload	1 (1.8)	0	1 (1.8)	0	0
Malnutrition	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal and connective tissue disorders					
-Total	24 (43.6)	10 (18.2)	12 (21.8)	2 (3.6)	0
Pain in extremity	12 (21.8)	3 (5.5)	9 (16.4)	0	0
Arthralgia	9 (16.4)	4 (7.3)	5 (9.1)	0	0
Back pain	5 (9.1)	1 (1.8)	2 (3.6)	2 (3.6)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myalgia	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Bone pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Groin pain	1 (1.8)	1 (1.8)	0	0	0
Growth retardation	1 (1.8)	0	1 (1.8)	0	0
Muscle spasms	1 (1.8)	0	1 (1.8)	0	0
Muscular weakness	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal chest pain	1 (1.8)	1 (1.8)	0	0	0
Neck pain	1 (1.8)	1 (1.8)	0	0	0
Osteonecrosis	1 (1.8)	1 (1.8)	0	0	0
Osteopenia	1 (1.8)	1 (1.8)	0	0	0
Pain in jaw	1 (1.8)	1 (1.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (5.5)	1 (1.8)	2 (3.6)	0	0
Skin papilloma	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Cancer pain	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	31 (56.4)	12 (21.8)	8 (14.5)	6 (10.9)	5 (9.1)

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	15 (27.3)	8 (14.5)	4 (7.3)	3 (5.5)	0
Encephalopathy	5 (9.1)	1 (1.8)	2 (3.6)	2 (3.6)	0
Dizziness	3 (5.5)	3 (5.5)	0	0	0
Cerebral haemorrhage	2 (3.6)	0	0	0	2 (3.6)
Cognitive disorder	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Dysarthria	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Dysgeusia	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Lethargy	2 (3.6)	2 (3.6)	0	0	0
Neuropathy peripheral	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Seizure	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Somnolence	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Autonomic neuropathy	1 (1.8)	0	0	1 (1.8)	0
Depressed level of consciousness	1 (1.8)	0	0	1 (1.8)	0
Haemorrhage intracranial	1 (1.8)	0	0	0	1 (1.8)
Hydrocephalus	1 (1.8)	0	0	0	1 (1.8)
Hypoaesthesia	1 (1.8)	1 (1.8)	0	0	0
Memory impairment	1 (1.8)	0	1 (1.8)	0	0
Neuralgia	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neurological decompensation	1 (1.8)	0	0	0	1 (1.8)
Psychiatric disorders					
-Total	21 (38.2)	7 (12.7)	12 (21.8)	2 (3.6)	0
Anxiety	9 (16.4)	2 (3.6)	7 (12.7)	0	0
Delirium	6 (10.9)	2 (3.6)	2 (3.6)	2 (3.6)	0
Agitation	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Confusional state	4 (7.3)	4 (7.3)	0	0	0
Insomnia	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Sleep disorder	2 (3.6)	0	2 (3.6)	0	0
Hallucination	1 (1.8)	0	1 (1.8)	0	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Mental status changes	1 (1.8)	0	1 (1.8)	0	0
Mood altered	1 (1.8)	1 (1.8)	0	0	0
Nightmare	1 (1.8)	1 (1.8)	0	0	0
Persistent depressive disorder	1 (1.8)	0	1 (1.8)	0	0
Restlessness	1 (1.8)	0	1 (1.8)	0	0
Tearfulness	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	19 (34.5)	9 (16.4)	4 (7.3)	3 (5.5)	3 (5.5)
Acute kidney injury	8 (14.5)	5 (9.1)	1 (1.8)	0	2 (3.6)
Haematuria	4 (7.3)	3 (5.5)	0	1 (1.8)	0
Dysuria	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Renal failure	2 (3.6)	0	1 (1.8)	0	1 (1.8)
Cystitis haemorrhagic	1 (1.8)	0	1 (1.8)	0	0
Incontinence	1 (1.8)	0	1 (1.8)	0	0
Kidney enlargement	1 (1.8)	0	1 (1.8)	0	0
Proteinuria	1 (1.8)	1 (1.8)	0	0	0
Renal mass	1 (1.8)	0	1 (1.8)	0	0
Renal pain	1 (1.8)	1 (1.8)	0	0	0
Renal tubular disorder	1 (1.8)	0	0	1 (1.8)	0
Renal tubular dysfunction	1 (1.8)	1 (1.8)	0	0	0
Renal tubular necrosis	1 (1.8)	0	0	1 (1.8)	0
Urinary tract disorder	1 (1.8)	0	1 (1.8)	0	0
Reproductive system and breast disorders					
-Total	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prostatitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	33 (60.0)	9 (16.4)	6 (10.9)	4 (7.3)	14 (25.5)
Cough	14 (25.5)	12 (21.8)	2 (3.6)	0	0
Hypoxia	12 (21.8)	0	4 (7.3)	4 (7.3)	4 (7.3)
Pleural effusion	9 (16.4)	3 (5.5)	3 (5.5)	2 (3.6)	1 (1.8)
Pulmonary oedema	8 (14.5)	2 (3.6)	2 (3.6)	2 (3.6)	2 (3.6)
Respiratory failure	7 (12.7)	0	0	0	7 (12.7)
Epistaxis	6 (10.9)	3 (5.5)	1 (1.8)	2 (3.6)	0
Nasal congestion	6 (10.9)	5 (9.1)	1 (1.8)	0	0
Oropharyngeal pain	6 (10.9)	4 (7.3)	2 (3.6)	0	0
Tachypnoea	5 (9.1)	2 (3.6)	1 (1.8)	1 (1.8)	1 (1.8)
Dyspnoea	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Respiratory distress	3 (5.5)	0	1 (1.8)	0	2 (3.6)
Rhinorrhoea	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Atelectasis	1 (1.8)	0	0	1 (1.8)	0
Bradypnoea	1 (1.8)	0	0	1 (1.8)	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchospasm	1 (1.8)	0	1 (1.8)	0	0
Laryngeal oedema	1 (1.8)	0	0	0	1 (1.8)
Lung disorder	1 (1.8)	1 (1.8)	0	0	0
Lung infiltration	1 (1.8)	0	0	1 (1.8)	0
Painful respiration	1 (1.8)	1 (1.8)	0	0	0
Paranasal sinus inflammation	1 (1.8)	1 (1.8)	0	0	0
Productive cough	1 (1.8)	1 (1.8)	0	0	0
Pulmonary haemorrhage	1 (1.8)	0	0	0	1 (1.8)
Respiratory disorder	1 (1.8)	0	1 (1.8)	0	0
Rhinitis allergic	1 (1.8)	1 (1.8)	0	0	0
Sleep apnoea syndrome	1 (1.8)	1 (1.8)	0	0	0
Wheezing	1 (1.8)	0	1 (1.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	26 (47.3)	11 (20.0)	11 (20.0)	4 (7.3)	0
Pruritus	6 (10.9)	2 (3.6)	4 (7.3)	0	0
Rash	6 (10.9)	3 (5.5)	3 (5.5)	0	0
Erythema	3 (5.5)	2 (3.6)	1 (1.8)	0	0

Gender: Male

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin ulcer	3 (5.5)	1 (1.8)	1 (1.8)	1 (1.8)	0
Blister	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Dermatitis atopic	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Dry skin	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Skin discolouration	2 (3.6)	2 (3.6)	0	0	0
Acne	1 (1.8)	1 (1.8)	0	0	0
Dermatitis	1 (1.8)	1 (1.8)	0	0	0
Dermatitis allergic	1 (1.8)	1 (1.8)	0	0	0
Drug eruption	1 (1.8)	0	1 (1.8)	0	0
Eczema	1 (1.8)	0	0	1 (1.8)	0
Erythema nodosum	1 (1.8)	1 (1.8)	0	0	0
Ingrowing nail	1 (1.8)	0	1 (1.8)	0	0
Miliaria	1 (1.8)	1 (1.8)	0	0	0
Night sweats	1 (1.8)	1 (1.8)	0	0	0
Papule	1 (1.8)	1 (1.8)	0	0	0
Petechiae	1 (1.8)	1 (1.8)	0	0	0
Photosensitivity reaction	1 (1.8)	0	1 (1.8)	0	0
Pruritus allergic	1 (1.8)	0	1 (1.8)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash maculo-papular	1 (1.8)	1 (1.8)	0	0	0
Rash papular	1 (1.8)	1 (1.8)	0	0	0
Scab	1 (1.8)	1 (1.8)	0	0	0
Skin swelling	1 (1.8)	1 (1.8)	0	0	0
Urticaria	1 (1.8)	0	1 (1.8)	0	0
Vancomycin infusion reaction	1 (1.8)	0	0	1 (1.8)	0
Vascular disorders					
-Total	28 (50.9)	3 (5.5)	9 (16.4)	12 (21.8)	4 (7.3)
Hypotension	18 (32.7)	1 (1.8)	6 (10.9)	8 (14.5)	3 (5.5)
Hypertension	11 (20.0)	3 (5.5)	5 (9.1)	3 (5.5)	0
Capillary leak syndrome	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Venoocclusive disease	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Flushing	1 (1.8)	1 (1.8)	0	0	0
Haematoma	1 (1.8)	1 (1.8)	0	0	0
Peripheral ischaemia	1 (1.8)	0	1 (1.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208b
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (95.3)	0	2 (4.7)	10 (23.3)	29 (67.4)
Blood and lymphatic system disorders					
-Total	32 (74.4)	1 (2.3)	2 (4.7)	20 (46.5)	9 (20.9)
Febrile neutropenia	22 (51.2)	0	0	19 (44.2)	3 (7.0)
Anaemia	17 (39.5)	4 (9.3)	5 (11.6)	8 (18.6)	0
Neutropenia	8 (18.6)	1 (2.3)	1 (2.3)	2 (4.7)	4 (9.3)
Thrombocytopenia	4 (9.3)	0	0	3 (7.0)	1 (2.3)
Coagulopathy	3 (7.0)	1 (2.3)	0	2 (4.7)	0
Pancytopenia	3 (7.0)	0	0	2 (4.7)	1 (2.3)
Disseminated intravascular coagulation	2 (4.7)	0	0	2 (4.7)	0
Splenomegaly	2 (4.7)	2 (4.7)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
B-cell aplasia	1 (2.3)	0	1 (2.3)	0	0
Hypofibrinogenaemia	1 (2.3)	0	1 (2.3)	0	0
Leukopenia	1 (2.3)	0	0	1 (2.3)	0
Lymphadenopathy	1 (2.3)	0	1 (2.3)	0	0
Cardiac disorders					
-Total	18 (41.9)	6 (14.0)	3 (7.0)	4 (9.3)	5 (11.6)
Tachycardia	9 (20.9)	4 (9.3)	3 (7.0)	1 (2.3)	1 (2.3)
Cardiac failure	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Sinus tachycardia	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Cardiac arrest	2 (4.7)	0	0	0	2 (4.7)
Bradycardia	1 (2.3)	0	1 (2.3)	0	0
Cardiac dysfunction	1 (2.3)	1 (2.3)	0	0	0
Left ventricular dysfunction	1 (2.3)	0	0	1 (2.3)	0
Pericardial effusion	1 (2.3)	0	0	1 (2.3)	0
Sinus bradycardia	1 (2.3)	0	0	1 (2.3)	0
Ear and labyrinth disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0
Ear pruritus	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Endocrine disorders					
-Total	5 (11.6)	0	5 (11.6)	0	0
Adrenal insufficiency	4 (9.3)	0	4 (9.3)	0	0
Hypothyroidism	1 (2.3)	0	1 (2.3)	0	0
Eye disorders					
-Total	7 (16.3)	4 (9.3)	3 (7.0)	0	0
Conjunctival haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Eye pain	1 (2.3)	1 (2.3)	0	0	0
Eyelid oedema	1 (2.3)	0	1 (2.3)	0	0
Ocular hyperaemia	1 (2.3)	1 (2.3)	0	0	0
Periorbital oedema	1 (2.3)	1 (2.3)	0	0	0
Periorbital swelling	1 (2.3)	0	1 (2.3)	0	0
Retinal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Vision blurred	1 (2.3)	1 (2.3)	0	0	0
Visual field defect	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	28 (65.1)	7 (16.3)	14 (32.6)	7 (16.3)	0
Nausea	13 (30.2)	4 (9.3)	8 (18.6)	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vomiting	13 (30.2)	6 (14.0)	5 (11.6)	2 (4.7)	0
Diarrhoea	12 (27.9)	8 (18.6)	4 (9.3)	0	0
Constipation	9 (20.9)	4 (9.3)	5 (11.6)	0	0
Abdominal pain	8 (18.6)	3 (7.0)	5 (11.6)	0	0
Stomatitis	8 (18.6)	1 (2.3)	5 (11.6)	2 (4.7)	0
Mouth haemorrhage	4 (9.3)	1 (2.3)	2 (4.7)	1 (2.3)	0
Abdominal distension	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Abdominal pain upper	2 (4.7)	2 (4.7)	0	0	0
Ascites	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Gingival bleeding	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Gingival erythema	2 (4.7)	2 (4.7)	0	0	0
Haematemesis	2 (4.7)	2 (4.7)	0	0	0
Oral pain	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Pancreatitis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Abdominal rigidity	1 (2.3)	0	1 (2.3)	0	0
Anal erythema	1 (2.3)	1 (2.3)	0	0	0
Anal fissure	1 (2.3)	0	1 (2.3)	0	0
Anal haemorrhage	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dyspepsia	1 (2.3)	1 (2.3)	0	0	0
Dysphagia	1 (2.3)	0	0	1 (2.3)	0
Gastrointestinal sounds abnormal	1 (2.3)	1 (2.3)	0	0	0
Gingivitis ulcerative	1 (2.3)	0	0	1 (2.3)	0
Ileus	1 (2.3)	0	1 (2.3)	0	0
Lip dry	1 (2.3)	0	1 (2.3)	0	0
Lip oedema	1 (2.3)	1 (2.3)	0	0	0
Lip pain	1 (2.3)	1 (2.3)	0	0	0
Lip ulceration	1 (2.3)	0	1 (2.3)	0	0
Melaena	1 (2.3)	0	0	1 (2.3)	0
Neutropenic colitis	1 (2.3)	0	1 (2.3)	0	0
Proctalgia	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					
-Total	25 (58.1)	13 (30.2)	5 (11.6)	5 (11.6)	2 (4.7)
Pyrexia	16 (37.2)	8 (18.6)	3 (7.0)	5 (11.6)	0
Fatigue	8 (18.6)	7 (16.3)	1 (2.3)	0	0
Chills	5 (11.6)	2 (4.7)	3 (7.0)	0	0

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Generalised oedema	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Oedema peripheral	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Pain	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Asthenia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Catheter site pain	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Drug withdrawal syndrome	2 (4.7)	0	2 (4.7)	0	0
Influenza like illness	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Localised oedema	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Multiple organ dysfunction syndrome	2 (4.7)	0	0	0	2 (4.7)
Catheter site haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Complication associated with device	1 (2.3)	1 (2.3)	0	0	0
Crying	1 (2.3)	0	1 (2.3)	0	0
Facial pain	1 (2.3)	0	1 (2.3)	0	0
Malaise	1 (2.3)	0	1 (2.3)	0	0
Non-cardiac chest pain	1 (2.3)	1 (2.3)	0	0	0
Sluggishness	1 (2.3)	0	1 (2.3)	0	0
Swelling face	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic inflammatory response syndrome	1 (2.3)	0	0	1 (2.3)	0
Thirst	1 (2.3)	1 (2.3)	0	0	0
Hepatobiliary disorders					
-Total	9 (20.9)	1 (2.3)	4 (9.3)	2 (4.7)	2 (4.7)
Hepatic function abnormal	3 (7.0)	0	2 (4.7)	1 (2.3)	0
Hyperbilirubinaemia	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Cholelithiasis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Cholestasis	1 (2.3)	0	0	0	1 (2.3)
Gallbladder enlargement	1 (2.3)	1 (2.3)	0	0	0
Hepatomegaly	1 (2.3)	0	0	0	1 (2.3)
Hypertransaminasaemia	1 (2.3)	0	1 (2.3)	0	0
Immune system disorders					
-Total	33 (76.7)	1 (2.3)	10 (23.3)	12 (27.9)	10 (23.3)
Cytokine release syndrome	30 (69.8)	2 (4.7)	9 (20.9)	9 (20.9)	10 (23.3)
Hypogammaglobulinaemia	16 (37.2)	1 (2.3)	11 (25.6)	4 (9.3)	0
Seasonal allergy	3 (7.0)	0	3 (7.0)	0	0
Haemophagocytic lymphohistiocytosis	2 (4.7)	0	1 (2.3)	0	1 (2.3)

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Allergy to immunoglobulin therapy	1 (2.3)	0	0	1 (2.3)	0
Drug hypersensitivity	1 (2.3)	0	0	1 (2.3)	0
Graft versus host disease	1 (2.3)	0	0	1 (2.3)	0
Immunodeficiency	1 (2.3)	0	0	1 (2.3)	0
Infections and infestations					
-Total	31 (72.1)	1 (2.3)	5 (11.6)	15 (34.9)	10 (23.3)
Gastroenteritis	5 (11.6)	2 (4.7)	1 (2.3)	2 (4.7)	0
Rhinovirus infection	5 (11.6)	0	4 (9.3)	1 (2.3)	0
Sinusitis	5 (11.6)	0	3 (7.0)	2 (4.7)	0
Upper respiratory tract infection	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Bacteraemia	4 (9.3)	0	0	3 (7.0)	1 (2.3)
Oral candidiasis	3 (7.0)	0	3 (7.0)	0	0
Parainfluenzae virus infection	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Pneumonia	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Septic shock	3 (7.0)	0	0	0	3 (7.0)
Staphylococcal bacteraemia	3 (7.0)	0	0	3 (7.0)	0
Staphylococcal infection	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Urinary tract infection	3 (7.0)	0	2 (4.7)	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute sinusitis	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Bronchitis	2 (4.7)	0	2 (4.7)	0	0
Bronchopulmonary aspergillosis	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Conjunctivitis	2 (4.7)	0	2 (4.7)	0	0
Device related infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Encephalitis viral	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Fungal infection	2 (4.7)	0	2 (4.7)	0	0
Fungal skin infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Gastroenteritis viral	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Herpes zoster	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Localised infection	2 (4.7)	2 (4.7)	0	0	0
Nail infection	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Nasopharyngitis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Oral herpes	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Otitis media	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Paronychia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Staphylococcal skin infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Adenovirus infection	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspergillus infection	1 (2.3)	0	0	0	1 (2.3)
Bronchiolitis	1 (2.3)	0	0	1 (2.3)	0
Candida infection	1 (2.3)	0	0	0	1 (2.3)
Catheter site infection	1 (2.3)	0	1 (2.3)	0	0
Clostridium difficile infection	1 (2.3)	0	0	1 (2.3)	0
Cystitis	1 (2.3)	0	1 (2.3)	0	0
Device related sepsis	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	1 (2.3)	0	0
Ear, nose and throat infection	1 (2.3)	0	1 (2.3)	0	0
Encephalitis	1 (2.3)	0	0	0	1 (2.3)
Enterobacter infection	1 (2.3)	0	0	1 (2.3)	0
Epstein-barr virus infection	1 (2.3)	0	1 (2.3)	0	0
Escherichia bacteraemia	1 (2.3)	0	0	0	1 (2.3)
Folliculitis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis norovirus	1 (2.3)	1 (2.3)	0	0	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Granulicatella infection	1 (2.3)	0	0	1 (2.3)	0
Herpes simplex	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (2.3)	0	0	1 (2.3)	0
Klebsiella infection	1 (2.3)	0	0	1 (2.3)	0
Mastoiditis	1 (2.3)	0	0	1 (2.3)	0
Meningitis bacterial	1 (2.3)	0	0	1 (2.3)	0
Meningitis pneumococcal	1 (2.3)	0	0	1 (2.3)	0
Myringitis	1 (2.3)	1 (2.3)	0	0	0
Neutropenic infection	1 (2.3)	0	0	1 (2.3)	0
Otitis externa	1 (2.3)	0	0	1 (2.3)	0
Pharyngitis streptococcal	1 (2.3)	0	0	1 (2.3)	0
Pneumonia respiratory syncytial viral	1 (2.3)	0	0	1 (2.3)	0
Pneumonia viral	1 (2.3)	0	0	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	0	0	1 (2.3)	0
Respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection viral	1 (2.3)	0	1 (2.3)	0	0
Rhinitis	1 (2.3)	0	1 (2.3)	0	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Stomatococcal infection	1 (2.3)	0	0	0	1 (2.3)

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic candida	1 (2.3)	0	0	1 (2.3)	0
Systemic mycosis	1 (2.3)	0	0	1 (2.3)	0
Urinary tract infection pseudomonal	1 (2.3)	0	1 (2.3)	0	0
Urinary tract infection viral	1 (2.3)	1 (2.3)	0	0	0
Varicella zoster virus infection	1 (2.3)	0	1 (2.3)	0	0
Viral upper respiratory tract infection	1 (2.3)	0	0	1 (2.3)	0
Vulval cellulitis	1 (2.3)	0	0	1 (2.3)	0
Injury, poisoning and procedural complications					
-Total	15 (34.9)	4 (9.3)	7 (16.3)	2 (4.7)	2 (4.7)
Procedural pain	4 (9.3)	1 (2.3)	2 (4.7)	1 (2.3)	0
Infusion related reaction	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Transfusion reaction	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Wound	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Abdominal injury	1 (2.3)	1 (2.3)	0	0	0
Contusion	1 (2.3)	1 (2.3)	0	0	0
Extradural haematoma	1 (2.3)	0	1 (2.3)	0	0
Fall	1 (2.3)	0	1 (2.3)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ligament sprain	1 (2.3)	1 (2.3)	0	0	0
Limb injury	1 (2.3)	0	1 (2.3)	0	0
Post-traumatic neck syndrome	1 (2.3)	0	1 (2.3)	0	0
Radius fracture	1 (2.3)	0	1 (2.3)	0	0
Skin abrasion	1 (2.3)	1 (2.3)	0	0	0
Skin injury	1 (2.3)	0	1 (2.3)	0	0
Skin wound	1 (2.3)	1 (2.3)	0	0	0
Transplant failure	1 (2.3)	0	0	0	1 (2.3)
Vasoplegia syndrome	1 (2.3)	0	0	0	1 (2.3)
Investigations					
-Total	31 (72.1)	1 (2.3)	2 (4.7)	9 (20.9)	19 (44.2)
White blood cell count decreased	16 (37.2)	2 (4.7)	2 (4.7)	0	12 (27.9)
Neutrophil count decreased	14 (32.6)	0	2 (4.7)	1 (2.3)	11 (25.6)
Platelet count decreased	14 (32.6)	4 (9.3)	1 (2.3)	2 (4.7)	7 (16.3)
Lymphocyte count decreased	11 (25.6)	0	1 (2.3)	5 (11.6)	5 (11.6)
Aspartate aminotransferase increased	7 (16.3)	1 (2.3)	1 (2.3)	4 (9.3)	1 (2.3)
International normalised ratio increased	7 (16.3)	4 (9.3)	3 (7.0)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	5 (11.6)	0	2 (4.7)	3 (7.0)	0
C-reactive protein increased	5 (11.6)	0	1 (2.3)	3 (7.0)	1 (2.3)
Blood bilirubin increased	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Blood fibrinogen decreased	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Blood immunoglobulin m decreased	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Serum ferritin increased	4 (9.3)	0	1 (2.3)	2 (4.7)	1 (2.3)
Blood immunoglobulin a decreased	3 (7.0)	3 (7.0)	0	0	0
Blood lactate dehydrogenase increased	3 (7.0)	0	0	3 (7.0)	0
Electrocardiogram qt prolonged	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)
Activated partial thromboplastin time prolonged	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Blood creatinine increased	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Blood immunoglobulin g decreased	2 (4.7)	0	2 (4.7)	0	0
Blood uric acid increased	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Fibrin d dimer increased	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Weight decreased	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Weight increased	2 (4.7)	0	1 (2.3)	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood alkaline phosphatase increased	1 (2.3)	1 (2.3)	0	0	0
Blood bicarbonate decreased	1 (2.3)	0	1 (2.3)	0	0
Blood creatine phosphokinase increased	1 (2.3)	0	0	0	1 (2.3)
Blood fibrinogen increased	1 (2.3)	0	1 (2.3)	0	0
Blood glucose increased	1 (2.3)	0	0	0	1 (2.3)
Blood phosphorus decreased	1 (2.3)	0	0	1 (2.3)	0
Blood phosphorus increased	1 (2.3)	0	1 (2.3)	0	0
Blood potassium decreased	1 (2.3)	0	0	0	1 (2.3)
Blood thyroid stimulating hormone increased	1 (2.3)	1 (2.3)	0	0	0
Breath sounds abnormal	1 (2.3)	0	1 (2.3)	0	0
Cardiac murmur	1 (2.3)	1 (2.3)	0	0	0
Electrocardiogram t wave abnormal	1 (2.3)	0	1 (2.3)	0	0
Enterovirus test positive	1 (2.3)	0	1 (2.3)	0	0
Haptoglobin decreased	1 (2.3)	1 (2.3)	0	0	0
Lipase increased	1 (2.3)	0	0	0	1 (2.3)
Troponin increased	1 (2.3)	0	0	1 (2.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urine output decreased	1 (2.3)	0	0	0	1 (2.3)
Metabolism and nutrition disorders					
-Total	24 (55.8)	3 (7.0)	3 (7.0)	13 (30.2)	5 (11.6)
Decreased appetite	16 (37.2)	6 (14.0)	3 (7.0)	7 (16.3)	0
Hypokalaemia	12 (27.9)	2 (4.7)	3 (7.0)	6 (14.0)	1 (2.3)
Hypophosphataemia	12 (27.9)	0	5 (11.6)	7 (16.3)	0
Hypocalcaemia	8 (18.6)	0	5 (11.6)	3 (7.0)	0
Hypoalbuminaemia	7 (16.3)	0	6 (14.0)	1 (2.3)	0
Hyperglycaemia	5 (11.6)	0	4 (9.3)	1 (2.3)	0
Hypervolaemia	5 (11.6)	0	1 (2.3)	4 (9.3)	0
Hypomagnesaemia	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Hyperuricaemia	4 (9.3)	3 (7.0)	0	1 (2.3)	0
Hyperphosphataemia	3 (7.0)	2 (4.7)	0	0	1 (2.3)
Hyponatraemia	3 (7.0)	3 (7.0)	0	0	0
Acidosis	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Hypercalcaemia	2 (4.7)	0	1 (2.3)	0	1 (2.3)
Hyperchloraemia	2 (4.7)	2 (4.7)	0	0	0
Hypernatraemia	2 (4.7)	0	0	1 (2.3)	1 (2.3)

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	2 (4.7)	0	0	0	2 (4.7)
Tumour lysis syndrome	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Calcium deficiency	1 (2.3)	1 (2.3)	0	0	0
Haemosiderosis	1 (2.3)	0	1 (2.3)	0	0
Hypercholesterolaemia	1 (2.3)	0	1 (2.3)	0	0
Hyperkalaemia	1 (2.3)	0	0	0	1 (2.3)
Hyperlactacidaemia	1 (2.3)	1 (2.3)	0	0	0
Hyperlipidaemia	1 (2.3)	0	1 (2.3)	0	0
Hypermagnesaemia	1 (2.3)	1 (2.3)	0	0	0
Hypertriglyceridaemia	1 (2.3)	0	1 (2.3)	0	0
Hypoglycaemia	1 (2.3)	0	1 (2.3)	0	0
Hypophagia	1 (2.3)	0	1 (2.3)	0	0
Iron overload	1 (2.3)	0	1 (2.3)	0	0
Malnutrition	1 (2.3)	0	0	1 (2.3)	0
Metabolic syndrome	1 (2.3)	0	1 (2.3)	0	0
Obesity	1 (2.3)	0	0	1 (2.3)	0
Polydipsia	1 (2.3)	0	0	1 (2.3)	0
Vitamin d deficiency	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	24 (55.8)	8 (18.6)	7 (16.3)	8 (18.6)	1 (2.3)
Pain in extremity	11 (25.6)	6 (14.0)	2 (4.7)	3 (7.0)	0
Back pain	7 (16.3)	1 (2.3)	4 (9.3)	2 (4.7)	0
Myalgia	7 (16.3)	4 (9.3)	3 (7.0)	0	0
Arthralgia	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Bone pain	2 (4.7)	0	2 (4.7)	0	0
Joint effusion	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Pain in jaw	2 (4.7)	0	0	2 (4.7)	0
Growth retardation	1 (2.3)	0	1 (2.3)	0	0
Haemarthrosis	1 (2.3)	0	0	1 (2.3)	0
Muscle rigidity	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	0	0	1 (2.3)	0
Musculoskeletal chest pain	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal pain	1 (2.3)	0	1 (2.3)	0	0
Myopathy	1 (2.3)	0	0	1 (2.3)	0
Myositis	1 (2.3)	0	1 (2.3)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neck pain	1 (2.3)	0	1 (2.3)	0	0
Rhabdomyolysis	1 (2.3)	0	0	0	1 (2.3)
Spinal pain	1 (2.3)	0	0	1 (2.3)	0
Synovitis	1 (2.3)	0	1 (2.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (4.7)	0	0	2 (4.7)	0
Bone giant cell tumour benign	1 (2.3)	0	0	1 (2.3)	0
Myelodysplastic syndrome	1 (2.3)	0	0	1 (2.3)	0
Nervous system disorders					
-Total	24 (55.8)	5 (11.6)	12 (27.9)	7 (16.3)	0
Headache	17 (39.5)	8 (18.6)	9 (20.9)	0	0
Tremor	6 (14.0)	5 (11.6)	1 (2.3)	0	0
Encephalopathy	4 (9.3)	0	1 (2.3)	3 (7.0)	0
Seizure	4 (9.3)	0	2 (4.7)	2 (4.7)	0
Somnolence	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Cognitive disorder	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Dizziness	2 (4.7)	2 (4.7)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lethargy	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Paraesthesia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Amnesia	1 (2.3)	0	1 (2.3)	0	0
Aphasia	1 (2.3)	1 (2.3)	0	0	0
Disturbance in attention	1 (2.3)	1 (2.3)	0	0	0
Dysgeusia	1 (2.3)	1 (2.3)	0	0	0
Extrapyramidal disorder	1 (2.3)	0	1 (2.3)	0	0
Generalised tonic-clonic seizure	1 (2.3)	0	1 (2.3)	0	0
Hyperaesthesia	1 (2.3)	1 (2.3)	0	0	0
Migraine	1 (2.3)	0	1 (2.3)	0	0
Monoparesis	1 (2.3)	0	1 (2.3)	0	0
Nervous system disorder	1 (2.3)	0	0	1 (2.3)	0
Neuropathy peripheral	1 (2.3)	0	0	1 (2.3)	0
Posterior reversible encephalopathy syndrome	1 (2.3)	0	1 (2.3)	0	0
Psychiatric disorders					
-Total	20 (46.5)	6 (14.0)	6 (14.0)	8 (18.6)	0
Anxiety	7 (16.3)	2 (4.7)	2 (4.7)	3 (7.0)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Agitation	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Confusional state	3 (7.0)	3 (7.0)	0	0	0
Irritability	3 (7.0)	2 (4.7)	0	1 (2.3)	0
Delirium	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hallucination	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Insomnia	2 (4.7)	0	2 (4.7)	0	0
Affect lability	1 (2.3)	0	1 (2.3)	0	0
Automatism	1 (2.3)	1 (2.3)	0	0	0
Hallucination, visual	1 (2.3)	0	1 (2.3)	0	0
Sleep disorder	1 (2.3)	0	1 (2.3)	0	0
Social avoidant behaviour	1 (2.3)	0	1 (2.3)	0	0
Tic	1 (2.3)	0	1 (2.3)	0	0
Renal and urinary disorders					
-Total	11 (25.6)	1 (2.3)	3 (7.0)	3 (7.0)	4 (9.3)
Acute kidney injury	7 (16.3)	0	1 (2.3)	3 (7.0)	3 (7.0)
Anuria	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Dysuria	2 (4.7)	2 (4.7)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pollakiuria	2 (4.7)	0	2 (4.7)	0	0
Urinary retention	2 (4.7)	0	2 (4.7)	0	0
Azotaemia	1 (2.3)	0	1 (2.3)	0	0
Bladder dilatation	1 (2.3)	0	1 (2.3)	0	0
Micturition urgency	1 (2.3)	0	1 (2.3)	0	0
Renal tubular necrosis	1 (2.3)	0	0	0	1 (2.3)
Urinary incontinence	1 (2.3)	0	1 (2.3)	0	0
Reproductive system and breast disorders					
-Total	6 (14.0)	1 (2.3)	3 (7.0)	2 (4.7)	0
Dysmenorrhoea	1 (2.3)	0	1 (2.3)	0	0
Endometriosis	1 (2.3)	0	0	1 (2.3)	0
Female genital tract fistula	1 (2.3)	1 (2.3)	0	0	0
Heavy menstrual bleeding	1 (2.3)	0	1 (2.3)	0	0
Perineal rash	1 (2.3)	0	1 (2.3)	0	0
Vaginal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Vaginal ulceration	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (67.4)	10 (23.3)	2 (4.7)	9 (20.9)	8 (18.6)
Cough	12 (27.9)	9 (20.9)	3 (7.0)	0	0
Hypoxia	9 (20.9)	0	1 (2.3)	6 (14.0)	2 (4.7)
Epistaxis	6 (14.0)	4 (9.3)	1 (2.3)	1 (2.3)	0
Pulmonary oedema	6 (14.0)	1 (2.3)	1 (2.3)	4 (9.3)	0
Dyspnoea	5 (11.6)	0	2 (4.7)	2 (4.7)	1 (2.3)
Nasal congestion	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Tachypnoea	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Acute respiratory distress syndrome	4 (9.3)	0	0	0	4 (9.3)
Oropharyngeal pain	4 (9.3)	4 (9.3)	0	0	0
Rhinorrhoea	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Respiratory failure	3 (7.0)	0	0	0	3 (7.0)
Atelectasis	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Pharyngeal erythema	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Acute respiratory failure	1 (2.3)	0	0	1 (2.3)	0
Bronchial oedema	1 (2.3)	1 (2.3)	0	0	0
Dyspnoea exertional	1 (2.3)	1 (2.3)	0	0	0
Haemoptysis	1 (2.3)	0	1 (2.3)	0	0

Gender: Female

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal discomfort	1 (2.3)	0	1 (2.3)	0	0
Nasal dryness	1 (2.3)	1 (2.3)	0	0	0
Oropharyngeal plaque	1 (2.3)	0	1 (2.3)	0	0
Paranasal sinus discomfort	1 (2.3)	0	1 (2.3)	0	0
Pharyngeal exudate	1 (2.3)	0	1 (2.3)	0	0
Pharyngeal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Pharyngeal oedema	1 (2.3)	0	1 (2.3)	0	0
Pleural effusion	1 (2.3)	1 (2.3)	0	0	0
Pulmonary mass	1 (2.3)	0	1 (2.3)	0	0
Respiratory acidosis	1 (2.3)	0	0	1 (2.3)	0
Respiratory distress	1 (2.3)	0	1 (2.3)	0	0
Rhinitis allergic	1 (2.3)	0	1 (2.3)	0	0
Sleep apnoea syndrome	1 (2.3)	0	1 (2.3)	0	0
Upper respiratory tract inflammation	1 (2.3)	0	1 (2.3)	0	0
Wheezing	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	22 (51.2)	11 (25.6)	7 (16.3)	4 (9.3)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	7 (16.3)	6 (14.0)	1 (2.3)	0	0
Pruritus	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Rash	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Erythema	3 (7.0)	3 (7.0)	0	0	0
Hyperhidrosis	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Ingrowing nail	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Rash maculo-papular	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Rash papular	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Decubitus ulcer	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Eczema	2 (4.7)	2 (4.7)	0	0	0
Petechiae	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Blister	1 (2.3)	1 (2.3)	0	0	0
Dermatitis atopic	1 (2.3)	1 (2.3)	0	0	0
Dermatitis diaper	1 (2.3)	0	1 (2.3)	0	0
Hangnail	1 (2.3)	1 (2.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.3)	1 (2.3)	0	0	0
Purpura	1 (2.3)	1 (2.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	1 (2.3)	1 (2.3)	0	0	0
Rash macular	1 (2.3)	0	0	1 (2.3)	0
Rash pruritic	1 (2.3)	1 (2.3)	0	0	0
Rash vesicular	1 (2.3)	1 (2.3)	0	0	0
Skin hypopigmentation	1 (2.3)	1 (2.3)	0	0	0
Skin lesion	1 (2.3)	0	1 (2.3)	0	0
Skin necrosis	1 (2.3)	0	0	1 (2.3)	0
Skin ulcer	1 (2.3)	1 (2.3)	0	0	0
Social circumstances					
-Total	1 (2.3)	0	1 (2.3)	0	0
Patient uncooperative	1 (2.3)	0	1 (2.3)	0	0
Surgical and medical procedures					
-Total	1 (2.3)	0	0	1 (2.3)	0
Thrombolysis	1 (2.3)	0	0	1 (2.3)	0
Vascular disorders					
-Total	15 (34.9)	2 (4.7)	2 (4.7)	4 (9.3)	7 (16.3)
Hypotension	12 (27.9)	1 (2.3)	0	4 (9.3)	7 (16.3)
Hypertension	8 (18.6)	1 (2.3)	5 (11.6)	2 (4.7)	0

Gender: Female

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flushing	1 (2.3)	1 (2.3)	0	0	0
Hot flush	1 (2.3)	1 (2.3)	0	0	0
Peripheral ischaemia	1 (2.3)	0	1 (2.3)	0	0
Thrombosis	1 (2.3)	0	1 (2.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208c
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (98.6)	0	3 (4.3)	17 (24.3)	49 (70.0)
Blood and lymphatic system disorders					
-Total	48 (68.6)	1 (1.4)	7 (10.0)	27 (38.6)	13 (18.6)
Anaemia	29 (41.4)	4 (5.7)	10 (14.3)	14 (20.0)	1 (1.4)
Febrile neutropenia	25 (35.7)	0	0	24 (34.3)	1 (1.4)
Neutropenia	12 (17.1)	1 (1.4)	2 (2.9)	3 (4.3)	6 (8.6)
Thrombocytopenia	9 (12.9)	0	1 (1.4)	3 (4.3)	5 (7.1)
Coagulopathy	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Disseminated intravascular coagulation	5 (7.1)	0	3 (4.3)	2 (2.9)	0
Pancytopenia	4 (5.7)	0	0	3 (4.3)	1 (1.4)
Leukopenia	3 (4.3)	0	0	1 (1.4)	2 (2.9)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
B-cell aplasia	1 (1.4)	0	1 (1.4)	0	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Leukocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Lymphocytosis	1 (1.4)	0	1 (1.4)	0	0
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Cardiac disorders					
-Total	26 (37.1)	7 (10.0)	7 (10.0)	9 (12.9)	3 (4.3)
Tachycardia	18 (25.7)	6 (8.6)	6 (8.6)	5 (7.1)	1 (1.4)
Bradycardia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Cardiac failure	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Left ventricular dysfunction	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Sinus tachycardia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Pericardial effusion	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	0	0	1 (1.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Cerebral cavernous malformation	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Ear pruritus	1 (1.4)	1 (1.4)	0	0	0
Vertigo	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	5 (7.1)	0	5 (7.1)	0	0
Adrenal insufficiency	3 (4.3)	0	3 (4.3)	0	0
Hypothyroidism	2 (2.9)	0	2 (2.9)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders					
-Total	14 (20.0)	9 (12.9)	4 (5.7)	1 (1.4)	0
Eye pain	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Eyelid oedema	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Ocular hyperaemia	3 (4.3)	3 (4.3)	0	0	0
Cataract	2 (2.9)	2 (2.9)	0	0	0
Conjunctival haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Visual impairment	2 (2.9)	2 (2.9)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Periorbital oedema	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0
Retinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	51 (72.9)	16 (22.9)	20 (28.6)	13 (18.6)	2 (2.9)
Nausea	23 (32.9)	9 (12.9)	12 (17.1)	2 (2.9)	0
Vomiting	22 (31.4)	15 (21.4)	7 (10.0)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Diarrhoea	19 (27.1)	12 (17.1)	5 (7.1)	2 (2.9)	0
Abdominal pain	13 (18.6)	4 (5.7)	7 (10.0)	2 (2.9)	0
Constipation	12 (17.1)	5 (7.1)	7 (10.0)	0	0
Stomatitis	7 (10.0)	0	4 (5.7)	3 (4.3)	0
Mouth haemorrhage	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Abdominal pain upper	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Ascites	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Gastrointestinal sounds abnormal	3 (4.3)	3 (4.3)	0	0	0
Gingival bleeding	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Abdominal compartment syndrome	2 (2.9)	0	0	0	2 (2.9)
Abdominal distension	2 (2.9)	0	2 (2.9)	0	0
Anal fissure	2 (2.9)	0	2 (2.9)	0	0
Dry mouth	2 (2.9)	0	2 (2.9)	0	0
Gastrointestinal haemorrhage	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Gingival erythema	2 (2.9)	2 (2.9)	0	0	0
Haematemesis	2 (2.9)	2 (2.9)	0	0	0
Ileus	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Neutropenic colitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancreatitis	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Proctalgia	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Anal fistula	1 (1.4)	0	0	1 (1.4)	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	1 (1.4)	0	0	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haemoperitoneum	1 (1.4)	0	0	0	1 (1.4)
Irritable bowel syndrome	1 (1.4)	0	1 (1.4)	0	0
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Melaena	1 (1.4)	0	0	1 (1.4)	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Oral disorder	1 (1.4)	1 (1.4)	0	0	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peritoneal haematoma	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	0	1 (1.4)	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	48 (68.6)	24 (34.3)	13 (18.6)	8 (11.4)	3 (4.3)
Pyrexia	33 (47.1)	15 (21.4)	9 (12.9)	7 (10.0)	2 (2.9)
Fatigue	16 (22.9)	13 (18.6)	3 (4.3)	0	0
Face oedema	8 (11.4)	5 (7.1)	2 (2.9)	1 (1.4)	0
Chills	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Oedema peripheral	7 (10.0)	5 (7.1)	1 (1.4)	1 (1.4)	0
Pain	7 (10.0)	1 (1.4)	5 (7.1)	1 (1.4)	0
Catheter site pain	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Asthenia	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Generalised oedema	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Localised oedema	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Influenza like illness	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Malaise	2 (2.9)	1 (1.4)	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site dermatitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Complication associated with device	1 (1.4)	1 (1.4)	0	0	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Drug withdrawal syndrome	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Multiple organ dysfunction syndrome	1 (1.4)	0	0	0	1 (1.4)
Non-cardiac chest pain	1 (1.4)	1 (1.4)	0	0	0
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Systemic inflammatory response syndrome	1 (1.4)	0	0	1 (1.4)	0
Thirst	1 (1.4)	1 (1.4)	0	0	0
Vascular device occlusion	1 (1.4)	1 (1.4)	0	0	0
Xerosis	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	16 (22.9)	6 (8.6)	7 (10.0)	2 (2.9)	1 (1.4)
Hyperbilirubinaemia	3 (4.3)	0	3 (4.3)	0	0
Hypertransaminasaemia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Cholelithiasis	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Gallbladder enlargement	2 (2.9)	2 (2.9)	0	0	0
Hepatic cytolysis	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Hepatomegaly	2 (2.9)	2 (2.9)	0	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Cholestasis	1 (1.4)	0	0	0	1 (1.4)
Drug-induced liver injury	1 (1.4)	0	0	1 (1.4)	0
Hepatic function abnormal	1 (1.4)	0	1 (1.4)	0	0
Hepatosplenomegaly	1 (1.4)	0	1 (1.4)	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Ocular icterus	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	53 (75.7)	1 (1.4)	19 (27.1)	21 (30.0)	12 (17.1)
Cytokine release syndrome	43 (61.4)	3 (4.3)	14 (20.0)	14 (20.0)	12 (17.1)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	27 (38.6)	1 (1.4)	18 (25.7)	8 (11.4)	0
Haemophagocytic lymphohistiocytosis	5 (7.1)	1 (1.4)	1 (1.4)	2 (2.9)	1 (1.4)
Graft versus host disease	3 (4.3)	0	0	3 (4.3)	0
Immunodeficiency	3 (4.3)	0	0	3 (4.3)	0
Drug hypersensitivity	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Seasonal allergy	2 (2.9)	0	2 (2.9)	0	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0	0	0
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	54 (77.1)	3 (4.3)	9 (12.9)	27 (38.6)	15 (21.4)
Upper respiratory tract infection	10 (14.3)	4 (5.7)	5 (7.1)	1 (1.4)	0
Conjunctivitis	8 (11.4)	3 (4.3)	5 (7.1)	0	0
Sinusitis	8 (11.4)	0	5 (7.1)	3 (4.3)	0
Pneumonia	7 (10.0)	1 (1.4)	2 (2.9)	3 (4.3)	1 (1.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	7 (10.0)	0	6 (8.6)	1 (1.4)	0
Staphylococcal infection	7 (10.0)	0	3 (4.3)	3 (4.3)	1 (1.4)
Gastroenteritis	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Nasopharyngitis	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Parainfluenzae virus infection	5 (7.1)	1 (1.4)	0	3 (4.3)	1 (1.4)
Paronychia	5 (7.1)	1 (1.4)	3 (4.3)	1 (1.4)	0
Candida infection	4 (5.7)	0	3 (4.3)	0	1 (1.4)
Clostridium difficile infection	4 (5.7)	1 (1.4)	0	3 (4.3)	0
Oral herpes	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Sepsis	4 (5.7)	0	0	1 (1.4)	3 (4.3)
Staphylococcal bacteraemia	4 (5.7)	0	0	4 (5.7)	0
Acute sinusitis	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Bacteraemia	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Bronchitis	3 (4.3)	0	3 (4.3)	0	0
Device related infection	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Gastroenteritis viral	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gingivitis	3 (4.3)	3 (4.3)	0	0	0
Herpes zoster	3 (4.3)	0	2 (2.9)	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Localised infection	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Metapneumovirus infection	3 (4.3)	0	0	3 (4.3)	0
Nail infection	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Oral candidiasis	3 (4.3)	0	3 (4.3)	0	0
Rhinitis	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Septic shock	3 (4.3)	0	0	0	3 (4.3)
Bronchiolitis	2 (2.9)	0	0	2 (2.9)	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Ear infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Encephalitis	2 (2.9)	0	0	0	2 (2.9)
Fungal infection	2 (2.9)	0	2 (2.9)	0	0
Herpes simplex	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Influenza	2 (2.9)	0	2 (2.9)	0	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Otitis media	2 (2.9)	0	2 (2.9)	0	0
Pneumocystis jirovecii pneumonia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Pneumonia fungal	2 (2.9)	0	0	2 (2.9)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Respiratory tract infection	2 (2.9)	0	2 (2.9)	0	0
Skin infection	2 (2.9)	0	2 (2.9)	0	0
Staphylococcal skin infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Urinary tract infection	2 (2.9)	0	2 (2.9)	0	0
Adenovirus infection	1 (1.4)	0	0	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Bk virus infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	1 (1.4)	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Clostridium difficile colitis	1 (1.4)	0	0	1 (1.4)	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Covid-19	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Cytomegalovirus infection reactivation	1 (1.4)	0	1 (1.4)	0	0
Device related bacteraemia	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Ear, nose and throat infection	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis escherichia coli	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Gastroenteritis salmonella	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal infection	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Human herpesvirus 6 infection	1 (1.4)	0	0	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	0	1 (1.4)	0	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Neutropenic infection	1 (1.4)	0	0	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection viral	1 (1.4)	0	1 (1.4)	0	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	0	0	1 (1.4)	0
Viral infection	1 (1.4)	0	1 (1.4)	0	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Vulval cellulitis	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	23 (32.9)	7 (10.0)	11 (15.7)	2 (2.9)	3 (4.3)
Infusion related reaction	5 (7.1)	1 (1.4)	3 (4.3)	1 (1.4)	0
Procedural pain	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Fall	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Transfusion reaction	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Wound	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Contusion	2 (2.9)	2 (2.9)	0	0	0
Ligament sprain	2 (2.9)	2 (2.9)	0	0	0
Skin abrasion	2 (2.9)	2 (2.9)	0	0	0
Fibula fracture	1 (1.4)	0	1 (1.4)	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Scratch	1 (1.4)	1 (1.4)	0	0	0
Skin injury	1 (1.4)	0	1 (1.4)	0	0
Skin wound	1 (1.4)	1 (1.4)	0	0	0
Tracheal obstruction	1 (1.4)	0	0	0	1 (1.4)
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Traumatic haematoma	1 (1.4)	0	1 (1.4)	0	0
Vasoplegia syndrome	1 (1.4)	0	0	0	1 (1.4)
Investigations					
-Total	49 (70.0)	1 (1.4)	5 (7.1)	17 (24.3)	26 (37.1)
White blood cell count decreased	22 (31.4)	3 (4.3)	3 (4.3)	1 (1.4)	15 (21.4)
Neutrophil count decreased	21 (30.0)	1 (1.4)	2 (2.9)	3 (4.3)	15 (21.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	21 (30.0)	5 (7.1)	2 (2.9)	4 (5.7)	10 (14.3)
Lymphocyte count decreased	19 (27.1)	1 (1.4)	1 (1.4)	8 (11.4)	9 (12.9)
Alanine aminotransferase increased	16 (22.9)	5 (7.1)	6 (8.6)	5 (7.1)	0
Aspartate aminotransferase increased	15 (21.4)	1 (1.4)	5 (7.1)	7 (10.0)	2 (2.9)
Blood bilirubin increased	9 (12.9)	1 (1.4)	1 (1.4)	7 (10.0)	0
C-reactive protein increased	7 (10.0)	2 (2.9)	1 (1.4)	4 (5.7)	0
International normalised ratio increased	7 (10.0)	5 (7.1)	2 (2.9)	0	0
Blood creatinine increased	6 (8.6)	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.4)
Blood immunoglobulin a decreased	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.6)	3 (4.3)	1 (1.4)	2 (2.9)	0
Weight increased	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Activated partial thromboplastin time prolonged	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Blood fibrinogen decreased	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Blood lactate dehydrogenase increased	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Electrocardiogram qt prolonged	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Weight decreased	4 (5.7)	0	2 (2.9)	2 (2.9)	0
Blood immunoglobulin g decreased	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Blood uric acid increased	3 (4.3)	2 (2.9)	0	0	1 (1.4)
Serum ferritin increased	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Amylase increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Blood fibrinogen increased	2 (2.9)	2 (2.9)	0	0	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Lipase increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Oxygen saturation decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Urine output decreased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Bacterial test positive	1 (1.4)	0	0	1 (1.4)	0
Blood alkaline phosphatase decreased	1 (1.4)	1 (1.4)	0	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	0	1 (1.4)
Blood glucose increased	1 (1.4)	0	0	0	1 (1.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood phosphorus decreased	1 (1.4)	0	0	1 (1.4)	0
Blood phosphorus increased	1 (1.4)	0	1 (1.4)	0	0
Blood potassium decreased	1 (1.4)	0	0	0	1 (1.4)
Blood testosterone decreased	1 (1.4)	1 (1.4)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0
Fibrin d dimer increased	1 (1.4)	1 (1.4)	0	0	0
Gamma-glutamyltransferase increased	1 (1.4)	0	0	1 (1.4)	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	43 (61.4)	6 (8.6)	9 (12.9)	18 (25.7)	10 (14.3)
Decreased appetite	26 (37.1)	10 (14.3)	7 (10.0)	7 (10.0)	2 (2.9)
Hypokalaemia	18 (25.7)	3 (4.3)	4 (5.7)	8 (11.4)	3 (4.3)
Hypophosphataemia	14 (20.0)	3 (4.3)	5 (7.1)	6 (8.6)	0
Hypocalcaemia	12 (17.1)	2 (2.9)	7 (10.0)	3 (4.3)	0
Hypervolaemia	7 (10.0)	1 (1.4)	2 (2.9)	4 (5.7)	0
Hypoalbuminaemia	7 (10.0)	0	7 (10.0)	0	0
Hyperuricaemia	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Hyperglycaemia	5 (7.1)	0	2 (2.9)	3 (4.3)	0
Hyperphosphataemia	5 (7.1)	5 (7.1)	0	0	0
Hypomagnesaemia	4 (5.7)	4 (5.7)	0	0	0
Metabolic acidosis	4 (5.7)	1 (1.4)	0	2 (2.9)	1 (1.4)
Hyperkalaemia	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Hypernatraemia	3 (4.3)	1 (1.4)	0	1 (1.4)	1 (1.4)
Hyponatraemia	3 (4.3)	2 (2.9)	0	0	1 (1.4)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	3 (4.3)	0	0	1 (1.4)	2 (2.9)
Hyperchloraemia	2 (2.9)	2 (2.9)	0	0	0
Hypermagnesaemia	2 (2.9)	2 (2.9)	0	0	0
Hypertriglyceridaemia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Acidosis	1 (1.4)	0	0	1 (1.4)	0
Dehydration	1 (1.4)	0	1 (1.4)	0	0
Eating disorder symptom	1 (1.4)	0	1 (1.4)	0	0
Haemochromatosis	1 (1.4)	0	0	1 (1.4)	0
Haemosiderosis	1 (1.4)	0	1 (1.4)	0	0
Hypercalcaemia	1 (1.4)	0	0	1 (1.4)	0
Hyperlactacidaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperlipidaemia	1 (1.4)	0	1 (1.4)	0	0
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	35 (50.0)	15 (21.4)	15 (21.4)	4 (5.7)	1 (1.4)
Pain in extremity	19 (27.1)	8 (11.4)	10 (14.3)	1 (1.4)	0
Arthralgia	8 (11.4)	4 (5.7)	4 (5.7)	0	0
Back pain	8 (11.4)	2 (2.9)	3 (4.3)	3 (4.3)	0
Myalgia	8 (11.4)	4 (5.7)	4 (5.7)	0	0
Bone pain	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Neck pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Pain in jaw	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Groin pain	1 (1.4)	1 (1.4)	0	0	0
Growth retardation	1 (1.4)	0	1 (1.4)	0	0
Joint effusion	1 (1.4)	0	0	1 (1.4)	0
Muscle rigidity	1 (1.4)	1 (1.4)	0	0	0
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Muscular weakness	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myositis	1 (1.4)	0	1 (1.4)	0	0
Osteonecrosis	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhabdomyolysis	1 (1.4)	0	0	0	1 (1.4)
Spinal pain	1 (1.4)	0	0	1 (1.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Bone giant cell tumour benign	1 (1.4)	0	0	1 (1.4)	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	42 (60.0)	13 (18.6)	14 (20.0)	11 (15.7)	4 (5.7)
Headache	26 (37.1)	13 (18.6)	10 (14.3)	3 (4.3)	0
Encephalopathy	9 (12.9)	1 (1.4)	3 (4.3)	5 (7.1)	0
Somnolence	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Dizziness	5 (7.1)	5 (7.1)	0	0	0
Tremor	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Seizure	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cerebral haemorrhage	2 (2.9)	0	0	0	2 (2.9)
Dysarthria	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Dysgeusia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Autonomic neuropathy	1 (1.4)	0	0	1 (1.4)	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Memory impairment	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Monoparesis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorder	1 (1.4)	0	0	1 (1.4)	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Psychiatric disorders					

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	31 (44.3)	11 (15.7)	13 (18.6)	7 (10.0)	0
Anxiety	9 (12.9)	4 (5.7)	4 (5.7)	1 (1.4)	0
Delirium	7 (10.0)	2 (2.9)	2 (2.9)	3 (4.3)	0
Agitation	6 (8.6)	3 (4.3)	3 (4.3)	0	0
Confusional state	5 (7.1)	5 (7.1)	0	0	0
Insomnia	5 (7.1)	2 (2.9)	3 (4.3)	0	0
Mental status changes	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Irritability	4 (5.7)	3 (4.3)	0	1 (1.4)	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Sleep disorder	3 (4.3)	0	3 (4.3)	0	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Automatism	1 (1.4)	1 (1.4)	0	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Persistent depressive disorder	1 (1.4)	0	1 (1.4)	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tic	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	24 (34.3)	8 (11.4)	5 (7.1)	6 (8.6)	5 (7.1)
Acute kidney injury	12 (17.1)	4 (5.7)	2 (2.9)	3 (4.3)	3 (4.3)
Dysuria	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Haematuria	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Anuria	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Pollakiuria	2 (2.9)	0	2 (2.9)	0	0
Renal failure	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Renal tubular necrosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Azotaemia	1 (1.4)	0	1 (1.4)	0	0
Bladder dilatation	1 (1.4)	0	1 (1.4)	0	0
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal pain	1 (1.4)	1 (1.4)	0	0	0
Renal tubular disorder	1 (1.4)	0	0	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	5 (7.1)	0	3 (4.3)	2 (2.9)	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Heavy menstrual bleeding	1 (1.4)	0	1 (1.4)	0	0
Perineal rash	1 (1.4)	0	1 (1.4)	0	0
Prostatitis	1 (1.4)	0	0	1 (1.4)	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Vaginal ulceration	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	45 (64.3)	16 (22.9)	5 (7.1)	10 (14.3)	14 (20.0)
Cough	21 (30.0)	17 (24.3)	4 (5.7)	0	0
Hypoxia	15 (21.4)	0	5 (7.1)	8 (11.4)	2 (2.9)
Pulmonary oedema	12 (17.1)	3 (4.3)	3 (4.3)	4 (5.7)	2 (2.9)

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	11 (15.7)	7 (10.0)	2 (2.9)	2 (2.9)	0
Nasal congestion	9 (12.9)	7 (10.0)	2 (2.9)	0	0
Oropharyngeal pain	9 (12.9)	7 (10.0)	2 (2.9)	0	0
Respiratory failure	8 (11.4)	0	0	0	8 (11.4)
Tachypnoea	7 (10.0)	2 (2.9)	1 (1.4)	4 (5.7)	0
Dyspnoea	6 (8.6)	1 (1.4)	2 (2.9)	2 (2.9)	1 (1.4)
Pleural effusion	6 (8.6)	3 (4.3)	1 (1.4)	2 (2.9)	0
Respiratory distress	4 (5.7)	0	2 (2.9)	0	2 (2.9)
Rhinorrhoea	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Acute respiratory distress syndrome	3 (4.3)	0	0	0	3 (4.3)
Atelectasis	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Pharyngeal erythema	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Acute respiratory failure	1 (1.4)	0	0	1 (1.4)	0
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Dyspnoea exertional	1 (1.4)	1 (1.4)	0	0	0
Laryngeal oedema	1 (1.4)	0	0	0	1 (1.4)
Lung disorder	1 (1.4)	1 (1.4)	0	0	0
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasal discomfort	1 (1.4)	0	1 (1.4)	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory acidosis	1 (1.4)	0	0	1 (1.4)	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0
Rhinitis allergic	1 (1.4)	1 (1.4)	0	0	0
Sleep apnoea syndrome	1 (1.4)	1 (1.4)	0	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	38 (54.3)	17 (24.3)	15 (21.4)	6 (8.6)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	9 (12.9)	4 (5.7)	5 (7.1)	0	0
Dry skin	8 (11.4)	6 (8.6)	2 (2.9)	0	0
Pruritus	7 (10.0)	2 (2.9)	5 (7.1)	0	0
Erythema	5 (7.1)	5 (7.1)	0	0	0
Ingrowing nail	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Rash papular	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Blister	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Dermatitis atopic	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Eczema	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Hyperhidrosis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Petechiae	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Skin ulcer	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Rash maculo-papular	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Skin discolouration	2 (2.9)	2 (2.9)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Decubitus ulcer	1 (1.4)	0	1 (1.4)	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis allergic	1 (1.4)	1 (1.4)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dermatitis diaper	1 (1.4)	0	1 (1.4)	0	0
Drug eruption	1 (1.4)	0	1 (1.4)	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Miliaria	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.4)	1 (1.4)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Rash erythematous	1 (1.4)	1 (1.4)	0	0	0
Rash macular	1 (1.4)	0	0	1 (1.4)	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Scab	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin necrosis	1 (1.4)	0	0	1 (1.4)	0

Race: White

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	29 (41.4)	4 (5.7)	7 (10.0)	11 (15.7)	7 (10.0)
Hypotension	26 (37.1)	2 (2.9)	6 (8.6)	11 (15.7)	7 (10.0)
Hypertension	10 (14.3)	3 (4.3)	6 (8.6)	1 (1.4)	0
Flushing	2 (2.9)	2 (2.9)	0	0	0
Peripheral ischaemia	2 (2.9)	0	2 (2.9)	0	0
Capillary leak syndrome	1 (1.4)	0	1 (1.4)	0	0
Haematoma	1 (1.4)	1 (1.4)	0	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Thrombosis	1 (1.4)	0	1 (1.4)	0	0
Venoocclusive disease	1 (1.4)	0	0	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208c
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (86.7)	0	2 (13.3)	3 (20.0)	8 (53.3)
Blood and lymphatic system disorders					
-Total	8 (53.3)	0	1 (6.7)	2 (13.3)	5 (33.3)
Febrile neutropenia	4 (26.7)	0	0	4 (26.7)	0
Neutropenia	4 (26.7)	0	0	0	4 (26.7)
Disseminated intravascular coagulation	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Leukopenia	2 (13.3)	0	0	0	2 (13.3)
Thrombocytopenia	2 (13.3)	0	0	0	2 (13.3)
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Hypofibrinogenaemia	1 (6.7)	0	1 (6.7)	0	0
Lymphopenia	1 (6.7)	0	0	0	1 (6.7)

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	1 (6.7)	1 (6.7)	0	0	0
Cardiac disorders					
-Total	5 (33.3)	2 (13.3)	0	1 (6.7)	2 (13.3)
Cardiac dysfunction	2 (13.3)	2 (13.3)	0	0	0
Cardiac arrest	1 (6.7)	0	0	0	1 (6.7)
Cardiac failure	1 (6.7)	0	0	0	1 (6.7)
Left ventricular dysfunction	1 (6.7)	0	0	1 (6.7)	0
Tachycardia	1 (6.7)	0	1 (6.7)	0	0
Eye disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Mydriasis	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal disorders					
-Total	10 (66.7)	2 (13.3)	5 (33.3)	3 (20.0)	0
Nausea	4 (26.7)	3 (20.0)	1 (6.7)	0	0
Constipation	3 (20.0)	3 (20.0)	0	0	0
Diarrhoea	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Abdominal pain	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pancreatitis	2 (13.3)	0	2 (13.3)	0	0

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Vomiting	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Anal inflammation	1 (6.7)	0	0	1 (6.7)	0
Duodenal perforation	1 (6.7)	0	0	1 (6.7)	0
Enteritis	1 (6.7)	0	1 (6.7)	0	0
Enterocolitis	1 (6.7)	0	1 (6.7)	0	0
Gastritis	1 (6.7)	0	1 (6.7)	0	0
Haematemesis	1 (6.7)	1 (6.7)	0	0	0
Haemorrhoids	1 (6.7)	0	1 (6.7)	0	0
Oral pain	1 (6.7)	0	0	1 (6.7)	0
Trichoglossia	1 (6.7)	1 (6.7)	0	0	0
General disorders and administration site conditions					
-Total	3 (20.0)	1 (6.7)	1 (6.7)	1 (6.7)	0
Pyrexia	3 (20.0)	1 (6.7)	1 (6.7)	1 (6.7)	0
Fatigue	1 (6.7)	1 (6.7)	0	0	0
Hepatobiliary disorders					
-Total	5 (33.3)	0	1 (6.7)	2 (13.3)	2 (13.3)

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic function abnormal	4 (26.7)	0	1 (6.7)	2 (13.3)	1 (6.7)
Hepatomegaly	1 (6.7)	0	0	0	1 (6.7)
Immune system disorders					
-Total	9 (60.0)	0	4 (26.7)	2 (13.3)	3 (20.0)
Cytokine release syndrome	8 (53.3)	1 (6.7)	2 (13.3)	2 (13.3)	3 (20.0)
Hypogammaglobulinaemia	5 (33.3)	0	5 (33.3)	0	0
Seasonal allergy	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	12 (80.0)	3 (20.0)	2 (13.3)	6 (40.0)	1 (6.7)
Bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Bk virus infection	1 (6.7)	1 (6.7)	0	0	0
Bronchopulmonary aspergillosis	1 (6.7)	0	0	1 (6.7)	0
Catheter site infection	1 (6.7)	0	1 (6.7)	0	0
Cytomegalovirus infection reactivation	1 (6.7)	0	0	1 (6.7)	0
Encephalitis viral	1 (6.7)	0	0	0	1 (6.7)
Epstein-barr virus infection	1 (6.7)	0	1 (6.7)	0	0
Escherichia bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Fungal skin infection	1 (6.7)	0	1 (6.7)	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (6.7)	0	0	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Meningitis bacterial	1 (6.7)	0	0	1 (6.7)	0
Nasopharyngitis	1 (6.7)	1 (6.7)	0	0	0
Oral herpes	1 (6.7)	0	0	1 (6.7)	0
Otitis externa	1 (6.7)	0	1 (6.7)	0	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Peritonitis	1 (6.7)	0	0	1 (6.7)	0
Pneumonia	1 (6.7)	0	0	1 (6.7)	0
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Tinea pedis	1 (6.7)	1 (6.7)	0	0	0
Upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Urinary tract infection viral	1 (6.7)	1 (6.7)	0	0	0
Varicella zoster virus infection	1 (6.7)	0	1 (6.7)	0	0
Viral infection	1 (6.7)	0	0	1 (6.7)	0
Investigations					
-Total	7 (46.7)	0	1 (6.7)	2 (13.3)	4 (26.7)

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	5 (33.3)	1 (6.7)	3 (20.0)	1 (6.7)	0
White blood cell count decreased	4 (26.7)	0	0	0	4 (26.7)
Blood fibrinogen decreased	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Alanine aminotransferase increased	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Aspartate aminotransferase increased	2 (13.3)	1 (6.7)	0	1 (6.7)	0
C-reactive protein increased	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Neutrophil count decreased	2 (13.3)	0	0	0	2 (13.3)
Blood bilirubin increased	1 (6.7)	0	0	1 (6.7)	0
Blood creatine phosphokinase increased	1 (6.7)	0	0	1 (6.7)	0
Blood glucose increased	1 (6.7)	1 (6.7)	0	0	0
Blood lactate dehydrogenase increased	1 (6.7)	0	0	1 (6.7)	0
Eosinophil count decreased	1 (6.7)	1 (6.7)	0	0	0
Fibrin d dimer increased	1 (6.7)	1 (6.7)	0	0	0
Gamma-glutamyltransferase increased	1 (6.7)	0	0	1 (6.7)	0
Haematocrit decreased	1 (6.7)	1 (6.7)	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haptoglobin decreased	1 (6.7)	1 (6.7)	0	0	0
International normalised ratio increased	1 (6.7)	0	1 (6.7)	0	0
Platelet count decreased	1 (6.7)	0	0	1 (6.7)	0
Red blood cell count decreased	1 (6.7)	1 (6.7)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (40.0)	2 (13.3)	1 (6.7)	1 (6.7)	2 (13.3)
Decreased appetite	2 (13.3)	2 (13.3)	0	0	0
Metabolic acidosis	2 (13.3)	0	0	0	2 (13.3)
Tumour lysis syndrome	2 (13.3)	0	0	2 (13.3)	0
Hypercalcaemia	1 (6.7)	0	0	0	1 (6.7)
Hypercholesterolaemia	1 (6.7)	0	1 (6.7)	0	0
Hyperkalaemia	1 (6.7)	0	0	0	1 (6.7)
Hyperphosphataemia	1 (6.7)	0	0	0	1 (6.7)
Hypertriglyceridaemia	1 (6.7)	0	1 (6.7)	0	0
Hyperuricaemia	1 (6.7)	1 (6.7)	0	0	0
Hypoalbuminaemia	1 (6.7)	0	1 (6.7)	0	0
Iron overload	1 (6.7)	0	1 (6.7)	0	0

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (6.7)	1 (6.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (40.0)	2 (13.3)	2 (13.3)	2 (13.3)	0
Arthralgia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Pain in extremity	3 (20.0)	1 (6.7)	1 (6.7)	1 (6.7)	0
Back pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Joint effusion	1 (6.7)	0	1 (6.7)	0	0
Muscular weakness	1 (6.7)	0	0	1 (6.7)	0
Musculoskeletal chest pain	1 (6.7)	1 (6.7)	0	0	0
Synovitis	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	5 (33.3)	2 (13.3)	2 (13.3)	0	1 (6.7)
Headache	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Seizure	2 (13.3)	0	2 (13.3)	0	0
Haemorrhage intracranial	1 (6.7)	0	0	0	1 (6.7)
Posterior reversible encephalopathy syndrome	1 (6.7)	0	1 (6.7)	0	0
Psychiatric disorders					

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Anxiety	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Delirium	1 (6.7)	0	1 (6.7)	0	0
Renal and urinary disorders					
-Total	4 (26.7)	1 (6.7)	1 (6.7)	0	2 (13.3)
Acute kidney injury	2 (13.3)	0	0	0	2 (13.3)
Cystitis haemorrhagic	1 (6.7)	0	1 (6.7)	0	0
Haematuria	1 (6.7)	1 (6.7)	0	0	0
Proteinuria	1 (6.7)	1 (6.7)	0	0	0
Reproductive system and breast disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Endometriosis	1 (6.7)	0	0	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (53.3)	2 (13.3)	2 (13.3)	0	4 (26.7)
Hypoxia	4 (26.7)	0	0	0	4 (26.7)
Pleural effusion	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Cough	1 (6.7)	1 (6.7)	0	0	0

Race: Asian

	All patients N=15				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (6.7)	0	0	1 (6.7)	0
Haemoptysis	1 (6.7)	0	1 (6.7)	0	0
Nasal congestion	1 (6.7)	1 (6.7)	0	0	0
Nasal dryness	1 (6.7)	1 (6.7)	0	0	0
Oropharyngeal pain	1 (6.7)	1 (6.7)	0	0	0
Respiratory failure	1 (6.7)	0	0	0	1 (6.7)
Upper respiratory tract inflammation	1 (6.7)	0	1 (6.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (33.3)	4 (26.7)	1 (6.7)	0	0
Pruritus	3 (20.0)	3 (20.0)	0	0	0
Dry skin	1 (6.7)	1 (6.7)	0	0	0
Erythema nodosum	1 (6.7)	1 (6.7)	0	0	0
Skin swelling	1 (6.7)	1 (6.7)	0	0	0
Skin ulcer	1 (6.7)	0	1 (6.7)	0	0
Vascular disorders					
-Total	5 (33.3)	0	3 (20.0)	1 (6.7)	1 (6.7)
Hypertension	3 (20.0)	0	3 (20.0)	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (13.3)	0	0	1 (6.7)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208c
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	0	0	13 (100)
Blood and lymphatic system disorders					
-Total	11 (84.6)	0	1 (7.7)	8 (61.5)	2 (15.4)
Febrile neutropenia	10 (76.9)	0	0	8 (61.5)	2 (15.4)
Anaemia	8 (61.5)	1 (7.7)	1 (7.7)	6 (46.2)	0
Thrombocytopenia	2 (15.4)	0	0	2 (15.4)	0
Hypercoagulation	1 (7.7)	0	1 (7.7)	0	0
Lymphadenopathy	1 (7.7)	1 (7.7)	0	0	0
Cardiac disorders					
-Total	4 (30.8)	1 (7.7)	1 (7.7)	1 (7.7)	1 (7.7)
Tachycardia	2 (15.4)	1 (7.7)	1 (7.7)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac arrest	1 (7.7)	0	0	0	1 (7.7)
Left ventricular dysfunction	1 (7.7)	0	0	1 (7.7)	0
Sinus bradycardia	1 (7.7)	0	0	1 (7.7)	0
Endocrine disorders					
-Total	4 (30.8)	0	4 (30.8)	0	0
Adrenal insufficiency	3 (23.1)	0	3 (23.1)	0	0
Delayed puberty	1 (7.7)	0	1 (7.7)	0	0
Hypothyroidism	1 (7.7)	0	1 (7.7)	0	0
Eye disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Dry eye	1 (7.7)	1 (7.7)	0	0	0
Vision blurred	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	11 (84.6)	2 (15.4)	5 (38.5)	4 (30.8)	0
Nausea	6 (46.2)	2 (15.4)	3 (23.1)	1 (7.7)	0
Vomiting	6 (46.2)	4 (30.8)	1 (7.7)	1 (7.7)	0
Diarrhoea	5 (38.5)	3 (23.1)	2 (15.4)	0	0
Constipation	4 (30.8)	1 (7.7)	3 (23.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abdominal pain	2 (15.4)	0	2 (15.4)	0	0
Pancreatitis	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Stomatitis	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Abdominal distension	1 (7.7)	1 (7.7)	0	0	0
Anal erythema	1 (7.7)	1 (7.7)	0	0	0
Haematemesis	1 (7.7)	1 (7.7)	0	0	0
Lip oedema	1 (7.7)	1 (7.7)	0	0	0
Lip pain	1 (7.7)	1 (7.7)	0	0	0
Lip ulceration	1 (7.7)	0	1 (7.7)	0	0
Mouth haemorrhage	1 (7.7)	0	0	1 (7.7)	0
General disorders and administration site conditions					
-Total	12 (92.3)	4 (30.8)	2 (15.4)	4 (30.8)	2 (15.4)
Pyrexia	7 (53.8)	2 (15.4)	2 (15.4)	3 (23.1)	0
Chills	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Fatigue	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Generalised oedema	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Multiple organ dysfunction syndrome	2 (15.4)	0	0	0	2 (15.4)

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Drug withdrawal syndrome	1 (7.7)	0	1 (7.7)	0	0
Non-cardiac chest pain	1 (7.7)	1 (7.7)	0	0	0
Oedema peripheral	1 (7.7)	1 (7.7)	0	0	0
Pain	1 (7.7)	0	0	1 (7.7)	0
Vascular device occlusion	1 (7.7)	1 (7.7)	0	0	0
Hepatobiliary disorders					
-Total	3 (23.1)	1 (7.7)	0	2 (15.4)	0
Hyperbilirubinaemia	3 (23.1)	1 (7.7)	0	2 (15.4)	0
Immune system disorders					
-Total	11 (84.6)	1 (7.7)	1 (7.7)	2 (15.4)	7 (53.8)
Cytokine release syndrome	10 (76.9)	1 (7.7)	2 (15.4)	1 (7.7)	6 (46.2)
Hypogammaglobulinaemia	4 (30.8)	1 (7.7)	3 (23.1)	0	0
Seasonal allergy	2 (15.4)	2 (15.4)	0	0	0
Allergy to immunoglobulin therapy	1 (7.7)	0	0	1 (7.7)	0
Chronic graft versus host disease	1 (7.7)	0	0	1 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Immunodeficiency	1 (7.7)	0	0	1 (7.7)	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	10 (76.9)	0	2 (15.4)	4 (30.8)	4 (30.8)
Upper respiratory tract infection	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Nasopharyngitis	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Otitis media	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Parainfluenzae virus infection	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Pneumonia	2 (15.4)	0	0	0	2 (15.4)
Rhinovirus infection	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Staphylococcal bacteraemia	2 (15.4)	0	0	2 (15.4)	0
Adenovirus infection	1 (7.7)	0	0	1 (7.7)	0
Bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Conjunctivitis	1 (7.7)	0	1 (7.7)	0	0
Covid-19	1 (7.7)	1 (7.7)	0	0	0
Covid-19 pneumonia	1 (7.7)	0	0	0	1 (7.7)
Ear infection	1 (7.7)	0	1 (7.7)	0	0
Encephalitis viral	1 (7.7)	0	0	1 (7.7)	0
Enterobacter infection	1 (7.7)	0	0	1 (7.7)	0
Enterovirus infection	1 (7.7)	0	0	1 (7.7)	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (7.7)	0	0	0	1 (7.7)
Fungaemia	1 (7.7)	0	0	0	1 (7.7)
Gastroenteritis	1 (7.7)	0	1 (7.7)	0	0
Herpes zoster	1 (7.7)	0	0	1 (7.7)	0
Influenza	1 (7.7)	0	0	0	1 (7.7)
Klebsiella infection	1 (7.7)	0	0	1 (7.7)	0
Mastoiditis	1 (7.7)	0	0	1 (7.7)	0
Nail infection	1 (7.7)	1 (7.7)	0	0	0
Oral herpes	1 (7.7)	0	0	1 (7.7)	0
Otitis externa	1 (7.7)	0	0	1 (7.7)	0
Pharyngitis streptococcal	1 (7.7)	0	0	1 (7.7)	0
Respiratory syncytial virus infection	1 (7.7)	0	0	1 (7.7)	0
Respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0
Skin infection	1 (7.7)	0	1 (7.7)	0	0
Syphilis	1 (7.7)	0	1 (7.7)	0	0
Urinary tract infection	1 (7.7)	0	0	1 (7.7)	0
Viral upper respiratory tract infection	1 (7.7)	0	0	1 (7.7)	0

Race: Other

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	4 (30.8)	2 (15.4)	1 (7.7)	1 (7.7)	0
Abdominal injury	1 (7.7)	1 (7.7)	0	0	0
Extradural haematoma	1 (7.7)	0	1 (7.7)	0	0
Infusion related reaction	1 (7.7)	1 (7.7)	0	0	0
Transfusion reaction	1 (7.7)	0	0	1 (7.7)	0
Investigations					
-Total	10 (76.9)	0	0	1 (7.7)	9 (69.2)
Neutrophil count decreased	6 (46.2)	0	0	0	6 (46.2)
Platelet count decreased	6 (46.2)	1 (7.7)	0	1 (7.7)	4 (30.8)
White blood cell count decreased	6 (46.2)	0	0	0	6 (46.2)
Alanine aminotransferase increased	4 (30.8)	0	1 (7.7)	3 (23.1)	0
Aspartate aminotransferase increased	4 (30.8)	0	0	2 (15.4)	2 (15.4)
Lymphocyte count decreased	4 (30.8)	0	0	1 (7.7)	3 (23.1)
Blood bilirubin increased	3 (23.1)	0	1 (7.7)	2 (15.4)	0
Serum ferritin increased	3 (23.1)	1 (7.7)	0	1 (7.7)	1 (7.7)

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Blood lactate dehydrogenase increased	2 (15.4)	0	0	2 (15.4)	0
C-reactive protein increased	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Fibrin d dimer increased	2 (15.4)	0	0	1 (7.7)	1 (7.7)
International normalised ratio increased	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Blood creatinine increased	1 (7.7)	0	0	1 (7.7)	0
Blood fibrinogen decreased	1 (7.7)	0	0	0	1 (7.7)
Blood fibrinogen increased	1 (7.7)	0	1 (7.7)	0	0
Blood immunoglobulin a decreased	1 (7.7)	1 (7.7)	0	0	0
Blood immunoglobulin g decreased	1 (7.7)	0	1 (7.7)	0	0
Blood immunoglobulin m decreased	1 (7.7)	1 (7.7)	0	0	0
Blood phosphorus increased	1 (7.7)	0	1 (7.7)	0	0
Blood uric acid increased	1 (7.7)	0	0	1 (7.7)	0
Electrocardiogram qt prolonged	1 (7.7)	0	0	0	1 (7.7)
Electrocardiogram t wave abnormal	1 (7.7)	0	1 (7.7)	0	0
Oxygen saturation decreased	1 (7.7)	0	0	1 (7.7)	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Troponin increased	1 (7.7)	0	0	1 (7.7)	0
Metabolism and nutrition disorders					
-Total	10 (76.9)	0	1 (7.7)	7 (53.8)	2 (15.4)
Hypokalaemia	7 (53.8)	1 (7.7)	1 (7.7)	5 (38.5)	0
Hypophosphataemia	7 (53.8)	0	3 (23.1)	3 (23.1)	1 (7.7)
Decreased appetite	6 (46.2)	0	1 (7.7)	5 (38.5)	0
Hypocalcaemia	6 (46.2)	0	3 (23.1)	3 (23.1)	0
Hypomagnesaemia	5 (38.5)	3 (23.1)	2 (15.4)	0	0
Hyperglycaemia	4 (30.8)	0	2 (15.4)	2 (15.4)	0
Hypoalbuminaemia	4 (30.8)	0	3 (23.1)	1 (7.7)	0
Hyperuricaemia	2 (15.4)	2 (15.4)	0	0	0
Hypervolaemia	2 (15.4)	0	0	2 (15.4)	0
Acidosis	1 (7.7)	0	0	0	1 (7.7)
Calcium deficiency	1 (7.7)	1 (7.7)	0	0	0
Hypercalcaemia	1 (7.7)	0	1 (7.7)	0	0
Hypoglycaemia	1 (7.7)	0	1 (7.7)	0	0
Hyponatraemia	1 (7.7)	1 (7.7)	0	0	0
Hypophagia	1 (7.7)	0	1 (7.7)	0	0

Race: Other

	All patients N=13				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (7.7)	0	0	1 (7.7)	0
Obesity	1 (7.7)	0	0	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (53.8)	1 (7.7)	2 (15.4)	4 (30.8)	0
Arthralgia	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Back pain	2 (15.4)	0	2 (15.4)	0	0
Myalgia	2 (15.4)	2 (15.4)	0	0	0
Bone pain	1 (7.7)	0	1 (7.7)	0	0
Growth retardation	1 (7.7)	0	1 (7.7)	0	0
Haemarthrosis	1 (7.7)	0	0	1 (7.7)	0
Myopathy	1 (7.7)	0	0	1 (7.7)	0
Osteopenia	1 (7.7)	1 (7.7)	0	0	0
Pain in extremity	1 (7.7)	0	0	1 (7.7)	0
Pain in jaw	1 (7.7)	0	0	1 (7.7)	0
Nervous system disorders					
-Total	8 (61.5)	2 (15.4)	4 (30.8)	2 (15.4)	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cognitive disorder	3 (23.1)	0	2 (15.4)	1 (7.7)	0
Headache	3 (23.1)	1 (7.7)	2 (15.4)	0	0
Paraesthesia	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Amnesia	1 (7.7)	0	1 (7.7)	0	0
Dysgeusia	1 (7.7)	1 (7.7)	0	0	0
Extrapyramidal disorder	1 (7.7)	0	1 (7.7)	0	0
Hyperaesthesia	1 (7.7)	1 (7.7)	0	0	0
Lethargy	1 (7.7)	1 (7.7)	0	0	0
Neuralgia	1 (7.7)	0	1 (7.7)	0	0
Neuropathy peripheral	1 (7.7)	0	0	1 (7.7)	0
Tremor	1 (7.7)	1 (7.7)	0	0	0
Psychiatric disorders					
-Total	8 (61.5)	2 (15.4)	4 (30.8)	2 (15.4)	0
Anxiety	5 (38.5)	0	4 (30.8)	1 (7.7)	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Agitation	1 (7.7)	1 (7.7)	0	0	0
Hallucination, visual	1 (7.7)	0	1 (7.7)	0	0
Insomnia	1 (7.7)	0	1 (7.7)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (7.7)	0	0	1 (7.7)	0
Renal and urinary disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Acute kidney injury	1 (7.7)	1 (7.7)	0	0	0
Urinary retention	1 (7.7)	0	1 (7.7)	0	0
Reproductive system and breast disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Female genital tract fistula	1 (7.7)	1 (7.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (69.2)	1 (7.7)	1 (7.7)	3 (23.1)	4 (30.8)
Cough	4 (30.8)	3 (23.1)	1 (7.7)	0	0
Tachypnoea	3 (23.1)	1 (7.7)	1 (7.7)	0	1 (7.7)
Hypoxia	2 (15.4)	0	0	2 (15.4)	0
Pleural effusion	2 (15.4)	0	1 (7.7)	0	1 (7.7)
Pulmonary oedema	2 (15.4)	0	0	2 (15.4)	0
Rhinorrhoea	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Acute respiratory distress syndrome	1 (7.7)	0	0	0	1 (7.7)

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchial oedema	1 (7.7)	1 (7.7)	0	0	0
Bronchospasm	1 (7.7)	0	1 (7.7)	0	0
Dyspnoea	1 (7.7)	0	0	0	1 (7.7)
Epistaxis	1 (7.7)	0	0	1 (7.7)	0
Nasal congestion	1 (7.7)	1 (7.7)	0	0	0
Pulmonary haemorrhage	1 (7.7)	0	0	0	1 (7.7)
Respiratory failure	1 (7.7)	0	0	0	1 (7.7)
Rhinitis allergic	1 (7.7)	0	1 (7.7)	0	0
Sleep apnoea syndrome	1 (7.7)	0	1 (7.7)	0	0
Wheezing	1 (7.7)	0	1 (7.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (38.5)	1 (7.7)	2 (15.4)	2 (15.4)	0
Rash maculo-papular	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Decubitus ulcer	1 (7.7)	0	0	1 (7.7)	0
Erythema	1 (7.7)	0	1 (7.7)	0	0
Pruritus	1 (7.7)	0	1 (7.7)	0	0
Purpura	1 (7.7)	1 (7.7)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	1 (7.7)	1 (7.7)	0	0	0
Surgical and medical procedures					
-Total	1 (7.7)	0	0	1 (7.7)	0
Thrombolysis	1 (7.7)	0	0	1 (7.7)	0
Vascular disorders					
-Total	9 (69.2)	1 (7.7)	1 (7.7)	4 (30.8)	3 (23.1)
Hypertension	6 (46.2)	1 (7.7)	1 (7.7)	4 (30.8)	0
Hypotension	2 (15.4)	0	0	0	2 (15.4)
Capillary leak syndrome	1 (7.7)	0	0	1 (7.7)	0
Venoocclusive disease	1 (7.7)	0	0	0	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208d
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	0	2 (11.1)	16 (88.9)
Blood and lymphatic system disorders					
-Total	12 (66.7)	0	1 (5.6)	8 (44.4)	3 (16.7)
Febrile neutropenia	10 (55.6)	0	0	8 (44.4)	2 (11.1)
Anaemia	7 (38.9)	0	1 (5.6)	5 (27.8)	1 (5.6)
Thrombocytopenia	3 (16.7)	0	0	3 (16.7)	0
Coagulopathy	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Disseminated intravascular coagulation	1 (5.6)	0	1 (5.6)	0	0
Leukocytosis	1 (5.6)	0	1 (5.6)	0	0
Cardiac disorders					
-Total	7 (38.9)	1 (5.6)	3 (16.7)	2 (11.1)	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	4 (22.2)	0	3 (16.7)	1 (5.6)	0
Sinus tachycardia	2 (11.1)	2 (11.1)	0	0	0
Cardiac arrest	1 (5.6)	0	0	0	1 (5.6)
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0
Sinus bradycardia	1 (5.6)	0	0	1 (5.6)	0
Endocrine disorders					
-Total	5 (27.8)	0	5 (27.8)	0	0
Adrenal insufficiency	4 (22.2)	0	4 (22.2)	0	0
Delayed puberty	1 (5.6)	0	1 (5.6)	0	0
Hypothyroidism	1 (5.6)	0	1 (5.6)	0	0
Eye disorders					
-Total	2 (11.1)	2 (11.1)	0	0	0
Dry eye	1 (5.6)	1 (5.6)	0	0	0
Visual impairment	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	15 (83.3)	6 (33.3)	6 (33.3)	2 (11.1)	1 (5.6)
Diarrhoea	6 (33.3)	3 (16.7)	3 (16.7)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	6 (33.3)	2 (11.1)	4 (22.2)	0	0
Vomiting	6 (33.3)	5 (27.8)	0	1 (5.6)	0
Constipation	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Mouth haemorrhage	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
Anal erythema	1 (5.6)	1 (5.6)	0	0	0
Dry mouth	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal inflammation	1 (5.6)	0	1 (5.6)	0	0
Gingival erythema	1 (5.6)	1 (5.6)	0	0	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Lip pain	1 (5.6)	1 (5.6)	0	0	0
Lip ulceration	1 (5.6)	0	1 (5.6)	0	0
Pancreatitis	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (72.2)	4 (22.2)	4 (22.2)	4 (22.2)	1 (5.6)
Pyrexia	8 (44.4)	2 (11.1)	2 (11.1)	4 (22.2)	0
Chills	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Fatigue	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Oedema peripheral	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Generalised oedema	2 (11.1)	0	2 (11.1)	0	0
Drug withdrawal syndrome	1 (5.6)	0	1 (5.6)	0	0
Face oedema	1 (5.6)	1 (5.6)	0	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Multiple organ dysfunction syndrome	1 (5.6)	0	0	0	1 (5.6)
Non-cardiac chest pain	1 (5.6)	1 (5.6)	0	0	0
Pain	1 (5.6)	0	1 (5.6)	0	0
Vascular device occlusion	1 (5.6)	1 (5.6)	0	0	0
Hepatobiliary disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Biliary tract disorder	1 (5.6)	1 (5.6)	0	0	0
Gallbladder enlargement	1 (5.6)	1 (5.6)	0	0	0
Hyperbilirubinaemia	1 (5.6)	0	0	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	16 (88.9)	0	6 (33.3)	2 (11.1)	8 (44.4)
Cytokine release syndrome	13 (72.2)	0	4 (22.2)	1 (5.6)	8 (44.4)
Hypogammaglobulinaemia	6 (33.3)	1 (5.6)	4 (22.2)	1 (5.6)	0
Seasonal allergy	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Allergy to immunoglobulin therapy	1 (5.6)	0	0	1 (5.6)	0
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Haemophagocytic lymphohistiocytosis	1 (5.6)	0	0	1 (5.6)	0
Selective igg subclass deficiency	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	14 (77.8)	0	3 (16.7)	7 (38.9)	4 (22.2)
Upper respiratory tract infection	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Bacteraemia	3 (16.7)	0	1 (5.6)	1 (5.6)	1 (5.6)
Adenovirus infection	2 (11.1)	0	0	2 (11.1)	0
Conjunctivitis	2 (11.1)	2 (11.1)	0	0	0
Escherichia bacteraemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Atypical pneumonia	1 (5.6)	1 (5.6)	0	0	0
Bk virus infection	1 (5.6)	0	0	1 (5.6)	0
Bronchitis	1 (5.6)	0	1 (5.6)	0	0
Candida infection	1 (5.6)	0	1 (5.6)	0	0
Covid-19	1 (5.6)	1 (5.6)	0	0	0
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Encephalitis viral	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis clostridial	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis norovirus	1 (5.6)	1 (5.6)	0	0	0
Gastroenteritis viral	1 (5.6)	0	0	1 (5.6)	0
Herpes simplex	1 (5.6)	0	1 (5.6)	0	0
Klebsiella bacteraemia	1 (5.6)	0	1 (5.6)	0	0
Localised infection	1 (5.6)	1 (5.6)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (5.6)	0	0	1 (5.6)	0
Otitis media	1 (5.6)	0	1 (5.6)	0	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	1 (5.6)	0	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0
Pharyngitis streptococcal	1 (5.6)	0	0	1 (5.6)	0
Pneumocystis jirovecii pneumonia	1 (5.6)	0	0	1 (5.6)	0
Pneumonia fungal	1 (5.6)	0	0	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0
Septic shock	1 (5.6)	0	0	0	1 (5.6)
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Sinusitis fungal	1 (5.6)	0	0	1 (5.6)	0
Skin infection	1 (5.6)	0	1 (5.6)	0	0
Staphylococcal infection	1 (5.6)	0	1 (5.6)	0	0
Syphilis	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Viral upper respiratory tract infection	1 (5.6)	0	0	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	7 (38.9)	2 (11.1)	3 (16.7)	2 (11.1)	0
Procedural pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Transfusion reaction	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal injury	1 (5.6)	1 (5.6)	0	0	0
Extradural haematoma	1 (5.6)	0	1 (5.6)	0	0
Infusion related reaction	1 (5.6)	0	1 (5.6)	0	0
Radius fracture	1 (5.6)	0	1 (5.6)	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	12 (66.7)	0	1 (5.6)	2 (11.1)	9 (50.0)
Aspartate aminotransferase increased	7 (38.9)	0	1 (5.6)	4 (22.2)	2 (11.1)
Alanine aminotransferase increased	5 (27.8)	0	1 (5.6)	4 (22.2)	0
Blood bilirubin increased	4 (22.2)	0	0	4 (22.2)	0
Neutrophil count decreased	4 (22.2)	0	0	0	4 (22.2)
Platelet count decreased	4 (22.2)	0	0	0	4 (22.2)
White blood cell count decreased	4 (22.2)	0	0	0	4 (22.2)

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Activated partial thromboplastin time prolonged	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Blood lactate dehydrogenase increased	2 (11.1)	0	0	2 (11.1)	0
Blood uric acid increased	2 (11.1)	1 (5.6)	0	0	1 (5.6)
C-reactive protein increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Fibrin d dimer increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
International normalised ratio increased	2 (11.1)	0	2 (11.1)	0	0
Serum ferritin increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Blood alkaline phosphatase increased	1 (5.6)	1 (5.6)	0	0	0
Blood fibrinogen increased	1 (5.6)	0	1 (5.6)	0	0
Blood immunoglobulin g decreased	1 (5.6)	0	1 (5.6)	0	0
Blood phosphorus increased	1 (5.6)	0	1 (5.6)	0	0
Ejection fraction decreased	1 (5.6)	0	1 (5.6)	0	0
Electrocardiogram qt prolonged	1 (5.6)	0	0	0	1 (5.6)
Electrocardiogram t wave abnormal	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heart sounds abnormal	1 (5.6)	1 (5.6)	0	0	0
Lymphocyte count decreased	1 (5.6)	0	0	0	1 (5.6)
Staphylococcus test positive	1 (5.6)	1 (5.6)	0	0	0
Troponin increased	1 (5.6)	0	0	1 (5.6)	0
Urine output decreased	1 (5.6)	0	0	1 (5.6)	0
Weight decreased	1 (5.6)	0	1 (5.6)	0	0
Weight increased	1 (5.6)	0	1 (5.6)	0	0
Metabolism and nutrition disorders					
-Total	14 (77.8)	0	3 (16.7)	7 (38.9)	4 (22.2)
Decreased appetite	10 (55.6)	0	4 (22.2)	6 (33.3)	0
Hypocalcaemia	9 (50.0)	0	5 (27.8)	4 (22.2)	0
Hypokalaemia	8 (44.4)	1 (5.6)	3 (16.7)	3 (16.7)	1 (5.6)
Hypophosphataemia	6 (33.3)	0	2 (11.1)	4 (22.2)	0
Hyperglycaemia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Hypoalbuminaemia	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Hypomagnesaemia	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Hyperuricaemia	4 (22.2)	3 (16.7)	0	1 (5.6)	0
Hyperkalaemia	3 (16.7)	0	1 (5.6)	2 (11.1)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	3 (16.7)	0	0	3 (16.7)	0
Tumour lysis syndrome	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Acidosis	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hypercalcaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Malnutrition	2 (11.1)	0	0	2 (11.1)	0
Metabolic acidosis	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Calcium deficiency	1 (5.6)	1 (5.6)	0	0	0
Hyperchloraemia	1 (5.6)	1 (5.6)	0	0	0
Hypermagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Hyperphosphataemia	1 (5.6)	1 (5.6)	0	0	0
Hypoglycaemia	1 (5.6)	0	1 (5.6)	0	0
Hyponatraemia	1 (5.6)	1 (5.6)	0	0	0
Obesity	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (55.6)	2 (11.1)	3 (16.7)	5 (27.8)	0
Pain in extremity	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0
Arthralgia	3 (16.7)	0	2 (11.1)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Back pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Growth retardation	1 (5.6)	0	1 (5.6)	0	0
Haemarthrosis	1 (5.6)	0	0	1 (5.6)	0
Muscle spasms	1 (5.6)	0	1 (5.6)	0	0
Myopathy	1 (5.6)	0	0	1 (5.6)	0
Neck pain	1 (5.6)	1 (5.6)	0	0	0
Osteopenia	1 (5.6)	1 (5.6)	0	0	0
Pain in jaw	1 (5.6)	0	0	1 (5.6)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.6)	0	1 (5.6)	0	0
Cancer pain	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	9 (50.0)	0	5 (27.8)	2 (11.1)	2 (11.1)
Headache	5 (27.8)	2 (11.1)	3 (16.7)	0	0
Cognitive disorder	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Paraesthesia	2 (11.1)	1 (5.6)	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Amnesia	1 (5.6)	0	1 (5.6)	0	0
Cerebral haemorrhage	1 (5.6)	0	0	0	1 (5.6)
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Extrapyramidal disorder	1 (5.6)	0	1 (5.6)	0	0
Hyperaesthesia	1 (5.6)	1 (5.6)	0	0	0
Lethargy	1 (5.6)	1 (5.6)	0	0	0
Neurological decompensation	1 (5.6)	0	0	0	1 (5.6)
Neuropathy peripheral	1 (5.6)	0	0	1 (5.6)	0
Tremor	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	9 (50.0)	1 (5.6)	5 (27.8)	3 (16.7)	0
Anxiety	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Mental status changes	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Insomnia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Agitation	1 (5.6)	0	1 (5.6)	0	0
Delirium	1 (5.6)	0	0	1 (5.6)	0
Hallucination, visual	1 (5.6)	0	1 (5.6)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	7 (38.9)	1 (5.6)	1 (5.6)	2 (11.1)	3 (16.7)
Acute kidney injury	5 (27.8)	1 (5.6)	1 (5.6)	1 (5.6)	2 (11.1)
Haematuria	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Dysuria	1 (5.6)	0	1 (5.6)	0	0
Kidney enlargement	1 (5.6)	0	1 (5.6)	0	0
Renal failure	1 (5.6)	0	0	0	1 (5.6)
Renal mass	1 (5.6)	0	1 (5.6)	0	0
Urinary retention	1 (5.6)	0	1 (5.6)	0	0
Reproductive system and breast disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Female genital tract fistula	1 (5.6)	1 (5.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (72.2)	2 (11.1)	2 (11.1)	3 (16.7)	6 (33.3)
Pulmonary oedema	5 (27.8)	1 (5.6)	1 (5.6)	2 (11.1)	1 (5.6)
Cough	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Hypoxia	3 (16.7)	0	0	2 (11.1)	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oropharyngeal pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Acute respiratory distress syndrome	2 (11.1)	0	0	0	2 (11.1)
Pleural effusion	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Respiratory failure	2 (11.1)	0	0	0	2 (11.1)
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Acute respiratory failure	1 (5.6)	0	0	1 (5.6)	0
Bronchial oedema	1 (5.6)	1 (5.6)	0	0	0
Epistaxis	1 (5.6)	0	0	1 (5.6)	0
Respiratory distress	1 (5.6)	0	0	0	1 (5.6)
Rhinorrhoea	1 (5.6)	0	1 (5.6)	0	0
Sleep apnoea syndrome	1 (5.6)	0	1 (5.6)	0	0
Tachypnoea	1 (5.6)	0	0	1 (5.6)	0
Wheezing	1 (5.6)	0	1 (5.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (44.4)	3 (16.7)	4 (22.2)	1 (5.6)	0
Dry skin	2 (11.1)	2 (11.1)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	2 (11.1)	0	2 (11.1)	0	0
Blister	1 (5.6)	0	1 (5.6)	0	0
Decubitus ulcer	1 (5.6)	0	0	1 (5.6)	0
Drug eruption	1 (5.6)	0	1 (5.6)	0	0
Hyperhidrosis	1 (5.6)	1 (5.6)	0	0	0
Ingrowing nail	1 (5.6)	1 (5.6)	0	0	0
Petechiae	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Rash maculo-papular	1 (5.6)	1 (5.6)	0	0	0
Scab	1 (5.6)	1 (5.6)	0	0	0
Skin hypopigmentation	1 (5.6)	1 (5.6)	0	0	0
Surgical and medical procedures					
-Total	1 (5.6)	0	0	1 (5.6)	0
Thrombolysis	1 (5.6)	0	0	1 (5.6)	0
Vascular disorders					
-Total	12 (66.7)	1 (5.6)	1 (5.6)	7 (38.9)	3 (16.7)
Hypotension	9 (50.0)	0	1 (5.6)	5 (27.8)	3 (16.7)
Hypertension	4 (22.2)	2 (11.1)	0	2 (11.1)	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Capillary leak syndrome	1 (5.6)	0	0	1 (5.6)	0
Flushing	1 (5.6)	1 (5.6)	0	0	0
Peripheral ischaemia	1 (5.6)	0	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208d
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	77 (96.3)	0	5 (6.3)	18 (22.5)	54 (67.5)
Blood and lymphatic system disorders					
-Total	55 (68.8)	1 (1.3)	8 (10.0)	29 (36.3)	17 (21.3)
Anaemia	31 (38.8)	5 (6.3)	10 (12.5)	16 (20.0)	0
Febrile neutropenia	29 (36.3)	0	0	28 (35.0)	1 (1.3)
Neutropenia	16 (20.0)	1 (1.3)	2 (2.5)	3 (3.8)	10 (12.5)
Thrombocytopenia	10 (12.5)	0	1 (1.3)	2 (2.5)	7 (8.8)
Disseminated intravascular coagulation	7 (8.8)	0	4 (5.0)	3 (3.8)	0
Leukopenia	5 (6.3)	0	0	1 (1.3)	4 (5.0)
Pancytopenia	4 (5.0)	0	0	3 (3.8)	1 (1.3)
Splenomegaly	4 (5.0)	3 (3.8)	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Coagulopathy	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Lymphadenopathy	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Lymphopenia	2 (2.5)	0	0	0	2 (2.5)
Agranulocytosis	1 (1.3)	0	0	1 (1.3)	0
B-cell aplasia	1 (1.3)	0	1 (1.3)	0	0
Eosinophilia	1 (1.3)	0	1 (1.3)	0	0
Hypercoagulation	1 (1.3)	0	1 (1.3)	0	0
Hypofibrinogenaemia	1 (1.3)	0	1 (1.3)	0	0
Lymphocytosis	1 (1.3)	0	1 (1.3)	0	0
Cardiac disorders					
-Total	28 (35.0)	9 (11.3)	5 (6.3)	9 (11.3)	5 (6.3)
Tachycardia	17 (21.3)	7 (8.8)	5 (6.3)	4 (5.0)	1 (1.3)
Left ventricular dysfunction	4 (5.0)	0	1 (1.3)	3 (3.8)	0
Bradycardia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Cardiac failure	3 (3.8)	0	0	1 (1.3)	2 (2.5)
Cardiac arrest	2 (2.5)	0	0	0	2 (2.5)
Cardiac dysfunction	2 (2.5)	2 (2.5)	0	0	0
Pericardial effusion	2 (2.5)	1 (1.3)	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Atrioventricular block first degree	1 (1.3)	0	1 (1.3)	0	0
Cardiac failure congestive	1 (1.3)	0	1 (1.3)	0	0
Mitral valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Right ventricular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Sinus tachycardia	1 (1.3)	0	1 (1.3)	0	0
Tricuspid valve incompetence	1 (1.3)	1 (1.3)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.3)	1 (1.3)	0	0	0
Cerebral cavernous malformation	1 (1.3)	1 (1.3)	0	0	0
Ear and labyrinth disorders					
-Total	4 (5.0)	2 (2.5)	2 (2.5)	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Ear pain	1 (1.3)	1 (1.3)	0	0	0
Ear pruritus	1 (1.3)	1 (1.3)	0	0	0
Vertigo	1 (1.3)	0	1 (1.3)	0	0
Endocrine disorders					
-Total	4 (5.0)	0	4 (5.0)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adrenal insufficiency	2 (2.5)	0	2 (2.5)	0	0
Hypothyroidism	2 (2.5)	0	2 (2.5)	0	0
Eye disorders					
-Total	15 (18.8)	9 (11.3)	5 (6.3)	1 (1.3)	0
Eye pain	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Eyelid oedema	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Ocular hyperaemia	3 (3.8)	3 (3.8)	0	0	0
Cataract	2 (2.5)	2 (2.5)	0	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Eye oedema	1 (1.3)	1 (1.3)	0	0	0
Hypermetropia	1 (1.3)	1 (1.3)	0	0	0
Mydriasis	1 (1.3)	0	1 (1.3)	0	0
Periorbital oedema	1 (1.3)	1 (1.3)	0	0	0
Periorbital swelling	1 (1.3)	0	1 (1.3)	0	0
Retinal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vision blurred	1 (1.3)	1 (1.3)	0	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Visual impairment	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders					
-Total	57 (71.3)	14 (17.5)	24 (30.0)	18 (22.5)	1 (1.3)
Nausea	27 (33.8)	12 (15.0)	12 (15.0)	3 (3.8)	0
Vomiting	24 (30.0)	15 (18.8)	8 (10.0)	1 (1.3)	0
Diarrhoea	21 (26.3)	14 (17.5)	5 (6.3)	2 (2.5)	0
Abdominal pain	16 (20.0)	5 (6.3)	9 (11.3)	2 (2.5)	0
Constipation	15 (18.8)	8 (10.0)	7 (8.8)	0	0
Stomatitis	10 (12.5)	1 (1.3)	4 (5.0)	5 (6.3)	0
Pancreatitis	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Abdominal pain upper	4 (5.0)	3 (3.8)	1 (1.3)	0	0
Mouth haemorrhage	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Abdominal distension	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Ascites	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Gastrointestinal sounds abnormal	3 (3.8)	3 (3.8)	0	0	0
Gingival bleeding	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Haematemesis	3 (3.8)	3 (3.8)	0	0	0
Anal fissure	2 (2.5)	0	2 (2.5)	0	0
Ileus	2 (2.5)	0	1 (1.3)	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutropenic colitis	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Oral pain	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Proctalgia	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Trichoglossia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Abdominal compartment syndrome	1 (1.3)	0	0	0	1 (1.3)
Abdominal rigidity	1 (1.3)	0	1 (1.3)	0	0
Anal fistula	1 (1.3)	0	0	1 (1.3)	0
Anal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Anal inflammation	1 (1.3)	0	0	1 (1.3)	0
Dry mouth	1 (1.3)	0	1 (1.3)	0	0
Duodenal perforation	1 (1.3)	0	0	1 (1.3)	0
Dyspepsia	1 (1.3)	1 (1.3)	0	0	0
Dysphagia	1 (1.3)	0	0	1 (1.3)	0
Enteritis	1 (1.3)	0	1 (1.3)	0	0
Enterocolitis	1 (1.3)	0	1 (1.3)	0	0
Gastritis	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Gastrooesophageal reflux disease	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gingival erythema	1 (1.3)	1 (1.3)	0	0	0
Gingivitis ulcerative	1 (1.3)	0	0	1 (1.3)	0
Haemoperitoneum	1 (1.3)	0	0	0	1 (1.3)
Haemorrhoids	1 (1.3)	0	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	1 (1.3)	0	0
Lip dry	1 (1.3)	0	1 (1.3)	0	0
Lip oedema	1 (1.3)	1 (1.3)	0	0	0
Melaena	1 (1.3)	0	0	1 (1.3)	0
Mouth swelling	1 (1.3)	1 (1.3)	0	0	0
Odynophagia	1 (1.3)	1 (1.3)	0	0	0
Oral disorder	1 (1.3)	1 (1.3)	0	0	0
Peritoneal haematoma	1 (1.3)	1 (1.3)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					
-Total	50 (62.5)	25 (31.3)	12 (15.0)	9 (11.3)	4 (5.0)
Pyrexia	35 (43.8)	16 (20.0)	10 (12.5)	7 (8.8)	2 (2.5)
Fatigue	15 (18.8)	12 (15.0)	3 (3.8)	0	0

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	7 (8.8)	4 (5.0)	2 (2.5)	1 (1.3)	0
Pain	7 (8.8)	1 (1.3)	4 (5.0)	2 (2.5)	0
Catheter site pain	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Chills	5 (6.3)	3 (3.8)	2 (2.5)	0	0
Oedema peripheral	5 (6.3)	4 (5.0)	0	1 (1.3)	0
Asthenia	4 (5.0)	3 (3.8)	1 (1.3)	0	0
Generalised oedema	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Localised oedema	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Influenza like illness	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Multiple organ dysfunction syndrome	2 (2.5)	0	0	0	2 (2.5)
Catheter site dermatitis	1 (1.3)	1 (1.3)	0	0	0
Catheter site erythema	1 (1.3)	1 (1.3)	0	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Chest discomfort	1 (1.3)	0	0	1 (1.3)	0
Complication associated with device	1 (1.3)	1 (1.3)	0	0	0
Crying	1 (1.3)	0	1 (1.3)	0	0
Drug withdrawal syndrome	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Malaise	1 (1.3)	0	1 (1.3)	0	0
Non-cardiac chest pain	1 (1.3)	1 (1.3)	0	0	0
Oedema due to hepatic disease	1 (1.3)	0	1 (1.3)	0	0
Sluggishness	1 (1.3)	0	1 (1.3)	0	0
Swelling face	1 (1.3)	1 (1.3)	0	0	0
Systemic inflammatory response syndrome	1 (1.3)	0	0	1 (1.3)	0
Thirst	1 (1.3)	1 (1.3)	0	0	0
Vascular device occlusion	1 (1.3)	1 (1.3)	0	0	0
Xerosis	1 (1.3)	1 (1.3)	0	0	0
Hepatobiliary disorders					
-Total	22 (27.5)	6 (7.5)	8 (10.0)	5 (6.3)	3 (3.8)
Hepatic function abnormal	5 (6.3)	0	2 (2.5)	2 (2.5)	1 (1.3)
Hyperbilirubinaemia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Hepatomegaly	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Cholelithiasis	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Hepatic cytolysis	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholestasis	1 (1.3)	0	0	0	1 (1.3)
Drug-induced liver injury	1 (1.3)	0	0	1 (1.3)	0
Gallbladder enlargement	1 (1.3)	1 (1.3)	0	0	0
Hepatosplenomegaly	1 (1.3)	0	1 (1.3)	0	0
Liver disorder	1 (1.3)	0	1 (1.3)	0	0
Ocular icterus	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	57 (71.3)	2 (2.5)	18 (22.5)	23 (28.8)	14 (17.5)
Cytokine release syndrome	48 (60.0)	5 (6.3)	14 (17.5)	16 (20.0)	13 (16.3)
Hypogammaglobulinaemia	30 (37.5)	1 (1.3)	22 (27.5)	7 (8.8)	0
Haemophagocytic lymphohistiocytosis	5 (6.3)	1 (1.3)	1 (1.3)	1 (1.3)	2 (2.5)
Immunodeficiency	4 (5.0)	0	0	4 (5.0)	0
Chronic graft versus host disease	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Graft versus host disease	2 (2.5)	0	0	2 (2.5)	0
Seasonal allergy	2 (2.5)	0	2 (2.5)	0	0
Allergy to immunoglobulin therapy	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Engraftment syndrome	1 (1.3)	0	0	1 (1.3)	0
Hypersensitivity	1 (1.3)	1 (1.3)	0	0	0
Infections and infestations					
-Total	62 (77.5)	6 (7.5)	10 (12.5)	30 (37.5)	16 (20.0)
Pneumonia	10 (12.5)	1 (1.3)	2 (2.5)	4 (5.0)	3 (3.8)
Upper respiratory tract infection	9 (11.3)	5 (6.3)	2 (2.5)	2 (2.5)	0
Nasopharyngitis	8 (10.0)	5 (6.3)	3 (3.8)	0	0
Rhinovirus infection	8 (10.0)	0	6 (7.5)	2 (2.5)	0
Sinusitis	8 (10.0)	0	6 (7.5)	2 (2.5)	0
Conjunctivitis	7 (8.8)	1 (1.3)	6 (7.5)	0	0
Parainfluenzae virus infection	6 (7.5)	1 (1.3)	0	4 (5.0)	1 (1.3)
Staphylococcal infection	6 (7.5)	0	2 (2.5)	3 (3.8)	1 (1.3)
Gastroenteritis	5 (6.3)	3 (3.8)	0	2 (2.5)	0
Paronychia	5 (6.3)	1 (1.3)	3 (3.8)	1 (1.3)	0
Staphylococcal bacteraemia	5 (6.3)	0	0	5 (6.3)	0
Clostridium difficile infection	4 (5.0)	1 (1.3)	0	3 (3.8)	0
Herpes zoster	4 (5.0)	0	2 (2.5)	2 (2.5)	0
Nail infection	4 (5.0)	3 (3.8)	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oral herpes	4 (5.0)	1 (1.3)	2 (2.5)	1 (1.3)	0
Otitis media	4 (5.0)	0	3 (3.8)	1 (1.3)	0
Sepsis	4 (5.0)	0	0	1 (1.3)	3 (3.8)
Acute sinusitis	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Bronchopulmonary aspergillosis	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Candida infection	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Catheter site infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Device related infection	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Ear infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Gingivitis	3 (3.8)	3 (3.8)	0	0	0
Influenza	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Oral candidiasis	3 (3.8)	0	3 (3.8)	0	0
Otitis externa	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Respiratory tract infection	3 (3.8)	0	2 (2.5)	1 (1.3)	0
Rhinitis	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Bronchiolitis	2 (2.5)	0	0	2 (2.5)	0
Bronchitis	2 (2.5)	0	2 (2.5)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cytomegalovirus infection reactivation	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Fungal skin infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Gastroenteritis viral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Localised infection	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Metapneumovirus infection	2 (2.5)	0	0	2 (2.5)	0
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Septic shock	2 (2.5)	0	0	0	2 (2.5)
Skin infection	2 (2.5)	0	2 (2.5)	0	0
Staphylococcal skin infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Tinea pedis	2 (2.5)	2 (2.5)	0	0	0
Urinary tract infection	2 (2.5)	0	2 (2.5)	0	0
Varicella zoster virus infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Viral infection	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Anal abscess	1 (1.3)	0	0	1 (1.3)	0
Bk virus infection	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis	1 (1.3)	0	1 (1.3)	0	0
Cholecystitis infective	1 (1.3)	0	1 (1.3)	0	0
Clostridium difficile colitis	1 (1.3)	0	0	1 (1.3)	0
Coronavirus infection	1 (1.3)	0	0	1 (1.3)	0
Covid-19	1 (1.3)	0	0	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	0	0	1 (1.3)
Cystitis	1 (1.3)	0	1 (1.3)	0	0
Device related bacteraemia	1 (1.3)	0	1 (1.3)	0	0
Device related sepsis	1 (1.3)	0	0	1 (1.3)	0
Ear, nose and throat infection	1 (1.3)	0	1 (1.3)	0	0
Encephalitis viral	1 (1.3)	0	0	0	1 (1.3)
Enterobacter infection	1 (1.3)	0	0	1 (1.3)	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Epstein-barr virus infection	1 (1.3)	0	1 (1.3)	0	0
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Fungaemia	1 (1.3)	0	0	0	1 (1.3)
Fungal pharyngitis	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis escherichia coli	1 (1.3)	0	0	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	0	0	1 (1.3)	0
Gastrointestinal infection	1 (1.3)	1 (1.3)	0	0	0
Granulicatella infection	1 (1.3)	0	0	1 (1.3)	0
Herpes simplex	1 (1.3)	0	0	1 (1.3)	0
Herpes virus infection	1 (1.3)	0	1 (1.3)	0	0
Klebsiella bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Mastoiditis	1 (1.3)	0	0	1 (1.3)	0
Meningitis bacterial	1 (1.3)	0	0	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	0	0	1 (1.3)	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Myringitis	1 (1.3)	1 (1.3)	0	0	0
Neutropenic infection	1 (1.3)	0	0	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	1 (1.3)	0	0
Peritonitis	1 (1.3)	0	0	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	0	0	1 (1.3)
Pneumonia fungal	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia respiratory syncytial viral	1 (1.3)	0	0	1 (1.3)	0
Pneumonia viral	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection viral	1 (1.3)	0	1 (1.3)	0	0
Salmonellosis	1 (1.3)	0	1 (1.3)	0	0
Serratia sepsis	1 (1.3)	0	0	0	1 (1.3)
Sialoadenitis	1 (1.3)	0	0	1 (1.3)	0
Soft tissue infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Stomatococcal infection	1 (1.3)	0	0	0	1 (1.3)
Streptococcal sepsis	1 (1.3)	0	1 (1.3)	0	0
Systemic candida	1 (1.3)	0	0	1 (1.3)	0
Systemic mycosis	1 (1.3)	0	0	1 (1.3)	0
Urinary tract infection pseudomonal	1 (1.3)	0	1 (1.3)	0	0
Urinary tract infection viral	1 (1.3)	1 (1.3)	0	0	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral skin infection	1 (1.3)	1 (1.3)	0	0	0
Vulval cellulitis	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	20 (25.0)	7 (8.8)	9 (11.3)	1 (1.3)	3 (3.8)
Infusion related reaction	5 (6.3)	2 (2.5)	2 (2.5)	1 (1.3)	0
Fall	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Wound	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Contusion	2 (2.5)	2 (2.5)	0	0	0
Ligament sprain	2 (2.5)	2 (2.5)	0	0	0
Procedural pain	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Transfusion reaction	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Fibula fracture	1 (1.3)	0	1 (1.3)	0	0
Limb injury	1 (1.3)	0	1 (1.3)	0	0
Post-traumatic neck syndrome	1 (1.3)	0	1 (1.3)	0	0
Scratch	1 (1.3)	1 (1.3)	0	0	0
Skin abrasion	1 (1.3)	1 (1.3)	0	0	0
Skin injury	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin wound	1 (1.3)	1 (1.3)	0	0	0
Tracheal obstruction	1 (1.3)	0	0	0	1 (1.3)
Transplant failure	1 (1.3)	0	0	0	1 (1.3)
Traumatic haematoma	1 (1.3)	0	1 (1.3)	0	0
Vasoplegia syndrome	1 (1.3)	0	0	0	1 (1.3)
Investigations					
-Total	54 (67.5)	1 (1.3)	5 (6.3)	18 (22.5)	30 (37.5)
White blood cell count decreased	28 (35.0)	3 (3.8)	3 (3.8)	1 (1.3)	21 (26.3)
Neutrophil count decreased	25 (31.3)	1 (1.3)	2 (2.5)	3 (3.8)	19 (23.8)
Platelet count decreased	24 (30.0)	6 (7.5)	2 (2.5)	6 (7.5)	10 (12.5)
Lymphocyte count decreased	22 (27.5)	1 (1.3)	1 (1.3)	9 (11.3)	11 (13.8)
Alanine aminotransferase increased	17 (21.3)	5 (6.3)	7 (8.8)	5 (6.3)	0
Aspartate aminotransferase increased	14 (17.5)	2 (2.5)	4 (5.0)	6 (7.5)	2 (2.5)
Blood bilirubin increased	9 (11.3)	1 (1.3)	2 (2.5)	6 (7.5)	0
C-reactive protein increased	9 (11.3)	3 (3.8)	2 (2.5)	4 (5.0)	0
Serum ferritin increased	9 (11.3)	2 (2.5)	5 (6.3)	2 (2.5)	0
Blood fibrinogen decreased	8 (10.0)	3 (3.8)	3 (3.8)	1 (1.3)	1 (1.3)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
International normalised ratio increased	8 (10.0)	6 (7.5)	2 (2.5)	0	0
Blood immunoglobulin a decreased	7 (8.8)	5 (6.3)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	7 (8.8)	4 (5.0)	1 (1.3)	2 (2.5)	0
Blood lactate dehydrogenase increased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
Weight increased	5 (6.3)	2 (2.5)	1 (1.3)	2 (2.5)	0
Activated partial thromboplastin time prolonged	4 (5.0)	3 (3.8)	1 (1.3)	0	0
Blood creatinine increased	4 (5.0)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)
Electrocardiogram qt prolonged	4 (5.0)	1 (1.3)	2 (2.5)	1 (1.3)	0
Blood immunoglobulin g decreased	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Oxygen saturation decreased	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Weight decreased	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Amylase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Blood creatine phosphokinase increased	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Blood fibrinogen increased	2 (2.5)	2 (2.5)	0	0	0
Blood glucose increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood uric acid increased	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Fibrin d dimer increased	2 (2.5)	2 (2.5)	0	0	0
Gamma-glutamyltransferase increased	2 (2.5)	0	0	2 (2.5)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.3)	0	0	1 (1.3)
Bacterial test positive	1 (1.3)	0	0	1 (1.3)	0
Blood alkaline phosphatase decreased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood phosphorus decreased	1 (1.3)	0	0	1 (1.3)	0
Blood phosphorus increased	1 (1.3)	0	1 (1.3)	0	0
Blood potassium decreased	1 (1.3)	0	0	0	1 (1.3)
Blood testosterone decreased	1 (1.3)	1 (1.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.3)	1 (1.3)	0	0	0
Blood urea increased	1 (1.3)	0	0	1 (1.3)	0
Bone density decreased	1 (1.3)	1 (1.3)	0	0	0
Breath sounds abnormal	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Coagulation test abnormal	1 (1.3)	1 (1.3)	0	0	0
Enterovirus test positive	1 (1.3)	0	1 (1.3)	0	0
Eosinophil count decreased	1 (1.3)	1 (1.3)	0	0	0
Haematocrit decreased	1 (1.3)	1 (1.3)	0	0	0
Haemoglobin decreased	1 (1.3)	0	0	1 (1.3)	0
Haptoglobin decreased	1 (1.3)	1 (1.3)	0	0	0
Hepatitis b virus test positive	1 (1.3)	0	1 (1.3)	0	0
Prothrombin time prolonged	1 (1.3)	0	1 (1.3)	0	0
Red blood cell count decreased	1 (1.3)	1 (1.3)	0	0	0
Urine output decreased	1 (1.3)	0	0	0	1 (1.3)
Metabolism and nutrition disorders					
-Total	45 (56.3)	8 (10.0)	8 (10.0)	19 (23.8)	10 (12.5)
Decreased appetite	24 (30.0)	12 (15.0)	4 (5.0)	6 (7.5)	2 (2.5)
Hypokalaemia	17 (21.3)	3 (3.8)	2 (2.5)	10 (12.5)	2 (2.5)
Hypophosphataemia	15 (18.8)	3 (3.8)	6 (7.5)	5 (6.3)	1 (1.3)
Hypocalcaemia	9 (11.3)	2 (2.5)	5 (6.3)	2 (2.5)	0
Hypoalbuminaemia	7 (8.8)	0	7 (8.8)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypervolaemia	6 (7.5)	1 (1.3)	2 (2.5)	3 (3.8)	0
Hyperphosphataemia	5 (6.3)	4 (5.0)	0	0	1 (1.3)
Hyperuricaemia	5 (6.3)	4 (5.0)	1 (1.3)	0	0
Hyperglycaemia	4 (5.0)	0	1 (1.3)	3 (3.8)	0
Hypomagnesaemia	4 (5.0)	4 (5.0)	0	0	0
Metabolic acidosis	4 (5.0)	1 (1.3)	0	1 (1.3)	2 (2.5)
Hypernatraemia	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Hypertriglyceridaemia	3 (3.8)	0	1 (1.3)	1 (1.3)	1 (1.3)
Hyponatraemia	3 (3.8)	2 (2.5)	0	0	1 (1.3)
Tumour lysis syndrome	3 (3.8)	0	0	2 (2.5)	1 (1.3)
Iron overload	2 (2.5)	0	2 (2.5)	0	0
Dehydration	1 (1.3)	0	1 (1.3)	0	0
Eating disorder symptom	1 (1.3)	0	1 (1.3)	0	0
Haemochromatosis	1 (1.3)	0	0	1 (1.3)	0
Haemosiderosis	1 (1.3)	0	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	0	0	0	1 (1.3)
Hyperchloraemia	1 (1.3)	1 (1.3)	0	0	0
Hypercholesterolaemia	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	1 (1.3)	0	0	0	1 (1.3)
Hyperlactacidaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperlipidaemia	1 (1.3)	0	1 (1.3)	0	0
Hypermagnesaemia	1 (1.3)	1 (1.3)	0	0	0
Hypophagia	1 (1.3)	0	1 (1.3)	0	0
Metabolic syndrome	1 (1.3)	0	1 (1.3)	0	0
Polydipsia	1 (1.3)	0	0	1 (1.3)	0
Vitamin d deficiency	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	38 (47.5)	16 (20.0)	16 (20.0)	5 (6.3)	1 (1.3)
Pain in extremity	19 (23.8)	8 (10.0)	9 (11.3)	2 (2.5)	0
Arthralgia	10 (12.5)	6 (7.5)	4 (5.0)	0	0
Back pain	10 (12.5)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	7 (8.8)	4 (5.0)	3 (3.8)	0	0
Bone pain	4 (5.0)	1 (1.3)	3 (3.8)	0	0
Joint effusion	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Muscular weakness	2 (2.5)	1 (1.3)	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal chest pain	2 (2.5)	2 (2.5)	0	0	0
Pain in jaw	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Groin pain	1 (1.3)	1 (1.3)	0	0	0
Growth retardation	1 (1.3)	0	1 (1.3)	0	0
Muscle rigidity	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal pain	1 (1.3)	0	1 (1.3)	0	0
Myositis	1 (1.3)	0	1 (1.3)	0	0
Neck pain	1 (1.3)	0	1 (1.3)	0	0
Osteonecrosis	1 (1.3)	1 (1.3)	0	0	0
Rhabdomyolysis	1 (1.3)	0	0	0	1 (1.3)
Spinal pain	1 (1.3)	0	0	1 (1.3)	0
Synovitis	1 (1.3)	0	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.0)	1 (1.3)	1 (1.3)	2 (2.5)	0
Skin papilloma	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Bone giant cell tumour benign	1 (1.3)	0	0	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	46 (57.5)	17 (21.3)	15 (18.8)	11 (13.8)	3 (3.8)
Headache	27 (33.8)	14 (17.5)	10 (12.5)	3 (3.8)	0
Encephalopathy	8 (10.0)	1 (1.3)	3 (3.8)	4 (5.0)	0
Seizure	6 (7.5)	0	3 (3.8)	3 (3.8)	0
Dizziness	5 (6.3)	5 (6.3)	0	0	0
Tremor	5 (6.3)	4 (5.0)	1 (1.3)	0	0
Somnolence	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Dysgeusia	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Lethargy	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Dysarthria	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Neuropathy peripheral	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Aphasia	1 (1.3)	1 (1.3)	0	0	0
Autonomic neuropathy	1 (1.3)	0	0	1 (1.3)	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0	1 (1.3)	0
Depressed level of consciousness	1 (1.3)	0	0	1 (1.3)	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Generalised tonic-clonic seizure	1 (1.3)	0	1 (1.3)	0	0
Haemorrhage intracranial	1 (1.3)	0	0	0	1 (1.3)
Hydrocephalus	1 (1.3)	0	0	0	1 (1.3)
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Memory impairment	1 (1.3)	0	1 (1.3)	0	0
Migraine	1 (1.3)	0	1 (1.3)	0	0
Monoparesis	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorder	1 (1.3)	0	0	1 (1.3)	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Posterior reversible encephalopathy syndrome	1 (1.3)	0	1 (1.3)	0	0
Psychiatric disorders					
-Total	32 (40.0)	12 (15.0)	13 (16.3)	7 (8.8)	0
Anxiety	11 (13.8)	4 (5.0)	5 (6.3)	2 (2.5)	0
Confusional state	7 (8.8)	7 (8.8)	0	0	0
Delirium	7 (8.8)	2 (2.5)	3 (3.8)	2 (2.5)	0
Agitation	6 (7.5)	4 (5.0)	2 (2.5)	0	0
Insomnia	4 (5.0)	1 (1.3)	3 (3.8)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	4 (5.0)	3 (3.8)	0	1 (1.3)	0
Hallucination	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Mental status changes	3 (3.8)	1 (1.3)	0	2 (2.5)	0
Sleep disorder	3 (3.8)	0	3 (3.8)	0	0
Affect lability	1 (1.3)	0	1 (1.3)	0	0
Automatism	1 (1.3)	1 (1.3)	0	0	0
Mood altered	1 (1.3)	1 (1.3)	0	0	0
Nightmare	1 (1.3)	1 (1.3)	0	0	0
Persistent depressive disorder	1 (1.3)	0	1 (1.3)	0	0
Restlessness	1 (1.3)	0	1 (1.3)	0	0
Social avoidant behaviour	1 (1.3)	0	1 (1.3)	0	0
Tearfulness	1 (1.3)	1 (1.3)	0	0	0
Tic	1 (1.3)	0	1 (1.3)	0	0
Renal and urinary disorders					
-Total	23 (28.8)	9 (11.3)	6 (7.5)	4 (5.0)	4 (5.0)
Acute kidney injury	10 (12.5)	4 (5.0)	1 (1.3)	2 (2.5)	3 (3.8)
Dysuria	4 (5.0)	4 (5.0)	0	0	0
Anuria	2 (2.5)	1 (1.3)	0	0	1 (1.3)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematuria	2 (2.5)	2 (2.5)	0	0	0
Pollakiuria	2 (2.5)	0	2 (2.5)	0	0
Renal tubular necrosis	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Azotaemia	1 (1.3)	0	1 (1.3)	0	0
Bladder dilatation	1 (1.3)	0	1 (1.3)	0	0
Cystitis haemorrhagic	1 (1.3)	0	1 (1.3)	0	0
Incontinence	1 (1.3)	0	1 (1.3)	0	0
Micturition urgency	1 (1.3)	0	1 (1.3)	0	0
Proteinuria	1 (1.3)	1 (1.3)	0	0	0
Renal failure	1 (1.3)	0	1 (1.3)	0	0
Renal pain	1 (1.3)	1 (1.3)	0	0	0
Renal tubular disorder	1 (1.3)	0	0	1 (1.3)	0
Renal tubular dysfunction	1 (1.3)	1 (1.3)	0	0	0
Urinary incontinence	1 (1.3)	0	1 (1.3)	0	0
Urinary retention	1 (1.3)	0	1 (1.3)	0	0
Urinary tract disorder	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (7.5)	0	3 (3.8)	3 (3.8)	0
Dysmenorrhoea	1 (1.3)	0	1 (1.3)	0	0
Endometriosis	1 (1.3)	0	0	1 (1.3)	0
Heavy menstrual bleeding	1 (1.3)	0	1 (1.3)	0	0
Perineal rash	1 (1.3)	0	1 (1.3)	0	0
Prostatitis	1 (1.3)	0	0	1 (1.3)	0
Vaginal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Vaginal ulceration	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	49 (61.3)	17 (21.3)	6 (7.5)	10 (12.5)	16 (20.0)
Cough	23 (28.8)	19 (23.8)	4 (5.0)	0	0
Hypoxia	18 (22.5)	0	5 (6.3)	8 (10.0)	5 (6.3)
Epistaxis	11 (13.8)	7 (8.8)	2 (2.5)	2 (2.5)	0
Pulmonary oedema	9 (11.3)	2 (2.5)	2 (2.5)	4 (5.0)	1 (1.3)
Tachypnoea	9 (11.3)	3 (3.8)	2 (2.5)	3 (3.8)	1 (1.3)
Dyspnoea	8 (10.0)	1 (1.3)	2 (2.5)	3 (3.8)	2 (2.5)
Nasal congestion	8 (10.0)	7 (8.8)	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	8 (10.0)	4 (5.0)	3 (3.8)	1 (1.3)	0
Respiratory failure	8 (10.0)	0	0	0	8 (10.0)
Oropharyngeal pain	7 (8.8)	6 (7.5)	1 (1.3)	0	0
Rhinorrhoea	5 (6.3)	4 (5.0)	1 (1.3)	0	0
Atelectasis	3 (3.8)	0	1 (1.3)	2 (2.5)	0
Respiratory distress	3 (3.8)	0	2 (2.5)	0	1 (1.3)
Acute respiratory distress syndrome	2 (2.5)	0	0	0	2 (2.5)
Pharyngeal erythema	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Bradypnoea	1 (1.3)	0	0	1 (1.3)	0
Bronchospasm	1 (1.3)	0	1 (1.3)	0	0
Dyspnoea exertional	1 (1.3)	1 (1.3)	0	0	0
Haemoptysis	1 (1.3)	0	1 (1.3)	0	0
Laryngeal oedema	1 (1.3)	0	0	0	1 (1.3)
Lung disorder	1 (1.3)	1 (1.3)	0	0	0
Lung infiltration	1 (1.3)	0	0	1 (1.3)	0
Nasal discomfort	1 (1.3)	0	1 (1.3)	0	0
Nasal dryness	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Painful respiration	1 (1.3)	1 (1.3)	0	0	0
Paranasal sinus discomfort	1 (1.3)	0	1 (1.3)	0	0
Paranasal sinus inflammation	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal exudate	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Pharyngeal oedema	1 (1.3)	0	1 (1.3)	0	0
Productive cough	1 (1.3)	1 (1.3)	0	0	0
Pulmonary haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory acidosis	1 (1.3)	0	0	1 (1.3)	0
Respiratory disorder	1 (1.3)	0	1 (1.3)	0	0
Sleep apnoea syndrome	1 (1.3)	1 (1.3)	0	0	0
Upper respiratory tract inflammation	1 (1.3)	0	1 (1.3)	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	40 (50.0)	19 (23.8)	14 (17.5)	7 (8.8)	0
Pruritus	9 (11.3)	5 (6.3)	4 (5.0)	0	0

Ethnicity: Other

	All patients N=80				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	9 (11.3)	4 (5.0)	5 (6.3)	0	0
Dry skin	7 (8.8)	5 (6.3)	2 (2.5)	0	0
Erythema	6 (7.5)	5 (6.3)	1 (1.3)	0	0
Rash papular	4 (5.0)	3 (3.8)	1 (1.3)	0	0
Skin ulcer	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Dermatitis atopic	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Eczema	3 (3.8)	2 (2.5)	0	1 (1.3)	0
Ingrowing nail	3 (3.8)	0	3 (3.8)	0	0
Rash maculo-papular	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Blister	2 (2.5)	2 (2.5)	0	0	0
Hyperhidrosis	2 (2.5)	0	2 (2.5)	0	0
Petechiae	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Skin discolouration	2 (2.5)	2 (2.5)	0	0	0
Acne	1 (1.3)	1 (1.3)	0	0	0
Decubitus ulcer	1 (1.3)	0	1 (1.3)	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis allergic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema nodosum	1 (1.3)	1 (1.3)	0	0	0
Hangnail	1 (1.3)	1 (1.3)	0	0	0
Miliaria	1 (1.3)	1 (1.3)	0	0	0
Night sweats	1 (1.3)	1 (1.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)	1 (1.3)	0	0	0
Papule	1 (1.3)	1 (1.3)	0	0	0
Photosensitivity reaction	1 (1.3)	0	1 (1.3)	0	0
Pruritus allergic	1 (1.3)	0	1 (1.3)	0	0
Purpura	1 (1.3)	1 (1.3)	0	0	0
Rash erythematous	1 (1.3)	1 (1.3)	0	0	0
Rash macular	1 (1.3)	0	0	1 (1.3)	0
Rash pruritic	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Skin lesion	1 (1.3)	0	1 (1.3)	0	0
Skin necrosis	1 (1.3)	0	0	1 (1.3)	0
Skin swelling	1 (1.3)	1 (1.3)	0	0	0
Urticaria	1 (1.3)	0	1 (1.3)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vancomycin infusion reaction	1 (1.3)	0	0	1 (1.3)	0
Social circumstances					
-Total	1 (1.3)	0	1 (1.3)	0	0
Patient uncooperative	1 (1.3)	0	1 (1.3)	0	0
Vascular disorders					
-Total	31 (38.8)	4 (5.0)	10 (12.5)	9 (11.3)	8 (10.0)
Hypotension	21 (26.3)	2 (2.5)	5 (6.3)	7 (8.8)	7 (8.8)
Hypertension	15 (18.8)	2 (2.5)	10 (12.5)	3 (3.8)	0
Venoocclusive disease	2 (2.5)	0	0	1 (1.3)	1 (1.3)
Capillary leak syndrome	1 (1.3)	0	1 (1.3)	0	0
Flushing	1 (1.3)	1 (1.3)	0	0	0
Haematoma	1 (1.3)	1 (1.3)	0	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Peripheral ischaemia	1 (1.3)	0	1 (1.3)	0	0
Thrombosis	1 (1.3)	0	1 (1.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208e
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	1 (12.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders					
-Total	6 (75.0)	0	1 (12.5)	3 (37.5)	2 (25.0)
Anaemia	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Febrile neutropenia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Coagulopathy	1 (12.5)	0	0	1 (12.5)	0
Disseminated intravascular coagulation	1 (12.5)	0	0	1 (12.5)	0
Lymphocytosis	1 (12.5)	0	1 (12.5)	0	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Sinus tachycardia	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Eyelid oedema	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	6 (75.0)	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)
Abdominal pain	2 (25.0)	2 (25.0)	0	0	0
Nausea	2 (25.0)	2 (25.0)	0	0	0
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Abdominal distension	1 (12.5)	0	1 (12.5)	0	0
Ascites	1 (12.5)	1 (12.5)	0	0	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
Irritable bowel syndrome	1 (12.5)	0	1 (12.5)	0	0
Melaena	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	1 (12.5)	0	1 (12.5)	0	0
Stomatitis	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	2 (25.0)	2 (25.0)	1 (12.5)
Pyrexia	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Fatigue	2 (25.0)	2 (25.0)	0	0	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Face oedema	1 (12.5)	0	1 (12.5)	0	0
Generalised oedema	1 (12.5)	0	1 (12.5)	0	0
Multiple organ dysfunction syndrome	1 (12.5)	0	0	0	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Systemic inflammatory response syndrome	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cholelithiasis	1 (12.5)	1 (12.5)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (12.5)	0	0	0	1 (12.5)
Gallbladder enlargement	1 (12.5)	1 (12.5)	0	0	0
Immune system disorders					
-Total	6 (75.0)	0	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Hypogammaglobulinaemia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Seasonal allergy	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0	0	0
Otitis externa	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)	0	0
Vulval cellulitis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					
-Total	3 (37.5)	0	2 (25.0)	0	1 (12.5)
Fibula fracture	1 (12.5)	0	1 (12.5)	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Skin injury	1 (12.5)	0	1 (12.5)	0	0
Skin wound	1 (12.5)	1 (12.5)	0	0	0
Vasoplegia syndrome	1 (12.5)	0	0	0	1 (12.5)
Wound	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	4 (50.0)	0	0	1 (12.5)	3 (37.5)
Neutrophil count decreased	3 (37.5)	0	0	1 (12.5)	2 (25.0)
White blood cell count decreased	3 (37.5)	1 (12.5)	1 (12.5)	0	1 (12.5)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Blood creatinine increased	2 (25.0)	2 (25.0)	0	0	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Blood alkaline phosphatase increased	1 (12.5)	1 (12.5)	0	0	0
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0
Blood creatine phosphokinase increased	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Electrocardiogram qt prolonged	1 (12.5)	0	1 (12.5)	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Lipase increased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	0	1 (12.5)	0	0
Metabolism and nutrition disorders					
-Total	7 (87.5)	1 (12.5)	1 (12.5)	4 (50.0)	1 (12.5)
Decreased appetite	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Hypocalcaemia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Hypophosphataemia	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Hyperuricaemia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Hypoalbuminaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Acidosis	1 (12.5)	0	0	1 (12.5)	0
Haemosiderosis	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (12.5)	0	1 (12.5)	0	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperlactacidaemia	1 (12.5)	1 (12.5)	0	0	0
Hypermagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypernatraemia	1 (12.5)	0	0	0	1 (12.5)
Hypokalaemia	1 (12.5)	0	0	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hyponatraemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Myalgia	1 (12.5)	1 (12.5)	0	0	0
Myositis	1 (12.5)	0	1 (12.5)	0	0
Rhabdomyolysis	1 (12.5)	0	0	0	1 (12.5)
Nervous system disorders					
-Total	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Headache	4 (50.0)	3 (37.5)	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Monoparesis	1 (12.5)	0	1 (12.5)	0	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Tremor	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Confusional state	1 (12.5)	1 (12.5)	0	0	0
Irritability	1 (12.5)	0	0	1 (12.5)	0
Persistent depressive disorder	1 (12.5)	0	1 (12.5)	0	0
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Acute kidney injury	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Bladder dilatation	1 (12.5)	0	1 (12.5)	0	0
Dysuria	1 (12.5)	1 (12.5)	0	0	0
Renal tubular necrosis	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Reproductive system and breast disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Vaginal ulceration	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (75.0)	2 (25.0)	0	1 (12.5)	3 (37.5)
Nasal congestion	2 (25.0)	2 (25.0)	0	0	0
Oropharyngeal pain	2 (25.0)	2 (25.0)	0	0	0
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Tachypnoea	2 (25.0)	0	0	2 (25.0)	0
Acute respiratory distress syndrome	1 (12.5)	0	0	0	1 (12.5)
Acute respiratory failure	1 (12.5)	0	0	1 (12.5)	0
Atelectasis	1 (12.5)	0	0	1 (12.5)	0
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)
Hypoxia	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory acidosis	1 (12.5)	0	0	1 (12.5)	0
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	0	1 (12.5)	0
Dry skin	2 (25.0)	2 (25.0)	0	0	0
Rash	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Decubitus ulcer	1 (12.5)	0	1 (12.5)	0	0
Erythema	1 (12.5)	1 (12.5)	0	0	0
Hyperhidrosis	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Petechiae	1 (12.5)	0	0	1 (12.5)	0
Pruritus	1 (12.5)	0	1 (12.5)	0	0
Skin hypopigmentation	1 (12.5)	1 (12.5)	0	0	0
Skin necrosis	1 (12.5)	0	0	1 (12.5)	0
Skin ulcer	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Hypotension	4 (50.0)	0	0	3 (37.5)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	1 (12.5)	0	0	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208e
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	87 (96.7)	0	4 (4.4)	18 (20.0)	65 (72.2)
Blood and lymphatic system disorders					
-Total	61 (67.8)	1 (1.1)	8 (8.9)	34 (37.8)	18 (20.0)
Febrile neutropenia	36 (40.0)	0	0	34 (37.8)	2 (2.2)
Anaemia	35 (38.9)	4 (4.4)	10 (11.1)	20 (22.2)	1 (1.1)
Neutropenia	16 (17.8)	1 (1.1)	2 (2.2)	3 (3.3)	10 (11.1)
Thrombocytopenia	12 (13.3)	0	1 (1.1)	5 (5.6)	6 (6.7)
Disseminated intravascular coagulation	7 (7.8)	0	5 (5.6)	2 (2.2)	0
Leukopenia	5 (5.6)	0	0	1 (1.1)	4 (4.4)
Coagulopathy	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Pancytopenia	4 (4.4)	0	0	3 (3.3)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Lymphadenopathy	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Lymphopenia	2 (2.2)	0	0	0	2 (2.2)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
B-cell aplasia	1 (1.1)	0	1 (1.1)	0	0
Eosinophilia	1 (1.1)	0	1 (1.1)	0	0
Hypercoagulation	1 (1.1)	0	1 (1.1)	0	0
Hypofibrinogenaemia	1 (1.1)	0	1 (1.1)	0	0
Leukocytosis	1 (1.1)	0	1 (1.1)	0	0
Cardiac disorders					
-Total	30 (33.3)	9 (10.0)	7 (7.8)	9 (10.0)	5 (5.6)
Tachycardia	16 (17.8)	6 (6.7)	7 (7.8)	3 (3.3)	0
Left ventricular dysfunction	5 (5.6)	0	1 (1.1)	4 (4.4)	0
Cardiac failure	4 (4.4)	0	0	2 (2.2)	2 (2.2)
Bradycardia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Cardiac arrest	3 (3.3)	0	0	0	3 (3.3)
Cardiac dysfunction	2 (2.2)	2 (2.2)	0	0	0
Pericardial effusion	2 (2.2)	1 (1.1)	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Atrioventricular block first degree	1 (1.1)	0	1 (1.1)	0	0
Cardiac failure congestive	1 (1.1)	0	1 (1.1)	0	0
Mitral valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Right ventricular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Sinus bradycardia	1 (1.1)	0	0	1 (1.1)	0
Tricuspid valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.1)	1 (1.1)	0	0	0
Cerebral cavernous malformation	1 (1.1)	1 (1.1)	0	0	0
Ear and labyrinth disorders					
-Total	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Deafness unilateral	1 (1.1)	0	1 (1.1)	0	0
Ear pain	1 (1.1)	1 (1.1)	0	0	0
Ear pruritus	1 (1.1)	1 (1.1)	0	0	0
Vertigo	1 (1.1)	0	1 (1.1)	0	0
Endocrine disorders					

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (10.0)	0	9 (10.0)	0	0
Adrenal insufficiency	6 (6.7)	0	6 (6.7)	0	0
Hypothyroidism	3 (3.3)	0	3 (3.3)	0	0
Delayed puberty	1 (1.1)	0	1 (1.1)	0	0
Eye disorders					
-Total	16 (17.8)	11 (12.2)	4 (4.4)	1 (1.1)	0
Eye pain	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Ocular hyperaemia	3 (3.3)	3 (3.3)	0	0	0
Cataract	2 (2.2)	2 (2.2)	0	0	0
Conjunctival haemorrhage	2 (2.2)	2 (2.2)	0	0	0
Eyelid oedema	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Visual impairment	2 (2.2)	2 (2.2)	0	0	0
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eye oedema	1 (1.1)	1 (1.1)	0	0	0
Hypermetropia	1 (1.1)	1 (1.1)	0	0	0
Mydriasis	1 (1.1)	0	1 (1.1)	0	0
Periorbital oedema	1 (1.1)	1 (1.1)	0	0	0
Periorbital swelling	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Vision blurred	1 (1.1)	1 (1.1)	0	0	0
Visual field defect	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal disorders					
-Total	66 (73.3)	17 (18.9)	29 (32.2)	19 (21.1)	1 (1.1)
Nausea	31 (34.4)	12 (13.3)	16 (17.8)	3 (3.3)	0
Vomiting	30 (33.3)	20 (22.2)	8 (8.9)	2 (2.2)	0
Diarrhoea	27 (30.0)	17 (18.9)	8 (8.9)	2 (2.2)	0
Constipation	18 (20.0)	8 (8.9)	10 (11.1)	0	0
Abdominal pain	15 (16.7)	3 (3.3)	10 (11.1)	2 (2.2)	0
Stomatitis	10 (11.1)	1 (1.1)	4 (4.4)	5 (5.6)	0
Pancreatitis	6 (6.7)	1 (1.1)	3 (3.3)	2 (2.2)	0
Mouth haemorrhage	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Abdominal pain upper	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Gastrointestinal sounds abnormal	3 (3.3)	3 (3.3)	0	0	0
Gingival bleeding	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Haematemesis	3 (3.3)	3 (3.3)	0	0	0
Abdominal distension	2 (2.2)	1 (1.1)	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	2 (2.2)	0	2 (2.2)	0	0
Ascites	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Dry mouth	2 (2.2)	0	2 (2.2)	0	0
Gastrointestinal haemorrhage	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Ileus	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Neutropenic colitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Oral pain	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Proctalgia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Trichoglossia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
Abdominal rigidity	1 (1.1)	0	1 (1.1)	0	0
Anal erythema	1 (1.1)	1 (1.1)	0	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0
Anal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0
Duodenal perforation	1 (1.1)	0	0	1 (1.1)	0
Dyspepsia	1 (1.1)	1 (1.1)	0	0	0
Dysphagia	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enteritis	1 (1.1)	0	1 (1.1)	0	0
Enterocolitis	1 (1.1)	0	1 (1.1)	0	0
Gastritis	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal inflammation	1 (1.1)	0	1 (1.1)	0	0
Gastrooesophageal reflux disease	1 (1.1)	0	1 (1.1)	0	0
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
Gingivitis ulcerative	1 (1.1)	0	0	1 (1.1)	0
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Lip dry	1 (1.1)	0	1 (1.1)	0	0
Lip oedema	1 (1.1)	1 (1.1)	0	0	0
Lip pain	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Mouth swelling	1 (1.1)	1 (1.1)	0	0	0
Odynophagia	1 (1.1)	1 (1.1)	0	0	0
Oral disorder	1 (1.1)	1 (1.1)	0	0	0
Peritoneal haematoma	1 (1.1)	1 (1.1)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	57 (63.3)	28 (31.1)	14 (15.6)	11 (12.2)	4 (4.4)
Pyrexia	38 (42.2)	18 (20.0)	9 (10.0)	9 (10.0)	2 (2.2)
Fatigue	17 (18.9)	13 (14.4)	4 (4.4)	0	0
Chills	8 (8.9)	5 (5.6)	3 (3.3)	0	0
Face oedema	7 (7.8)	5 (5.6)	1 (1.1)	1 (1.1)	0
Oedema peripheral	7 (7.8)	6 (6.7)	0	1 (1.1)	0
Pain	7 (7.8)	1 (1.1)	4 (4.4)	2 (2.2)	0
Generalised oedema	5 (5.6)	2 (2.2)	2 (2.2)	1 (1.1)	0
Asthenia	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Catheter site pain	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Localised oedema	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Drug withdrawal syndrome	2 (2.2)	0	2 (2.2)	0	0
Influenza like illness	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Malaise	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Multiple organ dysfunction syndrome	2 (2.2)	0	0	0	2 (2.2)
Non-cardiac chest pain	2 (2.2)	2 (2.2)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device occlusion	2 (2.2)	2 (2.2)	0	0	0
Catheter site dermatitis	1 (1.1)	1 (1.1)	0	0	0
Catheter site erythema	1 (1.1)	1 (1.1)	0	0	0
Catheter site haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Chest discomfort	1 (1.1)	0	0	1 (1.1)	0
Complication associated with device	1 (1.1)	1 (1.1)	0	0	0
Crying	1 (1.1)	0	1 (1.1)	0	0
Facial pain	1 (1.1)	0	1 (1.1)	0	0
Oedema due to hepatic disease	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0
Swelling face	1 (1.1)	1 (1.1)	0	0	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Xerosis	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	23 (25.6)	7 (7.8)	8 (8.9)	6 (6.7)	2 (2.2)
Hyperbilirubinaemia	6 (6.7)	1 (1.1)	3 (3.3)	2 (2.2)	0
Hepatic function abnormal	5 (5.6)	0	2 (2.2)	2 (2.2)	1 (1.1)
Hepatomegaly	3 (3.3)	2 (2.2)	0	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Hepatic cytolysis	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Biliary tract disorder	1 (1.1)	1 (1.1)	0	0	0
Cholelithiasis	1 (1.1)	0	1 (1.1)	0	0
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Gallbladder enlargement	1 (1.1)	1 (1.1)	0	0	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Liver disorder	1 (1.1)	0	1 (1.1)	0	0
Ocular icterus	1 (1.1)	1 (1.1)	0	0	0
Immune system disorders					
-Total	67 (74.4)	2 (2.2)	20 (22.2)	25 (27.8)	20 (22.2)
Cytokine release syndrome	56 (62.2)	4 (4.4)	16 (17.8)	17 (18.9)	19 (21.1)
Hypogammaglobulinaemia	33 (36.7)	2 (2.2)	24 (26.7)	7 (7.8)	0
Haemophagocytic lymphohistiocytosis	5 (5.6)	1 (1.1)	1 (1.1)	2 (2.2)	1 (1.1)
Immunodeficiency	4 (4.4)	0	0	4 (4.4)	0
Seasonal allergy	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Graft versus host disease	3 (3.3)	0	0	3 (3.3)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Chronic graft versus host disease	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Engraftment syndrome	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	1 (1.1)	0	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	70 (77.8)	6 (6.7)	13 (14.4)	34 (37.8)	17 (18.9)
Upper respiratory tract infection	13 (14.4)	5 (5.6)	5 (5.6)	3 (3.3)	0
Pneumonia	9 (10.0)	1 (1.1)	2 (2.2)	3 (3.3)	3 (3.3)
Conjunctivitis	8 (8.9)	3 (3.3)	5 (5.6)	0	0
Nasopharyngitis	8 (8.9)	5 (5.6)	3 (3.3)	0	0
Rhinovirus infection	8 (8.9)	0	6 (6.7)	2 (2.2)	0
Sinusitis	8 (8.9)	0	5 (5.6)	3 (3.3)	0
Parainfluenzae virus infection	7 (7.8)	1 (1.1)	1 (1.1)	4 (4.4)	1 (1.1)
Gastroenteritis	6 (6.7)	3 (3.3)	1 (1.1)	2 (2.2)	0
Oral herpes	6 (6.7)	1 (1.1)	3 (3.3)	2 (2.2)	0
Staphylococcal bacteraemia	6 (6.7)	0	0	6 (6.7)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	6 (6.7)	0	3 (3.3)	3 (3.3)	0
Bacteraemia	5 (5.6)	0	1 (1.1)	3 (3.3)	1 (1.1)
Otitis media	5 (5.6)	0	4 (4.4)	1 (1.1)	0
Paronychia	5 (5.6)	1 (1.1)	3 (3.3)	1 (1.1)	0
Candida infection	4 (4.4)	0	3 (3.3)	0	1 (1.1)
Clostridium difficile infection	4 (4.4)	1 (1.1)	0	3 (3.3)	0
Herpes zoster	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Nail infection	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Sepsis	4 (4.4)	0	0	1 (1.1)	3 (3.3)
Acute sinusitis	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Bronchitis	3 (3.3)	0	3 (3.3)	0	0
Bronchopulmonary aspergillosis	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Device related infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Ear infection	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Escherichia bacteraemia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Gingivitis	3 (3.3)	3 (3.3)	0	0	0
Influenza	3 (3.3)	0	2 (2.2)	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	3 (3.3)	0	0	3 (3.3)	0
Oral candidiasis	3 (3.3)	0	3 (3.3)	0	0
Respiratory syncytial virus infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Respiratory tract infection	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Rhinitis	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Septic shock	3 (3.3)	0	0	0	3 (3.3)
Skin infection	3 (3.3)	0	3 (3.3)	0	0
Urinary tract infection	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Adenovirus infection	2 (2.2)	0	0	2 (2.2)	0
Bk virus infection	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Bronchiolitis	2 (2.2)	0	0	2 (2.2)	0
Covid-19	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Encephalitis viral	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Fungal infection	2 (2.2)	0	2 (2.2)	0	0
Fungal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Herpes simplex	2 (2.2)	0	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	2 (2.2)	0	0	2 (2.2)	0
Klebsiella bacteraemia	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Oral infection	2 (2.2)	0	2 (2.2)	0	0
Otitis externa	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Pneumonia fungal	2 (2.2)	0	0	2 (2.2)	0
Staphylococcal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Tinea pedis	2 (2.2)	2 (2.2)	0	0	0
Varicella zoster virus infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cystitis	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Folliculitis	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	24 (26.7)	9 (10.0)	10 (11.1)	3 (3.3)	2 (2.2)
Infusion related reaction	5 (5.6)	2 (2.2)	2 (2.2)	1 (1.1)	0
Transfusion reaction	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Fall	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Procedural pain	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	2 (2.2)	2 (2.2)	0	0	0
Ligament sprain	2 (2.2)	2 (2.2)	0	0	0
Skin abrasion	2 (2.2)	2 (2.2)	0	0	0
Wound	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Abdominal injury	1 (1.1)	1 (1.1)	0	0	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Limb injury	1 (1.1)	0	1 (1.1)	0	0
Post-traumatic neck syndrome	1 (1.1)	0	1 (1.1)	0	0
Scratch	1 (1.1)	1 (1.1)	0	0	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Transplant failure	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Investigations					
-Total	62 (68.9)	1 (1.1)	6 (6.7)	19 (21.1)	36 (40.0)
White blood cell count decreased	29 (32.2)	2 (2.2)	2 (2.2)	1 (1.1)	24 (26.7)
Platelet count decreased	27 (30.0)	6 (6.7)	2 (2.2)	6 (6.7)	13 (14.4)
Neutrophil count decreased	26 (28.9)	1 (1.1)	2 (2.2)	2 (2.2)	21 (23.3)
Lymphocyte count decreased	21 (23.3)	0	1 (1.1)	8 (8.9)	12 (13.3)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	20 (22.2)	4 (4.4)	8 (8.9)	8 (8.9)	0
Aspartate aminotransferase increased	19 (21.1)	2 (2.2)	5 (5.6)	9 (10.0)	3 (3.3)
Blood bilirubin increased	12 (13.3)	1 (1.1)	2 (2.2)	9 (10.0)	0
C-reactive protein increased	11 (12.2)	3 (3.3)	2 (2.2)	5 (5.6)	1 (1.1)
Serum ferritin increased	11 (12.2)	2 (2.2)	5 (5.6)	3 (3.3)	1 (1.1)
International normalised ratio increased	9 (10.0)	5 (5.6)	4 (4.4)	0	0
Blood fibrinogen decreased	8 (8.9)	3 (3.3)	3 (3.3)	1 (1.1)	1 (1.1)
Blood immunoglobulin a decreased	7 (7.8)	5 (5.6)	1 (1.1)	1 (1.1)	0
Blood lactate dehydrogenase increased	7 (7.8)	3 (3.3)	1 (1.1)	3 (3.3)	0
Activated partial thromboplastin time prolonged	6 (6.7)	3 (3.3)	2 (2.2)	1 (1.1)	0
Blood immunoglobulin m decreased	6 (6.7)	4 (4.4)	0	2 (2.2)	0
Blood creatinine increased	5 (5.6)	0	1 (1.1)	3 (3.3)	1 (1.1)
Weight increased	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Blood uric acid increased	4 (4.4)	2 (2.2)	0	1 (1.1)	1 (1.1)
Electrocardiogram qt prolonged	4 (4.4)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	4 (4.4)	2 (2.2)	0	1 (1.1)	1 (1.1)
Weight decreased	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Blood fibrinogen increased	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Blood immunoglobulin g decreased	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Oxygen saturation decreased	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Amylase increased	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Blood glucose increased	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Blood phosphorus increased	2 (2.2)	0	2 (2.2)	0	0
Gamma-glutamyltransferase increased	2 (2.2)	0	0	2 (2.2)	0
Immunoglobulins decreased	2 (2.2)	0	2 (2.2)	0	0
Urine output decreased	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Bacterial test positive	1 (1.1)	0	0	1 (1.1)	0
Blood alkaline phosphatase decreased	1 (1.1)	1 (1.1)	0	0	0
Blood bicarbonate decreased	1 (1.1)	0	1 (1.1)	0	0
Blood creatine phosphokinase increased	1 (1.1)	0	0	1 (1.1)	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (1.1)	0	0	0	1 (1.1)
Blood testosterone decreased	1 (1.1)	1 (1.1)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.1)	1 (1.1)	0	0	0
Blood urea increased	1 (1.1)	0	0	1 (1.1)	0
Bone density decreased	1 (1.1)	1 (1.1)	0	0	0
Breath sounds abnormal	1 (1.1)	0	1 (1.1)	0	0
Cardiac murmur	1 (1.1)	1 (1.1)	0	0	0
Coagulation test abnormal	1 (1.1)	1 (1.1)	0	0	0
Ejection fraction decreased	1 (1.1)	0	1 (1.1)	0	0
Electrocardiogram t wave abnormal	1 (1.1)	0	1 (1.1)	0	0
Enterovirus test positive	1 (1.1)	0	1 (1.1)	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Haptoglobin decreased	1 (1.1)	1 (1.1)	0	0	0
Heart sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Hepatitis b virus test positive	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (1.1)	1 (1.1)	0	0	0
Prothrombin time prolonged	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Staphylococcus test positive	1 (1.1)	1 (1.1)	0	0	0
Troponin increased	1 (1.1)	0	0	1 (1.1)	0
Metabolism and nutrition disorders					
-Total	52 (57.8)	7 (7.8)	10 (11.1)	22 (24.4)	13 (14.4)
Decreased appetite	31 (34.4)	10 (11.1)	7 (7.8)	12 (13.3)	2 (2.2)
Hypokalaemia	24 (26.7)	4 (4.4)	5 (5.6)	13 (14.4)	2 (2.2)
Hypophosphataemia	18 (20.0)	3 (3.3)	7 (7.8)	7 (7.8)	1 (1.1)
Hypocalcaemia	15 (16.7)	2 (2.2)	8 (8.9)	5 (5.6)	0
Hypoalbuminaemia	10 (11.1)	0	9 (10.0)	1 (1.1)	0
Hypervolaemia	9 (10.0)	1 (1.1)	2 (2.2)	6 (6.7)	0
Hyperglycaemia	8 (8.9)	0	3 (3.3)	5 (5.6)	0
Hypomagnesaemia	8 (8.9)	6 (6.7)	2 (2.2)	0	0
Hyperuricaemia	7 (7.8)	6 (6.7)	1 (1.1)	0	0
Hyperphosphataemia	6 (6.7)	5 (5.6)	0	0	1 (1.1)
Tumour lysis syndrome	6 (6.7)	0	0	4 (4.4)	2 (2.2)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	4 (4.4)	1 (1.1)	0	0	3 (3.3)
Hypercalcaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hyperkalaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hypertriglyceridaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hyponatraemia	3 (3.3)	2 (2.2)	0	0	1 (1.1)
Hyperchloraemia	2 (2.2)	2 (2.2)	0	0	0
Hypernatraemia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Iron overload	2 (2.2)	0	2 (2.2)	0	0
Malnutrition	2 (2.2)	0	0	2 (2.2)	0
Acidosis	1 (1.1)	0	0	0	1 (1.1)
Calcium deficiency	1 (1.1)	1 (1.1)	0	0	0
Dehydration	1 (1.1)	0	1 (1.1)	0	0
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Haemochromatosis	1 (1.1)	0	0	1 (1.1)	0
Hypercholesterolaemia	1 (1.1)	0	1 (1.1)	0	0
Hyperlipidaemia	1 (1.1)	0	1 (1.1)	0	0
Hypermagnesaemia	1 (1.1)	1 (1.1)	0	0	0
Hypoglycaemia	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophagia	1 (1.1)	0	1 (1.1)	0	0
Metabolic syndrome	1 (1.1)	0	1 (1.1)	0	0
Obesity	1 (1.1)	0	0	1 (1.1)	0
Polydipsia	1 (1.1)	0	0	1 (1.1)	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	46 (51.1)	18 (20.0)	19 (21.1)	9 (10.0)	0
Pain in extremity	21 (23.3)	8 (8.9)	11 (12.2)	2 (2.2)	0
Arthralgia	13 (14.4)	6 (6.7)	6 (6.7)	1 (1.1)	0
Back pain	12 (13.3)	2 (2.2)	6 (6.7)	4 (4.4)	0
Myalgia	9 (10.0)	5 (5.6)	4 (4.4)	0	0
Bone pain	4 (4.4)	1 (1.1)	3 (3.3)	0	0
Pain in jaw	3 (3.3)	1 (1.1)	0	2 (2.2)	0
Growth retardation	2 (2.2)	0	2 (2.2)	0	0
Joint effusion	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Muscular weakness	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Musculoskeletal chest pain	2 (2.2)	2 (2.2)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Groin pain	1 (1.1)	1 (1.1)	0	0	0
Haemarthrosis	1 (1.1)	0	0	1 (1.1)	0
Muscle rigidity	1 (1.1)	1 (1.1)	0	0	0
Muscle spasms	1 (1.1)	0	1 (1.1)	0	0
Musculoskeletal pain	1 (1.1)	0	1 (1.1)	0	0
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Osteonecrosis	1 (1.1)	1 (1.1)	0	0	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Synovitis	1 (1.1)	0	1 (1.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (5.6)	1 (1.1)	2 (2.2)	2 (2.2)	0
Skin papilloma	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Bone giant cell tumour benign	1 (1.1)	0	0	1 (1.1)	0
Cancer pain	1 (1.1)	0	1 (1.1)	0	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	50 (55.6)	17 (18.9)	17 (18.9)	11 (12.2)	5 (5.6)
Headache	28 (31.1)	13 (14.4)	12 (13.3)	3 (3.3)	0
Encephalopathy	8 (8.9)	1 (1.1)	3 (3.3)	4 (4.4)	0
Seizure	6 (6.7)	0	3 (3.3)	3 (3.3)	0
Dizziness	5 (5.6)	5 (5.6)	0	0	0
Tremor	5 (5.6)	4 (4.4)	1 (1.1)	0	0
Lethargy	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Somnolence	4 (4.4)	1 (1.1)	1 (1.1)	2 (2.2)	0
Cognitive disorder	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Dysgeusia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Cerebral haemorrhage	2 (2.2)	0	0	0	2 (2.2)
Dysarthria	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Neuropathy peripheral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Paraesthesia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Autonomic neuropathy	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Extrapyramidal disorder	1 (1.1)	0	1 (1.1)	0	0
Generalised tonic-clonic seizure	1 (1.1)	0	1 (1.1)	0	0
Haemorrhage intracranial	1 (1.1)	0	0	0	1 (1.1)
Hydrocephalus	1 (1.1)	0	0	0	1 (1.1)
Hyperaesthesia	1 (1.1)	1 (1.1)	0	0	0
Hypoaesthesia	1 (1.1)	1 (1.1)	0	0	0
Memory impairment	1 (1.1)	0	1 (1.1)	0	0
Migraine	1 (1.1)	0	1 (1.1)	0	0
Nervous system disorder	1 (1.1)	0	0	1 (1.1)	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Neurological decompensation	1 (1.1)	0	0	0	1 (1.1)
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	38 (42.2)	12 (13.3)	17 (18.9)	9 (10.0)	0
Anxiety	16 (17.8)	4 (4.4)	9 (10.0)	3 (3.3)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	8 (8.9)	2 (2.2)	3 (3.3)	3 (3.3)	0
Agitation	7 (7.8)	4 (4.4)	3 (3.3)	0	0
Confusional state	6 (6.7)	6 (6.7)	0	0	0
Insomnia	6 (6.7)	2 (2.2)	4 (4.4)	0	0
Mental status changes	6 (6.7)	1 (1.1)	2 (2.2)	3 (3.3)	0
Hallucination	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Irritability	3 (3.3)	3 (3.3)	0	0	0
Sleep disorder	2 (2.2)	0	2 (2.2)	0	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Automatism	1 (1.1)	1 (1.1)	0	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0
Nightmare	1 (1.1)	1 (1.1)	0	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tearfulness	1 (1.1)	1 (1.1)	0	0	0
Tic	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	26 (28.9)	8 (8.9)	7 (7.8)	5 (5.6)	6 (6.7)
Acute kidney injury	11 (12.2)	3 (3.3)	2 (2.2)	2 (2.2)	4 (4.4)
Dysuria	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Haematuria	4 (4.4)	3 (3.3)	0	1 (1.1)	0
Anuria	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Pollakiuria	2 (2.2)	0	2 (2.2)	0	0
Renal failure	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Azotaemia	1 (1.1)	0	1 (1.1)	0	0
Cystitis haemorrhagic	1 (1.1)	0	1 (1.1)	0	0
Incontinence	1 (1.1)	0	1 (1.1)	0	0
Kidney enlargement	1 (1.1)	0	1 (1.1)	0	0
Micturition urgency	1 (1.1)	0	1 (1.1)	0	0
Proteinuria	1 (1.1)	1 (1.1)	0	0	0
Renal mass	1 (1.1)	0	1 (1.1)	0	0
Renal pain	1 (1.1)	1 (1.1)	0	0	0
Renal tubular disorder	1 (1.1)	0	0	1 (1.1)	0
Renal tubular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Renal tubular necrosis	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (1.1)	0	1 (1.1)	0	0
Urinary retention	1 (1.1)	0	1 (1.1)	0	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0
Reproductive system and breast disorders					
-Total	6 (6.7)	1 (1.1)	3 (3.3)	2 (2.2)	0
Dysmenorrhoea	1 (1.1)	0	1 (1.1)	0	0
Endometriosis	1 (1.1)	0	0	1 (1.1)	0
Female genital tract fistula	1 (1.1)	1 (1.1)	0	0	0
Heavy menstrual bleeding	1 (1.1)	0	1 (1.1)	0	0
Perineal rash	1 (1.1)	0	1 (1.1)	0	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Vaginal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	56 (62.2)	17 (18.9)	8 (8.9)	12 (13.3)	19 (21.1)
Cough	25 (27.8)	20 (22.2)	5 (5.6)	0	0
Hypoxia	20 (22.2)	0	5 (5.6)	9 (10.0)	6 (6.7)
Pulmonary oedema	13 (14.4)	3 (3.3)	3 (3.3)	6 (6.7)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	12 (13.3)	7 (7.8)	2 (2.2)	3 (3.3)	0
Pleural effusion	10 (11.1)	4 (4.4)	3 (3.3)	2 (2.2)	1 (1.1)
Nasal congestion	9 (10.0)	7 (7.8)	2 (2.2)	0	0
Oropharyngeal pain	8 (8.9)	6 (6.7)	2 (2.2)	0	0
Respiratory failure	8 (8.9)	0	0	0	8 (8.9)
Tachypnoea	8 (8.9)	3 (3.3)	2 (2.2)	2 (2.2)	1 (1.1)
Dyspnoea	7 (7.8)	1 (1.1)	2 (2.2)	3 (3.3)	1 (1.1)
Rhinorrhoea	6 (6.7)	4 (4.4)	2 (2.2)	0	0
Respiratory distress	4 (4.4)	0	2 (2.2)	0	2 (2.2)
Acute respiratory distress syndrome	3 (3.3)	0	0	0	3 (3.3)
Atelectasis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Pharyngeal erythema	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Rhinitis allergic	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Sleep apnoea syndrome	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Wheezing	2 (2.2)	0	2 (2.2)	0	0
Bradypnoea	1 (1.1)	0	0	1 (1.1)	0
Bronchial oedema	1 (1.1)	1 (1.1)	0	0	0
Bronchospasm	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (1.1)	1 (1.1)	0	0	0
Haemoptysis	1 (1.1)	0	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	0	0	1 (1.1)
Lung disorder	1 (1.1)	1 (1.1)	0	0	0
Lung infiltration	1 (1.1)	0	0	1 (1.1)	0
Nasal discomfort	1 (1.1)	0	1 (1.1)	0	0
Nasal dryness	1 (1.1)	1 (1.1)	0	0	0
Oropharyngeal plaque	1 (1.1)	0	1 (1.1)	0	0
Painful respiration	1 (1.1)	1 (1.1)	0	0	0
Paranasal sinus discomfort	1 (1.1)	0	1 (1.1)	0	0
Paranasal sinus inflammation	1 (1.1)	1 (1.1)	0	0	0
Pharyngeal exudate	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal oedema	1 (1.1)	0	1 (1.1)	0	0
Productive cough	1 (1.1)	1 (1.1)	0	0	0
Pulmonary haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Pulmonary mass	1 (1.1)	0	1 (1.1)	0	0
Respiratory disorder	1 (1.1)	0	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract inflammation	1 (1.1)	0	1 (1.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	44 (48.9)	19 (21.1)	18 (20.0)	7 (7.8)	0
Pruritus	10 (11.1)	5 (5.6)	5 (5.6)	0	0
Rash	8 (8.9)	4 (4.4)	4 (4.4)	0	0
Dry skin	7 (7.8)	5 (5.6)	2 (2.2)	0	0
Erythema	5 (5.6)	4 (4.4)	1 (1.1)	0	0
Rash maculo-papular	4 (4.4)	2 (2.2)	1 (1.1)	1 (1.1)	0
Rash papular	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Blister	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Dermatitis atopic	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Eczema	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Ingrowing nail	3 (3.3)	0	3 (3.3)	0	0
Skin ulcer	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Hyperhidrosis	2 (2.2)	0	2 (2.2)	0	0
Petechiae	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Skin discolouration	2 (2.2)	2 (2.2)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acne	1 (1.1)	1 (1.1)	0	0	0
Decubitus ulcer	1 (1.1)	0	0	1 (1.1)	0
Dermatitis	1 (1.1)	1 (1.1)	0	0	0
Dermatitis allergic	1 (1.1)	1 (1.1)	0	0	0
Dermatitis diaper	1 (1.1)	0	1 (1.1)	0	0
Drug eruption	1 (1.1)	0	1 (1.1)	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Hangnail	1 (1.1)	1 (1.1)	0	0	0
Miliaria	1 (1.1)	1 (1.1)	0	0	0
Night sweats	1 (1.1)	1 (1.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.1)	1 (1.1)	0	0	0
Papule	1 (1.1)	1 (1.1)	0	0	0
Photosensitivity reaction	1 (1.1)	0	1 (1.1)	0	0
Pruritus allergic	1 (1.1)	0	1 (1.1)	0	0
Purpura	1 (1.1)	1 (1.1)	0	0	0
Rash erythematous	1 (1.1)	1 (1.1)	0	0	0
Rash macular	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pruritic	1 (1.1)	1 (1.1)	0	0	0
Rash vesicular	1 (1.1)	1 (1.1)	0	0	0
Scab	1 (1.1)	1 (1.1)	0	0	0
Skin lesion	1 (1.1)	0	1 (1.1)	0	0
Skin swelling	1 (1.1)	1 (1.1)	0	0	0
Urticaria	1 (1.1)	0	1 (1.1)	0	0
Vancomycin infusion reaction	1 (1.1)	0	0	1 (1.1)	0
Social circumstances					
-Total	1 (1.1)	0	1 (1.1)	0	0
Patient uncooperative	1 (1.1)	0	1 (1.1)	0	0
Surgical and medical procedures					
-Total	1 (1.1)	0	0	1 (1.1)	0
Thrombolysis	1 (1.1)	0	0	1 (1.1)	0
Vascular disorders					
-Total	39 (43.3)	5 (5.6)	11 (12.2)	13 (14.4)	10 (11.1)
Hypotension	26 (28.9)	2 (2.2)	6 (6.7)	9 (10.0)	9 (10.0)
Hypertension	18 (20.0)	4 (4.4)	10 (11.1)	4 (4.4)	0
Capillary leak syndrome	2 (2.2)	0	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flushing	2 (2.2)	2 (2.2)	0	0	0
Peripheral ischaemia	2 (2.2)	0	2 (2.2)	0	0
Venoocclusive disease	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Haematoma	1 (1.1)	1 (1.1)	0	0	0
Hot flush	1 (1.1)	1 (1.1)	0	0	0
Thrombosis	1 (1.1)	0	1 (1.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208f
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)	0	0
Endocrine disorders					

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Delayed puberty	1 (50.0)	0	1 (50.0)	0	0
Hypothyroidism	1 (50.0)	0	1 (50.0)	0	0
Eye disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Dry eye	1 (50.0)	1 (50.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Nausea	1 (50.0)	1 (50.0)	0	0	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0	0	0
Vomiting	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Fatigue	1 (50.0)	0	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	1 (50.0)	0	0	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypogammaglobulinaemia	2 (100)	0	1 (50.0)	1 (50.0)	0
Seasonal allergy	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Device related bacteraemia	1 (50.0)	0	1 (50.0)	0	0
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (50.0)	0	0	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	1 (50.0)	0
Blood creatinine increased	1 (50.0)	0	0	1 (50.0)	0
Weight decreased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	0	0	1 (50.0)
Haemochromatosis	1 (50.0)	0	0	1 (50.0)	0
Hypocalcaemia	1 (50.0)	0	0	1 (50.0)	0
Hypokalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypophosphataemia	1 (50.0)	0	1 (50.0)	0	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Growth retardation	1 (50.0)	0	1 (50.0)	0	0
Osteopenia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	0	0	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Psychiatric disorders					
-Total	2 (100)	0	2 (100)	0	0
Anxiety	1 (50.0)	0	1 (50.0)	0	0
Sleep disorder	1 (50.0)	0	1 (50.0)	0	0
Renal and urinary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Renal tubular disorder	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Pleural effusion	2 (100)	0	1 (50.0)	0	1 (50.0)
Cough	1 (50.0)	0	1 (50.0)	0	0
Lung disorder	1 (50.0)	1 (50.0)	0	0	0
Rhinorrhoea	1 (50.0)	0	1 (50.0)	0	0
Wheezing	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	2 (100)	1 (50.0)	0	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208f
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	93 (96.9)	0	5 (5.2)	20 (20.8)	68 (70.8)
Blood and lymphatic system disorders					
-Total	65 (67.7)	1 (1.0)	9 (9.4)	36 (37.5)	19 (19.8)
Anaemia	38 (39.6)	5 (5.2)	11 (11.5)	21 (21.9)	1 (1.0)
Febrile neutropenia	38 (39.6)	0	0	35 (36.5)	3 (3.1)
Neutropenia	15 (15.6)	1 (1.0)	2 (2.1)	3 (3.1)	9 (9.4)
Thrombocytopenia	13 (13.5)	0	1 (1.0)	5 (5.2)	7 (7.3)
Disseminated intravascular coagulation	7 (7.3)	0	5 (5.2)	2 (2.1)	0
Coagulopathy	5 (5.2)	1 (1.0)	2 (2.1)	2 (2.1)	0
Leukopenia	5 (5.2)	0	0	1 (1.0)	4 (4.2)
Splenomegaly	4 (4.2)	3 (3.1)	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Lymphadenopathy	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.0)	0	0	1 (1.0)	0
B-cell aplasia	1 (1.0)	0	1 (1.0)	0	0
Eosinophilia	1 (1.0)	0	1 (1.0)	0	0
Hypercoagulation	1 (1.0)	0	1 (1.0)	0	0
Hypofibrinogenaemia	1 (1.0)	0	1 (1.0)	0	0
Leukocytosis	1 (1.0)	0	1 (1.0)	0	0
Lymphocytosis	1 (1.0)	0	1 (1.0)	0	0
Cardiac disorders					
-Total	34 (35.4)	10 (10.4)	7 (7.3)	11 (11.5)	6 (6.3)
Tachycardia	21 (21.9)	7 (7.3)	8 (8.3)	5 (5.2)	1 (1.0)
Cardiac failure	4 (4.2)	0	0	2 (2.1)	2 (2.1)
Left ventricular dysfunction	4 (4.2)	0	0	4 (4.2)	0
Bradycardia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cardiac arrest	3 (3.1)	0	0	0	3 (3.1)
Sinus tachycardia	3 (3.1)	2 (2.1)	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.1)	2 (2.1)	0	0	0
Pericardial effusion	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Atrioventricular block first degree	1 (1.0)	0	1 (1.0)	0	0
Cardiac failure congestive	1 (1.0)	0	1 (1.0)	0	0
Mitral valve incompetence	1 (1.0)	1 (1.0)	0	0	0
Right ventricular dysfunction	1 (1.0)	1 (1.0)	0	0	0
Sinus bradycardia	1 (1.0)	0	0	1 (1.0)	0
Tricuspid valve incompetence	1 (1.0)	1 (1.0)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.0)	1 (1.0)	0	0	0
Cerebral cavernous malformation	1 (1.0)	1 (1.0)	0	0	0
Ear and labyrinth disorders					
-Total	4 (4.2)	2 (2.1)	2 (2.1)	0	0
Deafness unilateral	1 (1.0)	0	1 (1.0)	0	0
Ear pain	1 (1.0)	1 (1.0)	0	0	0
Ear pruritus	1 (1.0)	1 (1.0)	0	0	0
Vertigo	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	8 (8.3)	0	8 (8.3)	0	0
Adrenal insufficiency	6 (6.3)	0	6 (6.3)	0	0
Hypothyroidism	2 (2.1)	0	2 (2.1)	0	0
Eye disorders					
-Total	16 (16.7)	10 (10.4)	5 (5.2)	1 (1.0)	0
Eye pain	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Eyelid oedema	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Ocular hyperaemia	3 (3.1)	3 (3.1)	0	0	0
Cataract	2 (2.1)	2 (2.1)	0	0	0
Conjunctival haemorrhage	2 (2.1)	2 (2.1)	0	0	0
Visual impairment	2 (2.1)	2 (2.1)	0	0	0
Eye oedema	1 (1.0)	1 (1.0)	0	0	0
Hypermetropia	1 (1.0)	1 (1.0)	0	0	0
Mydriasis	1 (1.0)	0	1 (1.0)	0	0
Periorbital oedema	1 (1.0)	1 (1.0)	0	0	0
Periorbital swelling	1 (1.0)	0	1 (1.0)	0	0
Retinal haemorrhage	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (1.0)	1 (1.0)	0	0	0
Visual field defect	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal disorders					
-Total	70 (72.9)	19 (19.8)	29 (30.2)	20 (20.8)	2 (2.1)
Nausea	32 (33.3)	13 (13.5)	16 (16.7)	3 (3.1)	0
Vomiting	29 (30.2)	19 (19.8)	8 (8.3)	2 (2.1)	0
Diarrhoea	26 (27.1)	17 (17.7)	7 (7.3)	2 (2.1)	0
Constipation	19 (19.8)	9 (9.4)	10 (10.4)	0	0
Abdominal pain	17 (17.7)	5 (5.2)	10 (10.4)	2 (2.1)	0
Stomatitis	11 (11.5)	1 (1.0)	5 (5.2)	5 (5.2)	0
Mouth haemorrhage	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Pancreatitis	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Abdominal pain upper	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Haematemesis	4 (4.2)	4 (4.2)	0	0	0
Abdominal distension	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Ascites	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Gastrointestinal sounds abnormal	3 (3.1)	3 (3.1)	0	0	0
Gingival bleeding	3 (3.1)	2 (2.1)	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	2 (2.1)	0	0	0	2 (2.1)
Anal fissure	2 (2.1)	0	2 (2.1)	0	0
Dry mouth	2 (2.1)	0	2 (2.1)	0	0
Gastrointestinal haemorrhage	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Gingival erythema	2 (2.1)	2 (2.1)	0	0	0
Ileus	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Neutropenic colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral pain	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Proctalgia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Trichoglossia	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Abdominal rigidity	1 (1.0)	0	1 (1.0)	0	0
Anal erythema	1 (1.0)	1 (1.0)	0	0	0
Anal fistula	1 (1.0)	0	0	1 (1.0)	0
Anal haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Anal inflammation	1 (1.0)	0	0	1 (1.0)	0
Duodenal perforation	1 (1.0)	0	0	1 (1.0)	0
Dyspepsia	1 (1.0)	1 (1.0)	0	0	0
Dysphagia	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enteritis	1 (1.0)	0	1 (1.0)	0	0
Enterocolitis	1 (1.0)	0	1 (1.0)	0	0
Gastritis	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal inflammation	1 (1.0)	0	1 (1.0)	0	0
Gastrooesophageal reflux disease	1 (1.0)	0	1 (1.0)	0	0
Gingivitis ulcerative	1 (1.0)	0	0	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	0	0	1 (1.0)
Haemorrhoids	1 (1.0)	0	1 (1.0)	0	0
Irritable bowel syndrome	1 (1.0)	0	1 (1.0)	0	0
Lip dry	1 (1.0)	0	1 (1.0)	0	0
Lip oedema	1 (1.0)	1 (1.0)	0	0	0
Lip pain	1 (1.0)	1 (1.0)	0	0	0
Lip ulceration	1 (1.0)	0	1 (1.0)	0	0
Melaena	1 (1.0)	0	0	1 (1.0)	0
Mouth swelling	1 (1.0)	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	1 (1.0)	0	0	0
Oral disorder	1 (1.0)	1 (1.0)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	62 (64.6)	29 (30.2)	16 (16.7)	12 (12.5)	5 (5.2)
Pyrexia	42 (43.8)	18 (18.8)	12 (12.5)	10 (10.4)	2 (2.1)
Fatigue	18 (18.8)	15 (15.6)	3 (3.1)	0	0
Chills	9 (9.4)	5 (5.2)	4 (4.2)	0	0
Face oedema	8 (8.3)	5 (5.2)	2 (2.1)	1 (1.0)	0
Oedema peripheral	8 (8.3)	6 (6.3)	1 (1.0)	1 (1.0)	0
Pain	8 (8.3)	1 (1.0)	5 (5.2)	2 (2.1)	0
Generalised oedema	6 (6.3)	2 (2.1)	3 (3.1)	1 (1.0)	0
Catheter site pain	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	0
Asthenia	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Localised oedema	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Multiple organ dysfunction syndrome	3 (3.1)	0	0	0	3 (3.1)
Drug withdrawal syndrome	2 (2.1)	0	2 (2.1)	0	0
Influenza like illness	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Malaise	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Non-cardiac chest pain	2 (2.1)	2 (2.1)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device occlusion	2 (2.1)	2 (2.1)	0	0	0
Catheter site dermatitis	1 (1.0)	1 (1.0)	0	0	0
Catheter site erythema	1 (1.0)	1 (1.0)	0	0	0
Catheter site haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Chest discomfort	1 (1.0)	0	0	1 (1.0)	0
Complication associated with device	1 (1.0)	1 (1.0)	0	0	0
Crying	1 (1.0)	0	1 (1.0)	0	0
Facial pain	1 (1.0)	0	1 (1.0)	0	0
Oedema due to hepatic disease	1 (1.0)	0	1 (1.0)	0	0
Sluggishness	1 (1.0)	0	1 (1.0)	0	0
Swelling face	1 (1.0)	1 (1.0)	0	0	0
Systemic inflammatory response syndrome	1 (1.0)	0	0	1 (1.0)	0
Thirst	1 (1.0)	1 (1.0)	0	0	0
Xerosis	1 (1.0)	1 (1.0)	0	0	0
Hepatobiliary disorders					
-Total	23 (24.0)	6 (6.3)	8 (8.3)	6 (6.3)	3 (3.1)
Hyperbilirubinaemia	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	5 (5.2)	0	2 (2.1)	2 (2.1)	1 (1.0)
Hepatomegaly	3 (3.1)	2 (2.1)	0	0	1 (1.0)
Hypertransaminasaemia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cholelithiasis	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Gallbladder enlargement	2 (2.1)	2 (2.1)	0	0	0
Biliary tract disorder	1 (1.0)	1 (1.0)	0	0	0
Cholestasis	1 (1.0)	0	0	0	1 (1.0)
Drug-induced liver injury	1 (1.0)	0	0	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	0	0	1 (1.0)	0
Hepatosplenomegaly	1 (1.0)	0	1 (1.0)	0	0
Liver disorder	1 (1.0)	0	1 (1.0)	0	0
Ocular icterus	1 (1.0)	1 (1.0)	0	0	0
Immune system disorders					
-Total	71 (74.0)	2 (2.1)	24 (25.0)	24 (25.0)	21 (21.9)
Cytokine release syndrome	59 (61.5)	5 (5.2)	18 (18.8)	16 (16.7)	20 (20.8)
Hypogammaglobulinaemia	34 (35.4)	2 (2.1)	25 (26.0)	7 (7.3)	0
Haemophagocytic lymphohistiocytosis	6 (6.3)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	4 (4.2)	0	0	4 (4.2)	0
Seasonal allergy	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Graft versus host disease	3 (3.1)	0	0	3 (3.1)	0
Allergy to immunoglobulin therapy	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Chronic graft versus host disease	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Drug hypersensitivity	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Engraftment syndrome	1 (1.0)	0	0	1 (1.0)	0
Hypersensitivity	1 (1.0)	1 (1.0)	0	0	0
Selective igg subclass deficiency	1 (1.0)	0	1 (1.0)	0	0
Infections and infestations					
-Total	74 (77.1)	6 (6.3)	13 (13.5)	36 (37.5)	19 (19.8)
Upper respiratory tract infection	13 (13.5)	5 (5.2)	6 (6.3)	2 (2.1)	0
Pneumonia	10 (10.4)	1 (1.0)	2 (2.1)	4 (4.2)	3 (3.1)
Conjunctivitis	9 (9.4)	3 (3.1)	6 (6.3)	0	0
Rhinovirus infection	9 (9.4)	0	7 (7.3)	2 (2.1)	0
Sinusitis	9 (9.4)	0	6 (6.3)	3 (3.1)	0
Nasopharyngitis	8 (8.3)	5 (5.2)	3 (3.1)	0	0
Gastroenteritis	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	7 (7.3)	1 (1.0)	1 (1.0)	4 (4.2)	1 (1.0)
Staphylococcal bacteraemia	7 (7.3)	0	0	7 (7.3)	0
Staphylococcal infection	7 (7.3)	0	3 (3.1)	3 (3.1)	1 (1.0)
Oral herpes	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Bacteraemia	5 (5.2)	0	1 (1.0)	3 (3.1)	1 (1.0)
Otitis media	5 (5.2)	0	4 (4.2)	1 (1.0)	0
Candida infection	4 (4.2)	0	3 (3.1)	0	1 (1.0)
Clostridium difficile infection	4 (4.2)	1 (1.0)	0	3 (3.1)	0
Herpes zoster	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Nail infection	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Paronychia	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Acute sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Bronchitis	3 (3.1)	0	3 (3.1)	0	0
Bronchopulmonary aspergillosis	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Device related infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Ear infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Escherichia bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Gingivitis	3 (3.1)	3 (3.1)	0	0	0
Influenza	3 (3.1)	0	2 (2.1)	0	1 (1.0)
Localised infection	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Metapneumovirus infection	3 (3.1)	0	0	3 (3.1)	0
Oral candidiasis	3 (3.1)	0	3 (3.1)	0	0
Otitis externa	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Respiratory tract infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Rhinitis	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Sepsis	3 (3.1)	0	0	0	3 (3.1)
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Skin infection	3 (3.1)	0	3 (3.1)	0	0
Urinary tract infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Covid-19	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.0)	1 (1.0)	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungal infection	2 (2.1)	0	2 (2.1)	0	0
Fungal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Herpes simplex	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0
Klebsiella bacteraemia	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pneumonia fungal	2 (2.1)	0	0	2 (2.1)	0
Respiratory syncytial virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Viral infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Anal abscess	1 (1.0)	0	0	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Atypical pneumonia	1 (1.0)	1 (1.0)	0	0	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.0)	0	1 (1.0)	0	0
Clostridium difficile colitis	1 (1.0)	0	0	1 (1.0)	0
Coronavirus infection	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cystitis	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Ear, nose and throat infection	1 (1.0)	0	1 (1.0)	0	0
Encephalitis	1 (1.0)	0	0	0	1 (1.0)
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Enterovirus infection	1 (1.0)	0	0	1 (1.0)	0
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Folliculitis	1 (1.0)	0	1 (1.0)	0	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis clostridial	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis norovirus	1 (1.0)	1 (1.0)	0	0	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal infection	1 (1.0)	1 (1.0)	0	0	0
Granulicatella infection	1 (1.0)	0	0	1 (1.0)	0
Herpes virus infection	1 (1.0)	0	1 (1.0)	0	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Molluscum contagiosum	1 (1.0)	1 (1.0)	0	0	0
Myringitis	1 (1.0)	1 (1.0)	0	0	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis media acute	1 (1.0)	0	1 (1.0)	0	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (1.0)	0	1 (1.0)	0	0
Salmonellosis	1 (1.0)	0	1 (1.0)	0	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis fungal	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal sepsis	1 (1.0)	0	0	0	1 (1.0)
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Streptococcal sepsis	1 (1.0)	0	1 (1.0)	0	0
Syphilis	1 (1.0)	0	1 (1.0)	0	0
Systemic candida	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection pseudomonal	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection viral	1 (1.0)	1 (1.0)	0	0	0
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral skin infection	1 (1.0)	1 (1.0)	0	0	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulval cellulitis	1 (1.0)	0	0	1 (1.0)	0
Injury, poisoning and procedural complications					
-Total	27 (28.1)	9 (9.4)	12 (12.5)	3 (3.1)	3 (3.1)
Infusion related reaction	6 (6.3)	2 (2.1)	3 (3.1)	1 (1.0)	0
Procedural pain	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Transfusion reaction	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Fall	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Wound	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Contusion	2 (2.1)	2 (2.1)	0	0	0
Ligament sprain	2 (2.1)	2 (2.1)	0	0	0
Skin abrasion	2 (2.1)	2 (2.1)	0	0	0
Abdominal injury	1 (1.0)	1 (1.0)	0	0	0
Extradural haematoma	1 (1.0)	0	1 (1.0)	0	0
Fibula fracture	1 (1.0)	0	1 (1.0)	0	0
Limb injury	1 (1.0)	0	1 (1.0)	0	0
Post-traumatic neck syndrome	1 (1.0)	0	1 (1.0)	0	0
Radius fracture	1 (1.0)	0	1 (1.0)	0	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scratch	1 (1.0)	1 (1.0)	0	0	0
Skin injury	1 (1.0)	0	1 (1.0)	0	0
Skin wound	1 (1.0)	1 (1.0)	0	0	0
Tracheal obstruction	1 (1.0)	0	0	0	1 (1.0)
Transplant failure	1 (1.0)	0	0	0	1 (1.0)
Traumatic haematoma	1 (1.0)	0	1 (1.0)	0	0
Vasoplegia syndrome	1 (1.0)	0	0	0	1 (1.0)
Investigations					
-Total	64 (66.7)	1 (1.0)	6 (6.3)	19 (19.8)	38 (39.6)
White blood cell count decreased	32 (33.3)	3 (3.1)	3 (3.1)	1 (1.0)	25 (26.0)
Neutrophil count decreased	29 (30.2)	1 (1.0)	2 (2.1)	3 (3.1)	23 (24.0)
Platelet count decreased	28 (29.2)	6 (6.3)	2 (2.1)	6 (6.3)	14 (14.6)
Lymphocyte count decreased	23 (24.0)	1 (1.0)	1 (1.0)	9 (9.4)	12 (12.5)
Alanine aminotransferase increased	21 (21.9)	5 (5.2)	8 (8.3)	8 (8.3)	0
Aspartate aminotransferase increased	20 (20.8)	2 (2.1)	5 (5.2)	10 (10.4)	3 (3.1)
Blood bilirubin increased	12 (12.5)	1 (1.0)	2 (2.1)	9 (9.4)	0
C-reactive protein increased	11 (11.5)	3 (3.1)	2 (2.1)	5 (5.2)	1 (1.0)

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	11 (11.5)	2 (2.1)	5 (5.2)	3 (3.1)	1 (1.0)
International normalised ratio increased	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Blood fibrinogen decreased	8 (8.3)	3 (3.1)	3 (3.1)	1 (1.0)	1 (1.0)
Blood immunoglobulin a decreased	7 (7.3)	5 (5.2)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Blood lactate dehydrogenase increased	7 (7.3)	3 (3.1)	1 (1.0)	3 (3.1)	0
Blood creatinine increased	6 (6.3)	2 (2.1)	1 (1.0)	2 (2.1)	1 (1.0)
Weight increased	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Activated partial thromboplastin time prolonged	5 (5.2)	3 (3.1)	2 (2.1)	0	0
Electrocardiogram qt prolonged	5 (5.2)	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.0)
Blood immunoglobulin g decreased	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Blood uric acid increased	4 (4.2)	2 (2.1)	0	1 (1.0)	1 (1.0)
Fibrin d dimer increased	4 (4.2)	2 (2.1)	0	1 (1.0)	1 (1.0)
Blood fibrinogen increased	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Oxygen saturation decreased	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Weight decreased	3 (3.1)	0	2 (2.1)	1 (1.0)	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amylase increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Blood creatine phosphokinase increased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Blood glucose increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Blood phosphorus increased	2 (2.1)	0	2 (2.1)	0	0
Gamma-glutamyltransferase increased	2 (2.1)	0	0	2 (2.1)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
Lipase increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Urine output decreased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Bacterial test positive	1 (1.0)	0	0	1 (1.0)	0
Blood alkaline phosphatase decreased	1 (1.0)	1 (1.0)	0	0	0
Blood alkaline phosphatase increased	1 (1.0)	1 (1.0)	0	0	0
Blood bicarbonate decreased	1 (1.0)	0	1 (1.0)	0	0
Blood phosphorus decreased	1 (1.0)	0	0	1 (1.0)	0
Blood potassium decreased	1 (1.0)	0	0	0	1 (1.0)
Blood testosterone decreased	1 (1.0)	1 (1.0)	0	0	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood thyroid stimulating hormone increased	1 (1.0)	1 (1.0)	0	0	0
Blood urea increased	1 (1.0)	0	0	1 (1.0)	0
Bone density decreased	1 (1.0)	1 (1.0)	0	0	0
Breath sounds abnormal	1 (1.0)	0	1 (1.0)	0	0
Cardiac murmur	1 (1.0)	1 (1.0)	0	0	0
Coagulation test abnormal	1 (1.0)	1 (1.0)	0	0	0
Ejection fraction decreased	1 (1.0)	0	1 (1.0)	0	0
Electrocardiogram t wave abnormal	1 (1.0)	0	1 (1.0)	0	0
Enterovirus test positive	1 (1.0)	0	1 (1.0)	0	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Haemoglobin decreased	1 (1.0)	0	0	1 (1.0)	0
Haptoglobin decreased	1 (1.0)	1 (1.0)	0	0	0
Heart sounds abnormal	1 (1.0)	1 (1.0)	0	0	0
Hepatitis b virus test positive	1 (1.0)	0	1 (1.0)	0	0
Prothrombin time prolonged	1 (1.0)	0	1 (1.0)	0	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcus test positive	1 (1.0)	1 (1.0)	0	0	0
Troponin increased	1 (1.0)	0	0	1 (1.0)	0
Metabolism and nutrition disorders					
-Total	57 (59.4)	8 (8.3)	11 (11.5)	25 (26.0)	13 (13.5)
Decreased appetite	33 (34.4)	12 (12.5)	8 (8.3)	12 (12.5)	1 (1.0)
Hypokalaemia	24 (25.0)	4 (4.2)	5 (5.2)	12 (12.5)	3 (3.1)
Hypophosphataemia	20 (20.8)	3 (3.1)	7 (7.3)	9 (9.4)	1 (1.0)
Hypocalcaemia	17 (17.7)	2 (2.1)	10 (10.4)	5 (5.2)	0
Hypoalbuminaemia	12 (12.5)	0	11 (11.5)	1 (1.0)	0
Hyperglycaemia	9 (9.4)	0	4 (4.2)	5 (5.2)	0
Hyperuricaemia	9 (9.4)	7 (7.3)	1 (1.0)	1 (1.0)	0
Hypervolaemia	9 (9.4)	1 (1.0)	2 (2.1)	6 (6.3)	0
Hypomagnesaemia	9 (9.4)	7 (7.3)	2 (2.1)	0	0
Hyperphosphataemia	6 (6.3)	5 (5.2)	0	0	1 (1.0)
Metabolic acidosis	6 (6.3)	1 (1.0)	0	2 (2.1)	3 (3.1)
Tumour lysis syndrome	5 (5.2)	0	0	3 (3.1)	2 (2.1)
Hyperkalaemia	4 (4.2)	0	1 (1.0)	2 (2.1)	1 (1.0)
Hyponatraemia	4 (4.2)	3 (3.1)	0	0	1 (1.0)

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Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	3 (3.1)	0	1 (1.0)	1 (1.0)	1 (1.0)
Hypernatraemia	3 (3.1)	1 (1.0)	0	1 (1.0)	1 (1.0)
Hypertriglyceridaemia	3 (3.1)	0	1 (1.0)	1 (1.0)	1 (1.0)
Acidosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Hyperchloraemia	2 (2.1)	2 (2.1)	0	0	0
Hypermagnesaemia	2 (2.1)	2 (2.1)	0	0	0
Iron overload	2 (2.1)	0	2 (2.1)	0	0
Malnutrition	2 (2.1)	0	0	2 (2.1)	0
Calcium deficiency	1 (1.0)	1 (1.0)	0	0	0
Dehydration	1 (1.0)	0	1 (1.0)	0	0
Eating disorder symptom	1 (1.0)	0	1 (1.0)	0	0
Haemosiderosis	1 (1.0)	0	1 (1.0)	0	0
Hypercholesterolaemia	1 (1.0)	0	1 (1.0)	0	0
Hyperlactacidaemia	1 (1.0)	1 (1.0)	0	0	0
Hyperlipidaemia	1 (1.0)	0	1 (1.0)	0	0
Hypoglycaemia	1 (1.0)	0	1 (1.0)	0	0
Hypophagia	1 (1.0)	0	1 (1.0)	0	0
Metabolic syndrome	1 (1.0)	0	1 (1.0)	0	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Obesity	1 (1.0)	0	0	1 (1.0)	0
Polydipsia	1 (1.0)	0	0	1 (1.0)	0
Vitamin d deficiency	1 (1.0)	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	47 (49.0)	18 (18.8)	18 (18.8)	10 (10.4)	1 (1.0)
Pain in extremity	23 (24.0)	9 (9.4)	11 (11.5)	3 (3.1)	0
Arthralgia	13 (13.5)	6 (6.3)	6 (6.3)	1 (1.0)	0
Back pain	12 (12.5)	2 (2.1)	6 (6.3)	4 (4.2)	0
Myalgia	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Bone pain	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Pain in jaw	3 (3.1)	1 (1.0)	0	2 (2.1)	0
Joint effusion	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Muscular weakness	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Musculoskeletal chest pain	2 (2.1)	2 (2.1)	0	0	0
Neck pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Groin pain	1 (1.0)	1 (1.0)	0	0	0
Growth retardation	1 (1.0)	0	1 (1.0)	0	0

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	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (1.0)	0	0	1 (1.0)	0
Muscle rigidity	1 (1.0)	1 (1.0)	0	0	0
Muscle spasms	1 (1.0)	0	1 (1.0)	0	0
Musculoskeletal pain	1 (1.0)	0	1 (1.0)	0	0
Myopathy	1 (1.0)	0	0	1 (1.0)	0
Myositis	1 (1.0)	0	1 (1.0)	0	0
Osteonecrosis	1 (1.0)	1 (1.0)	0	0	0
Rhabdomyolysis	1 (1.0)	0	0	0	1 (1.0)
Spinal pain	1 (1.0)	0	0	1 (1.0)	0
Synovitis	1 (1.0)	0	1 (1.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (5.2)	1 (1.0)	2 (2.1)	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Bone giant cell tumour benign	1 (1.0)	0	0	1 (1.0)	0
Cancer pain	1 (1.0)	0	1 (1.0)	0	0
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Nervous system disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	53 (55.2)	17 (17.7)	19 (19.8)	13 (13.5)	4 (4.2)
Headache	32 (33.3)	16 (16.7)	13 (13.5)	3 (3.1)	0
Encephalopathy	9 (9.4)	1 (1.0)	3 (3.1)	5 (5.2)	0
Somnolence	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.3)	5 (5.2)	1 (1.0)	0	0
Dizziness	5 (5.2)	5 (5.2)	0	0	0
Seizure	5 (5.2)	0	3 (3.1)	2 (2.1)	0
Lethargy	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Cognitive disorder	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Dysgeusia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Neuropathy peripheral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Paraesthesia	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Amnesia	1 (1.0)	0	1 (1.0)	0	0
Aphasia	1 (1.0)	1 (1.0)	0	0	0
Cerebral haemorrhage	1 (1.0)	0	0	0	1 (1.0)
Depressed level of consciousness	1 (1.0)	0	0	1 (1.0)	0
Disturbance in attention	1 (1.0)	1 (1.0)	0	0	0
Dysarthria	1 (1.0)	0	0	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extrapyramidal disorder	1 (1.0)	0	1 (1.0)	0	0
Generalised tonic-clonic seizure	1 (1.0)	0	1 (1.0)	0	0
Haemorrhage intracranial	1 (1.0)	0	0	0	1 (1.0)
Hydrocephalus	1 (1.0)	0	0	0	1 (1.0)
Hyperaesthesia	1 (1.0)	1 (1.0)	0	0	0
Hypoaesthesia	1 (1.0)	1 (1.0)	0	0	0
Migraine	1 (1.0)	0	1 (1.0)	0	0
Monoparesis	1 (1.0)	0	1 (1.0)	0	0
Nervous system disorder	1 (1.0)	0	0	1 (1.0)	0
Neuralgia	1 (1.0)	0	1 (1.0)	0	0
Neurological decompensation	1 (1.0)	0	0	0	1 (1.0)
Posterior reversible encephalopathy syndrome	1 (1.0)	0	1 (1.0)	0	0
Psychiatric disorders					
-Total	39 (40.6)	13 (13.5)	16 (16.7)	10 (10.4)	0
Anxiety	15 (15.6)	4 (4.2)	8 (8.3)	3 (3.1)	0
Delirium	8 (8.3)	2 (2.1)	3 (3.1)	3 (3.1)	0
Agitation	7 (7.3)	4 (4.2)	3 (3.1)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	7 (7.3)	7 (7.3)	0	0	0
Insomnia	6 (6.3)	2 (2.1)	4 (4.2)	0	0
Mental status changes	6 (6.3)	1 (1.0)	2 (2.1)	3 (3.1)	0
Irritability	4 (4.2)	3 (3.1)	0	1 (1.0)	0
Hallucination	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Sleep disorder	2 (2.1)	0	2 (2.1)	0	0
Affect lability	1 (1.0)	0	1 (1.0)	0	0
Automatism	1 (1.0)	1 (1.0)	0	0	0
Hallucination, visual	1 (1.0)	0	1 (1.0)	0	0
Mood altered	1 (1.0)	1 (1.0)	0	0	0
Nightmare	1 (1.0)	1 (1.0)	0	0	0
Persistent depressive disorder	1 (1.0)	0	1 (1.0)	0	0
Restlessness	1 (1.0)	0	1 (1.0)	0	0
Social avoidant behaviour	1 (1.0)	0	1 (1.0)	0	0
Tearfulness	1 (1.0)	1 (1.0)	0	0	0
Tic	1 (1.0)	0	1 (1.0)	0	0
Renal and urinary disorders					
-Total	29 (30.2)	10 (10.4)	7 (7.3)	5 (5.2)	7 (7.3)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	15 (15.6)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Dysuria	5 (5.2)	4 (4.2)	1 (1.0)	0	0
Haematuria	4 (4.2)	3 (3.1)	0	1 (1.0)	0
Anuria	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Pollakiuria	2 (2.1)	0	2 (2.1)	0	0
Renal failure	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Renal tubular necrosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Urinary retention	2 (2.1)	0	2 (2.1)	0	0
Azotaemia	1 (1.0)	0	1 (1.0)	0	0
Bladder dilatation	1 (1.0)	0	1 (1.0)	0	0
Cystitis haemorrhagic	1 (1.0)	0	1 (1.0)	0	0
Incontinence	1 (1.0)	0	1 (1.0)	0	0
Kidney enlargement	1 (1.0)	0	1 (1.0)	0	0
Micturition urgency	1 (1.0)	0	1 (1.0)	0	0
Proteinuria	1 (1.0)	1 (1.0)	0	0	0
Renal mass	1 (1.0)	0	1 (1.0)	0	0
Renal pain	1 (1.0)	1 (1.0)	0	0	0
Renal tubular dysfunction	1 (1.0)	1 (1.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (1.0)	0	1 (1.0)	0	0
Urinary tract disorder	1 (1.0)	0	1 (1.0)	0	0
Reproductive system and breast disorders					
-Total	7 (7.3)	1 (1.0)	3 (3.1)	3 (3.1)	0
Dysmenorrhoea	1 (1.0)	0	1 (1.0)	0	0
Endometriosis	1 (1.0)	0	0	1 (1.0)	0
Female genital tract fistula	1 (1.0)	1 (1.0)	0	0	0
Heavy menstrual bleeding	1 (1.0)	0	1 (1.0)	0	0
Perineal rash	1 (1.0)	0	1 (1.0)	0	0
Prostatitis	1 (1.0)	0	0	1 (1.0)	0
Vaginal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Vaginal ulceration	1 (1.0)	0	0	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	60 (62.5)	19 (19.8)	7 (7.3)	13 (13.5)	21 (21.9)
Cough	25 (26.0)	21 (21.9)	4 (4.2)	0	0
Hypoxia	21 (21.9)	0	5 (5.2)	10 (10.4)	6 (6.3)
Pulmonary oedema	14 (14.6)	3 (3.1)	3 (3.1)	6 (6.3)	2 (2.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	12 (12.5)	7 (7.3)	2 (2.1)	3 (3.1)	0
Nasal congestion	11 (11.5)	9 (9.4)	2 (2.1)	0	0
Oropharyngeal pain	10 (10.4)	8 (8.3)	2 (2.1)	0	0
Respiratory failure	10 (10.4)	0	0	0	10 (10.4)
Tachypnoea	10 (10.4)	3 (3.1)	2 (2.1)	4 (4.2)	1 (1.0)
Dyspnoea	8 (8.3)	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)
Pleural effusion	8 (8.3)	4 (4.2)	2 (2.1)	2 (2.1)	0
Rhinorrhoea	5 (5.2)	4 (4.2)	1 (1.0)	0	0
Acute respiratory distress syndrome	4 (4.2)	0	0	0	4 (4.2)
Respiratory distress	4 (4.2)	0	2 (2.1)	0	2 (2.1)
Atelectasis	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Pharyngeal erythema	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Rhinitis allergic	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Sleep apnoea syndrome	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Acute respiratory failure	1 (1.0)	0	0	1 (1.0)	0
Bradypnoea	1 (1.0)	0	0	1 (1.0)	0
Bronchial oedema	1 (1.0)	1 (1.0)	0	0	0
Bronchospasm	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (1.0)	1 (1.0)	0	0	0
Haemoptysis	1 (1.0)	0	1 (1.0)	0	0
Laryngeal oedema	1 (1.0)	0	0	0	1 (1.0)
Lung infiltration	1 (1.0)	0	0	1 (1.0)	0
Nasal discomfort	1 (1.0)	0	1 (1.0)	0	0
Nasal dryness	1 (1.0)	1 (1.0)	0	0	0
Oropharyngeal plaque	1 (1.0)	0	1 (1.0)	0	0
Painful respiration	1 (1.0)	1 (1.0)	0	0	0
Paranasal sinus discomfort	1 (1.0)	0	1 (1.0)	0	0
Paranasal sinus inflammation	1 (1.0)	1 (1.0)	0	0	0
Pharyngeal exudate	1 (1.0)	0	1 (1.0)	0	0
Pharyngeal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Pharyngeal oedema	1 (1.0)	0	1 (1.0)	0	0
Productive cough	1 (1.0)	1 (1.0)	0	0	0
Pulmonary haemorrhage	1 (1.0)	0	0	0	1 (1.0)
Pulmonary mass	1 (1.0)	0	1 (1.0)	0	0
Respiratory acidosis	1 (1.0)	0	0	1 (1.0)	0
Respiratory disorder	1 (1.0)	0	1 (1.0)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract inflammation	1 (1.0)	0	1 (1.0)	0	0
Wheezing	1 (1.0)	0	1 (1.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	48 (50.0)	22 (22.9)	18 (18.8)	8 (8.3)	0
Pruritus	11 (11.5)	5 (5.2)	6 (6.3)	0	0
Rash	10 (10.4)	5 (5.2)	5 (5.2)	0	0
Dry skin	9 (9.4)	7 (7.3)	2 (2.1)	0	0
Erythema	6 (6.3)	5 (5.2)	1 (1.0)	0	0
Ingrowing nail	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Rash maculo-papular	4 (4.2)	2 (2.1)	1 (1.0)	1 (1.0)	0
Rash papular	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Skin ulcer	4 (4.2)	2 (2.1)	1 (1.0)	1 (1.0)	0
Blister	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Dermatitis atopic	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Eczema	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Hyperhidrosis	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Petechiae	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decubitus ulcer	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Skin discolouration	2 (2.1)	2 (2.1)	0	0	0
Acne	1 (1.0)	1 (1.0)	0	0	0
Dermatitis	1 (1.0)	1 (1.0)	0	0	0
Dermatitis allergic	1 (1.0)	1 (1.0)	0	0	0
Dermatitis diaper	1 (1.0)	0	1 (1.0)	0	0
Drug eruption	1 (1.0)	0	1 (1.0)	0	0
Erythema nodosum	1 (1.0)	1 (1.0)	0	0	0
Hangnail	1 (1.0)	1 (1.0)	0	0	0
Miliaria	1 (1.0)	1 (1.0)	0	0	0
Night sweats	1 (1.0)	1 (1.0)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.0)	1 (1.0)	0	0	0
Papule	1 (1.0)	1 (1.0)	0	0	0
Photosensitivity reaction	1 (1.0)	0	1 (1.0)	0	0
Pruritus allergic	1 (1.0)	0	1 (1.0)	0	0
Purpura	1 (1.0)	1 (1.0)	0	0	0
Rash erythematous	1 (1.0)	1 (1.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (1.0)	0	0	1 (1.0)	0
Rash pruritic	1 (1.0)	1 (1.0)	0	0	0
Rash vesicular	1 (1.0)	1 (1.0)	0	0	0
Scab	1 (1.0)	1 (1.0)	0	0	0
Skin hypopigmentation	1 (1.0)	1 (1.0)	0	0	0
Skin lesion	1 (1.0)	0	1 (1.0)	0	0
Skin necrosis	1 (1.0)	0	0	1 (1.0)	0
Skin swelling	1 (1.0)	1 (1.0)	0	0	0
Urticaria	1 (1.0)	0	1 (1.0)	0	0
Vancomycin infusion reaction	1 (1.0)	0	0	1 (1.0)	0
Social circumstances					
-Total	1 (1.0)	0	1 (1.0)	0	0
Patient uncooperative	1 (1.0)	0	1 (1.0)	0	0
Surgical and medical procedures					
-Total	1 (1.0)	0	0	1 (1.0)	0
Thrombolysis	1 (1.0)	0	0	1 (1.0)	0
Vascular disorders					
-Total	41 (42.7)	4 (4.2)	11 (11.5)	15 (15.6)	11 (11.5)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	29 (30.2)	1 (1.0)	6 (6.3)	12 (12.5)	10 (10.4)
Hypertension	19 (19.8)	4 (4.2)	10 (10.4)	5 (5.2)	0
Flushing	2 (2.1)	2 (2.1)	0	0	0
Peripheral ischaemia	2 (2.1)	0	2 (2.1)	0	0
Venoocclusive disease	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Capillary leak syndrome	1 (1.0)	0	1 (1.0)	0	0
Haematoma	1 (1.0)	1 (1.0)	0	0	0
Hot flush	1 (1.0)	1 (1.0)	0	0	0
Thrombosis	1 (1.0)	0	1 (1.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208g
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Anal fissure	1 (100)	0	1 (100)	0	0
Anal haemorrhage	1 (100)	1 (100)	0	0	0
Diarrhoea	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0
Proctalgia	1 (100)	1 (100)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (100)	1 (100)	0	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0
Blood fibrinogen decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Blood uric acid increased	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	1 (100)	0	0	0
Decreased appetite	1 (100)	1 (100)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	1 (100)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (100)	1 (100)	0	0	0
Psychiatric disorders					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Rhinorrhoea	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dry skin	1 (100)	1 (100)	0	0	0
Rash papular	1 (100)	1 (100)	0	0	0
Rash pruritic	1 (100)	1 (100)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208g
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	94 (96.9)	0	4 (4.1)	20 (20.6)	70 (72.2)
Blood and lymphatic system disorders					
-Total	66 (68.0)	0	9 (9.3)	37 (38.1)	20 (20.6)
Febrile neutropenia	39 (40.2)	0	0	36 (37.1)	3 (3.1)
Anaemia	37 (38.1)	4 (4.1)	11 (11.3)	21 (21.6)	1 (1.0)
Neutropenia	16 (16.5)	1 (1.0)	2 (2.1)	3 (3.1)	10 (10.3)
Thrombocytopenia	13 (13.4)	0	1 (1.0)	5 (5.2)	7 (7.2)
Disseminated intravascular coagulation	8 (8.2)	0	5 (5.2)	3 (3.1)	0
Coagulopathy	5 (5.2)	1 (1.0)	2 (2.1)	2 (2.1)	0
Leukopenia	5 (5.2)	0	0	1 (1.0)	4 (4.1)
Pancytopenia	4 (4.1)	0	0	3 (3.1)	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Lymphadenopathy	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.0)	0	0	1 (1.0)	0
B-cell aplasia	1 (1.0)	0	1 (1.0)	0	0
Eosinophilia	1 (1.0)	0	1 (1.0)	0	0
Hypercoagulation	1 (1.0)	0	1 (1.0)	0	0
Hypofibrinogenaemia	1 (1.0)	0	1 (1.0)	0	0
Leukocytosis	1 (1.0)	0	1 (1.0)	0	0
Lymphocytosis	1 (1.0)	0	1 (1.0)	0	0
Cardiac disorders					
-Total	35 (36.1)	10 (10.3)	8 (8.2)	11 (11.3)	6 (6.2)
Tachycardia	21 (21.6)	7 (7.2)	8 (8.2)	5 (5.2)	1 (1.0)
Left ventricular dysfunction	5 (5.2)	0	1 (1.0)	4 (4.1)	0
Cardiac failure	4 (4.1)	0	0	2 (2.1)	2 (2.1)
Bradycardia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cardiac arrest	3 (3.1)	0	0	0	3 (3.1)
Sinus tachycardia	3 (3.1)	2 (2.1)	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.1)	2 (2.1)	0	0	0
Pericardial effusion	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Atrioventricular block first degree	1 (1.0)	0	1 (1.0)	0	0
Cardiac failure congestive	1 (1.0)	0	1 (1.0)	0	0
Mitral valve incompetence	1 (1.0)	1 (1.0)	0	0	0
Right ventricular dysfunction	1 (1.0)	1 (1.0)	0	0	0
Sinus bradycardia	1 (1.0)	0	0	1 (1.0)	0
Tricuspid valve incompetence	1 (1.0)	1 (1.0)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.0)	1 (1.0)	0	0	0
Cerebral cavernous malformation	1 (1.0)	1 (1.0)	0	0	0
Ear and labyrinth disorders					
-Total	4 (4.1)	2 (2.1)	2 (2.1)	0	0
Deafness unilateral	1 (1.0)	0	1 (1.0)	0	0
Ear pain	1 (1.0)	1 (1.0)	0	0	0
Ear pruritus	1 (1.0)	1 (1.0)	0	0	0
Vertigo	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	9 (9.3)	0	9 (9.3)	0	0
Adrenal insufficiency	6 (6.2)	0	6 (6.2)	0	0
Hypothyroidism	3 (3.1)	0	3 (3.1)	0	0
Delayed puberty	1 (1.0)	0	1 (1.0)	0	0
Eye disorders					
-Total	17 (17.5)	11 (11.3)	5 (5.2)	1 (1.0)	0
Eye pain	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Eyelid oedema	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Ocular hyperaemia	3 (3.1)	3 (3.1)	0	0	0
Cataract	2 (2.1)	2 (2.1)	0	0	0
Conjunctival haemorrhage	2 (2.1)	2 (2.1)	0	0	0
Visual impairment	2 (2.1)	2 (2.1)	0	0	0
Dry eye	1 (1.0)	1 (1.0)	0	0	0
Eye oedema	1 (1.0)	1 (1.0)	0	0	0
Hypermetropia	1 (1.0)	1 (1.0)	0	0	0
Mydriasis	1 (1.0)	0	1 (1.0)	0	0
Periorbital oedema	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital swelling	1 (1.0)	0	1 (1.0)	0	0
Retinal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Vision blurred	1 (1.0)	1 (1.0)	0	0	0
Visual field defect	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal disorders					
-Total	71 (73.2)	20 (20.6)	29 (29.9)	20 (20.6)	2 (2.1)
Nausea	32 (33.0)	13 (13.4)	16 (16.5)	3 (3.1)	0
Vomiting	29 (29.9)	19 (19.6)	8 (8.2)	2 (2.1)	0
Diarrhoea	26 (26.8)	16 (16.5)	8 (8.2)	2 (2.1)	0
Constipation	19 (19.6)	9 (9.3)	10 (10.3)	0	0
Abdominal pain	16 (16.5)	4 (4.1)	10 (10.3)	2 (2.1)	0
Stomatitis	11 (11.3)	1 (1.0)	5 (5.2)	5 (5.2)	0
Mouth haemorrhage	6 (6.2)	2 (2.1)	2 (2.1)	2 (2.1)	0
Pancreatitis	6 (6.2)	1 (1.0)	3 (3.1)	2 (2.1)	0
Abdominal pain upper	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Haematemesis	4 (4.1)	4 (4.1)	0	0	0
Abdominal distension	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Ascites	3 (3.1)	2 (2.1)	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	3 (3.1)	3 (3.1)	0	0	0
Gingival bleeding	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Abdominal compartment syndrome	2 (2.1)	0	0	0	2 (2.1)
Dry mouth	2 (2.1)	0	2 (2.1)	0	0
Gastrointestinal haemorrhage	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Gingival erythema	2 (2.1)	2 (2.1)	0	0	0
Ileus	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Neutropenic colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral pain	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Trichoglossia	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Abdominal rigidity	1 (1.0)	0	1 (1.0)	0	0
Anal erythema	1 (1.0)	1 (1.0)	0	0	0
Anal fissure	1 (1.0)	0	1 (1.0)	0	0
Anal fistula	1 (1.0)	0	0	1 (1.0)	0
Anal inflammation	1 (1.0)	0	0	1 (1.0)	0
Duodenal perforation	1 (1.0)	0	0	1 (1.0)	0
Dyspepsia	1 (1.0)	1 (1.0)	0	0	0
Dysphagia	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enteritis	1 (1.0)	0	1 (1.0)	0	0
Enterocolitis	1 (1.0)	0	1 (1.0)	0	0
Gastritis	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal inflammation	1 (1.0)	0	1 (1.0)	0	0
Gastrooesophageal reflux disease	1 (1.0)	0	1 (1.0)	0	0
Gingivitis ulcerative	1 (1.0)	0	0	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	0	0	1 (1.0)
Haemorrhoids	1 (1.0)	0	1 (1.0)	0	0
Irritable bowel syndrome	1 (1.0)	0	1 (1.0)	0	0
Lip dry	1 (1.0)	0	1 (1.0)	0	0
Lip oedema	1 (1.0)	1 (1.0)	0	0	0
Lip pain	1 (1.0)	1 (1.0)	0	0	0
Lip ulceration	1 (1.0)	0	1 (1.0)	0	0
Melaena	1 (1.0)	0	0	1 (1.0)	0
Mouth swelling	1 (1.0)	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	1 (1.0)	0	0	0
Oral disorder	1 (1.0)	1 (1.0)	0	0	0
Peritoneal haematoma	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (1.0)	0	0	1 (1.0)	0
Upper gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0	0	0
General disorders and administration site conditions					
-Total	63 (64.9)	29 (29.9)	16 (16.5)	13 (13.4)	5 (5.2)
Pyrexia	43 (44.3)	18 (18.6)	12 (12.4)	11 (11.3)	2 (2.1)
Fatigue	19 (19.6)	15 (15.5)	4 (4.1)	0	0
Chills	9 (9.3)	5 (5.2)	4 (4.1)	0	0
Face oedema	8 (8.2)	5 (5.2)	2 (2.1)	1 (1.0)	0
Oedema peripheral	8 (8.2)	6 (6.2)	1 (1.0)	1 (1.0)	0
Pain	8 (8.2)	1 (1.0)	5 (5.2)	2 (2.1)	0
Generalised oedema	6 (6.2)	2 (2.1)	3 (3.1)	1 (1.0)	0
Catheter site pain	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	0
Asthenia	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Localised oedema	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Multiple organ dysfunction syndrome	3 (3.1)	0	0	0	3 (3.1)
Drug withdrawal syndrome	2 (2.1)	0	2 (2.1)	0	0
Influenza like illness	2 (2.1)	1 (1.0)	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Non-cardiac chest pain	2 (2.1)	2 (2.1)	0	0	0
Vascular device occlusion	2 (2.1)	2 (2.1)	0	0	0
Catheter site dermatitis	1 (1.0)	1 (1.0)	0	0	0
Catheter site erythema	1 (1.0)	1 (1.0)	0	0	0
Catheter site haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Chest discomfort	1 (1.0)	0	0	1 (1.0)	0
Complication associated with device	1 (1.0)	1 (1.0)	0	0	0
Crying	1 (1.0)	0	1 (1.0)	0	0
Facial pain	1 (1.0)	0	1 (1.0)	0	0
Oedema due to hepatic disease	1 (1.0)	0	1 (1.0)	0	0
Sluggishness	1 (1.0)	0	1 (1.0)	0	0
Swelling face	1 (1.0)	1 (1.0)	0	0	0
Systemic inflammatory response syndrome	1 (1.0)	0	0	1 (1.0)	0
Thirst	1 (1.0)	1 (1.0)	0	0	0
Xerosis	1 (1.0)	1 (1.0)	0	0	0
Hepatobiliary disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (24.7)	7 (7.2)	8 (8.2)	6 (6.2)	3 (3.1)
Hyperbilirubinaemia	6 (6.2)	1 (1.0)	3 (3.1)	2 (2.1)	0
Hepatic function abnormal	5 (5.2)	0	2 (2.1)	2 (2.1)	1 (1.0)
Hepatomegaly	3 (3.1)	2 (2.1)	0	0	1 (1.0)
Hypertransaminasaemia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cholelithiasis	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Gallbladder enlargement	2 (2.1)	2 (2.1)	0	0	0
Hepatic cytolysis	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Biliary tract disorder	1 (1.0)	1 (1.0)	0	0	0
Cholestasis	1 (1.0)	0	0	0	1 (1.0)
Drug-induced liver injury	1 (1.0)	0	0	1 (1.0)	0
Hepatosplenomegaly	1 (1.0)	0	1 (1.0)	0	0
Liver disorder	1 (1.0)	0	1 (1.0)	0	0
Ocular icterus	1 (1.0)	1 (1.0)	0	0	0
Immune system disorders					
-Total	72 (74.2)	2 (2.1)	23 (23.7)	25 (25.8)	22 (22.7)
Cytokine release syndrome	61 (62.9)	5 (5.2)	18 (18.6)	17 (17.5)	21 (21.6)
Hypogammaglobulinaemia	35 (36.1)	2 (2.1)	25 (25.8)	8 (8.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	6 (6.2)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)
Seasonal allergy	5 (5.2)	2 (2.1)	3 (3.1)	0	0
Immunodeficiency	4 (4.1)	0	0	4 (4.1)	0
Graft versus host disease	3 (3.1)	0	0	3 (3.1)	0
Allergy to immunoglobulin therapy	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Chronic graft versus host disease	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Drug hypersensitivity	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Engraftment syndrome	1 (1.0)	0	0	1 (1.0)	0
Hypersensitivity	1 (1.0)	1 (1.0)	0	0	0
Selective igg subclass deficiency	1 (1.0)	0	1 (1.0)	0	0
Infections and infestations					
-Total	76 (78.4)	6 (6.2)	13 (13.4)	37 (38.1)	20 (20.6)
Upper respiratory tract infection	14 (14.4)	5 (5.2)	6 (6.2)	3 (3.1)	0
Pneumonia	10 (10.3)	1 (1.0)	2 (2.1)	4 (4.1)	3 (3.1)
Conjunctivitis	9 (9.3)	3 (3.1)	6 (6.2)	0	0
Rhinovirus infection	9 (9.3)	0	7 (7.2)	2 (2.1)	0
Sinusitis	9 (9.3)	0	6 (6.2)	3 (3.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	8 (8.2)	5 (5.2)	3 (3.1)	0	0
Gastroenteritis	7 (7.2)	4 (4.1)	1 (1.0)	2 (2.1)	0
Parainfluenzae virus infection	7 (7.2)	1 (1.0)	1 (1.0)	4 (4.1)	1 (1.0)
Staphylococcal bacteraemia	7 (7.2)	0	0	7 (7.2)	0
Staphylococcal infection	7 (7.2)	0	3 (3.1)	3 (3.1)	1 (1.0)
Oral herpes	6 (6.2)	1 (1.0)	3 (3.1)	2 (2.1)	0
Bacteraemia	5 (5.2)	0	1 (1.0)	3 (3.1)	1 (1.0)
Otitis media	5 (5.2)	0	4 (4.1)	1 (1.0)	0
Paronychia	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Candida infection	4 (4.1)	0	3 (3.1)	0	1 (1.0)
Clostridium difficile infection	4 (4.1)	1 (1.0)	0	3 (3.1)	0
Herpes zoster	4 (4.1)	0	2 (2.1)	2 (2.1)	0
Nail infection	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Sepsis	4 (4.1)	0	0	1 (1.0)	3 (3.1)
Acute sinusitis	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Bronchitis	3 (3.1)	0	3 (3.1)	0	0
Bronchopulmonary aspergillosis	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Ear infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Escherichia bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Gastroenteritis viral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Gingivitis	3 (3.1)	3 (3.1)	0	0	0
Influenza	3 (3.1)	0	2 (2.1)	0	1 (1.0)
Localised infection	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Metapneumovirus infection	3 (3.1)	0	0	3 (3.1)	0
Oral candidiasis	3 (3.1)	0	3 (3.1)	0	0
Otitis externa	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Respiratory syncytial virus infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Respiratory tract infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Rhinitis	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Skin infection	3 (3.1)	0	3 (3.1)	0	0
Urinary tract infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Covid-19	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungal infection	2 (2.1)	0	2 (2.1)	0	0
Fungal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Herpes simplex	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0
Klebsiella bacteraemia	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pneumonia fungal	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Viral infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Anal abscess	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Atypical pneumonia	1 (1.0)	1 (1.0)	0	0	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cholecystitis infective	1 (1.0)	0	1 (1.0)	0	0
Clostridium difficile colitis	1 (1.0)	0	0	1 (1.0)	0
Coronavirus infection	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cystitis	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Ear, nose and throat infection	1 (1.0)	0	1 (1.0)	0	0
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Enterovirus infection	1 (1.0)	0	0	1 (1.0)	0
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Folliculitis	1 (1.0)	0	1 (1.0)	0	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis clostridial	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis norovirus	1 (1.0)	1 (1.0)	0	0	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal infection	1 (1.0)	1 (1.0)	0	0	0
Granulicatella infection	1 (1.0)	0	0	1 (1.0)	0
Herpes virus infection	1 (1.0)	0	1 (1.0)	0	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Molluscum contagiosum	1 (1.0)	1 (1.0)	0	0	0
Myringitis	1 (1.0)	1 (1.0)	0	0	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis media acute	1 (1.0)	0	1 (1.0)	0	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Respiratory tract infection viral	1 (1.0)	0	1 (1.0)	0	0
Salmonellosis	1 (1.0)	0	1 (1.0)	0	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis fungal	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal sepsis	1 (1.0)	0	0	0	1 (1.0)
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Streptococcal sepsis	1 (1.0)	0	1 (1.0)	0	0
Syphilis	1 (1.0)	0	1 (1.0)	0	0
Systemic candida	1 (1.0)	0	0	1 (1.0)	0
Systemic mycosis	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection pseudomonal	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection viral	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	0	0	1 (1.0)	0
Viral skin infection	1 (1.0)	1 (1.0)	0	0	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Vulval cellulitis	1 (1.0)	0	0	1 (1.0)	0
Injury, poisoning and procedural complications					
-Total	27 (27.8)	9 (9.3)	12 (12.4)	3 (3.1)	3 (3.1)
Infusion related reaction	6 (6.2)	2 (2.1)	3 (3.1)	1 (1.0)	0
Procedural pain	4 (4.1)	1 (1.0)	2 (2.1)	1 (1.0)	0
Transfusion reaction	4 (4.1)	1 (1.0)	2 (2.1)	1 (1.0)	0
Fall	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Wound	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Contusion	2 (2.1)	2 (2.1)	0	0	0
Ligament sprain	2 (2.1)	2 (2.1)	0	0	0
Skin abrasion	2 (2.1)	2 (2.1)	0	0	0
Abdominal injury	1 (1.0)	1 (1.0)	0	0	0
Extradural haematoma	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibula fracture	1 (1.0)	0	1 (1.0)	0	0
Limb injury	1 (1.0)	0	1 (1.0)	0	0
Post-traumatic neck syndrome	1 (1.0)	0	1 (1.0)	0	0
Radius fracture	1 (1.0)	0	1 (1.0)	0	0
Scratch	1 (1.0)	1 (1.0)	0	0	0
Skin injury	1 (1.0)	0	1 (1.0)	0	0
Skin wound	1 (1.0)	1 (1.0)	0	0	0
Tracheal obstruction	1 (1.0)	0	0	0	1 (1.0)
Transplant failure	1 (1.0)	0	0	0	1 (1.0)
Traumatic haematoma	1 (1.0)	0	1 (1.0)	0	0
Vasoplegia syndrome	1 (1.0)	0	0	0	1 (1.0)
Investigations					
-Total	65 (67.0)	0	6 (6.2)	20 (20.6)	39 (40.2)
White blood cell count decreased	31 (32.0)	2 (2.1)	3 (3.1)	1 (1.0)	25 (25.8)
Neutrophil count decreased	29 (29.9)	1 (1.0)	2 (2.1)	3 (3.1)	23 (23.7)
Platelet count decreased	27 (27.8)	5 (5.2)	2 (2.1)	6 (6.2)	14 (14.4)
Lymphocyte count decreased	23 (23.7)	1 (1.0)	1 (1.0)	9 (9.3)	12 (12.4)
Alanine aminotransferase increased	22 (22.7)	5 (5.2)	8 (8.2)	9 (9.3)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	21 (21.6)	2 (2.1)	5 (5.2)	10 (10.3)	4 (4.1)
Blood bilirubin increased	13 (13.4)	1 (1.0)	2 (2.1)	10 (10.3)	0
C-reactive protein increased	11 (11.3)	3 (3.1)	2 (2.1)	5 (5.2)	1 (1.0)
Serum ferritin increased	11 (11.3)	2 (2.1)	5 (5.2)	3 (3.1)	1 (1.0)
International normalised ratio increased	10 (10.3)	6 (6.2)	4 (4.1)	0	0
Blood creatinine increased	7 (7.2)	2 (2.1)	1 (1.0)	3 (3.1)	1 (1.0)
Blood fibrinogen decreased	7 (7.2)	2 (2.1)	3 (3.1)	1 (1.0)	1 (1.0)
Blood lactate dehydrogenase increased	7 (7.2)	3 (3.1)	1 (1.0)	3 (3.1)	0
Activated partial thromboplastin time prolonged	6 (6.2)	3 (3.1)	2 (2.1)	1 (1.0)	0
Blood immunoglobulin a decreased	6 (6.2)	4 (4.1)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	6 (6.2)	3 (3.1)	1 (1.0)	2 (2.1)	0
Weight increased	6 (6.2)	2 (2.1)	2 (2.1)	2 (2.1)	0
Electrocardiogram qt prolonged	5 (5.2)	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.0)
Blood immunoglobulin g decreased	4 (4.1)	1 (1.0)	3 (3.1)	0	0
Fibrin d dimer increased	4 (4.1)	2 (2.1)	0	1 (1.0)	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	4 (4.1)	0	2 (2.1)	2 (2.1)	0
Blood fibrinogen increased	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Blood uric acid increased	3 (3.1)	1 (1.0)	0	1 (1.0)	1 (1.0)
Oxygen saturation decreased	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Amylase increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Blood creatine phosphokinase increased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Blood glucose increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Blood phosphorus increased	2 (2.1)	0	2 (2.1)	0	0
Gamma-glutamyltransferase increased	2 (2.1)	0	0	2 (2.1)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
Lipase increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Urine output decreased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Bacterial test positive	1 (1.0)	0	0	1 (1.0)	0
Blood alkaline phosphatase decreased	1 (1.0)	1 (1.0)	0	0	0
Blood alkaline phosphatase increased	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (1.0)	0	1 (1.0)	0	0
Blood phosphorus decreased	1 (1.0)	0	0	1 (1.0)	0
Blood potassium decreased	1 (1.0)	0	0	0	1 (1.0)
Blood testosterone decreased	1 (1.0)	1 (1.0)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.0)	1 (1.0)	0	0	0
Blood urea increased	1 (1.0)	0	0	1 (1.0)	0
Bone density decreased	1 (1.0)	1 (1.0)	0	0	0
Breath sounds abnormal	1 (1.0)	0	1 (1.0)	0	0
Cardiac murmur	1 (1.0)	1 (1.0)	0	0	0
Coagulation test abnormal	1 (1.0)	1 (1.0)	0	0	0
Ejection fraction decreased	1 (1.0)	0	1 (1.0)	0	0
Electrocardiogram t wave abnormal	1 (1.0)	0	1 (1.0)	0	0
Enterovirus test positive	1 (1.0)	0	1 (1.0)	0	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Haemoglobin decreased	1 (1.0)	0	0	1 (1.0)	0
Haptoglobin decreased	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heart sounds abnormal	1 (1.0)	1 (1.0)	0	0	0
Hepatitis b virus test positive	1 (1.0)	0	1 (1.0)	0	0
Prothrombin time prolonged	1 (1.0)	0	1 (1.0)	0	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Staphylococcus test positive	1 (1.0)	1 (1.0)	0	0	0
Troponin increased	1 (1.0)	0	0	1 (1.0)	0
Metabolism and nutrition disorders					
-Total	58 (59.8)	7 (7.2)	11 (11.3)	26 (26.8)	14 (14.4)
Decreased appetite	33 (34.0)	11 (11.3)	8 (8.2)	12 (12.4)	2 (2.1)
Hypokalaemia	25 (25.8)	4 (4.1)	5 (5.2)	13 (13.4)	3 (3.1)
Hypophosphataemia	21 (21.6)	3 (3.1)	8 (8.2)	9 (9.3)	1 (1.0)
Hypocalcaemia	18 (18.6)	2 (2.1)	10 (10.3)	6 (6.2)	0
Hypoalbuminaemia	12 (12.4)	0	11 (11.3)	1 (1.0)	0
Hyperglycaemia	9 (9.3)	0	4 (4.1)	5 (5.2)	0
Hyperuricaemia	9 (9.3)	7 (7.2)	1 (1.0)	1 (1.0)	0
Hypervolaemia	9 (9.3)	1 (1.0)	2 (2.1)	6 (6.2)	0
Hypomagnesaemia	9 (9.3)	7 (7.2)	2 (2.1)	0	0
Hyperphosphataemia	6 (6.2)	5 (5.2)	0	0	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	6 (6.2)	1 (1.0)	0	2 (2.1)	3 (3.1)
Tumour lysis syndrome	6 (6.2)	0	0	4 (4.1)	2 (2.1)
Hyperkalaemia	4 (4.1)	0	1 (1.0)	2 (2.1)	1 (1.0)
Hyponatraemia	4 (4.1)	3 (3.1)	0	0	1 (1.0)
Hypercalcaemia	3 (3.1)	0	1 (1.0)	1 (1.0)	1 (1.0)
Hypernatraemia	3 (3.1)	1 (1.0)	0	1 (1.0)	1 (1.0)
Hypertriglyceridaemia	3 (3.1)	0	1 (1.0)	1 (1.0)	1 (1.0)
Acidosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Hyperchloraemia	2 (2.1)	2 (2.1)	0	0	0
Hypermagnesaemia	2 (2.1)	2 (2.1)	0	0	0
Iron overload	2 (2.1)	0	2 (2.1)	0	0
Malnutrition	2 (2.1)	0	0	2 (2.1)	0
Calcium deficiency	1 (1.0)	1 (1.0)	0	0	0
Dehydration	1 (1.0)	0	1 (1.0)	0	0
Eating disorder symptom	1 (1.0)	0	1 (1.0)	0	0
Haemochromatosis	1 (1.0)	0	0	1 (1.0)	0
Haemosiderosis	1 (1.0)	0	1 (1.0)	0	0
Hypercholesterolaemia	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlactacidaemia	1 (1.0)	1 (1.0)	0	0	0
Hyperlipidaemia	1 (1.0)	0	1 (1.0)	0	0
Hypoglycaemia	1 (1.0)	0	1 (1.0)	0	0
Hypophagia	1 (1.0)	0	1 (1.0)	0	0
Metabolic syndrome	1 (1.0)	0	1 (1.0)	0	0
Obesity	1 (1.0)	0	0	1 (1.0)	0
Polydipsia	1 (1.0)	0	0	1 (1.0)	0
Vitamin d deficiency	1 (1.0)	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	47 (48.5)	17 (17.5)	19 (19.6)	10 (10.3)	1 (1.0)
Pain in extremity	22 (22.7)	8 (8.2)	11 (11.3)	3 (3.1)	0
Arthralgia	13 (13.4)	6 (6.2)	6 (6.2)	1 (1.0)	0
Back pain	12 (12.4)	2 (2.1)	6 (6.2)	4 (4.1)	0
Myalgia	10 (10.3)	6 (6.2)	4 (4.1)	0	0
Bone pain	4 (4.1)	1 (1.0)	3 (3.1)	0	0
Pain in jaw	3 (3.1)	1 (1.0)	0	2 (2.1)	0
Growth retardation	2 (2.1)	0	2 (2.1)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint effusion	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Muscular weakness	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Musculoskeletal chest pain	2 (2.1)	2 (2.1)	0	0	0
Neck pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Groin pain	1 (1.0)	1 (1.0)	0	0	0
Haemarthrosis	1 (1.0)	0	0	1 (1.0)	0
Muscle rigidity	1 (1.0)	1 (1.0)	0	0	0
Muscle spasms	1 (1.0)	0	1 (1.0)	0	0
Musculoskeletal pain	1 (1.0)	0	1 (1.0)	0	0
Myopathy	1 (1.0)	0	0	1 (1.0)	0
Myositis	1 (1.0)	0	1 (1.0)	0	0
Osteonecrosis	1 (1.0)	1 (1.0)	0	0	0
Osteopenia	1 (1.0)	1 (1.0)	0	0	0
Rhabdomyolysis	1 (1.0)	0	0	0	1 (1.0)
Spinal pain	1 (1.0)	0	0	1 (1.0)	0
Synovitis	1 (1.0)	0	1 (1.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (5.2)	1 (1.0)	2 (2.1)	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Bone giant cell tumour benign	1 (1.0)	0	0	1 (1.0)	0
Cancer pain	1 (1.0)	0	1 (1.0)	0	0
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Nervous system disorders					
-Total	55 (56.7)	17 (17.5)	20 (20.6)	13 (13.4)	5 (5.2)
Headache	32 (33.0)	16 (16.5)	13 (13.4)	3 (3.1)	0
Encephalopathy	9 (9.3)	1 (1.0)	3 (3.1)	5 (5.2)	0
Seizure	6 (6.2)	0	3 (3.1)	3 (3.1)	0
Somnolence	6 (6.2)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.2)	5 (5.2)	1 (1.0)	0	0
Dizziness	5 (5.2)	5 (5.2)	0	0	0
Cognitive disorder	4 (4.1)	0	2 (2.1)	2 (2.1)	0
Lethargy	4 (4.1)	3 (3.1)	1 (1.0)	0	0
Dysgeusia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Neuropathy peripheral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Cerebral haemorrhage	2 (2.1)	0	0	0	2 (2.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Paraesthesia	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Amnesia	1 (1.0)	0	1 (1.0)	0	0
Aphasia	1 (1.0)	1 (1.0)	0	0	0
Autonomic neuropathy	1 (1.0)	0	0	1 (1.0)	0
Depressed level of consciousness	1 (1.0)	0	0	1 (1.0)	0
Disturbance in attention	1 (1.0)	1 (1.0)	0	0	0
Extrapyramidal disorder	1 (1.0)	0	1 (1.0)	0	0
Generalised tonic-clonic seizure	1 (1.0)	0	1 (1.0)	0	0
Haemorrhage intracranial	1 (1.0)	0	0	0	1 (1.0)
Hydrocephalus	1 (1.0)	0	0	0	1 (1.0)
Hyperaesthesia	1 (1.0)	1 (1.0)	0	0	0
Hypoaesthesia	1 (1.0)	1 (1.0)	0	0	0
Memory impairment	1 (1.0)	0	1 (1.0)	0	0
Migraine	1 (1.0)	0	1 (1.0)	0	0
Monoparesis	1 (1.0)	0	1 (1.0)	0	0
Nervous system disorder	1 (1.0)	0	0	1 (1.0)	0
Neuralgia	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neurological decompensation	1 (1.0)	0	0	0	1 (1.0)
Posterior reversible encephalopathy syndrome	1 (1.0)	0	1 (1.0)	0	0
Psychiatric disorders					
-Total	40 (41.2)	12 (12.4)	18 (18.6)	10 (10.3)	0
Anxiety	16 (16.5)	4 (4.1)	9 (9.3)	3 (3.1)	0
Delirium	8 (8.2)	2 (2.1)	3 (3.1)	3 (3.1)	0
Agitation	7 (7.2)	4 (4.1)	3 (3.1)	0	0
Confusional state	7 (7.2)	7 (7.2)	0	0	0
Insomnia	6 (6.2)	2 (2.1)	4 (4.1)	0	0
Mental status changes	6 (6.2)	1 (1.0)	2 (2.1)	3 (3.1)	0
Hallucination	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Irritability	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Sleep disorder	3 (3.1)	0	3 (3.1)	0	0
Affect lability	1 (1.0)	0	1 (1.0)	0	0
Automatism	1 (1.0)	1 (1.0)	0	0	0
Hallucination, visual	1 (1.0)	0	1 (1.0)	0	0
Mood altered	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nightmare	1 (1.0)	1 (1.0)	0	0	0
Persistent depressive disorder	1 (1.0)	0	1 (1.0)	0	0
Restlessness	1 (1.0)	0	1 (1.0)	0	0
Social avoidant behaviour	1 (1.0)	0	1 (1.0)	0	0
Tearfulness	1 (1.0)	1 (1.0)	0	0	0
Tic	1 (1.0)	0	1 (1.0)	0	0
Renal and urinary disorders					
-Total	30 (30.9)	10 (10.3)	7 (7.2)	6 (6.2)	7 (7.2)
Acute kidney injury	15 (15.5)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Dysuria	5 (5.2)	4 (4.1)	1 (1.0)	0	0
Haematuria	4 (4.1)	3 (3.1)	0	1 (1.0)	0
Anuria	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Pollakiuria	2 (2.1)	0	2 (2.1)	0	0
Renal failure	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Renal tubular necrosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Urinary retention	2 (2.1)	0	2 (2.1)	0	0
Azotaemia	1 (1.0)	0	1 (1.0)	0	0
Bladder dilatation	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (1.0)	0	1 (1.0)	0	0
Incontinence	1 (1.0)	0	1 (1.0)	0	0
Kidney enlargement	1 (1.0)	0	1 (1.0)	0	0
Micturition urgency	1 (1.0)	0	1 (1.0)	0	0
Proteinuria	1 (1.0)	1 (1.0)	0	0	0
Renal mass	1 (1.0)	0	1 (1.0)	0	0
Renal pain	1 (1.0)	1 (1.0)	0	0	0
Renal tubular disorder	1 (1.0)	0	0	1 (1.0)	0
Renal tubular dysfunction	1 (1.0)	1 (1.0)	0	0	0
Urinary incontinence	1 (1.0)	0	1 (1.0)	0	0
Urinary tract disorder	1 (1.0)	0	1 (1.0)	0	0
Reproductive system and breast disorders					
-Total	7 (7.2)	1 (1.0)	3 (3.1)	3 (3.1)	0
Dysmenorrhoea	1 (1.0)	0	1 (1.0)	0	0
Endometriosis	1 (1.0)	0	0	1 (1.0)	0
Female genital tract fistula	1 (1.0)	1 (1.0)	0	0	0
Heavy menstrual bleeding	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Perineal rash	1 (1.0)	0	1 (1.0)	0	0
Prostatitis	1 (1.0)	0	0	1 (1.0)	0
Vaginal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Vaginal ulceration	1 (1.0)	0	0	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	61 (62.9)	18 (18.6)	8 (8.2)	13 (13.4)	22 (22.7)
Cough	25 (25.8)	20 (20.6)	5 (5.2)	0	0
Hypoxia	21 (21.6)	0	5 (5.2)	10 (10.3)	6 (6.2)
Pulmonary oedema	14 (14.4)	3 (3.1)	3 (3.1)	6 (6.2)	2 (2.1)
Epistaxis	12 (12.4)	7 (7.2)	2 (2.1)	3 (3.1)	0
Nasal congestion	11 (11.3)	9 (9.3)	2 (2.1)	0	0
Oropharyngeal pain	10 (10.3)	8 (8.2)	2 (2.1)	0	0
Pleural effusion	10 (10.3)	4 (4.1)	3 (3.1)	2 (2.1)	1 (1.0)
Respiratory failure	10 (10.3)	0	0	0	10 (10.3)
Tachypnoea	10 (10.3)	3 (3.1)	2 (2.1)	4 (4.1)	1 (1.0)
Dyspnoea	8 (8.2)	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)
Rhinorrhoea	5 (5.2)	3 (3.1)	2 (2.1)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	4 (4.1)	0	0	0	4 (4.1)
Respiratory distress	4 (4.1)	0	2 (2.1)	0	2 (2.1)
Atelectasis	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Pharyngeal erythema	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Rhinitis allergic	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Sleep apnoea syndrome	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Wheezing	2 (2.1)	0	2 (2.1)	0	0
Acute respiratory failure	1 (1.0)	0	0	1 (1.0)	0
Bradypnoea	1 (1.0)	0	0	1 (1.0)	0
Bronchial oedema	1 (1.0)	1 (1.0)	0	0	0
Bronchospasm	1 (1.0)	0	1 (1.0)	0	0
Dyspnoea exertional	1 (1.0)	1 (1.0)	0	0	0
Haemoptysis	1 (1.0)	0	1 (1.0)	0	0
Laryngeal oedema	1 (1.0)	0	0	0	1 (1.0)
Lung disorder	1 (1.0)	1 (1.0)	0	0	0
Lung infiltration	1 (1.0)	0	0	1 (1.0)	0
Nasal discomfort	1 (1.0)	0	1 (1.0)	0	0
Nasal dryness	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (1.0)	0	1 (1.0)	0	0
Painful respiration	1 (1.0)	1 (1.0)	0	0	0
Paranasal sinus discomfort	1 (1.0)	0	1 (1.0)	0	0
Paranasal sinus inflammation	1 (1.0)	1 (1.0)	0	0	0
Pharyngeal exudate	1 (1.0)	0	1 (1.0)	0	0
Pharyngeal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Pharyngeal oedema	1 (1.0)	0	1 (1.0)	0	0
Productive cough	1 (1.0)	1 (1.0)	0	0	0
Pulmonary haemorrhage	1 (1.0)	0	0	0	1 (1.0)
Pulmonary mass	1 (1.0)	0	1 (1.0)	0	0
Respiratory acidosis	1 (1.0)	0	0	1 (1.0)	0
Respiratory disorder	1 (1.0)	0	1 (1.0)	0	0
Upper respiratory tract inflammation	1 (1.0)	0	1 (1.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	47 (48.5)	21 (21.6)	18 (18.6)	8 (8.2)	0
Pruritus	11 (11.3)	5 (5.2)	6 (6.2)	0	0
Rash	10 (10.3)	5 (5.2)	5 (5.2)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	8 (8.2)	6 (6.2)	2 (2.1)	0	0
Erythema	6 (6.2)	5 (5.2)	1 (1.0)	0	0
Ingrowing nail	4 (4.1)	1 (1.0)	3 (3.1)	0	0
Rash maculo-papular	4 (4.1)	2 (2.1)	1 (1.0)	1 (1.0)	0
Skin ulcer	4 (4.1)	2 (2.1)	1 (1.0)	1 (1.0)	0
Blister	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Dermatitis atopic	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Eczema	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Hyperhidrosis	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Petechiae	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Rash papular	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Decubitus ulcer	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Skin discolouration	2 (2.1)	2 (2.1)	0	0	0
Acne	1 (1.0)	1 (1.0)	0	0	0
Dermatitis	1 (1.0)	1 (1.0)	0	0	0
Dermatitis allergic	1 (1.0)	1 (1.0)	0	0	0
Dermatitis diaper	1 (1.0)	0	1 (1.0)	0	0
Drug eruption	1 (1.0)	0	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema nodosum	1 (1.0)	1 (1.0)	0	0	0
Hangnail	1 (1.0)	1 (1.0)	0	0	0
Miliaria	1 (1.0)	1 (1.0)	0	0	0
Night sweats	1 (1.0)	1 (1.0)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.0)	1 (1.0)	0	0	0
Papule	1 (1.0)	1 (1.0)	0	0	0
Photosensitivity reaction	1 (1.0)	0	1 (1.0)	0	0
Pruritus allergic	1 (1.0)	0	1 (1.0)	0	0
Purpura	1 (1.0)	1 (1.0)	0	0	0
Rash erythematous	1 (1.0)	1 (1.0)	0	0	0
Rash macular	1 (1.0)	0	0	1 (1.0)	0
Rash vesicular	1 (1.0)	1 (1.0)	0	0	0
Scab	1 (1.0)	1 (1.0)	0	0	0
Skin hypopigmentation	1 (1.0)	1 (1.0)	0	0	0
Skin lesion	1 (1.0)	0	1 (1.0)	0	0
Skin necrosis	1 (1.0)	0	0	1 (1.0)	0
Skin swelling	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urticaria	1 (1.0)	0	1 (1.0)	0	0
Vancomycin infusion reaction	1 (1.0)	0	0	1 (1.0)	0
Social circumstances					
-Total	1 (1.0)	0	1 (1.0)	0	0
Patient uncooperative	1 (1.0)	0	1 (1.0)	0	0
Surgical and medical procedures					
-Total	1 (1.0)	0	0	1 (1.0)	0
Thrombolysis	1 (1.0)	0	0	1 (1.0)	0
Vascular disorders					
-Total	43 (44.3)	5 (5.2)	11 (11.3)	16 (16.5)	11 (11.3)
Hypotension	30 (30.9)	2 (2.1)	6 (6.2)	12 (12.4)	10 (10.3)
Hypertension	19 (19.6)	4 (4.1)	10 (10.3)	5 (5.2)	0
Capillary leak syndrome	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Flushing	2 (2.1)	2 (2.1)	0	0	0
Peripheral ischaemia	2 (2.1)	0	2 (2.1)	0	0
Venoocclusive disease	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Haematoma	1 (1.0)	1 (1.0)	0	0	0
Hot flush	1 (1.0)	1 (1.0)	0	0	0

Mixed-lineage leukemia rearrangement: No

Primary system organ class Preferred term	All patients N=97 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombosis	1 (1.0)	0	1 (1.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208h
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Lymphadenopathy	1 (33.3)	0	1 (33.3)	0	0
Cardiac disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	0	0	1 (33.3)

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	1 (33.3)	0	1 (33.3)	0	0
Haemoperitoneum	1 (33.3)	0	0	0	1 (33.3)
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pain	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Immune system disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Hypogammaglobulinaemia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	3 (100)	0	1 (33.3)	1 (33.3)	1 (33.3)
Bronchitis	1 (33.3)	0	1 (33.3)	0	0
Cystitis	1 (33.3)	0	1 (33.3)	0	0
Gastroenteritis	1 (33.3)	1 (33.3)	0	0	0
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Nasopharyngitis	1 (33.3)	1 (33.3)	0	0	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Investigations					
-Total	2 (66.7)	0	0	0	2 (66.7)
Lymphocyte count decreased	2 (66.7)	1 (33.3)	0	0	1 (33.3)
White blood cell count decreased	2 (66.7)	1 (33.3)	0	0	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Aspartate aminotransferase increased	1 (33.3)	0	0	0	1 (33.3)
Blood creatinine increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	1 (33.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0

Hypodiploidy: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Acute kidney injury	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	1 (33.3)	0	0	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Dermatitis atopic	1 (33.3)	1 (33.3)	0	0	0
Rash vesicular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypotension	2 (66.7)	0	0	2 (66.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208h
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	92 (96.8)	0	5 (5.3)	19 (20.0)	68 (71.6)
Blood and lymphatic system disorders					
-Total	65 (68.4)	1 (1.1)	8 (8.4)	36 (37.9)	20 (21.1)
Febrile neutropenia	39 (41.1)	0	0	36 (37.9)	3 (3.2)
Anaemia	37 (38.9)	5 (5.3)	11 (11.6)	20 (21.1)	1 (1.1)
Neutropenia	16 (16.8)	1 (1.1)	2 (2.1)	3 (3.2)	10 (10.5)
Thrombocytopenia	13 (13.7)	0	1 (1.1)	5 (5.3)	7 (7.4)
Disseminated intravascular coagulation	8 (8.4)	0	5 (5.3)	3 (3.2)	0
Coagulopathy	5 (5.3)	1 (1.1)	2 (2.1)	2 (2.1)	0
Leukopenia	5 (5.3)	0	0	1 (1.1)	4 (4.2)
Pancytopenia	4 (4.2)	0	0	3 (3.2)	1 (1.1)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
B-cell aplasia	1 (1.1)	0	1 (1.1)	0	0
Eosinophilia	1 (1.1)	0	1 (1.1)	0	0
Hypercoagulation	1 (1.1)	0	1 (1.1)	0	0
Hypofibrinogenaemia	1 (1.1)	0	1 (1.1)	0	0
Leukocytosis	1 (1.1)	0	1 (1.1)	0	0
Lymphadenopathy	1 (1.1)	1 (1.1)	0	0	0
Lymphocytosis	1 (1.1)	0	1 (1.1)	0	0
Cardiac disorders					
-Total	33 (34.7)	10 (10.5)	8 (8.4)	9 (9.5)	6 (6.3)
Tachycardia	20 (21.1)	7 (7.4)	8 (8.4)	4 (4.2)	1 (1.1)
Cardiac failure	4 (4.2)	0	0	2 (2.1)	2 (2.1)
Left ventricular dysfunction	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Bradycardia	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Cardiac arrest	3 (3.2)	0	0	0	3 (3.2)
Sinus tachycardia	3 (3.2)	2 (2.1)	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac dysfunction	2 (2.1)	2 (2.1)	0	0	0
Pericardial effusion	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Atrioventricular block first degree	1 (1.1)	0	1 (1.1)	0	0
Cardiac failure congestive	1 (1.1)	0	1 (1.1)	0	0
Mitral valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Right ventricular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Sinus bradycardia	1 (1.1)	0	0	1 (1.1)	0
Tricuspid valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.1)	1 (1.1)	0	0	0
Cerebral cavernous malformation	1 (1.1)	1 (1.1)	0	0	0
Ear and labyrinth disorders					
-Total	4 (4.2)	2 (2.1)	2 (2.1)	0	0
Deafness unilateral	1 (1.1)	0	1 (1.1)	0	0
Ear pain	1 (1.1)	1 (1.1)	0	0	0
Ear pruritus	1 (1.1)	1 (1.1)	0	0	0
Vertigo	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	9 (9.5)	0	9 (9.5)	0	0
Adrenal insufficiency	6 (6.3)	0	6 (6.3)	0	0
Hypothyroidism	3 (3.2)	0	3 (3.2)	0	0
Delayed puberty	1 (1.1)	0	1 (1.1)	0	0
Eye disorders					
-Total	17 (17.9)	11 (11.6)	5 (5.3)	1 (1.1)	0
Eye pain	3 (3.2)	2 (2.1)	0	1 (1.1)	0
Eyelid oedema	3 (3.2)	1 (1.1)	2 (2.1)	0	0
Ocular hyperaemia	3 (3.2)	3 (3.2)	0	0	0
Cataract	2 (2.1)	2 (2.1)	0	0	0
Conjunctival haemorrhage	2 (2.1)	2 (2.1)	0	0	0
Visual impairment	2 (2.1)	2 (2.1)	0	0	0
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eye oedema	1 (1.1)	1 (1.1)	0	0	0
Hypermetropia	1 (1.1)	1 (1.1)	0	0	0
Mydriasis	1 (1.1)	0	1 (1.1)	0	0
Periorbital oedema	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Periorbital swelling	1 (1.1)	0	1 (1.1)	0	0
Retinal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Vision blurred	1 (1.1)	1 (1.1)	0	0	0
Visual field defect	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal disorders					
-Total	70 (73.7)	20 (21.1)	29 (30.5)	20 (21.1)	1 (1.1)
Nausea	33 (34.7)	14 (14.7)	16 (16.8)	3 (3.2)	0
Vomiting	30 (31.6)	20 (21.1)	8 (8.4)	2 (2.1)	0
Diarrhoea	27 (28.4)	17 (17.9)	8 (8.4)	2 (2.1)	0
Constipation	18 (18.9)	9 (9.5)	9 (9.5)	0	0
Abdominal pain	17 (17.9)	5 (5.3)	10 (10.5)	2 (2.1)	0
Stomatitis	11 (11.6)	1 (1.1)	5 (5.3)	5 (5.3)	0
Mouth haemorrhage	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Pancreatitis	6 (6.3)	1 (1.1)	3 (3.2)	2 (2.1)	0
Abdominal pain upper	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Haematemesis	4 (4.2)	4 (4.2)	0	0	0
Abdominal distension	3 (3.2)	1 (1.1)	2 (2.1)	0	0
Ascites	3 (3.2)	2 (2.1)	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	3 (3.2)	3 (3.2)	0	0	0
Gingival bleeding	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Anal fissure	2 (2.1)	0	2 (2.1)	0	0
Dry mouth	2 (2.1)	0	2 (2.1)	0	0
Gastrointestinal haemorrhage	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Gingival erythema	2 (2.1)	2 (2.1)	0	0	0
Ileus	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Neutropenic colitis	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Oral pain	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Proctalgia	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Trichoglossia	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
Abdominal rigidity	1 (1.1)	0	1 (1.1)	0	0
Anal erythema	1 (1.1)	1 (1.1)	0	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0
Anal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0
Duodenal perforation	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (1.1)	1 (1.1)	0	0	0
Dysphagia	1 (1.1)	0	0	1 (1.1)	0
Enteritis	1 (1.1)	0	1 (1.1)	0	0
Enterocolitis	1 (1.1)	0	1 (1.1)	0	0
Gastritis	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal inflammation	1 (1.1)	0	1 (1.1)	0	0
Gastrooesophageal reflux disease	1 (1.1)	0	1 (1.1)	0	0
Gingivitis ulcerative	1 (1.1)	0	0	1 (1.1)	0
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Irritable bowel syndrome	1 (1.1)	0	1 (1.1)	0	0
Lip dry	1 (1.1)	0	1 (1.1)	0	0
Lip oedema	1 (1.1)	1 (1.1)	0	0	0
Lip pain	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Melaena	1 (1.1)	0	0	1 (1.1)	0
Mouth swelling	1 (1.1)	1 (1.1)	0	0	0
Odynophagia	1 (1.1)	1 (1.1)	0	0	0
Oral disorder	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peritoneal haematoma	1 (1.1)	1 (1.1)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
General disorders and administration site conditions					
-Total	62 (65.3)	29 (30.5)	15 (15.8)	13 (13.7)	5 (5.3)
Pyrexia	42 (44.2)	18 (18.9)	11 (11.6)	11 (11.6)	2 (2.1)
Fatigue	19 (20.0)	15 (15.8)	4 (4.2)	0	0
Chills	9 (9.5)	5 (5.3)	4 (4.2)	0	0
Face oedema	8 (8.4)	5 (5.3)	2 (2.1)	1 (1.1)	0
Oedema peripheral	8 (8.4)	6 (6.3)	1 (1.1)	1 (1.1)	0
Pain	7 (7.4)	1 (1.1)	4 (4.2)	2 (2.1)	0
Generalised oedema	6 (6.3)	2 (2.1)	3 (3.2)	1 (1.1)	0
Catheter site pain	5 (5.3)	2 (2.1)	2 (2.1)	1 (1.1)	0
Asthenia	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Localised oedema	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Multiple organ dysfunction syndrome	3 (3.2)	0	0	0	3 (3.2)
Drug withdrawal syndrome	2 (2.1)	0	2 (2.1)	0	0
Influenza like illness	2 (2.1)	1 (1.1)	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Non-cardiac chest pain	2 (2.1)	2 (2.1)	0	0	0
Vascular device occlusion	2 (2.1)	2 (2.1)	0	0	0
Catheter site dermatitis	1 (1.1)	1 (1.1)	0	0	0
Catheter site erythema	1 (1.1)	1 (1.1)	0	0	0
Catheter site haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Chest discomfort	1 (1.1)	0	0	1 (1.1)	0
Complication associated with device	1 (1.1)	1 (1.1)	0	0	0
Crying	1 (1.1)	0	1 (1.1)	0	0
Facial pain	1 (1.1)	0	1 (1.1)	0	0
Oedema due to hepatic disease	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0
Swelling face	1 (1.1)	1 (1.1)	0	0	0
Systemic inflammatory response syndrome	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Xerosis	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	24 (25.3)	7 (7.4)	8 (8.4)	6 (6.3)	3 (3.2)
Hyperbilirubinaemia	6 (6.3)	1 (1.1)	3 (3.2)	2 (2.1)	0
Hepatic function abnormal	5 (5.3)	0	2 (2.1)	2 (2.1)	1 (1.1)
Hepatomegaly	3 (3.2)	2 (2.1)	0	0	1 (1.1)
Hypertransaminasaemia	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Cholelithiasis	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Gallbladder enlargement	2 (2.1)	2 (2.1)	0	0	0
Hepatic cytolysis	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Biliary tract disorder	1 (1.1)	1 (1.1)	0	0	0
Cholestasis	1 (1.1)	0	0	0	1 (1.1)
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Liver disorder	1 (1.1)	0	1 (1.1)	0	0
Ocular icterus	1 (1.1)	1 (1.1)	0	0	0
Immune system disorders					
-Total	72 (75.8)	2 (2.1)	23 (24.2)	25 (26.3)	22 (23.2)
Cytokine release syndrome	61 (64.2)	5 (5.3)	18 (18.9)	17 (17.9)	21 (22.1)
Hypogammaglobulinaemia	35 (36.8)	2 (2.1)	25 (26.3)	8 (8.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophagocytic lymphohistiocytosis	6 (6.3)	1 (1.1)	1 (1.1)	2 (2.1)	2 (2.1)
Seasonal allergy	5 (5.3)	2 (2.1)	3 (3.2)	0	0
Immunodeficiency	4 (4.2)	0	0	4 (4.2)	0
Graft versus host disease	3 (3.2)	0	0	3 (3.2)	0
Allergy to immunoglobulin therapy	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Chronic graft versus host disease	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Engraftment syndrome	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	1 (1.1)	0	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	73 (76.8)	6 (6.3)	12 (12.6)	36 (37.9)	19 (20.0)
Upper respiratory tract infection	14 (14.7)	5 (5.3)	6 (6.3)	3 (3.2)	0
Pneumonia	10 (10.5)	1 (1.1)	2 (2.1)	4 (4.2)	3 (3.2)
Conjunctivitis	9 (9.5)	3 (3.2)	6 (6.3)	0	0
Rhinovirus infection	9 (9.5)	0	7 (7.4)	2 (2.1)	0
Sinusitis	9 (9.5)	0	6 (6.3)	3 (3.2)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasopharyngitis	7 (7.4)	4 (4.2)	3 (3.2)	0	0
Parainfluenzae virus infection	7 (7.4)	1 (1.1)	1 (1.1)	4 (4.2)	1 (1.1)
Staphylococcal bacteraemia	7 (7.4)	0	0	7 (7.4)	0
Gastroenteritis	6 (6.3)	3 (3.2)	1 (1.1)	2 (2.1)	0
Oral herpes	6 (6.3)	1 (1.1)	3 (3.2)	2 (2.1)	0
Staphylococcal infection	6 (6.3)	0	3 (3.2)	3 (3.2)	0
Bacteraemia	5 (5.3)	0	1 (1.1)	3 (3.2)	1 (1.1)
Otitis media	5 (5.3)	0	4 (4.2)	1 (1.1)	0
Paronychia	5 (5.3)	1 (1.1)	3 (3.2)	1 (1.1)	0
Candida infection	4 (4.2)	0	3 (3.2)	0	1 (1.1)
Clostridium difficile infection	4 (4.2)	1 (1.1)	0	3 (3.2)	0
Herpes zoster	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Nail infection	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Sepsis	4 (4.2)	0	0	1 (1.1)	3 (3.2)
Acute sinusitis	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Bronchopulmonary aspergillosis	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Catheter site infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Device related infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Escherichia bacteraemia	3 (3.2)	0	0	2 (2.1)	1 (1.1)
Gastroenteritis viral	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Gingivitis	3 (3.2)	3 (3.2)	0	0	0
Influenza	3 (3.2)	0	2 (2.1)	0	1 (1.1)
Localised infection	3 (3.2)	2 (2.1)	0	1 (1.1)	0
Metapneumovirus infection	3 (3.2)	0	0	3 (3.2)	0
Oral candidiasis	3 (3.2)	0	3 (3.2)	0	0
Otitis externa	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Respiratory syncytial virus infection	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Respiratory tract infection	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Rhinitis	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Septic shock	3 (3.2)	0	0	0	3 (3.2)
Skin infection	3 (3.2)	0	3 (3.2)	0	0
Urinary tract infection	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0
Bk virus infection	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	2 (2.1)	0	2 (2.1)	0	0
Covid-19	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Fungal infection	2 (2.1)	0	2 (2.1)	0	0
Fungal skin infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Herpes simplex	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Pneumonia fungal	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Clostridium difficile colitis	1 (1.1)	0	0	1 (1.1)	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Folliculitis	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal infection	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Vulval cellulitis	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	27 (28.4)	9 (9.5)	12 (12.6)	3 (3.2)	3 (3.2)
Infusion related reaction	6 (6.3)	2 (2.1)	3 (3.2)	1 (1.1)	0
Procedural pain	4 (4.2)	1 (1.1)	2 (2.1)	1 (1.1)	0
Transfusion reaction	4 (4.2)	1 (1.1)	2 (2.1)	1 (1.1)	0
Fall	3 (3.2)	1 (1.1)	2 (2.1)	0	0
Wound	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Contusion	2 (2.1)	2 (2.1)	0	0	0
Ligament sprain	2 (2.1)	2 (2.1)	0	0	0
Skin abrasion	2 (2.1)	2 (2.1)	0	0	0
Abdominal injury	1 (1.1)	1 (1.1)	0	0	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Fibula fracture	1 (1.1)	0	1 (1.1)	0	0
Limb injury	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Post-traumatic neck syndrome	1 (1.1)	0	1 (1.1)	0	0
Radius fracture	1 (1.1)	0	1 (1.1)	0	0
Scratch	1 (1.1)	1 (1.1)	0	0	0
Skin injury	1 (1.1)	0	1 (1.1)	0	0
Skin wound	1 (1.1)	1 (1.1)	0	0	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Transplant failure	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Vasoplegia syndrome	1 (1.1)	0	0	0	1 (1.1)
Investigations					
-Total	64 (67.4)	1 (1.1)	6 (6.3)	20 (21.1)	37 (38.9)
White blood cell count decreased	30 (31.6)	2 (2.1)	3 (3.2)	1 (1.1)	24 (25.3)
Neutrophil count decreased	28 (29.5)	1 (1.1)	2 (2.1)	3 (3.2)	22 (23.2)
Platelet count decreased	27 (28.4)	5 (5.3)	2 (2.1)	6 (6.3)	14 (14.7)
Alanine aminotransferase increased	21 (22.1)	4 (4.2)	8 (8.4)	9 (9.5)	0
Lymphocyte count decreased	21 (22.1)	0	1 (1.1)	9 (9.5)	11 (11.6)
Aspartate aminotransferase increased	20 (21.1)	2 (2.1)	5 (5.3)	10 (10.5)	3 (3.2)

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	13 (13.7)	1 (1.1)	2 (2.1)	10 (10.5)	0
C-reactive protein increased	11 (11.6)	3 (3.2)	2 (2.1)	5 (5.3)	1 (1.1)
Serum ferritin increased	11 (11.6)	2 (2.1)	5 (5.3)	3 (3.2)	1 (1.1)
International normalised ratio increased	10 (10.5)	6 (6.3)	4 (4.2)	0	0
Blood fibrinogen decreased	8 (8.4)	3 (3.2)	3 (3.2)	1 (1.1)	1 (1.1)
Blood immunoglobulin a decreased	7 (7.4)	5 (5.3)	1 (1.1)	1 (1.1)	0
Blood immunoglobulin m decreased	7 (7.4)	4 (4.2)	1 (1.1)	2 (2.1)	0
Blood lactate dehydrogenase increased	7 (7.4)	3 (3.2)	1 (1.1)	3 (3.2)	0
Activated partial thromboplastin time prolonged	6 (6.3)	3 (3.2)	2 (2.1)	1 (1.1)	0
Blood creatinine increased	6 (6.3)	1 (1.1)	1 (1.1)	3 (3.2)	1 (1.1)
Weight increased	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Electrocardiogram qt prolonged	5 (5.3)	1 (1.1)	2 (2.1)	1 (1.1)	1 (1.1)
Blood immunoglobulin g decreased	4 (4.2)	1 (1.1)	3 (3.2)	0	0
Blood uric acid increased	4 (4.2)	2 (2.1)	0	1 (1.1)	1 (1.1)
Fibrin d dimer increased	4 (4.2)	2 (2.1)	0	1 (1.1)	1 (1.1)
Weight decreased	4 (4.2)	0	2 (2.1)	2 (2.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood fibrinogen increased	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Oxygen saturation decreased	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Amylase increased	2 (2.1)	1 (1.1)	0	0	1 (1.1)
Blood creatine phosphokinase increased	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Blood glucose increased	2 (2.1)	1 (1.1)	0	0	1 (1.1)
Blood phosphorus increased	2 (2.1)	0	2 (2.1)	0	0
Gamma-glutamyltransferase increased	2 (2.1)	0	0	2 (2.1)	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
Lipase increased	2 (2.1)	1 (1.1)	0	0	1 (1.1)
Urine output decreased	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Bacterial test positive	1 (1.1)	0	0	1 (1.1)	0
Blood alkaline phosphatase decreased	1 (1.1)	1 (1.1)	0	0	0
Blood alkaline phosphatase increased	1 (1.1)	1 (1.1)	0	0	0
Blood bicarbonate decreased	1 (1.1)	0	1 (1.1)	0	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (1.1)	0	0	0	1 (1.1)
Blood testosterone decreased	1 (1.1)	1 (1.1)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.1)	1 (1.1)	0	0	0
Blood urea increased	1 (1.1)	0	0	1 (1.1)	0
Bone density decreased	1 (1.1)	1 (1.1)	0	0	0
Breath sounds abnormal	1 (1.1)	0	1 (1.1)	0	0
Cardiac murmur	1 (1.1)	1 (1.1)	0	0	0
Coagulation test abnormal	1 (1.1)	1 (1.1)	0	0	0
Ejection fraction decreased	1 (1.1)	0	1 (1.1)	0	0
Electrocardiogram t wave abnormal	1 (1.1)	0	1 (1.1)	0	0
Enterovirus test positive	1 (1.1)	0	1 (1.1)	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Haptoglobin decreased	1 (1.1)	1 (1.1)	0	0	0
Heart sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Hepatitis b virus test positive	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Staphylococcus test positive	1 (1.1)	1 (1.1)	0	0	0
Troponin increased	1 (1.1)	0	0	1 (1.1)	0
Metabolism and nutrition disorders					
-Total	58 (61.1)	8 (8.4)	11 (11.6)	25 (26.3)	14 (14.7)
Decreased appetite	34 (35.8)	12 (12.6)	8 (8.4)	12 (12.6)	2 (2.1)
Hypokalaemia	25 (26.3)	4 (4.2)	5 (5.3)	13 (13.7)	3 (3.2)
Hypophosphataemia	21 (22.1)	3 (3.2)	8 (8.4)	9 (9.5)	1 (1.1)
Hypocalcaemia	17 (17.9)	2 (2.1)	9 (9.5)	6 (6.3)	0
Hypoalbuminaemia	11 (11.6)	0	10 (10.5)	1 (1.1)	0
Hyperglycaemia	9 (9.5)	0	4 (4.2)	5 (5.3)	0
Hyperuricaemia	9 (9.5)	7 (7.4)	1 (1.1)	1 (1.1)	0
Hypervolaemia	9 (9.5)	1 (1.1)	2 (2.1)	6 (6.3)	0
Hypomagnesaemia	9 (9.5)	7 (7.4)	2 (2.1)	0	0
Hyperphosphataemia	6 (6.3)	5 (5.3)	0	0	1 (1.1)
Tumour lysis syndrome	6 (6.3)	0	0	4 (4.2)	2 (2.1)
Metabolic acidosis	5 (5.3)	1 (1.1)	0	1 (1.1)	3 (3.2)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	4 (4.2)	0	1 (1.1)	2 (2.1)	1 (1.1)
Hyponatraemia	4 (4.2)	3 (3.2)	0	0	1 (1.1)
Hypercalcaemia	3 (3.2)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hypernatraemia	3 (3.2)	1 (1.1)	0	1 (1.1)	1 (1.1)
Hypertriglyceridaemia	3 (3.2)	0	1 (1.1)	1 (1.1)	1 (1.1)
Acidosis	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Hyperchloraemia	2 (2.1)	2 (2.1)	0	0	0
Hypermagnesaemia	2 (2.1)	2 (2.1)	0	0	0
Iron overload	2 (2.1)	0	2 (2.1)	0	0
Malnutrition	2 (2.1)	0	0	2 (2.1)	0
Calcium deficiency	1 (1.1)	1 (1.1)	0	0	0
Dehydration	1 (1.1)	0	1 (1.1)	0	0
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Haemochromatosis	1 (1.1)	0	0	1 (1.1)	0
Haemosiderosis	1 (1.1)	0	1 (1.1)	0	0
Hypercholesterolaemia	1 (1.1)	0	1 (1.1)	0	0
Hyperlactacidaemia	1 (1.1)	1 (1.1)	0	0	0
Hyperlipidaemia	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoglycaemia	1 (1.1)	0	1 (1.1)	0	0
Hypophagia	1 (1.1)	0	1 (1.1)	0	0
Metabolic syndrome	1 (1.1)	0	1 (1.1)	0	0
Obesity	1 (1.1)	0	0	1 (1.1)	0
Polydipsia	1 (1.1)	0	0	1 (1.1)	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	48 (50.5)	18 (18.9)	19 (20.0)	10 (10.5)	1 (1.1)
Pain in extremity	23 (24.2)	9 (9.5)	11 (11.6)	3 (3.2)	0
Arthralgia	13 (13.7)	6 (6.3)	6 (6.3)	1 (1.1)	0
Back pain	12 (12.6)	2 (2.1)	6 (6.3)	4 (4.2)	0
Myalgia	10 (10.5)	6 (6.3)	4 (4.2)	0	0
Bone pain	4 (4.2)	1 (1.1)	3 (3.2)	0	0
Pain in jaw	3 (3.2)	1 (1.1)	0	2 (2.1)	0
Growth retardation	2 (2.1)	0	2 (2.1)	0	0
Joint effusion	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Muscular weakness	2 (2.1)	1 (1.1)	0	1 (1.1)	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	2 (2.1)	2 (2.1)	0	0	0
Neck pain	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Groin pain	1 (1.1)	1 (1.1)	0	0	0
Haemarthrosis	1 (1.1)	0	0	1 (1.1)	0
Muscle rigidity	1 (1.1)	1 (1.1)	0	0	0
Muscle spasms	1 (1.1)	0	1 (1.1)	0	0
Musculoskeletal pain	1 (1.1)	0	1 (1.1)	0	0
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Myositis	1 (1.1)	0	1 (1.1)	0	0
Osteonecrosis	1 (1.1)	1 (1.1)	0	0	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0
Rhabdomyolysis	1 (1.1)	0	0	0	1 (1.1)
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Synovitis	1 (1.1)	0	1 (1.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (5.3)	1 (1.1)	2 (2.1)	2 (2.1)	0
Skin papilloma	2 (2.1)	1 (1.1)	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bone giant cell tumour benign	1 (1.1)	0	0	1 (1.1)	0
Cancer pain	1 (1.1)	0	1 (1.1)	0	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Nervous system disorders					
-Total	54 (56.8)	17 (17.9)	20 (21.1)	12 (12.6)	5 (5.3)
Headache	32 (33.7)	16 (16.8)	13 (13.7)	3 (3.2)	0
Encephalopathy	9 (9.5)	1 (1.1)	3 (3.2)	5 (5.3)	0
Seizure	6 (6.3)	0	3 (3.2)	3 (3.2)	0
Somnolence	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.3)	5 (5.3)	1 (1.1)	0	0
Dizziness	5 (5.3)	5 (5.3)	0	0	0
Lethargy	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Cognitive disorder	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Dysgeusia	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Neuropathy peripheral	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Cerebral haemorrhage	2 (2.1)	0	0	0	2 (2.1)
Dysarthria	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Paraesthesia	2 (2.1)	1 (1.1)	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Autonomic neuropathy	1 (1.1)	0	0	1 (1.1)	0
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Extrapyramidal disorder	1 (1.1)	0	1 (1.1)	0	0
Generalised tonic-clonic seizure	1 (1.1)	0	1 (1.1)	0	0
Haemorrhage intracranial	1 (1.1)	0	0	0	1 (1.1)
Hydrocephalus	1 (1.1)	0	0	0	1 (1.1)
Hyperaesthesia	1 (1.1)	1 (1.1)	0	0	0
Hypoaesthesia	1 (1.1)	1 (1.1)	0	0	0
Memory impairment	1 (1.1)	0	1 (1.1)	0	0
Migraine	1 (1.1)	0	1 (1.1)	0	0
Monoparesis	1 (1.1)	0	1 (1.1)	0	0
Nervous system disorder	1 (1.1)	0	0	1 (1.1)	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Neurological decompensation	1 (1.1)	0	0	0	1 (1.1)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	41 (43.2)	13 (13.7)	18 (18.9)	10 (10.5)	0
Anxiety	16 (16.8)	4 (4.2)	9 (9.5)	3 (3.2)	0
Delirium	8 (8.4)	2 (2.1)	3 (3.2)	3 (3.2)	0
Agitation	7 (7.4)	4 (4.2)	3 (3.2)	0	0
Confusional state	7 (7.4)	7 (7.4)	0	0	0
Insomnia	6 (6.3)	2 (2.1)	4 (4.2)	0	0
Mental status changes	6 (6.3)	1 (1.1)	2 (2.1)	3 (3.2)	0
Irritability	4 (4.2)	3 (3.2)	0	1 (1.1)	0
Hallucination	3 (3.2)	1 (1.1)	2 (2.1)	0	0
Sleep disorder	3 (3.2)	0	3 (3.2)	0	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Automatism	1 (1.1)	1 (1.1)	0	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0
Nightmare	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Persistent depressive disorder	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tearfulness	1 (1.1)	1 (1.1)	0	0	0
Tic	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					
-Total	29 (30.5)	9 (9.5)	7 (7.4)	6 (6.3)	7 (7.4)
Acute kidney injury	14 (14.7)	4 (4.2)	2 (2.1)	3 (3.2)	5 (5.3)
Dysuria	5 (5.3)	4 (4.2)	1 (1.1)	0	0
Haematuria	4 (4.2)	3 (3.2)	0	1 (1.1)	0
Anuria	2 (2.1)	1 (1.1)	0	0	1 (1.1)
Pollakiuria	2 (2.1)	0	2 (2.1)	0	0
Renal failure	2 (2.1)	0	1 (1.1)	0	1 (1.1)
Renal tubular necrosis	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Urinary retention	2 (2.1)	0	2 (2.1)	0	0
Azotaemia	1 (1.1)	0	1 (1.1)	0	0
Bladder dilatation	1 (1.1)	0	1 (1.1)	0	0
Cystitis haemorrhagic	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Incontinence	1 (1.1)	0	1 (1.1)	0	0
Kidney enlargement	1 (1.1)	0	1 (1.1)	0	0
Micturition urgency	1 (1.1)	0	1 (1.1)	0	0
Proteinuria	1 (1.1)	1 (1.1)	0	0	0
Renal mass	1 (1.1)	0	1 (1.1)	0	0
Renal pain	1 (1.1)	1 (1.1)	0	0	0
Renal tubular disorder	1 (1.1)	0	0	1 (1.1)	0
Renal tubular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Urinary incontinence	1 (1.1)	0	1 (1.1)	0	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0
Reproductive system and breast disorders					
-Total	7 (7.4)	1 (1.1)	3 (3.2)	3 (3.2)	0
Dysmenorrhoea	1 (1.1)	0	1 (1.1)	0	0
Endometriosis	1 (1.1)	0	0	1 (1.1)	0
Female genital tract fistula	1 (1.1)	1 (1.1)	0	0	0
Heavy menstrual bleeding	1 (1.1)	0	1 (1.1)	0	0
Perineal rash	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Vaginal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Vaginal ulceration	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	60 (63.2)	18 (18.9)	8 (8.4)	13 (13.7)	21 (22.1)
Cough	25 (26.3)	20 (21.1)	5 (5.3)	0	0
Hypoxia	21 (22.1)	0	5 (5.3)	10 (10.5)	6 (6.3)
Pulmonary oedema	13 (13.7)	3 (3.2)	3 (3.2)	6 (6.3)	1 (1.1)
Epistaxis	12 (12.6)	7 (7.4)	2 (2.1)	3 (3.2)	0
Nasal congestion	11 (11.6)	9 (9.5)	2 (2.1)	0	0
Oropharyngeal pain	10 (10.5)	8 (8.4)	2 (2.1)	0	0
Pleural effusion	10 (10.5)	4 (4.2)	3 (3.2)	2 (2.1)	1 (1.1)
Tachypnoea	10 (10.5)	3 (3.2)	2 (2.1)	4 (4.2)	1 (1.1)
Respiratory failure	9 (9.5)	0	0	0	9 (9.5)
Dyspnoea	8 (8.4)	1 (1.1)	2 (2.1)	3 (3.2)	2 (2.1)
Rhinorrhoea	6 (6.3)	4 (4.2)	2 (2.1)	0	0
Acute respiratory distress syndrome	4 (4.2)	0	0	0	4 (4.2)

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	4 (4.2)	0	2 (2.1)	0	2 (2.1)
Atelectasis	3 (3.2)	0	1 (1.1)	2 (2.1)	0
Pharyngeal erythema	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Rhinitis allergic	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Sleep apnoea syndrome	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Wheezing	2 (2.1)	0	2 (2.1)	0	0
Acute respiratory failure	1 (1.1)	0	0	1 (1.1)	0
Bradypnoea	1 (1.1)	0	0	1 (1.1)	0
Bronchial oedema	1 (1.1)	1 (1.1)	0	0	0
Bronchospasm	1 (1.1)	0	1 (1.1)	0	0
Dyspnoea exertional	1 (1.1)	1 (1.1)	0	0	0
Haemoptysis	1 (1.1)	0	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	0	0	1 (1.1)
Lung disorder	1 (1.1)	1 (1.1)	0	0	0
Lung infiltration	1 (1.1)	0	0	1 (1.1)	0
Nasal discomfort	1 (1.1)	0	1 (1.1)	0	0
Nasal dryness	1 (1.1)	1 (1.1)	0	0	0
Oropharyngeal plaque	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Painful respiration	1 (1.1)	1 (1.1)	0	0	0
Paranasal sinus discomfort	1 (1.1)	0	1 (1.1)	0	0
Paranasal sinus inflammation	1 (1.1)	1 (1.1)	0	0	0
Pharyngeal exudate	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal oedema	1 (1.1)	0	1 (1.1)	0	0
Productive cough	1 (1.1)	1 (1.1)	0	0	0
Pulmonary haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Pulmonary mass	1 (1.1)	0	1 (1.1)	0	0
Respiratory acidosis	1 (1.1)	0	0	1 (1.1)	0
Respiratory disorder	1 (1.1)	0	1 (1.1)	0	0
Upper respiratory tract inflammation	1 (1.1)	0	1 (1.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	47 (49.5)	21 (22.1)	18 (18.9)	8 (8.4)	0
Pruritus	11 (11.6)	5 (5.3)	6 (6.3)	0	0
Rash	10 (10.5)	5 (5.3)	5 (5.3)	0	0
Dry skin	9 (9.5)	7 (7.4)	2 (2.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema	6 (6.3)	5 (5.3)	1 (1.1)	0	0
Ingrowing nail	4 (4.2)	1 (1.1)	3 (3.2)	0	0
Rash maculo-papular	4 (4.2)	2 (2.1)	1 (1.1)	1 (1.1)	0
Rash papular	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Skin ulcer	4 (4.2)	2 (2.1)	1 (1.1)	1 (1.1)	0
Blister	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Eczema	3 (3.2)	2 (2.1)	0	1 (1.1)	0
Hyperhidrosis	3 (3.2)	1 (1.1)	2 (2.1)	0	0
Petechiae	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Decubitus ulcer	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Dermatitis atopic	2 (2.1)	1 (1.1)	0	1 (1.1)	0
Skin discolouration	2 (2.1)	2 (2.1)	0	0	0
Acne	1 (1.1)	1 (1.1)	0	0	0
Dermatitis	1 (1.1)	1 (1.1)	0	0	0
Dermatitis allergic	1 (1.1)	1 (1.1)	0	0	0
Dermatitis diaper	1 (1.1)	0	1 (1.1)	0	0
Drug eruption	1 (1.1)	0	1 (1.1)	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hangnail	1 (1.1)	1 (1.1)	0	0	0
Miliaria	1 (1.1)	1 (1.1)	0	0	0
Night sweats	1 (1.1)	1 (1.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.1)	1 (1.1)	0	0	0
Papule	1 (1.1)	1 (1.1)	0	0	0
Photosensitivity reaction	1 (1.1)	0	1 (1.1)	0	0
Pruritus allergic	1 (1.1)	0	1 (1.1)	0	0
Purpura	1 (1.1)	1 (1.1)	0	0	0
Rash erythematous	1 (1.1)	1 (1.1)	0	0	0
Rash macular	1 (1.1)	0	0	1 (1.1)	0
Rash pruritic	1 (1.1)	1 (1.1)	0	0	0
Scab	1 (1.1)	1 (1.1)	0	0	0
Skin hypopigmentation	1 (1.1)	1 (1.1)	0	0	0
Skin lesion	1 (1.1)	0	1 (1.1)	0	0
Skin necrosis	1 (1.1)	0	0	1 (1.1)	0
Skin swelling	1 (1.1)	1 (1.1)	0	0	0
Urticaria	1 (1.1)	0	1 (1.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vancomycin infusion reaction	1 (1.1)	0	0	1 (1.1)	0
Social circumstances					
-Total	1 (1.1)	0	1 (1.1)	0	0
Patient uncooperative	1 (1.1)	0	1 (1.1)	0	0
Surgical and medical procedures					
-Total	1 (1.1)	0	0	1 (1.1)	0
Thrombolysis	1 (1.1)	0	0	1 (1.1)	0
Vascular disorders					
-Total	41 (43.2)	5 (5.3)	11 (11.6)	14 (14.7)	11 (11.6)
Hypotension	28 (29.5)	2 (2.1)	6 (6.3)	10 (10.5)	10 (10.5)
Hypertension	19 (20.0)	4 (4.2)	10 (10.5)	5 (5.3)	0
Capillary leak syndrome	2 (2.1)	0	1 (1.1)	1 (1.1)	0
Flushing	2 (2.1)	2 (2.1)	0	0	0
Peripheral ischaemia	2 (2.1)	0	2 (2.1)	0	0
Venoocclusive disease	2 (2.1)	0	0	1 (1.1)	1 (1.1)
Haematoma	1 (1.1)	1 (1.1)	0	0	0
Hot flush	1 (1.1)	1 (1.1)	0	0	0
Thrombosis	1 (1.1)	0	1 (1.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208i
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Acute sinusitis	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal infection	1 (50.0)	0	1 (50.0)	0	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Gamma-glutamyltransferase increased	1 (50.0)	0	0	1 (50.0)	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Photosensitivity reaction	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208i
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	93 (96.9)	0	5 (5.2)	19 (19.8)	69 (71.9)
Blood and lymphatic system disorders					
-Total	66 (68.8)	1 (1.0)	9 (9.4)	36 (37.5)	20 (20.8)
Anaemia	38 (39.6)	5 (5.2)	11 (11.5)	21 (21.9)	1 (1.0)
Febrile neutropenia	38 (39.6)	0	0	35 (36.5)	3 (3.1)
Neutropenia	16 (16.7)	1 (1.0)	2 (2.1)	3 (3.1)	10 (10.4)
Thrombocytopenia	13 (13.5)	0	1 (1.0)	5 (5.2)	7 (7.3)
Disseminated intravascular coagulation	8 (8.3)	0	5 (5.2)	3 (3.1)	0
Coagulopathy	5 (5.2)	1 (1.0)	2 (2.1)	2 (2.1)	0
Leukopenia	5 (5.2)	0	0	1 (1.0)	4 (4.2)
Pancytopenia	4 (4.2)	0	0	3 (3.1)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Splenomegaly	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Lymphadenopathy	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Lymphopenia	2 (2.1)	0	0	0	2 (2.1)
Agranulocytosis	1 (1.0)	0	0	1 (1.0)	0
B-cell aplasia	1 (1.0)	0	1 (1.0)	0	0
Eosinophilia	1 (1.0)	0	1 (1.0)	0	0
Hypercoagulation	1 (1.0)	0	1 (1.0)	0	0
Hypofibrinogenaemia	1 (1.0)	0	1 (1.0)	0	0
Leukocytosis	1 (1.0)	0	1 (1.0)	0	0
Lymphocytosis	1 (1.0)	0	1 (1.0)	0	0
Cardiac disorders					
-Total	35 (36.5)	10 (10.4)	8 (8.3)	11 (11.5)	6 (6.3)
Tachycardia	21 (21.9)	7 (7.3)	8 (8.3)	5 (5.2)	1 (1.0)
Left ventricular dysfunction	5 (5.2)	0	1 (1.0)	4 (4.2)	0
Cardiac failure	4 (4.2)	0	0	2 (2.1)	2 (2.1)
Bradycardia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cardiac arrest	3 (3.1)	0	0	0	3 (3.1)
Sinus tachycardia	3 (3.1)	2 (2.1)	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	2 (2.1)	2 (2.1)	0	0	0
Pericardial effusion	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Atrioventricular block first degree	1 (1.0)	0	1 (1.0)	0	0
Cardiac failure congestive	1 (1.0)	0	1 (1.0)	0	0
Mitral valve incompetence	1 (1.0)	1 (1.0)	0	0	0
Right ventricular dysfunction	1 (1.0)	1 (1.0)	0	0	0
Sinus bradycardia	1 (1.0)	0	0	1 (1.0)	0
Tricuspid valve incompetence	1 (1.0)	1 (1.0)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.0)	1 (1.0)	0	0	0
Cerebral cavernous malformation	1 (1.0)	1 (1.0)	0	0	0
Ear and labyrinth disorders					
-Total	4 (4.2)	2 (2.1)	2 (2.1)	0	0
Deafness unilateral	1 (1.0)	0	1 (1.0)	0	0
Ear pain	1 (1.0)	1 (1.0)	0	0	0
Ear pruritus	1 (1.0)	1 (1.0)	0	0	0
Vertigo	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	9 (9.4)	0	9 (9.4)	0	0
Adrenal insufficiency	6 (6.3)	0	6 (6.3)	0	0
Hypothyroidism	3 (3.1)	0	3 (3.1)	0	0
Delayed puberty	1 (1.0)	0	1 (1.0)	0	0
Eye disorders					
-Total	17 (17.7)	11 (11.5)	5 (5.2)	1 (1.0)	0
Eye pain	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Eyelid oedema	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Ocular hyperaemia	3 (3.1)	3 (3.1)	0	0	0
Cataract	2 (2.1)	2 (2.1)	0	0	0
Conjunctival haemorrhage	2 (2.1)	2 (2.1)	0	0	0
Visual impairment	2 (2.1)	2 (2.1)	0	0	0
Dry eye	1 (1.0)	1 (1.0)	0	0	0
Eye oedema	1 (1.0)	1 (1.0)	0	0	0
Hypermetropia	1 (1.0)	1 (1.0)	0	0	0
Mydriasis	1 (1.0)	0	1 (1.0)	0	0
Periorbital oedema	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital swelling	1 (1.0)	0	1 (1.0)	0	0
Retinal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Vision blurred	1 (1.0)	1 (1.0)	0	0	0
Visual field defect	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal disorders					
-Total	72 (75.0)	20 (20.8)	30 (31.3)	20 (20.8)	2 (2.1)
Nausea	33 (34.4)	14 (14.6)	16 (16.7)	3 (3.1)	0
Vomiting	30 (31.3)	20 (20.8)	8 (8.3)	2 (2.1)	0
Diarrhoea	27 (28.1)	17 (17.7)	8 (8.3)	2 (2.1)	0
Constipation	19 (19.8)	9 (9.4)	10 (10.4)	0	0
Abdominal pain	17 (17.7)	5 (5.2)	10 (10.4)	2 (2.1)	0
Stomatitis	11 (11.5)	1 (1.0)	5 (5.2)	5 (5.2)	0
Mouth haemorrhage	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Pancreatitis	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Abdominal pain upper	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Haematemesis	4 (4.2)	4 (4.2)	0	0	0
Abdominal distension	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Ascites	3 (3.1)	2 (2.1)	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	3 (3.1)	3 (3.1)	0	0	0
Gingival bleeding	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Abdominal compartment syndrome	2 (2.1)	0	0	0	2 (2.1)
Anal fissure	2 (2.1)	0	2 (2.1)	0	0
Dry mouth	2 (2.1)	0	2 (2.1)	0	0
Gastrointestinal haemorrhage	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Gingival erythema	2 (2.1)	2 (2.1)	0	0	0
Ileus	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Neutropenic colitis	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral pain	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Proctalgia	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Trichoglossia	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Abdominal rigidity	1 (1.0)	0	1 (1.0)	0	0
Anal erythema	1 (1.0)	1 (1.0)	0	0	0
Anal fistula	1 (1.0)	0	0	1 (1.0)	0
Anal haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Anal inflammation	1 (1.0)	0	0	1 (1.0)	0
Duodenal perforation	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (1.0)	1 (1.0)	0	0	0
Dysphagia	1 (1.0)	0	0	1 (1.0)	0
Enteritis	1 (1.0)	0	1 (1.0)	0	0
Enterocolitis	1 (1.0)	0	1 (1.0)	0	0
Gastritis	1 (1.0)	0	1 (1.0)	0	0
Gastrointestinal inflammation	1 (1.0)	0	1 (1.0)	0	0
Gastrooesophageal reflux disease	1 (1.0)	0	1 (1.0)	0	0
Gingivitis ulcerative	1 (1.0)	0	0	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	0	0	1 (1.0)
Haemorrhoids	1 (1.0)	0	1 (1.0)	0	0
Irritable bowel syndrome	1 (1.0)	0	1 (1.0)	0	0
Lip dry	1 (1.0)	0	1 (1.0)	0	0
Lip oedema	1 (1.0)	1 (1.0)	0	0	0
Lip pain	1 (1.0)	1 (1.0)	0	0	0
Lip ulceration	1 (1.0)	0	1 (1.0)	0	0
Melaena	1 (1.0)	0	0	1 (1.0)	0
Mouth swelling	1 (1.0)	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral disorder	1 (1.0)	1 (1.0)	0	0	0
Peritoneal haematoma	1 (1.0)	1 (1.0)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0	0	0
General disorders and administration site conditions					
-Total	62 (64.6)	28 (29.2)	16 (16.7)	13 (13.5)	5 (5.2)
Pyrexia	42 (43.8)	17 (17.7)	12 (12.5)	11 (11.5)	2 (2.1)
Fatigue	19 (19.8)	15 (15.6)	4 (4.2)	0	0
Chills	9 (9.4)	5 (5.2)	4 (4.2)	0	0
Face oedema	8 (8.3)	5 (5.2)	2 (2.1)	1 (1.0)	0
Oedema peripheral	8 (8.3)	6 (6.3)	1 (1.0)	1 (1.0)	0
Pain	8 (8.3)	1 (1.0)	5 (5.2)	2 (2.1)	0
Generalised oedema	6 (6.3)	2 (2.1)	3 (3.1)	1 (1.0)	0
Catheter site pain	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	0
Asthenia	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Localised oedema	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Multiple organ dysfunction syndrome	3 (3.1)	0	0	0	3 (3.1)
Drug withdrawal syndrome	2 (2.1)	0	2 (2.1)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza like illness	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Malaise	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Non-cardiac chest pain	2 (2.1)	2 (2.1)	0	0	0
Vascular device occlusion	2 (2.1)	2 (2.1)	0	0	0
Catheter site dermatitis	1 (1.0)	1 (1.0)	0	0	0
Catheter site erythema	1 (1.0)	1 (1.0)	0	0	0
Catheter site haemorrhage	1 (1.0)	1 (1.0)	0	0	0
Chest discomfort	1 (1.0)	0	0	1 (1.0)	0
Complication associated with device	1 (1.0)	1 (1.0)	0	0	0
Crying	1 (1.0)	0	1 (1.0)	0	0
Facial pain	1 (1.0)	0	1 (1.0)	0	0
Oedema due to hepatic disease	1 (1.0)	0	1 (1.0)	0	0
Sluggishness	1 (1.0)	0	1 (1.0)	0	0
Swelling face	1 (1.0)	1 (1.0)	0	0	0
Systemic inflammatory response syndrome	1 (1.0)	0	0	1 (1.0)	0
Thirst	1 (1.0)	1 (1.0)	0	0	0
Xerosis	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	24 (25.0)	7 (7.3)	8 (8.3)	6 (6.3)	3 (3.1)
Hyperbilirubinaemia	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Hepatic function abnormal	5 (5.2)	0	2 (2.1)	2 (2.1)	1 (1.0)
Hepatomegaly	3 (3.1)	2 (2.1)	0	0	1 (1.0)
Hypertransaminasaemia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Cholelithiasis	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Gallbladder enlargement	2 (2.1)	2 (2.1)	0	0	0
Hepatic cytolysis	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Biliary tract disorder	1 (1.0)	1 (1.0)	0	0	0
Cholestasis	1 (1.0)	0	0	0	1 (1.0)
Drug-induced liver injury	1 (1.0)	0	0	1 (1.0)	0
Hepatosplenomegaly	1 (1.0)	0	1 (1.0)	0	0
Liver disorder	1 (1.0)	0	1 (1.0)	0	0
Ocular icterus	1 (1.0)	1 (1.0)	0	0	0
Immune system disorders					
-Total	73 (76.0)	2 (2.1)	24 (25.0)	25 (26.0)	22 (22.9)
Cytokine release syndrome	61 (63.5)	5 (5.2)	18 (18.8)	17 (17.7)	21 (21.9)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	36 (37.5)	2 (2.1)	26 (27.1)	8 (8.3)	0
Haemophagocytic lymphohistiocytosis	6 (6.3)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)
Seasonal allergy	5 (5.2)	2 (2.1)	3 (3.1)	0	0
Immunodeficiency	4 (4.2)	0	0	4 (4.2)	0
Graft versus host disease	3 (3.1)	0	0	3 (3.1)	0
Allergy to immunoglobulin therapy	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Chronic graft versus host disease	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Drug hypersensitivity	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Engraftment syndrome	1 (1.0)	0	0	1 (1.0)	0
Hypersensitivity	1 (1.0)	1 (1.0)	0	0	0
Selective igg subclass deficiency	1 (1.0)	0	1 (1.0)	0	0
Infections and infestations					
-Total	74 (77.1)	6 (6.3)	12 (12.5)	36 (37.5)	20 (20.8)
Upper respiratory tract infection	14 (14.6)	5 (5.2)	6 (6.3)	3 (3.1)	0
Pneumonia	10 (10.4)	1 (1.0)	2 (2.1)	4 (4.2)	3 (3.1)
Conjunctivitis	9 (9.4)	3 (3.1)	6 (6.3)	0	0
Rhinovirus infection	9 (9.4)	0	7 (7.3)	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	9 (9.4)	0	6 (6.3)	3 (3.1)	0
Nasopharyngitis	8 (8.3)	5 (5.2)	3 (3.1)	0	0
Gastroenteritis	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Parainfluenzae virus infection	7 (7.3)	1 (1.0)	1 (1.0)	4 (4.2)	1 (1.0)
Staphylococcal bacteraemia	7 (7.3)	0	0	7 (7.3)	0
Oral herpes	6 (6.3)	1 (1.0)	3 (3.1)	2 (2.1)	0
Staphylococcal infection	6 (6.3)	0	2 (2.1)	3 (3.1)	1 (1.0)
Bacteraemia	5 (5.2)	0	1 (1.0)	3 (3.1)	1 (1.0)
Otitis media	5 (5.2)	0	4 (4.2)	1 (1.0)	0
Paronychia	5 (5.2)	1 (1.0)	3 (3.1)	1 (1.0)	0
Candida infection	4 (4.2)	0	3 (3.1)	0	1 (1.0)
Clostridium difficile infection	4 (4.2)	1 (1.0)	0	3 (3.1)	0
Herpes zoster	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Nail infection	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Sepsis	4 (4.2)	0	0	1 (1.0)	3 (3.1)
Bronchitis	3 (3.1)	0	3 (3.1)	0	0
Bronchopulmonary aspergillosis	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Catheter site infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Ear infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Escherichia bacteraemia	3 (3.1)	0	0	2 (2.1)	1 (1.0)
Gastroenteritis viral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Gingivitis	3 (3.1)	3 (3.1)	0	0	0
Influenza	3 (3.1)	0	2 (2.1)	0	1 (1.0)
Localised infection	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Metapneumovirus infection	3 (3.1)	0	0	3 (3.1)	0
Oral candidiasis	3 (3.1)	0	3 (3.1)	0	0
Otitis externa	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Respiratory syncytial virus infection	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Respiratory tract infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Rhinitis	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Septic shock	3 (3.1)	0	0	0	3 (3.1)
Skin infection	3 (3.1)	0	3 (3.1)	0	0
Urinary tract infection	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Acute sinusitis	2 (2.1)	0	2 (2.1)	0	0
Adenovirus infection	2 (2.1)	0	0	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Bronchiolitis	2 (2.1)	0	0	2 (2.1)	0
Covid-19	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Cytomegalovirus infection reactivation	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Encephalitis	2 (2.1)	0	0	0	2 (2.1)
Encephalitis viral	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Fungal infection	2 (2.1)	0	2 (2.1)	0	0
Herpes simplex	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	2 (2.1)	0	0	2 (2.1)	0
Klebsiella bacteraemia	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Oral infection	2 (2.1)	0	2 (2.1)	0	0
Pneumocystis jirovecii pneumonia	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Pneumonia fungal	2 (2.1)	0	0	2 (2.1)	0
Staphylococcal skin infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Tinea pedis	2 (2.1)	2 (2.1)	0	0	0
Varicella zoster virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Viral infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Anal abscess	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.0)	0	0	0	1 (1.0)
Atypical pneumonia	1 (1.0)	1 (1.0)	0	0	0
Cellulitis	1 (1.0)	0	1 (1.0)	0	0
Cholecystitis infective	1 (1.0)	0	1 (1.0)	0	0
Clostridium difficile colitis	1 (1.0)	0	0	1 (1.0)	0
Coronavirus infection	1 (1.0)	0	0	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	0	0	1 (1.0)
Cystitis	1 (1.0)	0	1 (1.0)	0	0
Device related bacteraemia	1 (1.0)	0	1 (1.0)	0	0
Device related sepsis	1 (1.0)	0	0	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	0	0	1 (1.0)
Ear, nose and throat infection	1 (1.0)	0	1 (1.0)	0	0
Enterobacter infection	1 (1.0)	0	0	1 (1.0)	0
Enterovirus infection	1 (1.0)	0	0	1 (1.0)	0
Epstein-barr virus infection	1 (1.0)	0	1 (1.0)	0	0
Folliculitis	1 (1.0)	0	1 (1.0)	0	0
Fungaemia	1 (1.0)	0	0	0	1 (1.0)
Fungal pharyngitis	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis clostridial	1 (1.0)	0	1 (1.0)	0	0
Gastroenteritis escherichia coli	1 (1.0)	0	0	1 (1.0)	0
Gastroenteritis norovirus	1 (1.0)	1 (1.0)	0	0	0
Gastroenteritis salmonella	1 (1.0)	0	0	1 (1.0)	0
Gastrointestinal infection	1 (1.0)	1 (1.0)	0	0	0
Granulicatella infection	1 (1.0)	0	0	1 (1.0)	0
Herpes virus infection	1 (1.0)	0	1 (1.0)	0	0
Klebsiella infection	1 (1.0)	0	0	1 (1.0)	0
Mastoiditis	1 (1.0)	0	0	1 (1.0)	0
Meningitis bacterial	1 (1.0)	0	0	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	0	0	1 (1.0)	0
Molluscum contagiosum	1 (1.0)	1 (1.0)	0	0	0
Myringitis	1 (1.0)	1 (1.0)	0	0	0
Neutropenic infection	1 (1.0)	0	0	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	1 (1.0)	0	0
Otitis media acute	1 (1.0)	0	1 (1.0)	0	0
Peritonitis	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (1.0)	0	0	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	0	0	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	0	0	1 (1.0)	0
Pneumonia viral	1 (1.0)	0	0	1 (1.0)	0
Respiratory tract infection viral	1 (1.0)	0	1 (1.0)	0	0
Salmonellosis	1 (1.0)	0	1 (1.0)	0	0
Serratia sepsis	1 (1.0)	0	0	0	1 (1.0)
Sialoadenitis	1 (1.0)	0	0	1 (1.0)	0
Sinusitis fungal	1 (1.0)	0	0	1 (1.0)	0
Soft tissue infection	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	0	0	1 (1.0)	0
Staphylococcal sepsis	1 (1.0)	0	0	0	1 (1.0)
Stomatococcal infection	1 (1.0)	0	0	0	1 (1.0)
Streptococcal sepsis	1 (1.0)	0	1 (1.0)	0	0
Syphilis	1 (1.0)	0	1 (1.0)	0	0
Systemic candida	1 (1.0)	0	0	1 (1.0)	0
Urinary tract infection pseudomonal	1 (1.0)	0	1 (1.0)	0	0
Urinary tract infection viral	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.0)	0	0	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	0	0	1 (1.0)	0
Viral skin infection	1 (1.0)	1 (1.0)	0	0	0
Viral upper respiratory tract infection	1 (1.0)	0	0	1 (1.0)	0
Vulval cellulitis	1 (1.0)	0	0	1 (1.0)	0
Injury, poisoning and procedural complications					
-Total	27 (28.1)	9 (9.4)	12 (12.5)	3 (3.1)	3 (3.1)
Infusion related reaction	6 (6.3)	2 (2.1)	3 (3.1)	1 (1.0)	0
Procedural pain	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Transfusion reaction	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Fall	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Wound	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Contusion	2 (2.1)	2 (2.1)	0	0	0
Ligament sprain	2 (2.1)	2 (2.1)	0	0	0
Skin abrasion	2 (2.1)	2 (2.1)	0	0	0
Abdominal injury	1 (1.0)	1 (1.0)	0	0	0
Extradural haematoma	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibula fracture	1 (1.0)	0	1 (1.0)	0	0
Limb injury	1 (1.0)	0	1 (1.0)	0	0
Post-traumatic neck syndrome	1 (1.0)	0	1 (1.0)	0	0
Radius fracture	1 (1.0)	0	1 (1.0)	0	0
Scratch	1 (1.0)	1 (1.0)	0	0	0
Skin injury	1 (1.0)	0	1 (1.0)	0	0
Skin wound	1 (1.0)	1 (1.0)	0	0	0
Tracheal obstruction	1 (1.0)	0	0	0	1 (1.0)
Transplant failure	1 (1.0)	0	0	0	1 (1.0)
Traumatic haematoma	1 (1.0)	0	1 (1.0)	0	0
Vasoplegia syndrome	1 (1.0)	0	0	0	1 (1.0)
Investigations					
-Total	65 (67.7)	1 (1.0)	6 (6.3)	20 (20.8)	38 (39.6)
White blood cell count decreased	31 (32.3)	3 (3.1)	3 (3.1)	1 (1.0)	24 (25.0)
Neutrophil count decreased	29 (30.2)	1 (1.0)	2 (2.1)	3 (3.1)	23 (24.0)
Platelet count decreased	28 (29.2)	6 (6.3)	2 (2.1)	6 (6.3)	14 (14.6)
Lymphocyte count decreased	23 (24.0)	1 (1.0)	1 (1.0)	9 (9.4)	12 (12.5)
Alanine aminotransferase increased	21 (21.9)	4 (4.2)	8 (8.3)	9 (9.4)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	21 (21.9)	2 (2.1)	5 (5.2)	10 (10.4)	4 (4.2)
Blood bilirubin increased	13 (13.5)	1 (1.0)	2 (2.1)	10 (10.4)	0
C-reactive protein increased	11 (11.5)	3 (3.1)	2 (2.1)	5 (5.2)	1 (1.0)
Serum ferritin increased	11 (11.5)	2 (2.1)	5 (5.2)	3 (3.1)	1 (1.0)
International normalised ratio increased	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Blood fibrinogen decreased	8 (8.3)	3 (3.1)	3 (3.1)	1 (1.0)	1 (1.0)
Blood creatinine increased	7 (7.3)	2 (2.1)	1 (1.0)	3 (3.1)	1 (1.0)
Blood immunoglobulin a decreased	7 (7.3)	5 (5.2)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	7 (7.3)	4 (4.2)	1 (1.0)	2 (2.1)	0
Blood lactate dehydrogenase increased	7 (7.3)	3 (3.1)	1 (1.0)	3 (3.1)	0
Activated partial thromboplastin time prolonged	6 (6.3)	3 (3.1)	2 (2.1)	1 (1.0)	0
Weight increased	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Electrocardiogram qt prolonged	5 (5.2)	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.0)
Blood immunoglobulin g decreased	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Blood uric acid increased	4 (4.2)	2 (2.1)	0	1 (1.0)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	4 (4.2)	2 (2.1)	0	1 (1.0)	1 (1.0)
Weight decreased	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Blood fibrinogen increased	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Oxygen saturation decreased	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Amylase increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Blood creatine phosphokinase increased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Blood glucose increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Blood phosphorus increased	2 (2.1)	0	2 (2.1)	0	0
Immunoglobulins decreased	2 (2.1)	0	2 (2.1)	0	0
Lipase increased	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Urine output decreased	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Bacterial test positive	1 (1.0)	0	0	1 (1.0)	0
Blood alkaline phosphatase decreased	1 (1.0)	1 (1.0)	0	0	0
Blood alkaline phosphatase increased	1 (1.0)	1 (1.0)	0	0	0
Blood bicarbonate decreased	1 (1.0)	0	1 (1.0)	0	0
Blood phosphorus decreased	1 (1.0)	0	0	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood potassium decreased	1 (1.0)	0	0	0	1 (1.0)
Blood testosterone decreased	1 (1.0)	1 (1.0)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.0)	1 (1.0)	0	0	0
Blood urea increased	1 (1.0)	0	0	1 (1.0)	0
Bone density decreased	1 (1.0)	1 (1.0)	0	0	0
Breath sounds abnormal	1 (1.0)	0	1 (1.0)	0	0
Cardiac murmur	1 (1.0)	1 (1.0)	0	0	0
Coagulation test abnormal	1 (1.0)	1 (1.0)	0	0	0
Ejection fraction decreased	1 (1.0)	0	1 (1.0)	0	0
Electrocardiogram t wave abnormal	1 (1.0)	0	1 (1.0)	0	0
Enterovirus test positive	1 (1.0)	0	1 (1.0)	0	0
Eosinophil count decreased	1 (1.0)	1 (1.0)	0	0	0
Gamma-glutamyltransferase increased	1 (1.0)	0	0	1 (1.0)	0
Haematocrit decreased	1 (1.0)	1 (1.0)	0	0	0
Haemoglobin decreased	1 (1.0)	0	0	1 (1.0)	0
Haptoglobin decreased	1 (1.0)	1 (1.0)	0	0	0
Heart sounds abnormal	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=96 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatitis b virus test positive	1 (1.0)	0	1 (1.0)	0	0
Prothrombin time prolonged	1 (1.0)	0	1 (1.0)	0	0
Red blood cell count decreased	1 (1.0)	1 (1.0)	0	0	0
Staphylococcus test positive	1 (1.0)	1 (1.0)	0	0	0
Troponin increased	1 (1.0)	0	0	1 (1.0)	0
Metabolism and nutrition disorders					
-Total	59 (61.5)	8 (8.3)	11 (11.5)	26 (27.1)	14 (14.6)
Decreased appetite	34 (35.4)	12 (12.5)	8 (8.3)	12 (12.5)	2 (2.1)
Hypokalaemia	25 (26.0)	4 (4.2)	5 (5.2)	13 (13.5)	3 (3.1)
Hypophosphataemia	21 (21.9)	3 (3.1)	8 (8.3)	9 (9.4)	1 (1.0)
Hypocalcaemia	18 (18.8)	2 (2.1)	10 (10.4)	6 (6.3)	0
Hypoalbuminaemia	12 (12.5)	0	11 (11.5)	1 (1.0)	0
Hyperglycaemia	9 (9.4)	0	4 (4.2)	5 (5.2)	0
Hyperuricaemia	9 (9.4)	7 (7.3)	1 (1.0)	1 (1.0)	0
Hypervolaemia	9 (9.4)	1 (1.0)	2 (2.1)	6 (6.3)	0
Hypomagnesaemia	9 (9.4)	7 (7.3)	2 (2.1)	0	0
Hyperphosphataemia	6 (6.3)	5 (5.2)	0	0	1 (1.0)
Metabolic acidosis	6 (6.3)	1 (1.0)	0	2 (2.1)	3 (3.1)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	6 (6.3)	0	0	4 (4.2)	2 (2.1)
Hyperkalaemia	4 (4.2)	0	1 (1.0)	2 (2.1)	1 (1.0)
Hyponatraemia	4 (4.2)	3 (3.1)	0	0	1 (1.0)
Hypercalcaemia	3 (3.1)	0	1 (1.0)	1 (1.0)	1 (1.0)
Hypernatraemia	3 (3.1)	1 (1.0)	0	1 (1.0)	1 (1.0)
Hypertriglyceridaemia	3 (3.1)	0	1 (1.0)	1 (1.0)	1 (1.0)
Acidosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Hyperchloraemia	2 (2.1)	2 (2.1)	0	0	0
Hypermagnesaemia	2 (2.1)	2 (2.1)	0	0	0
Iron overload	2 (2.1)	0	2 (2.1)	0	0
Malnutrition	2 (2.1)	0	0	2 (2.1)	0
Calcium deficiency	1 (1.0)	1 (1.0)	0	0	0
Dehydration	1 (1.0)	0	1 (1.0)	0	0
Eating disorder symptom	1 (1.0)	0	1 (1.0)	0	0
Haemochromatosis	1 (1.0)	0	0	1 (1.0)	0
Haemosiderosis	1 (1.0)	0	1 (1.0)	0	0
Hypercholesterolaemia	1 (1.0)	0	1 (1.0)	0	0
Hyperlactacidaemia	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlipidaemia	1 (1.0)	0	1 (1.0)	0	0
Hypoglycaemia	1 (1.0)	0	1 (1.0)	0	0
Hypophagia	1 (1.0)	0	1 (1.0)	0	0
Metabolic syndrome	1 (1.0)	0	1 (1.0)	0	0
Obesity	1 (1.0)	0	0	1 (1.0)	0
Polydipsia	1 (1.0)	0	0	1 (1.0)	0
Vitamin d deficiency	1 (1.0)	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	48 (50.0)	18 (18.8)	19 (19.8)	10 (10.4)	1 (1.0)
Pain in extremity	23 (24.0)	9 (9.4)	11 (11.5)	3 (3.1)	0
Arthralgia	13 (13.5)	6 (6.3)	6 (6.3)	1 (1.0)	0
Back pain	12 (12.5)	2 (2.1)	6 (6.3)	4 (4.2)	0
Myalgia	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Bone pain	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Pain in jaw	3 (3.1)	1 (1.0)	0	2 (2.1)	0
Growth retardation	2 (2.1)	0	2 (2.1)	0	0
Joint effusion	2 (2.1)	0	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (2.1)	1 (1.0)	0	1 (1.0)	0
Musculoskeletal chest pain	2 (2.1)	2 (2.1)	0	0	0
Neck pain	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Groin pain	1 (1.0)	1 (1.0)	0	0	0
Haemarthrosis	1 (1.0)	0	0	1 (1.0)	0
Muscle rigidity	1 (1.0)	1 (1.0)	0	0	0
Muscle spasms	1 (1.0)	0	1 (1.0)	0	0
Musculoskeletal pain	1 (1.0)	0	1 (1.0)	0	0
Myopathy	1 (1.0)	0	0	1 (1.0)	0
Myositis	1 (1.0)	0	1 (1.0)	0	0
Osteonecrosis	1 (1.0)	1 (1.0)	0	0	0
Osteopenia	1 (1.0)	1 (1.0)	0	0	0
Rhabdomyolysis	1 (1.0)	0	0	0	1 (1.0)
Spinal pain	1 (1.0)	0	0	1 (1.0)	0
Synovitis	1 (1.0)	0	1 (1.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (5.2)	1 (1.0)	2 (2.1)	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Bone giant cell tumour benign	1 (1.0)	0	0	1 (1.0)	0
Cancer pain	1 (1.0)	0	1 (1.0)	0	0
Myelodysplastic syndrome	1 (1.0)	0	0	1 (1.0)	0
Nervous system disorders					
-Total	55 (57.3)	17 (17.7)	20 (20.8)	13 (13.5)	5 (5.2)
Headache	32 (33.3)	16 (16.7)	13 (13.5)	3 (3.1)	0
Encephalopathy	9 (9.4)	1 (1.0)	3 (3.1)	5 (5.2)	0
Seizure	6 (6.3)	0	3 (3.1)	3 (3.1)	0
Somnolence	6 (6.3)	2 (2.1)	2 (2.1)	2 (2.1)	0
Tremor	6 (6.3)	5 (5.2)	1 (1.0)	0	0
Dizziness	5 (5.2)	5 (5.2)	0	0	0
Cognitive disorder	4 (4.2)	0	2 (2.1)	2 (2.1)	0
Lethargy	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Dysgeusia	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Neuropathy peripheral	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Cerebral haemorrhage	2 (2.1)	0	0	0	2 (2.1)
Dysarthria	2 (2.1)	0	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Amnesia	1 (1.0)	0	1 (1.0)	0	0
Aphasia	1 (1.0)	1 (1.0)	0	0	0
Autonomic neuropathy	1 (1.0)	0	0	1 (1.0)	0
Depressed level of consciousness	1 (1.0)	0	0	1 (1.0)	0
Disturbance in attention	1 (1.0)	1 (1.0)	0	0	0
Extrapyramidal disorder	1 (1.0)	0	1 (1.0)	0	0
Generalised tonic-clonic seizure	1 (1.0)	0	1 (1.0)	0	0
Haemorrhage intracranial	1 (1.0)	0	0	0	1 (1.0)
Hydrocephalus	1 (1.0)	0	0	0	1 (1.0)
Hyperaesthesia	1 (1.0)	1 (1.0)	0	0	0
Hypoaesthesia	1 (1.0)	1 (1.0)	0	0	0
Memory impairment	1 (1.0)	0	1 (1.0)	0	0
Migraine	1 (1.0)	0	1 (1.0)	0	0
Monoparesis	1 (1.0)	0	1 (1.0)	0	0
Nervous system disorder	1 (1.0)	0	0	1 (1.0)	0
Neuralgia	1 (1.0)	0	1 (1.0)	0	0
Neurological decompensation	1 (1.0)	0	0	0	1 (1.0)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Posterior reversible encephalopathy syndrome	1 (1.0)	0	1 (1.0)	0	0
Psychiatric disorders					
-Total	41 (42.7)	13 (13.5)	18 (18.8)	10 (10.4)	0
Anxiety	16 (16.7)	4 (4.2)	9 (9.4)	3 (3.1)	0
Delirium	8 (8.3)	2 (2.1)	3 (3.1)	3 (3.1)	0
Agitation	7 (7.3)	4 (4.2)	3 (3.1)	0	0
Confusional state	7 (7.3)	7 (7.3)	0	0	0
Insomnia	6 (6.3)	2 (2.1)	4 (4.2)	0	0
Mental status changes	6 (6.3)	1 (1.0)	2 (2.1)	3 (3.1)	0
Irritability	4 (4.2)	3 (3.1)	0	1 (1.0)	0
Hallucination	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Sleep disorder	3 (3.1)	0	3 (3.1)	0	0
Affect lability	1 (1.0)	0	1 (1.0)	0	0
Automatism	1 (1.0)	1 (1.0)	0	0	0
Hallucination, visual	1 (1.0)	0	1 (1.0)	0	0
Mood altered	1 (1.0)	1 (1.0)	0	0	0
Nightmare	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Persistent depressive disorder	1 (1.0)	0	1 (1.0)	0	0
Restlessness	1 (1.0)	0	1 (1.0)	0	0
Social avoidant behaviour	1 (1.0)	0	1 (1.0)	0	0
Tearfulness	1 (1.0)	1 (1.0)	0	0	0
Tic	1 (1.0)	0	1 (1.0)	0	0
Renal and urinary disorders					
-Total	30 (31.3)	10 (10.4)	7 (7.3)	6 (6.3)	7 (7.3)
Acute kidney injury	15 (15.6)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Dysuria	5 (5.2)	4 (4.2)	1 (1.0)	0	0
Haematuria	4 (4.2)	3 (3.1)	0	1 (1.0)	0
Anuria	2 (2.1)	1 (1.0)	0	0	1 (1.0)
Pollakiuria	2 (2.1)	0	2 (2.1)	0	0
Renal failure	2 (2.1)	0	1 (1.0)	0	1 (1.0)
Renal tubular necrosis	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Urinary retention	2 (2.1)	0	2 (2.1)	0	0
Azotaemia	1 (1.0)	0	1 (1.0)	0	0
Bladder dilatation	1 (1.0)	0	1 (1.0)	0	0
Cystitis haemorrhagic	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Incontinence	1 (1.0)	0	1 (1.0)	0	0
Kidney enlargement	1 (1.0)	0	1 (1.0)	0	0
Micturition urgency	1 (1.0)	0	1 (1.0)	0	0
Proteinuria	1 (1.0)	1 (1.0)	0	0	0
Renal mass	1 (1.0)	0	1 (1.0)	0	0
Renal pain	1 (1.0)	1 (1.0)	0	0	0
Renal tubular disorder	1 (1.0)	0	0	1 (1.0)	0
Renal tubular dysfunction	1 (1.0)	1 (1.0)	0	0	0
Urinary incontinence	1 (1.0)	0	1 (1.0)	0	0
Urinary tract disorder	1 (1.0)	0	1 (1.0)	0	0
Reproductive system and breast disorders					
-Total	7 (7.3)	1 (1.0)	3 (3.1)	3 (3.1)	0
Dysmenorrhoea	1 (1.0)	0	1 (1.0)	0	0
Endometriosis	1 (1.0)	0	0	1 (1.0)	0
Female genital tract fistula	1 (1.0)	1 (1.0)	0	0	0
Heavy menstrual bleeding	1 (1.0)	0	1 (1.0)	0	0
Perineal rash	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prostatitis	1 (1.0)	0	0	1 (1.0)	0
Vaginal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Vaginal ulceration	1 (1.0)	0	0	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	62 (64.6)	19 (19.8)	8 (8.3)	13 (13.5)	22 (22.9)
Cough	26 (27.1)	21 (21.9)	5 (5.2)	0	0
Hypoxia	21 (21.9)	0	5 (5.2)	10 (10.4)	6 (6.3)
Pulmonary oedema	14 (14.6)	3 (3.1)	3 (3.1)	6 (6.3)	2 (2.1)
Epistaxis	12 (12.5)	7 (7.3)	2 (2.1)	3 (3.1)	0
Nasal congestion	11 (11.5)	9 (9.4)	2 (2.1)	0	0
Oropharyngeal pain	10 (10.4)	8 (8.3)	2 (2.1)	0	0
Pleural effusion	10 (10.4)	4 (4.2)	3 (3.1)	2 (2.1)	1 (1.0)
Respiratory failure	10 (10.4)	0	0	0	10 (10.4)
Tachypnoea	10 (10.4)	3 (3.1)	2 (2.1)	4 (4.2)	1 (1.0)
Dyspnoea	8 (8.3)	1 (1.0)	2 (2.1)	3 (3.1)	2 (2.1)
Rhinorrhoea	6 (6.3)	4 (4.2)	2 (2.1)	0	0
Acute respiratory distress syndrome	4 (4.2)	0	0	0	4 (4.2)

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	4 (4.2)	0	2 (2.1)	0	2 (2.1)
Atelectasis	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Pharyngeal erythema	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Rhinitis allergic	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Sleep apnoea syndrome	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Wheezing	2 (2.1)	0	2 (2.1)	0	0
Acute respiratory failure	1 (1.0)	0	0	1 (1.0)	0
Bradypnoea	1 (1.0)	0	0	1 (1.0)	0
Bronchial oedema	1 (1.0)	1 (1.0)	0	0	0
Bronchospasm	1 (1.0)	0	1 (1.0)	0	0
Dyspnoea exertional	1 (1.0)	1 (1.0)	0	0	0
Haemoptysis	1 (1.0)	0	1 (1.0)	0	0
Laryngeal oedema	1 (1.0)	0	0	0	1 (1.0)
Lung disorder	1 (1.0)	1 (1.0)	0	0	0
Lung infiltration	1 (1.0)	0	0	1 (1.0)	0
Nasal discomfort	1 (1.0)	0	1 (1.0)	0	0
Nasal dryness	1 (1.0)	1 (1.0)	0	0	0
Oropharyngeal plaque	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Painful respiration	1 (1.0)	1 (1.0)	0	0	0
Paranasal sinus discomfort	1 (1.0)	0	1 (1.0)	0	0
Paranasal sinus inflammation	1 (1.0)	1 (1.0)	0	0	0
Pharyngeal exudate	1 (1.0)	0	1 (1.0)	0	0
Pharyngeal haemorrhage	1 (1.0)	0	1 (1.0)	0	0
Pharyngeal oedema	1 (1.0)	0	1 (1.0)	0	0
Productive cough	1 (1.0)	1 (1.0)	0	0	0
Pulmonary haemorrhage	1 (1.0)	0	0	0	1 (1.0)
Pulmonary mass	1 (1.0)	0	1 (1.0)	0	0
Respiratory acidosis	1 (1.0)	0	0	1 (1.0)	0
Respiratory disorder	1 (1.0)	0	1 (1.0)	0	0
Upper respiratory tract inflammation	1 (1.0)	0	1 (1.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	47 (49.0)	22 (22.9)	17 (17.7)	8 (8.3)	0
Pruritus	11 (11.5)	5 (5.2)	6 (6.3)	0	0
Rash	10 (10.4)	5 (5.2)	5 (5.2)	0	0
Dry skin	9 (9.4)	7 (7.3)	2 (2.1)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	6 (6.3)	5 (5.2)	1 (1.0)	0	0
Ingrowing nail	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Rash maculo-papular	4 (4.2)	2 (2.1)	1 (1.0)	1 (1.0)	0
Rash papular	4 (4.2)	3 (3.1)	1 (1.0)	0	0
Skin ulcer	4 (4.2)	2 (2.1)	1 (1.0)	1 (1.0)	0
Blister	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Dermatitis atopic	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Eczema	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Hyperhidrosis	3 (3.1)	1 (1.0)	2 (2.1)	0	0
Petechiae	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.0)	0
Decubitus ulcer	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Skin discolouration	2 (2.1)	2 (2.1)	0	0	0
Acne	1 (1.0)	1 (1.0)	0	0	0
Dermatitis	1 (1.0)	1 (1.0)	0	0	0
Dermatitis allergic	1 (1.0)	1 (1.0)	0	0	0
Dermatitis diaper	1 (1.0)	0	1 (1.0)	0	0
Drug eruption	1 (1.0)	0	1 (1.0)	0	0
Erythema nodosum	1 (1.0)	1 (1.0)	0	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hangnail	1 (1.0)	1 (1.0)	0	0	0
Miliaria	1 (1.0)	1 (1.0)	0	0	0
Night sweats	1 (1.0)	1 (1.0)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.0)	1 (1.0)	0	0	0
Papule	1 (1.0)	1 (1.0)	0	0	0
Pruritus allergic	1 (1.0)	0	1 (1.0)	0	0
Purpura	1 (1.0)	1 (1.0)	0	0	0
Rash erythematous	1 (1.0)	1 (1.0)	0	0	0
Rash macular	1 (1.0)	0	0	1 (1.0)	0
Rash pruritic	1 (1.0)	1 (1.0)	0	0	0
Rash vesicular	1 (1.0)	1 (1.0)	0	0	0
Scab	1 (1.0)	1 (1.0)	0	0	0
Skin hypopigmentation	1 (1.0)	1 (1.0)	0	0	0
Skin lesion	1 (1.0)	0	1 (1.0)	0	0
Skin necrosis	1 (1.0)	0	0	1 (1.0)	0
Skin swelling	1 (1.0)	1 (1.0)	0	0	0
Urticaria	1 (1.0)	0	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vancomycin infusion reaction	1 (1.0)	0	0	1 (1.0)	0
Social circumstances					
-Total	1 (1.0)	0	1 (1.0)	0	0
Patient uncooperative	1 (1.0)	0	1 (1.0)	0	0
Surgical and medical procedures					
-Total	1 (1.0)	0	0	1 (1.0)	0
Thrombolysis	1 (1.0)	0	0	1 (1.0)	0
Vascular disorders					
-Total	43 (44.8)	5 (5.2)	11 (11.5)	16 (16.7)	11 (11.5)
Hypotension	30 (31.3)	2 (2.1)	6 (6.3)	12 (12.5)	10 (10.4)
Hypertension	19 (19.8)	4 (4.2)	10 (10.4)	5 (5.2)	0
Capillary leak syndrome	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Flushing	2 (2.1)	2 (2.1)	0	0	0
Peripheral ischaemia	2 (2.1)	0	2 (2.1)	0	0
Venoocclusive disease	2 (2.1)	0	0	1 (1.0)	1 (1.0)
Haematoma	1 (1.0)	1 (1.0)	0	0	0
Hot flush	1 (1.0)	1 (1.0)	0	0	0
Thrombosis	1 (1.0)	0	1 (1.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208j
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (100)	0	2 (6.7)	6 (20.0)	22 (73.3)
Blood and lymphatic system disorders					
-Total	19 (63.3)	1 (3.3)	3 (10.0)	9 (30.0)	6 (20.0)
Anaemia	11 (36.7)	2 (6.7)	4 (13.3)	5 (16.7)	0
Febrile neutropenia	9 (30.0)	0	0	9 (30.0)	0
Neutropenia	7 (23.3)	1 (3.3)	1 (3.3)	1 (3.3)	4 (13.3)
Disseminated intravascular coagulation	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Thrombocytopenia	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Agranulocytosis	1 (3.3)	0	0	1 (3.3)	0
Coagulopathy	1 (3.3)	1 (3.3)	0	0	0
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Splenomegaly	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	10 (33.3)	3 (10.0)	3 (10.0)	2 (6.7)	2 (6.7)
Tachycardia	5 (16.7)	1 (3.3)	1 (3.3)	2 (6.7)	1 (3.3)
Bradycardia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Sinus tachycardia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Cardiac dysfunction	1 (3.3)	1 (3.3)	0	0	0
Cardiac failure	1 (3.3)	0	0	0	1 (3.3)
Ear and labyrinth disorders					
-Total	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Ear pruritus	1 (3.3)	1 (3.3)	0	0	0
Vertigo	1 (3.3)	0	1 (3.3)	0	0
Endocrine disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Hypothyroidism	1 (3.3)	0	1 (3.3)	0	0
Eye disorders					
-Total	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	0
Eyelid oedema	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Eye pain	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Conjunctival haemorrhage	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	25 (83.3)	5 (16.7)	11 (36.7)	8 (26.7)	1 (3.3)
Diarrhoea	11 (36.7)	7 (23.3)	2 (6.7)	2 (6.7)	0
Nausea	10 (33.3)	5 (16.7)	4 (13.3)	1 (3.3)	0
Abdominal pain	9 (30.0)	3 (10.0)	6 (20.0)	0	0
Vomiting	8 (26.7)	7 (23.3)	1 (3.3)	0	0
Constipation	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Pancreatitis	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Stomatitis	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Abdominal pain upper	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Mouth haemorrhage	2 (6.7)	0	2 (6.7)	0	0
Proctalgia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Abdominal compartment syndrome	1 (3.3)	0	0	0	1 (3.3)
Abdominal distension	1 (3.3)	0	1 (3.3)	0	0
Anal fissure	1 (3.3)	0	1 (3.3)	0	0
Anal fistula	1 (3.3)	0	0	1 (3.3)	0
Anal haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Ascites	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (3.3)	0	1 (3.3)	0	0
Dysphagia	1 (3.3)	0	0	1 (3.3)	0
Enteritis	1 (3.3)	0	1 (3.3)	0	0
Enterocolitis	1 (3.3)	0	1 (3.3)	0	0
Gastrooesophageal reflux disease	1 (3.3)	0	1 (3.3)	0	0
Gingival erythema	1 (3.3)	1 (3.3)	0	0	0
Haemoperitoneum	1 (3.3)	0	0	0	1 (3.3)
Haemorrhoids	1 (3.3)	0	1 (3.3)	0	0
Melaena	1 (3.3)	0	0	1 (3.3)	0
Neutropenic colitis	1 (3.3)	0	1 (3.3)	0	0
Oral pain	1 (3.3)	0	1 (3.3)	0	0
Trichoglossia	1 (3.3)	1 (3.3)	0	0	0
General disorders and administration site conditions					
-Total	19 (63.3)	9 (30.0)	5 (16.7)	3 (10.0)	2 (6.7)
Pyrexia	13 (43.3)	6 (20.0)	4 (13.3)	2 (6.7)	1 (3.3)
Fatigue	6 (20.0)	5 (16.7)	1 (3.3)	0	0
Oedema peripheral	4 (13.3)	4 (13.3)	0	0	0
Face oedema	3 (10.0)	2 (6.7)	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Asthenia	2 (6.7)	2 (6.7)	0	0	0
Catheter site pain	2 (6.7)	0	2 (6.7)	0	0
Generalised oedema	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Pain	2 (6.7)	0	2 (6.7)	0	0
Catheter site erythema	1 (3.3)	1 (3.3)	0	0	0
Catheter site haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Complication associated with device	1 (3.3)	1 (3.3)	0	0	0
Localised oedema	1 (3.3)	1 (3.3)	0	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	0	0	1 (3.3)
Oedema due to hepatic disease	1 (3.3)	0	1 (3.3)	0	0
Systemic inflammatory response syndrome	1 (3.3)	0	0	1 (3.3)	0
Xerosis	1 (3.3)	1 (3.3)	0	0	0
Hepatobiliary disorders					
-Total	10 (33.3)	1 (3.3)	3 (10.0)	4 (13.3)	2 (6.7)
Hepatic function abnormal	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hyperbilirubinaemia	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Hypertransaminasaemia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Cholelithiasis	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (3.3)	0	0	0	1 (3.3)
Gallbladder enlargement	1 (3.3)	1 (3.3)	0	0	0
Hepatic cytolysis	1 (3.3)	0	0	1 (3.3)	0
Liver disorder	1 (3.3)	0	1 (3.3)	0	0
Immune system disorders					
-Total	24 (80.0)	0	5 (16.7)	10 (33.3)	9 (30.0)
Cytokine release syndrome	20 (66.7)	0	3 (10.0)	8 (26.7)	9 (30.0)
Hypogammaglobulinaemia	11 (36.7)	1 (3.3)	7 (23.3)	3 (10.0)	0
Haemophagocytic lymphohistiocytosis	4 (13.3)	1 (3.3)	1 (3.3)	1 (3.3)	1 (3.3)
Immunodeficiency	2 (6.7)	0	0	2 (6.7)	0
Allergy to immunoglobulin therapy	1 (3.3)	1 (3.3)	0	0	0
Drug hypersensitivity	1 (3.3)	0	0	1 (3.3)	0
Engraftment syndrome	1 (3.3)	0	0	1 (3.3)	0
Graft versus host disease	1 (3.3)	0	0	1 (3.3)	0
Seasonal allergy	1 (3.3)	0	1 (3.3)	0	0
Infections and infestations					
-Total	25 (83.3)	2 (6.7)	1 (3.3)	13 (43.3)	9 (30.0)
Conjunctivitis	5 (16.7)	1 (3.3)	4 (13.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Nasopharyngitis	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Staphylococcal infection	4 (13.3)	0	1 (3.3)	2 (6.7)	1 (3.3)
Bacteraemia	3 (10.0)	0	0	3 (10.0)	0
Nail infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Paronychia	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	3 (10.0)	0	3 (10.0)	0	0
Sinusitis	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Bronchiolitis	2 (6.7)	0	0	2 (6.7)	0
Clostridium difficile infection	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Ear infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Gastroenteritis	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Gastroenteritis viral	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Herpes zoster	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Oral herpes	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Oral infection	2 (6.7)	0	2 (6.7)	0	0
Otitis media	2 (6.7)	0	2 (6.7)	0	0
Respiratory tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Sepsis	2 (6.7)	0	0	0	2 (6.7)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (6.7)	0	2 (6.7)	0	0
Upper respiratory tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Anal abscess	1 (3.3)	0	0	1 (3.3)	0
Aspergillus infection	1 (3.3)	0	0	0	1 (3.3)
Bk virus infection	1 (3.3)	1 (3.3)	0	0	0
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Bronchopulmonary aspergillosis	1 (3.3)	0	0	1 (3.3)	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Catheter site infection	1 (3.3)	0	0	1 (3.3)	0
Cholecystitis infective	1 (3.3)	0	1 (3.3)	0	0
Coronavirus infection	1 (3.3)	0	0	1 (3.3)	0
Covid-19	1 (3.3)	0	0	1 (3.3)	0
Cytomegalovirus infection reactivation	1 (3.3)	0	1 (3.3)	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Device related sepsis	1 (3.3)	0	0	1 (3.3)	0
Encephalitis	1 (3.3)	0	0	0	1 (3.3)
Encephalitis viral	1 (3.3)	0	0	0	1 (3.3)
Folliculitis	1 (3.3)	0	1 (3.3)	0	0
Fungaemia	1 (3.3)	0	0	0	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal pharyngitis	1 (3.3)	0	0	1 (3.3)	0
Gastroenteritis norovirus	1 (3.3)	1 (3.3)	0	0	0
Herpes virus infection	1 (3.3)	0	1 (3.3)	0	0
Influenza	1 (3.3)	0	1 (3.3)	0	0
Localised infection	1 (3.3)	1 (3.3)	0	0	0
Meningitis bacterial	1 (3.3)	0	0	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	0	0	1 (3.3)	0
Myringitis	1 (3.3)	1 (3.3)	0	0	0
Ophthalmic herpes zoster	1 (3.3)	0	1 (3.3)	0	0
Otitis externa	1 (3.3)	0	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Pneumocystis jirovecii pneumonia	1 (3.3)	0	0	0	1 (3.3)
Pneumonia respiratory syncytial viral	1 (3.3)	0	0	1 (3.3)	0
Rhinitis	1 (3.3)	1 (3.3)	0	0	0
Salmonellosis	1 (3.3)	0	1 (3.3)	0	0
Septic shock	1 (3.3)	0	0	0	1 (3.3)
Serratia sepsis	1 (3.3)	0	0	0	1 (3.3)
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal sepsis	1 (3.3)	0	0	0	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (3.3)	0	1 (3.3)	0	0
Tinea pedis	1 (3.3)	1 (3.3)	0	0	0
Viral infection	1 (3.3)	0	1 (3.3)	0	0
Vulval cellulitis	1 (3.3)	0	0	1 (3.3)	0
Injury, poisoning and procedural complications					
-Total	11 (36.7)	3 (10.0)	4 (13.3)	2 (6.7)	2 (6.7)
Procedural pain	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Infusion related reaction	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Wound	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Contusion	1 (3.3)	1 (3.3)	0	0	0
Fall	1 (3.3)	0	1 (3.3)	0	0
Ligament sprain	1 (3.3)	1 (3.3)	0	0	0
Scratch	1 (3.3)	1 (3.3)	0	0	0
Skin abrasion	1 (3.3)	1 (3.3)	0	0	0
Skin injury	1 (3.3)	0	1 (3.3)	0	0
Skin wound	1 (3.3)	1 (3.3)	0	0	0
Tracheal obstruction	1 (3.3)	0	0	0	1 (3.3)
Transfusion reaction	1 (3.3)	0	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (3.3)	0	0	0	1 (3.3)
Investigations					
-Total	23 (76.7)	1 (3.3)	1 (3.3)	7 (23.3)	14 (46.7)
Neutrophil count decreased	10 (33.3)	0	1 (3.3)	0	9 (30.0)
Platelet count decreased	10 (33.3)	2 (6.7)	1 (3.3)	2 (6.7)	5 (16.7)
White blood cell count decreased	10 (33.3)	2 (6.7)	1 (3.3)	1 (3.3)	6 (20.0)
Lymphocyte count decreased	8 (26.7)	1 (3.3)	1 (3.3)	3 (10.0)	3 (10.0)
Alanine aminotransferase increased	7 (23.3)	2 (6.7)	2 (6.7)	3 (10.0)	0
Aspartate aminotransferase increased	6 (20.0)	0	4 (13.3)	1 (3.3)	1 (3.3)
Blood fibrinogen decreased	6 (20.0)	2 (6.7)	3 (10.0)	0	1 (3.3)
Blood bilirubin increased	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Serum ferritin increased	4 (13.3)	0	4 (13.3)	0	0
Blood creatinine increased	3 (10.0)	1 (3.3)	1 (3.3)	0	1 (3.3)
Blood immunoglobulin m decreased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Blood uric acid increased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
Electrocardiogram qt prolonged	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Activated partial thromboplastin time prolonged	2 (6.7)	2 (6.7)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Blood immunoglobulin a decreased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Blood lactate dehydrogenase increased	2 (6.7)	1 (3.3)	1 (3.3)	0	0
C-reactive protein increased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
International normalised ratio increased	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Lipase increased	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Weight decreased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Amylase increased	1 (3.3)	1 (3.3)	0	0	0
Bacterial test positive	1 (3.3)	0	0	1 (3.3)	0
Blood alkaline phosphatase decreased	1 (3.3)	1 (3.3)	0	0	0
Blood bicarbonate decreased	1 (3.3)	0	1 (3.3)	0	0
Blood fibrinogen increased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Blood phosphorus increased	1 (3.3)	0	1 (3.3)	0	0
Blood thyroid stimulating hormone increased	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (3.3)	0	0	1 (3.3)	0
Cardiac murmur	1 (3.3)	1 (3.3)	0	0	0
Coagulation test abnormal	1 (3.3)	1 (3.3)	0	0	0
Fibrin d dimer increased	1 (3.3)	1 (3.3)	0	0	0
Haemoglobin decreased	1 (3.3)	0	0	1 (3.3)	0
Immunoglobulins decreased	1 (3.3)	0	1 (3.3)	0	0
Oxygen saturation decreased	1 (3.3)	0	1 (3.3)	0	0
Urine output decreased	1 (3.3)	0	0	0	1 (3.3)
Weight increased	1 (3.3)	0	0	1 (3.3)	0
Metabolism and nutrition disorders					
-Total	20 (66.7)	5 (16.7)	1 (3.3)	9 (30.0)	5 (16.7)
Hypokalaemia	13 (43.3)	2 (6.7)	2 (6.7)	8 (26.7)	1 (3.3)
Decreased appetite	9 (30.0)	5 (16.7)	0	4 (13.3)	0
Hypophosphataemia	7 (23.3)	2 (6.7)	2 (6.7)	2 (6.7)	1 (3.3)
Hypocalcaemia	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hypoalbuminaemia	4 (13.3)	0	4 (13.3)	0	0
Hyperuricaemia	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Tumour lysis syndrome	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hyperchloraemia	2 (6.7)	2 (6.7)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Hyperphosphataemia	2 (6.7)	2 (6.7)	0	0	0
Hypervolaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Hypomagnesaemia	2 (6.7)	2 (6.7)	0	0	0
Metabolic acidosis	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Eating disorder symptom	1 (3.3)	0	1 (3.3)	0	0
Haemosiderosis	1 (3.3)	0	1 (3.3)	0	0
Hyperlactacidaemia	1 (3.3)	1 (3.3)	0	0	0
Hyperlipidaemia	1 (3.3)	0	1 (3.3)	0	0
Hypertriglyceridaemia	1 (3.3)	0	0	0	1 (3.3)
Hyponatraemia	1 (3.3)	1 (3.3)	0	0	0
Metabolic syndrome	1 (3.3)	0	1 (3.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	15 (50.0)	8 (26.7)	6 (20.0)	0	1 (3.3)
Pain in extremity	10 (33.3)	5 (16.7)	5 (16.7)	0	0
Arthralgia	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Myalgia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Back pain	1 (3.3)	0	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle rigidity	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal chest pain	1 (3.3)	1 (3.3)	0	0	0
Myositis	1 (3.3)	0	1 (3.3)	0	0
Osteonecrosis	1 (3.3)	1 (3.3)	0	0	0
Rhabdomyolysis	1 (3.3)	0	0	0	1 (3.3)
Nervous system disorders					
-Total	15 (50.0)	5 (16.7)	5 (16.7)	4 (13.3)	1 (3.3)
Headache	9 (30.0)	4 (13.3)	4 (13.3)	1 (3.3)	0
Dizziness	3 (10.0)	3 (10.0)	0	0	0
Encephalopathy	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Tremor	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Somnolence	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Cognitive disorder	1 (3.3)	0	0	1 (3.3)	0
Generalised tonic-clonic seizure	1 (3.3)	0	1 (3.3)	0	0
Hydrocephalus	1 (3.3)	0	0	0	1 (3.3)
Hypoaesthesia	1 (3.3)	1 (3.3)	0	0	0
Monoparesis	1 (3.3)	0	1 (3.3)	0	0
Neuralgia	1 (3.3)	0	1 (3.3)	0	0
Seizure	1 (3.3)	0	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	13 (43.3)	6 (20.0)	3 (10.0)	4 (13.3)	0
Mental status changes	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Anxiety	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Delirium	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Insomnia	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Confusional state	2 (6.7)	2 (6.7)	0	0	0
Irritability	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Agitation	1 (3.3)	0	1 (3.3)	0	0
Automatism	1 (3.3)	1 (3.3)	0	0	0
Sleep disorder	1 (3.3)	0	1 (3.3)	0	0
Renal and urinary disorders					
-Total	14 (46.7)	6 (20.0)	3 (10.0)	1 (3.3)	4 (13.3)
Acute kidney injury	8 (26.7)	3 (10.0)	0	1 (3.3)	4 (13.3)
Dysuria	2 (6.7)	2 (6.7)	0	0	0
Anuria	1 (3.3)	1 (3.3)	0	0	0
Azotaemia	1 (3.3)	0	1 (3.3)	0	0
Bladder dilatation	1 (3.3)	0	1 (3.3)	0	0
Cystitis haemorrhagic	1 (3.3)	0	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (3.3)	1 (3.3)	0	0	0
Micturition urgency	1 (3.3)	0	1 (3.3)	0	0
Pollakiuria	1 (3.3)	0	1 (3.3)	0	0
Proteinuria	1 (3.3)	1 (3.3)	0	0	0
Renal failure	1 (3.3)	0	1 (3.3)	0	0
Renal pain	1 (3.3)	1 (3.3)	0	0	0
Renal tubular necrosis	1 (3.3)	0	0	0	1 (3.3)
Urinary retention	1 (3.3)	0	1 (3.3)	0	0
Reproductive system and breast disorders					
-Total	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Dysmenorrhoea	1 (3.3)	0	1 (3.3)	0	0
Perineal rash	1 (3.3)	0	1 (3.3)	0	0
Prostatitis	1 (3.3)	0	0	1 (3.3)	0
Vaginal ulceration	1 (3.3)	0	0	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (73.3)	8 (26.7)	2 (6.7)	3 (10.0)	9 (30.0)
Hypoxia	9 (30.0)	0	1 (3.3)	4 (13.3)	4 (13.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	7 (23.3)	6 (20.0)	1 (3.3)	0	0
Pleural effusion	5 (16.7)	3 (10.0)	1 (3.3)	1 (3.3)	0
Pulmonary oedema	5 (16.7)	2 (6.7)	1 (3.3)	1 (3.3)	1 (3.3)
Oropharyngeal pain	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Tachypnoea	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Epistaxis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Respiratory failure	3 (10.0)	0	0	0	3 (10.0)
Acute respiratory distress syndrome	2 (6.7)	0	0	0	2 (6.7)
Atelectasis	2 (6.7)	0	0	2 (6.7)	0
Dyspnoea	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Nasal congestion	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Respiratory distress	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Rhinorrhoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Bradypnoea	1 (3.3)	0	0	1 (3.3)	0
Nasal discomfort	1 (3.3)	0	1 (3.3)	0	0
Paranasal sinus inflammation	1 (3.3)	1 (3.3)	0	0	0
Pharyngeal haemorrhage	1 (3.3)	0	1 (3.3)	0	0
Productive cough	1 (3.3)	1 (3.3)	0	0	0
Pulmonary haemorrhage	1 (3.3)	0	0	0	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory acidosis	1 (3.3)	0	0	1 (3.3)	0
Sleep apnoea syndrome	1 (3.3)	1 (3.3)	0	0	0
Wheezing	1 (3.3)	0	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (50.0)	4 (13.3)	6 (20.0)	5 (16.7)	0
Dry skin	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Pruritus	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Rash	4 (13.3)	0	4 (13.3)	0	0
Skin ulcer	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Eczema	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Erythema	2 (6.7)	2 (6.7)	0	0	0
Ingrowing nail	2 (6.7)	0	2 (6.7)	0	0
Petechiae	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Blister	1 (3.3)	1 (3.3)	0	0	0
Decubitus ulcer	1 (3.3)	0	1 (3.3)	0	0
Dermatitis diaper	1 (3.3)	0	1 (3.3)	0	0
Erythema nodosum	1 (3.3)	1 (3.3)	0	0	0
Hangnail	1 (3.3)	1 (3.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papule	1 (3.3)	1 (3.3)	0	0	0
Pruritus allergic	1 (3.3)	0	1 (3.3)	0	0
Rash erythematous	1 (3.3)	1 (3.3)	0	0	0
Rash macular	1 (3.3)	0	0	1 (3.3)	0
Rash papular	1 (3.3)	1 (3.3)	0	0	0
Rash pruritic	1 (3.3)	1 (3.3)	0	0	0
Skin discolouration	1 (3.3)	1 (3.3)	0	0	0
Skin necrosis	1 (3.3)	0	0	1 (3.3)	0
Skin swelling	1 (3.3)	1 (3.3)	0	0	0
Urticaria	1 (3.3)	0	1 (3.3)	0	0
Vancomycin infusion reaction	1 (3.3)	0	0	1 (3.3)	0
Vascular disorders					
-Total	15 (50.0)	1 (3.3)	5 (16.7)	3 (10.0)	6 (20.0)
Hypotension	9 (30.0)	0	2 (6.7)	2 (6.7)	5 (16.7)
Hypertension	8 (26.7)	1 (3.3)	5 (16.7)	2 (6.7)	0
Venoocclusive disease	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Capillary leak syndrome	1 (3.3)	0	1 (3.3)	0	0
Haematoma	1 (3.3)	1 (3.3)	0	0	0
Thrombosis	1 (3.3)	0	1 (3.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208j
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (95.6)	0	3 (4.4)	14 (20.6)	48 (70.6)
Blood and lymphatic system disorders					
-Total	48 (70.6)	0	6 (8.8)	28 (41.2)	14 (20.6)
Febrile neutropenia	30 (44.1)	0	0	27 (39.7)	3 (4.4)
Anaemia	27 (39.7)	3 (4.4)	7 (10.3)	16 (23.5)	1 (1.5)
Neutropenia	9 (13.2)	0	1 (1.5)	2 (2.9)	6 (8.8)
Thrombocytopenia	9 (13.2)	0	1 (1.5)	4 (5.9)	4 (5.9)
Coagulopathy	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Disseminated intravascular coagulation	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Leukopenia	4 (5.9)	0	0	1 (1.5)	3 (4.4)
Pancytopenia	4 (5.9)	0	0	3 (4.4)	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Lymphadenopathy	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Lymphopenia	2 (2.9)	0	0	0	2 (2.9)
B-cell aplasia	1 (1.5)	0	1 (1.5)	0	0
Eosinophilia	1 (1.5)	0	1 (1.5)	0	0
Hypercoagulation	1 (1.5)	0	1 (1.5)	0	0
Hypofibrinogenaemia	1 (1.5)	0	1 (1.5)	0	0
Leukocytosis	1 (1.5)	0	1 (1.5)	0	0
Lymphocytosis	1 (1.5)	0	1 (1.5)	0	0
Cardiac disorders					
-Total	25 (36.8)	7 (10.3)	5 (7.4)	9 (13.2)	4 (5.9)
Tachycardia	16 (23.5)	6 (8.8)	7 (10.3)	3 (4.4)	0
Left ventricular dysfunction	5 (7.4)	0	1 (1.5)	4 (5.9)	0
Cardiac arrest	3 (4.4)	0	0	0	3 (4.4)
Cardiac failure	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Pericardial effusion	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Atrioventricular block first degree	1 (1.5)	0	1 (1.5)	0	0
Bradycardia	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	1 (1.5)	1 (1.5)	0	0	0
Cardiac failure congestive	1 (1.5)	0	1 (1.5)	0	0
Mitral valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Right ventricular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Sinus bradycardia	1 (1.5)	0	0	1 (1.5)	0
Sinus tachycardia	1 (1.5)	1 (1.5)	0	0	0
Tricuspid valve incompetence	1 (1.5)	1 (1.5)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Cerebral cavernous malformation	1 (1.5)	1 (1.5)	0	0	0
Ear and labyrinth disorders					
-Total	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Deafness unilateral	1 (1.5)	0	1 (1.5)	0	0
Ear pain	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					
-Total	8 (11.8)	0	8 (11.8)	0	0
Adrenal insufficiency	6 (8.8)	0	6 (8.8)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypothyroidism	2 (2.9)	0	2 (2.9)	0	0
Delayed puberty	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	13 (19.1)	10 (14.7)	3 (4.4)	0	0
Ocular hyperaemia	3 (4.4)	3 (4.4)	0	0	0
Cataract	2 (2.9)	2 (2.9)	0	0	0
Visual impairment	2 (2.9)	2 (2.9)	0	0	0
Conjunctival haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Dry eye	1 (1.5)	1 (1.5)	0	0	0
Eye oedema	1 (1.5)	1 (1.5)	0	0	0
Eye pain	1 (1.5)	1 (1.5)	0	0	0
Hypermetropia	1 (1.5)	1 (1.5)	0	0	0
Mydriasis	1 (1.5)	0	1 (1.5)	0	0
Periorbital swelling	1 (1.5)	0	1 (1.5)	0	0
Retinal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Vision blurred	1 (1.5)	1 (1.5)	0	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	47 (69.1)	15 (22.1)	19 (27.9)	12 (17.6)	1 (1.5)
Nausea	23 (33.8)	9 (13.2)	12 (17.6)	2 (2.9)	0
Vomiting	22 (32.4)	13 (19.1)	7 (10.3)	2 (2.9)	0
Diarrhoea	16 (23.5)	10 (14.7)	6 (8.8)	0	0
Constipation	13 (19.1)	5 (7.4)	8 (11.8)	0	0
Abdominal pain	8 (11.8)	2 (2.9)	4 (5.9)	2 (2.9)	0
Stomatitis	7 (10.3)	1 (1.5)	3 (4.4)	3 (4.4)	0
Haematemesis	4 (5.9)	4 (5.9)	0	0	0
Mouth haemorrhage	4 (5.9)	2 (2.9)	0	2 (2.9)	0
Gastrointestinal sounds abnormal	3 (4.4)	3 (4.4)	0	0	0
Gingival bleeding	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Abdominal distension	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Ascites	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Gastrointestinal haemorrhage	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Ileus	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Pancreatitis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Abdominal compartment syndrome	1 (1.5)	0	0	0	1 (1.5)
Abdominal pain upper	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (1.5)	0	1 (1.5)	0	0
Anal erythema	1 (1.5)	1 (1.5)	0	0	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Anal inflammation	1 (1.5)	0	0	1 (1.5)	0
Dry mouth	1 (1.5)	0	1 (1.5)	0	0
Duodenal perforation	1 (1.5)	0	0	1 (1.5)	0
Dyspepsia	1 (1.5)	1 (1.5)	0	0	0
Gastritis	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal inflammation	1 (1.5)	0	1 (1.5)	0	0
Gingival erythema	1 (1.5)	1 (1.5)	0	0	0
Gingivitis ulcerative	1 (1.5)	0	0	1 (1.5)	0
Irritable bowel syndrome	1 (1.5)	0	1 (1.5)	0	0
Lip dry	1 (1.5)	0	1 (1.5)	0	0
Lip oedema	1 (1.5)	1 (1.5)	0	0	0
Lip pain	1 (1.5)	1 (1.5)	0	0	0
Lip ulceration	1 (1.5)	0	1 (1.5)	0	0
Mouth swelling	1 (1.5)	1 (1.5)	0	0	0
Neutropenic colitis	1 (1.5)	0	0	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Odynophagia	1 (1.5)	1 (1.5)	0	0	0
Oral disorder	1 (1.5)	1 (1.5)	0	0	0
Oral pain	1 (1.5)	0	0	1 (1.5)	0
Peritoneal haematoma	1 (1.5)	1 (1.5)	0	0	0
Trichoglossia	1 (1.5)	0	1 (1.5)	0	0
Upper gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	44 (64.7)	20 (29.4)	11 (16.2)	10 (14.7)	3 (4.4)
Pyrexia	30 (44.1)	12 (17.6)	8 (11.8)	9 (13.2)	1 (1.5)
Fatigue	13 (19.1)	10 (14.7)	3 (4.4)	0	0
Chills	9 (13.2)	5 (7.4)	4 (5.9)	0	0
Pain	6 (8.8)	1 (1.5)	3 (4.4)	2 (2.9)	0
Face oedema	5 (7.4)	3 (4.4)	1 (1.5)	1 (1.5)	0
Generalised oedema	4 (5.9)	1 (1.5)	3 (4.4)	0	0
Oedema peripheral	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Catheter site pain	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Asthenia	2 (2.9)	1 (1.5)	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug withdrawal syndrome	2 (2.9)	0	2 (2.9)	0	0
Influenza like illness	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Localised oedema	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Malaise	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Multiple organ dysfunction syndrome	2 (2.9)	0	0	0	2 (2.9)
Non-cardiac chest pain	2 (2.9)	2 (2.9)	0	0	0
Vascular device occlusion	2 (2.9)	2 (2.9)	0	0	0
Catheter site dermatitis	1 (1.5)	1 (1.5)	0	0	0
Chest discomfort	1 (1.5)	0	0	1 (1.5)	0
Crying	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Sluggishness	1 (1.5)	0	1 (1.5)	0	0
Swelling face	1 (1.5)	1 (1.5)	0	0	0
Thirst	1 (1.5)	1 (1.5)	0	0	0
Hepatobiliary disorders					
-Total	14 (20.6)	6 (8.8)	5 (7.4)	2 (2.9)	1 (1.5)
Hepatomegaly	3 (4.4)	2 (2.9)	0	0	1 (1.5)
Hyperbilirubinaemia	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	2 (2.9)	0	2 (2.9)	0	0
Biliary tract disorder	1 (1.5)	1 (1.5)	0	0	0
Cholelithiasis	1 (1.5)	0	1 (1.5)	0	0
Drug-induced liver injury	1 (1.5)	0	0	1 (1.5)	0
Gallbladder enlargement	1 (1.5)	1 (1.5)	0	0	0
Hepatic cytolysis	1 (1.5)	1 (1.5)	0	0	0
Hepatosplenomegaly	1 (1.5)	0	1 (1.5)	0	0
Hypertransaminasaemia	1 (1.5)	1 (1.5)	0	0	0
Ocular icterus	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	49 (72.1)	2 (2.9)	19 (27.9)	15 (22.1)	13 (19.1)
Cytokine release syndrome	41 (60.3)	5 (7.4)	15 (22.1)	9 (13.2)	12 (17.6)
Hypogammaglobulinaemia	25 (36.8)	1 (1.5)	19 (27.9)	5 (7.4)	0
Seasonal allergy	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Chronic graft versus host disease	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Graft versus host disease	2 (2.9)	0	0	2 (2.9)	0
Haemophagocytic lymphohistiocytosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	2 (2.9)	0	0	2 (2.9)	0
Allergy to immunoglobulin therapy	1 (1.5)	0	0	1 (1.5)	0
Drug hypersensitivity	1 (1.5)	0	1 (1.5)	0	0
Hypersensitivity	1 (1.5)	1 (1.5)	0	0	0
Selective igg subclass deficiency	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	51 (75.0)	4 (5.9)	12 (17.6)	24 (35.3)	11 (16.2)
Upper respiratory tract infection	12 (17.6)	5 (7.4)	5 (7.4)	2 (2.9)	0
Parainfluenzae virus infection	6 (8.8)	1 (1.5)	1 (1.5)	3 (4.4)	1 (1.5)
Rhinovirus infection	6 (8.8)	0	4 (5.9)	2 (2.9)	0
Sinusitis	6 (8.8)	0	4 (5.9)	2 (2.9)	0
Staphylococcal bacteraemia	6 (8.8)	0	0	6 (8.8)	0
Gastroenteritis	5 (7.4)	3 (4.4)	1 (1.5)	1 (1.5)	0
Pneumonia	5 (7.4)	0	1 (1.5)	1 (1.5)	3 (4.4)
Conjunctivitis	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Nasopharyngitis	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Oral herpes	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Acute sinusitis	3 (4.4)	0	2 (2.9)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	3 (4.4)	0	2 (2.9)	0	1 (1.5)
Escherichia bacteraemia	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Gingivitis	3 (4.4)	3 (4.4)	0	0	0
Oral candidiasis	3 (4.4)	0	3 (4.4)	0	0
Otitis media	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Respiratory syncytial virus infection	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Staphylococcal infection	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Urinary tract infection	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Adenovirus infection	2 (2.9)	0	0	2 (2.9)	0
Bacteraemia	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Bronchitis	2 (2.9)	0	2 (2.9)	0	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Catheter site infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Clostridium difficile infection	2 (2.9)	0	0	2 (2.9)	0
Device related infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Fungal infection	2 (2.9)	0	2 (2.9)	0	0
Fungal skin infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Herpes simplex	2 (2.9)	0	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Human herpesvirus 6 infection	2 (2.9)	0	0	2 (2.9)	0
Influenza	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Klebsiella bacteraemia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Localised infection	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0
Otitis externa	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Paronychia	2 (2.9)	0	2 (2.9)	0	0
Pneumonia fungal	2 (2.9)	0	0	2 (2.9)	0
Rhinitis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Sepsis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Septic shock	2 (2.9)	0	0	0	2 (2.9)
Staphylococcal skin infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Varicella zoster virus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Atypical pneumonia	1 (1.5)	1 (1.5)	0	0	0
Bk virus infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	1 (1.5)	0	0
Clostridium difficile colitis	1 (1.5)	0	0	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (1.5)	1 (1.5)	0	0	0
Covid-19 pneumonia	1 (1.5)	0	0	0	1 (1.5)
Cystitis	1 (1.5)	0	1 (1.5)	0	0
Cytomegalovirus infection reactivation	1 (1.5)	0	0	1 (1.5)	0
Device related bacteraemia	1 (1.5)	0	1 (1.5)	0	0
Disseminated trichosporonosis	1 (1.5)	0	0	0	1 (1.5)
Ear infection	1 (1.5)	0	1 (1.5)	0	0
Ear, nose and throat infection	1 (1.5)	0	1 (1.5)	0	0
Encephalitis	1 (1.5)	0	0	0	1 (1.5)
Encephalitis viral	1 (1.5)	0	0	1 (1.5)	0
Enterobacter infection	1 (1.5)	0	0	1 (1.5)	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Epstein-barr virus infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis clostridial	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis escherichia coli	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	0	0	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	0	0	1 (1.5)	0
Gastrointestinal infection	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Granulicatella infection	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Mastoiditis	1 (1.5)	0	0	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	0	0	1 (1.5)	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Nail infection	1 (1.5)	1 (1.5)	0	0	0
Neutropenic infection	1 (1.5)	0	0	1 (1.5)	0
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Peritonitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis	1 (1.5)	0	0	1 (1.5)	0
Pharyngitis streptococcal	1 (1.5)	0	0	1 (1.5)	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	0	1 (1.5)	0
Pneumonia viral	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory tract infection viral	1 (1.5)	0	1 (1.5)	0	0
Sialoadenitis	1 (1.5)	0	0	1 (1.5)	0
Sinusitis fungal	1 (1.5)	0	0	1 (1.5)	0
Skin infection	1 (1.5)	0	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	0	0	1 (1.5)	0
Stomatococcal infection	1 (1.5)	0	0	0	1 (1.5)
Syphilis	1 (1.5)	0	1 (1.5)	0	0
Systemic candida	1 (1.5)	0	0	1 (1.5)	0
Systemic mycosis	1 (1.5)	0	0	1 (1.5)	0
Tinea pedis	1 (1.5)	1 (1.5)	0	0	0
Urinary tract infection pseudomonal	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection viral	1 (1.5)	1 (1.5)	0	0	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	0	0	1 (1.5)	0
Viral infection	1 (1.5)	0	0	1 (1.5)	0
Viral skin infection	1 (1.5)	1 (1.5)	0	0	0
Viral upper respiratory tract infection	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	16 (23.5)	6 (8.8)	8 (11.8)	1 (1.5)	1 (1.5)
Infusion related reaction	4 (5.9)	2 (2.9)	2 (2.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Fall	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Abdominal injury	1 (1.5)	1 (1.5)	0	0	0
Contusion	1 (1.5)	1 (1.5)	0	0	0
Extradural haematoma	1 (1.5)	0	1 (1.5)	0	0
Fibula fracture	1 (1.5)	0	1 (1.5)	0	0
Ligament sprain	1 (1.5)	1 (1.5)	0	0	0
Limb injury	1 (1.5)	0	1 (1.5)	0	0
Post-traumatic neck syndrome	1 (1.5)	0	1 (1.5)	0	0
Procedural pain	1 (1.5)	0	1 (1.5)	0	0
Radius fracture	1 (1.5)	0	1 (1.5)	0	0
Skin abrasion	1 (1.5)	1 (1.5)	0	0	0
Transplant failure	1 (1.5)	0	0	0	1 (1.5)
Traumatic haematoma	1 (1.5)	0	1 (1.5)	0	0
Wound	1 (1.5)	1 (1.5)	0	0	0
Investigations					
-Total	43 (63.2)	0	5 (7.4)	13 (19.1)	25 (36.8)
White blood cell count decreased	22 (32.4)	1 (1.5)	2 (2.9)	0	19 (27.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	19 (27.9)	1 (1.5)	1 (1.5)	3 (4.4)	14 (20.6)
Platelet count decreased	18 (26.5)	4 (5.9)	1 (1.5)	4 (5.9)	9 (13.2)
Alanine aminotransferase increased	15 (22.1)	3 (4.4)	6 (8.8)	6 (8.8)	0
Aspartate aminotransferase increased	15 (22.1)	2 (2.9)	1 (1.5)	9 (13.2)	3 (4.4)
Lymphocyte count decreased	15 (22.1)	0	0	6 (8.8)	9 (13.2)
Blood bilirubin increased	9 (13.2)	0	1 (1.5)	8 (11.8)	0
C-reactive protein increased	9 (13.2)	2 (2.9)	2 (2.9)	4 (5.9)	1 (1.5)
International normalised ratio increased	8 (11.8)	5 (7.4)	3 (4.4)	0	0
Serum ferritin increased	7 (10.3)	2 (2.9)	1 (1.5)	3 (4.4)	1 (1.5)
Blood immunoglobulin a decreased	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Blood lactate dehydrogenase increased	5 (7.4)	2 (2.9)	0	3 (4.4)	0
Weight increased	5 (7.4)	2 (2.9)	2 (2.9)	1 (1.5)	0
Activated partial thromboplastin time prolonged	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Blood creatinine increased	4 (5.9)	1 (1.5)	0	3 (4.4)	0
Blood immunoglobulin m decreased	4 (5.9)	3 (4.4)	0	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Fibrin d dimer increased	3 (4.4)	1 (1.5)	0	1 (1.5)	1 (1.5)
Blood fibrinogen decreased	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Blood fibrinogen increased	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Blood glucose increased	2 (2.9)	1 (1.5)	0	0	1 (1.5)
Electrocardiogram qt prolonged	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Gamma-glutamyltransferase increased	2 (2.9)	0	0	2 (2.9)	0
Oxygen saturation decreased	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Weight decreased	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Amylase increased	1 (1.5)	0	0	0	1 (1.5)
Blood alkaline phosphatase increased	1 (1.5)	1 (1.5)	0	0	0
Blood phosphorus decreased	1 (1.5)	0	0	1 (1.5)	0
Blood phosphorus increased	1 (1.5)	0	1 (1.5)	0	0
Blood potassium decreased	1 (1.5)	0	0	0	1 (1.5)
Blood testosterone decreased	1 (1.5)	1 (1.5)	0	0	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Bone density decreased	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Breath sounds abnormal	1 (1.5)	0	1 (1.5)	0	0
Ejection fraction decreased	1 (1.5)	0	1 (1.5)	0	0
Electrocardiogram t wave abnormal	1 (1.5)	0	1 (1.5)	0	0
Enterovirus test positive	1 (1.5)	0	1 (1.5)	0	0
Eosinophil count decreased	1 (1.5)	1 (1.5)	0	0	0
Haematocrit decreased	1 (1.5)	1 (1.5)	0	0	0
Haptoglobin decreased	1 (1.5)	1 (1.5)	0	0	0
Heart sounds abnormal	1 (1.5)	1 (1.5)	0	0	0
Hepatitis b virus test positive	1 (1.5)	0	1 (1.5)	0	0
Immunoglobulins decreased	1 (1.5)	0	1 (1.5)	0	0
Prothrombin time prolonged	1 (1.5)	0	1 (1.5)	0	0
Red blood cell count decreased	1 (1.5)	1 (1.5)	0	0	0
Staphylococcus test positive	1 (1.5)	1 (1.5)	0	0	0
Troponin increased	1 (1.5)	0	0	1 (1.5)	0
Urine output decreased	1 (1.5)	0	0	1 (1.5)	0
Metabolism and nutrition disorders					
-Total	39 (57.4)	3 (4.4)	10 (14.7)	17 (25.0)	9 (13.2)
Decreased appetite	25 (36.8)	7 (10.3)	8 (11.8)	8 (11.8)	2 (2.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	14 (20.6)	1 (1.5)	6 (8.8)	7 (10.3)	0
Hypocalcaemia	13 (19.1)	1 (1.5)	8 (11.8)	4 (5.9)	0
Hypokalaemia	12 (17.6)	2 (2.9)	3 (4.4)	5 (7.4)	2 (2.9)
Hyperglycaemia	9 (13.2)	0	4 (5.9)	5 (7.4)	0
Hypoalbuminaemia	8 (11.8)	0	7 (10.3)	1 (1.5)	0
Hypervolaemia	7 (10.3)	1 (1.5)	1 (1.5)	5 (7.4)	0
Hypomagnesaemia	7 (10.3)	5 (7.4)	2 (2.9)	0	0
Hyperuricaemia	6 (8.8)	5 (7.4)	0	1 (1.5)	0
Hyperkalaemia	4 (5.9)	0	1 (1.5)	2 (2.9)	1 (1.5)
Hyperphosphataemia	4 (5.9)	3 (4.4)	0	0	1 (1.5)
Metabolic acidosis	4 (5.9)	1 (1.5)	0	1 (1.5)	2 (2.9)
Hypercalcaemia	3 (4.4)	0	1 (1.5)	1 (1.5)	1 (1.5)
Hyponatraemia	3 (4.4)	2 (2.9)	0	0	1 (1.5)
Tumour lysis syndrome	3 (4.4)	0	0	2 (2.9)	1 (1.5)
Acidosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Hypermagnesaemia	2 (2.9)	2 (2.9)	0	0	0
Hypertriglyceridaemia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Iron overload	2 (2.9)	0	2 (2.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	2 (2.9)	0	0	2 (2.9)	0
Calcium deficiency	1 (1.5)	1 (1.5)	0	0	0
Dehydration	1 (1.5)	0	1 (1.5)	0	0
Haemochromatosis	1 (1.5)	0	0	1 (1.5)	0
Hypercholesterolaemia	1 (1.5)	0	1 (1.5)	0	0
Hypernatraemia	1 (1.5)	0	0	1 (1.5)	0
Hypoglycaemia	1 (1.5)	0	1 (1.5)	0	0
Hypophagia	1 (1.5)	0	1 (1.5)	0	0
Obesity	1 (1.5)	0	0	1 (1.5)	0
Polydipsia	1 (1.5)	0	0	1 (1.5)	0
Vitamin d deficiency	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	33 (48.5)	10 (14.7)	13 (19.1)	10 (14.7)	0
Pain in extremity	13 (19.1)	4 (5.9)	6 (8.8)	3 (4.4)	0
Back pain	11 (16.2)	2 (2.9)	5 (7.4)	4 (5.9)	0
Arthralgia	9 (13.2)	4 (5.9)	4 (5.9)	1 (1.5)	0
Myalgia	8 (11.8)	5 (7.4)	3 (4.4)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	4 (5.9)	1 (1.5)	3 (4.4)	0	0
Pain in jaw	3 (4.4)	1 (1.5)	0	2 (2.9)	0
Growth retardation	2 (2.9)	0	2 (2.9)	0	0
Joint effusion	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Muscular weakness	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Neck pain	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Groin pain	1 (1.5)	1 (1.5)	0	0	0
Haemarthrosis	1 (1.5)	0	0	1 (1.5)	0
Muscle spasms	1 (1.5)	0	1 (1.5)	0	0
Musculoskeletal chest pain	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal pain	1 (1.5)	0	1 (1.5)	0	0
Myopathy	1 (1.5)	0	0	1 (1.5)	0
Osteopenia	1 (1.5)	1 (1.5)	0	0	0
Spinal pain	1 (1.5)	0	0	1 (1.5)	0
Synovitis	1 (1.5)	0	1 (1.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (7.4)	1 (1.5)	2 (2.9)	2 (2.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Bone giant cell tumour benign	1 (1.5)	0	0	1 (1.5)	0
Cancer pain	1 (1.5)	0	1 (1.5)	0	0
Myelodysplastic syndrome	1 (1.5)	0	0	1 (1.5)	0
Nervous system disorders					
-Total	40 (58.8)	12 (17.6)	15 (22.1)	9 (13.2)	4 (5.9)
Headache	23 (33.8)	12 (17.6)	9 (13.2)	2 (2.9)	0
Encephalopathy	6 (8.8)	0	3 (4.4)	3 (4.4)	0
Seizure	5 (7.4)	0	2 (2.9)	3 (4.4)	0
Lethargy	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Somnolence	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Cognitive disorder	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Dysgeusia	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Neuropathy peripheral	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Tremor	3 (4.4)	3 (4.4)	0	0	0
Cerebral haemorrhage	2 (2.9)	0	0	0	2 (2.9)
Dizziness	2 (2.9)	2 (2.9)	0	0	0
Dysarthria	2 (2.9)	0	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paraesthesia	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Amnesia	1 (1.5)	0	1 (1.5)	0	0
Aphasia	1 (1.5)	1 (1.5)	0	0	0
Autonomic neuropathy	1 (1.5)	0	0	1 (1.5)	0
Depressed level of consciousness	1 (1.5)	0	0	1 (1.5)	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Extrapyramidal disorder	1 (1.5)	0	1 (1.5)	0	0
Haemorrhage intracranial	1 (1.5)	0	0	0	1 (1.5)
Hyperaesthesia	1 (1.5)	1 (1.5)	0	0	0
Memory impairment	1 (1.5)	0	1 (1.5)	0	0
Migraine	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorder	1 (1.5)	0	0	1 (1.5)	0
Neurological decompensation	1 (1.5)	0	0	0	1 (1.5)
Posterior reversible encephalopathy syndrome	1 (1.5)	0	1 (1.5)	0	0
Psychiatric disorders					
-Total	28 (41.2)	7 (10.3)	15 (22.1)	6 (8.8)	0
Anxiety	13 (19.1)	4 (5.9)	7 (10.3)	2 (2.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	6 (8.8)	4 (5.9)	2 (2.9)	0	0
Confusional state	5 (7.4)	5 (7.4)	0	0	0
Delirium	5 (7.4)	0	2 (2.9)	3 (4.4)	0
Hallucination	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Insomnia	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Mental status changes	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Sleep disorder	2 (2.9)	0	2 (2.9)	0	0
Affect lability	1 (1.5)	0	1 (1.5)	0	0
Hallucination, visual	1 (1.5)	0	1 (1.5)	0	0
Mood altered	1 (1.5)	1 (1.5)	0	0	0
Nightmare	1 (1.5)	1 (1.5)	0	0	0
Persistent depressive disorder	1 (1.5)	0	1 (1.5)	0	0
Restlessness	1 (1.5)	0	1 (1.5)	0	0
Social avoidant behaviour	1 (1.5)	0	1 (1.5)	0	0
Tearfulness	1 (1.5)	1 (1.5)	0	0	0
Tic	1 (1.5)	0	1 (1.5)	0	0
Renal and urinary disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (23.5)	4 (5.9)	4 (5.9)	5 (7.4)	3 (4.4)
Acute kidney injury	7 (10.3)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.5)
Dysuria	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Haematuria	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Anuria	1 (1.5)	0	0	0	1 (1.5)
Incontinence	1 (1.5)	0	1 (1.5)	0	0
Kidney enlargement	1 (1.5)	0	1 (1.5)	0	0
Pollakiuria	1 (1.5)	0	1 (1.5)	0	0
Renal failure	1 (1.5)	0	0	0	1 (1.5)
Renal mass	1 (1.5)	0	1 (1.5)	0	0
Renal tubular disorder	1 (1.5)	0	0	1 (1.5)	0
Renal tubular dysfunction	1 (1.5)	1 (1.5)	0	0	0
Renal tubular necrosis	1 (1.5)	0	0	1 (1.5)	0
Urinary incontinence	1 (1.5)	0	1 (1.5)	0	0
Urinary retention	1 (1.5)	0	1 (1.5)	0	0
Urinary tract disorder	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Endometriosis	1 (1.5)	0	0	1 (1.5)	0
Female genital tract fistula	1 (1.5)	1 (1.5)	0	0	0
Heavy menstrual bleeding	1 (1.5)	0	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	40 (58.8)	11 (16.2)	6 (8.8)	10 (14.7)	13 (19.1)
Cough	19 (27.9)	15 (22.1)	4 (5.9)	0	0
Hypoxia	12 (17.6)	0	4 (5.9)	6 (8.8)	2 (2.9)
Epistaxis	9 (13.2)	6 (8.8)	0	3 (4.4)	0
Nasal congestion	9 (13.2)	8 (11.8)	1 (1.5)	0	0
Pulmonary oedema	9 (13.2)	1 (1.5)	2 (2.9)	5 (7.4)	1 (1.5)
Respiratory failure	7 (10.3)	0	0	0	7 (10.3)
Dyspnoea	6 (8.8)	1 (1.5)	1 (1.5)	3 (4.4)	1 (1.5)
Oropharyngeal pain	6 (8.8)	5 (7.4)	1 (1.5)	0	0
Tachypnoea	6 (8.8)	2 (2.9)	1 (1.5)	2 (2.9)	1 (1.5)
Pleural effusion	5 (7.4)	1 (1.5)	2 (2.9)	1 (1.5)	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Acute respiratory distress syndrome	2 (2.9)	0	0	0	2 (2.9)
Pharyngeal erythema	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Respiratory distress	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Rhinitis allergic	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Acute respiratory failure	1 (1.5)	0	0	1 (1.5)	0
Atelectasis	1 (1.5)	0	1 (1.5)	0	0
Bronchial oedema	1 (1.5)	1 (1.5)	0	0	0
Bronchospasm	1 (1.5)	0	1 (1.5)	0	0
Dyspnoea exertional	1 (1.5)	1 (1.5)	0	0	0
Haemoptysis	1 (1.5)	0	1 (1.5)	0	0
Laryngeal oedema	1 (1.5)	0	0	0	1 (1.5)
Lung disorder	1 (1.5)	1 (1.5)	0	0	0
Lung infiltration	1 (1.5)	0	0	1 (1.5)	0
Nasal dryness	1 (1.5)	1 (1.5)	0	0	0
Oropharyngeal plaque	1 (1.5)	0	1 (1.5)	0	0
Painful respiration	1 (1.5)	1 (1.5)	0	0	0
Paranasal sinus discomfort	1 (1.5)	0	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal exudate	1 (1.5)	0	1 (1.5)	0	0
Pharyngeal oedema	1 (1.5)	0	1 (1.5)	0	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory disorder	1 (1.5)	0	1 (1.5)	0	0
Sleep apnoea syndrome	1 (1.5)	0	1 (1.5)	0	0
Upper respiratory tract inflammation	1 (1.5)	0	1 (1.5)	0	0
Wheezing	1 (1.5)	0	1 (1.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	33 (48.5)	18 (26.5)	12 (17.6)	3 (4.4)	0
Pruritus	7 (10.3)	4 (5.9)	3 (4.4)	0	0
Rash	6 (8.8)	5 (7.4)	1 (1.5)	0	0
Dry skin	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Erythema	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Rash maculo-papular	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Dermatitis atopic	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Hyperhidrosis	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Rash papular	3 (4.4)	2 (2.9)	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Ingrowing nail	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Acne	1 (1.5)	1 (1.5)	0	0	0
Decubitus ulcer	1 (1.5)	0	0	1 (1.5)	0
Dermatitis	1 (1.5)	1 (1.5)	0	0	0
Dermatitis allergic	1 (1.5)	1 (1.5)	0	0	0
Drug eruption	1 (1.5)	0	1 (1.5)	0	0
Eczema	1 (1.5)	1 (1.5)	0	0	0
Miliaria	1 (1.5)	1 (1.5)	0	0	0
Night sweats	1 (1.5)	1 (1.5)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.5)	1 (1.5)	0	0	0
Petechiae	1 (1.5)	1 (1.5)	0	0	0
Photosensitivity reaction	1 (1.5)	0	1 (1.5)	0	0
Purpura	1 (1.5)	1 (1.5)	0	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Scab	1 (1.5)	1 (1.5)	0	0	0
Skin discolouration	1 (1.5)	1 (1.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin hypopigmentation	1 (1.5)	1 (1.5)	0	0	0
Skin lesion	1 (1.5)	0	1 (1.5)	0	0
Social circumstances					
-Total	1 (1.5)	0	1 (1.5)	0	0
Patient uncooperative	1 (1.5)	0	1 (1.5)	0	0
Surgical and medical procedures					
-Total	1 (1.5)	0	0	1 (1.5)	0
Thrombolysis	1 (1.5)	0	0	1 (1.5)	0
Vascular disorders					
-Total	28 (41.2)	4 (5.9)	6 (8.8)	13 (19.1)	5 (7.4)
Hypotension	21 (30.9)	2 (2.9)	4 (5.9)	10 (14.7)	5 (7.4)
Hypertension	11 (16.2)	3 (4.4)	5 (7.4)	3 (4.4)	0
Flushing	2 (2.9)	2 (2.9)	0	0	0
Peripheral ischaemia	2 (2.9)	0	2 (2.9)	0	0
Capillary leak syndrome	1 (1.5)	0	0	1 (1.5)	0
Hot flush	1 (1.5)	1 (1.5)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208k
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	1 (3.1)	8 (25.0)	23 (71.9)
Blood and lymphatic system disorders					
-Total	22 (68.8)	0	2 (6.3)	14 (43.8)	6 (18.8)
Anaemia	11 (34.4)	1 (3.1)	1 (3.1)	9 (28.1)	0
Febrile neutropenia	11 (34.4)	0	0	10 (31.3)	1 (3.1)
Neutropenia	7 (21.9)	0	1 (3.1)	2 (6.3)	4 (12.5)
Thrombocytopenia	4 (12.5)	0	0	2 (6.3)	2 (6.3)
Disseminated intravascular coagulation	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Pancytopenia	3 (9.4)	0	0	3 (9.4)	0
Coagulopathy	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Leukopenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphadenopathy	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Agranulocytosis	1 (3.1)	0	0	1 (3.1)	0
Eosinophilia	1 (3.1)	0	1 (3.1)	0	0
Hypercoagulation	1 (3.1)	0	1 (3.1)	0	0
Splenomegaly	1 (3.1)	0	1 (3.1)	0	0
Cardiac disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Left ventricular dysfunction	1 (3.1)	0	1 (3.1)	0	0
Pericardial effusion	1 (3.1)	1 (3.1)	0	0	0
Sinus tachycardia	1 (3.1)	0	1 (3.1)	0	0
Ear and labyrinth disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Vertigo	1 (3.1)	0	1 (3.1)	0	0
Endocrine disorders					
-Total	3 (9.4)	0	3 (9.4)	0	0
Adrenal insufficiency	2 (6.3)	0	2 (6.3)	0	0
Hypothyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Eye pain	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Eyelid oedema	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Eye oedema	1 (3.1)	1 (3.1)	0	0	0
Retinal haemorrhage	1 (3.1)	0	1 (3.1)	0	0
Visual field defect	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	21 (65.6)	8 (25.0)	9 (28.1)	4 (12.5)	0
Diarrhoea	8 (25.0)	3 (9.4)	4 (12.5)	1 (3.1)	0
Vomiting	8 (25.0)	6 (18.8)	2 (6.3)	0	0
Nausea	7 (21.9)	1 (3.1)	5 (15.6)	1 (3.1)	0
Abdominal pain	6 (18.8)	1 (3.1)	5 (15.6)	0	0
Constipation	5 (15.6)	1 (3.1)	4 (12.5)	0	0
Abdominal pain upper	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Stomatitis	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Pancreatitis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Abdominal rigidity	1 (3.1)	0	1 (3.1)	0	0
Anal erythema	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ascites	1 (3.1)	0	1 (3.1)	0	0
Dyspepsia	1 (3.1)	1 (3.1)	0	0	0
Ileus	1 (3.1)	0	0	1 (3.1)	0
Mouth haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Mouth swelling	1 (3.1)	1 (3.1)	0	0	0
Odynophagia	1 (3.1)	1 (3.1)	0	0	0
Oral disorder	1 (3.1)	1 (3.1)	0	0	0
Peritoneal haematoma	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	21 (65.6)	12 (37.5)	5 (15.6)	3 (9.4)	1 (3.1)
Pyrexia	14 (43.8)	7 (21.9)	5 (15.6)	2 (6.3)	0
Asthenia	3 (9.4)	3 (9.4)	0	0	0
Face oedema	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Localised oedema	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Oedema peripheral	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Catheter site erythema	1 (3.1)	1 (3.1)	0	0	0
Catheter site pain	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fatigue	1 (3.1)	1 (3.1)	0	0	0
Generalised oedema	1 (3.1)	0	1 (3.1)	0	0
Influenza like illness	1 (3.1)	0	1 (3.1)	0	0
Multiple organ dysfunction syndrome	1 (3.1)	0	0	0	1 (3.1)
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0
Hepatobiliary disorders					
-Total	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Hepatic cytolysis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Cholelithiasis	1 (3.1)	0	1 (3.1)	0	0
Hepatomegaly	1 (3.1)	1 (3.1)	0	0	0
Hyperbilirubinaemia	1 (3.1)	0	1 (3.1)	0	0
Liver disorder	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	22 (68.8)	0	3 (9.4)	10 (31.3)	9 (28.1)
Cytokine release syndrome	19 (59.4)	0	6 (18.8)	5 (15.6)	8 (25.0)
Hypogammaglobulinaemia	12 (37.5)	1 (3.1)	6 (18.8)	5 (15.6)	0
Immunodeficiency	4 (12.5)	0	0	4 (12.5)	0
Chronic graft versus host disease	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophagocytic lymphohistiocytosis	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Allergy to immunoglobulin therapy	1 (3.1)	1 (3.1)	0	0	0
Drug hypersensitivity	1 (3.1)	0	0	1 (3.1)	0
Graft versus host disease	1 (3.1)	0	0	1 (3.1)	0
Hypersensitivity	1 (3.1)	1 (3.1)	0	0	0
Infections and infestations					
-Total	27 (84.4)	2 (6.3)	5 (15.6)	11 (34.4)	9 (28.1)
Nasopharyngitis	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Pneumonia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Conjunctivitis	5 (15.6)	1 (3.1)	4 (12.5)	0	0
Gastroenteritis	5 (15.6)	2 (6.3)	1 (3.1)	2 (6.3)	0
Device related infection	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Herpes zoster	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Nail infection	3 (9.4)	3 (9.4)	0	0	0
Parainfluenzae virus infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Respiratory tract infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Rhinitis	3 (9.4)	2 (6.3)	1 (3.1)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Upper respiratory tract infection	3 (9.4)	3 (9.4)	0	0	0
Bacteraemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Bronchopulmonary aspergillosis	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Gingivitis	2 (6.3)	2 (6.3)	0	0	0
Oral herpes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Oral infection	2 (6.3)	0	2 (6.3)	0	0
Paronychia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Rhinovirus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Staphylococcal infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Adenovirus infection	1 (3.1)	0	0	1 (3.1)	0
Bronchiolitis	1 (3.1)	0	0	1 (3.1)	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Candida infection	1 (3.1)	0	1 (3.1)	0	0
Covid-19	1 (3.1)	0	0	1 (3.1)	0
Covid-19 pneumonia	1 (3.1)	0	0	0	1 (3.1)
Cystitis	1 (3.1)	0	1 (3.1)	0	0
Cytomegalovirus infection reactivation	1 (3.1)	0	1 (3.1)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related bacteraemia	1 (3.1)	0	1 (3.1)	0	0
Device related sepsis	1 (3.1)	0	0	1 (3.1)	0
Ear infection	1 (3.1)	0	1 (3.1)	0	0
Ear, nose and throat infection	1 (3.1)	0	1 (3.1)	0	0
Encephalitis	1 (3.1)	0	0	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	0	1 (3.1)	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	0	1 (3.1)
Fungal infection	1 (3.1)	0	1 (3.1)	0	0
Herpes virus infection	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	0	0	0	1 (3.1)
Localised infection	1 (3.1)	0	0	1 (3.1)	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Myringitis	1 (3.1)	1 (3.1)	0	0	0
Neutropenic infection	1 (3.1)	0	0	1 (3.1)	0
Ophthalmic herpes zoster	1 (3.1)	0	1 (3.1)	0	0
Oral candidiasis	1 (3.1)	0	1 (3.1)	0	0
Otitis media	1 (3.1)	0	1 (3.1)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumocystis jirovecii pneumonia	1 (3.1)	0	0	0	1 (3.1)
Pneumonia fungal	1 (3.1)	0	0	1 (3.1)	0
Pneumonia viral	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection viral	1 (3.1)	0	1 (3.1)	0	0
Sialoadenitis	1 (3.1)	0	0	1 (3.1)	0
Sinusitis	1 (3.1)	0	0	1 (3.1)	0
Skin infection	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal skin infection	1 (3.1)	0	1 (3.1)	0	0
Streptococcal sepsis	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Viral haemorrhagic cystitis	1 (3.1)	0	0	1 (3.1)	0
Viral infection	1 (3.1)	0	1 (3.1)	0	0
Viral skin infection	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	7 (21.9)	2 (6.3)	5 (15.6)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infusion related reaction	2 (6.3)	0	2 (6.3)	0	0
Extradural haematoma	1 (3.1)	0	1 (3.1)	0	0
Fall	1 (3.1)	0	1 (3.1)	0	0
Ligament sprain	1 (3.1)	1 (3.1)	0	0	0
Procedural pain	1 (3.1)	1 (3.1)	0	0	0
Traumatic haematoma	1 (3.1)	0	1 (3.1)	0	0
Wound	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	21 (65.6)	0	3 (9.4)	7 (21.9)	11 (34.4)
Lymphocyte count decreased	10 (31.3)	0	0	1 (3.1)	9 (28.1)
White blood cell count decreased	10 (31.3)	0	0	0	10 (31.3)
Neutrophil count decreased	8 (25.0)	0	0	0	8 (25.0)
Platelet count decreased	8 (25.0)	2 (6.3)	0	1 (3.1)	5 (15.6)
C-reactive protein increased	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Alanine aminotransferase increased	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Immunoglobulins decreased	2 (6.3)	0	2 (6.3)	0	0
Weight decreased	2 (6.3)	0	0	2 (6.3)	0
Amylase increased	1 (3.1)	0	0	0	1 (3.1)

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	1 (3.1)	0	0	1 (3.1)	0
Blood bilirubin increased	1 (3.1)	0	0	1 (3.1)	0
Blood fibrinogen decreased	1 (3.1)	0	0	0	1 (3.1)
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Blood lactate dehydrogenase increased	1 (3.1)	0	1 (3.1)	0	0
Blood uric acid increased	1 (3.1)	0	0	1 (3.1)	0
Bone density decreased	1 (3.1)	1 (3.1)	0	0	0
Gamma-glutamyltransferase increased	1 (3.1)	0	0	1 (3.1)	0
Hepatitis b virus test positive	1 (3.1)	0	1 (3.1)	0	0
Oxygen saturation decreased	1 (3.1)	0	0	1 (3.1)	0
Prothrombin time prolonged	1 (3.1)	0	1 (3.1)	0	0
Serum ferritin increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	15 (46.9)	2 (6.3)	2 (6.3)	6 (18.8)	5 (15.6)
Hypokalaemia	8 (25.0)	1 (3.1)	1 (3.1)	5 (15.6)	1 (3.1)
Decreased appetite	5 (15.6)	2 (6.3)	1 (3.1)	1 (3.1)	1 (3.1)

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Hyperglycaemia	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Hypomagnesaemia	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Hypocalcaemia	2 (6.3)	0	0	2 (6.3)	0
Eating disorder symptom	1 (3.1)	0	1 (3.1)	0	0
Haemochromatosis	1 (3.1)	0	0	1 (3.1)	0
Hypernatraemia	1 (3.1)	1 (3.1)	0	0	0
Hyperuricaemia	1 (3.1)	0	1 (3.1)	0	0
Hypoalbuminaemia	1 (3.1)	0	1 (3.1)	0	0
Hyponatraemia	1 (3.1)	0	0	0	1 (3.1)
Malnutrition	1 (3.1)	0	0	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	0	0	1 (3.1)
Musculoskeletal and connective tissue disorders					
-Total	14 (43.8)	5 (15.6)	7 (21.9)	2 (6.3)	0
Pain in extremity	6 (18.8)	1 (3.1)	5 (15.6)	0	0
Back pain	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Arthralgia	4 (12.5)	2 (6.3)	2 (6.3)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Growth retardation	1 (3.1)	0	1 (3.1)	0	0
Muscular weakness	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal chest pain	1 (3.1)	1 (3.1)	0	0	0
Myalgia	1 (3.1)	1 (3.1)	0	0	0
Myopathy	1 (3.1)	0	0	1 (3.1)	0
Osteonecrosis	1 (3.1)	1 (3.1)	0	0	0
Pain in jaw	1 (3.1)	1 (3.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Skin papilloma	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bone giant cell tumour benign	1 (3.1)	0	0	1 (3.1)	0
Myelodysplastic syndrome	1 (3.1)	0	0	1 (3.1)	0
Nervous system disorders					
-Total	19 (59.4)	5 (15.6)	7 (21.9)	5 (15.6)	2 (6.3)
Headache	11 (34.4)	6 (18.8)	4 (12.5)	1 (3.1)	0
Encephalopathy	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Seizure	2 (6.3)	0	0	2 (6.3)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tremor	2 (6.3)	2 (6.3)	0	0	0
Amnesia	1 (3.1)	0	1 (3.1)	0	0
Autonomic neuropathy	1 (3.1)	0	0	1 (3.1)	0
Cerebral haemorrhage	1 (3.1)	0	0	0	1 (3.1)
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Dysgeusia	1 (3.1)	1 (3.1)	0	0	0
Hydrocephalus	1 (3.1)	0	0	0	1 (3.1)
Hyperaesthesia	1 (3.1)	1 (3.1)	0	0	0
Memory impairment	1 (3.1)	0	1 (3.1)	0	0
Neuralgia	1 (3.1)	0	1 (3.1)	0	0
Neuropathy peripheral	1 (3.1)	0	0	1 (3.1)	0
Paraesthesia	1 (3.1)	0	1 (3.1)	0	0
Psychiatric disorders					
-Total	11 (34.4)	3 (9.4)	7 (21.9)	1 (3.1)	0
Anxiety	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Confusional state	2 (6.3)	2 (6.3)	0	0	0
Hallucination	2 (6.3)	0	2 (6.3)	0	0
Insomnia	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sleep disorder	2 (6.3)	0	2 (6.3)	0	0
Agitation	1 (3.1)	1 (3.1)	0	0	0
Hallucination, visual	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	6 (18.8)	2 (6.3)	2 (6.3)	1 (3.1)	1 (3.1)
Dysuria	2 (6.3)	2 (6.3)	0	0	0
Anuria	1 (3.1)	0	0	0	1 (3.1)
Renal failure	1 (3.1)	0	1 (3.1)	0	0
Renal tubular disorder	1 (3.1)	0	0	1 (3.1)	0
Urinary tract disorder	1 (3.1)	0	1 (3.1)	0	0
Reproductive system and breast disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Female genital tract fistula	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (53.1)	8 (25.0)	4 (12.5)	3 (9.4)	2 (6.3)
Cough	10 (31.3)	8 (25.0)	2 (6.3)	0	0
Pulmonary oedema	4 (12.5)	1 (3.1)	0	3 (9.4)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	3 (9.4)	0	3 (9.4)	0	0
Oropharyngeal pain	3 (9.4)	3 (9.4)	0	0	0
Epistaxis	2 (6.3)	2 (6.3)	0	0	0
Pleural effusion	2 (6.3)	0	2 (6.3)	0	0
Bronchial oedema	1 (3.1)	1 (3.1)	0	0	0
Bronchospasm	1 (3.1)	0	1 (3.1)	0	0
Dyspnoea	1 (3.1)	0	0	0	1 (3.1)
Dyspnoea exertional	1 (3.1)	1 (3.1)	0	0	0
Lung disorder	1 (3.1)	1 (3.1)	0	0	0
Painful respiration	1 (3.1)	1 (3.1)	0	0	0
Pharyngeal erythema	1 (3.1)	1 (3.1)	0	0	0
Productive cough	1 (3.1)	1 (3.1)	0	0	0
Respiratory disorder	1 (3.1)	0	1 (3.1)	0	0
Respiratory failure	1 (3.1)	0	0	0	1 (3.1)
Tachypnoea	1 (3.1)	0	0	0	1 (3.1)
Skin and subcutaneous tissue disorders					
-Total	15 (46.9)	5 (15.6)	7 (21.9)	3 (9.4)	0

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dermatitis atopic	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Pruritus	3 (9.4)	0	3 (9.4)	0	0
Rash	3 (9.4)	0	3 (9.4)	0	0
Dry skin	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Erythema	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acne	1 (3.1)	1 (3.1)	0	0	0
Decubitus ulcer	1 (3.1)	0	0	1 (3.1)	0
Dermatitis allergic	1 (3.1)	1 (3.1)	0	0	0
Hangnail	1 (3.1)	1 (3.1)	0	0	0
Papule	1 (3.1)	1 (3.1)	0	0	0
Photosensitivity reaction	1 (3.1)	0	1 (3.1)	0	0
Pruritus allergic	1 (3.1)	0	1 (3.1)	0	0
Rash macular	1 (3.1)	0	0	1 (3.1)	0
Rash maculo-papular	1 (3.1)	0	1 (3.1)	0	0
Rash vesicular	1 (3.1)	1 (3.1)	0	0	0
Urticaria	1 (3.1)	0	1 (3.1)	0	0
Vascular disorders					
-Total	8 (25.0)	2 (6.3)	2 (6.3)	3 (9.4)	1 (3.1)

Region: Europe

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Hypertension	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Haematoma	1 (3.1)	1 (3.1)	0	0	0
Venoocclusive disease	1 (3.1)	0	0	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208k
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (94.7)	0	3 (5.3)	11 (19.3)	40 (70.2)
Blood and lymphatic system disorders					
-Total	39 (68.4)	1 (1.8)	5 (8.8)	23 (40.4)	10 (17.5)
Febrile neutropenia	27 (47.4)	0	0	25 (43.9)	2 (3.5)
Anaemia	26 (45.6)	4 (7.0)	9 (15.8)	12 (21.1)	1 (1.8)
Thrombocytopenia	8 (14.0)	0	1 (1.8)	3 (5.3)	4 (7.0)
Neutropenia	6 (10.5)	1 (1.8)	1 (1.8)	1 (1.8)	3 (5.3)
Coagulopathy	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Disseminated intravascular coagulation	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Splenomegaly	3 (5.3)	3 (5.3)	0	0	0
Leukopenia	2 (3.5)	0	0	0	2 (3.5)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	2 (3.5)	0	0	0	2 (3.5)
Leukocytosis	1 (1.8)	0	1 (1.8)	0	0
Lymphocytosis	1 (1.8)	0	1 (1.8)	0	0
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)
Cardiac disorders					
-Total	29 (50.9)	7 (12.3)	6 (10.5)	11 (19.3)	5 (8.8)
Tachycardia	21 (36.8)	7 (12.3)	8 (14.0)	5 (8.8)	1 (1.8)
Left ventricular dysfunction	4 (7.0)	0	0	4 (7.0)	0
Bradycardia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Cardiac arrest	3 (5.3)	0	0	0	3 (5.3)
Cardiac failure	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Sinus tachycardia	2 (3.5)	2 (3.5)	0	0	0
Atrioventricular block first degree	1 (1.8)	0	1 (1.8)	0	0
Cardiac failure congestive	1 (1.8)	0	1 (1.8)	0	0
Mitral valve incompetence	1 (1.8)	1 (1.8)	0	0	0
Pericardial effusion	1 (1.8)	0	0	1 (1.8)	0
Right ventricular dysfunction	1 (1.8)	1 (1.8)	0	0	0
Sinus bradycardia	1 (1.8)	0	0	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tricuspid valve incompetence	1 (1.8)	1 (1.8)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Cerebral cavernous malformation	1 (1.8)	1 (1.8)	0	0	0
Ear and labyrinth disorders					
-Total	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Deafness unilateral	1 (1.8)	0	1 (1.8)	0	0
Ear pain	1 (1.8)	1 (1.8)	0	0	0
Ear pruritus	1 (1.8)	1 (1.8)	0	0	0
Endocrine disorders					
-Total	6 (10.5)	0	6 (10.5)	0	0
Adrenal insufficiency	4 (7.0)	0	4 (7.0)	0	0
Hypothyroidism	2 (3.5)	0	2 (3.5)	0	0
Delayed puberty	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	12 (21.1)	9 (15.8)	3 (5.3)	0	0
Ocular hyperaemia	3 (5.3)	3 (5.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cataract	2 (3.5)	2 (3.5)	0	0	0
Conjunctival haemorrhage	2 (3.5)	2 (3.5)	0	0	0
Visual impairment	2 (3.5)	2 (3.5)	0	0	0
Dry eye	1 (1.8)	1 (1.8)	0	0	0
Eyelid oedema	1 (1.8)	0	1 (1.8)	0	0
Hypermetropia	1 (1.8)	1 (1.8)	0	0	0
Mydriasis	1 (1.8)	0	1 (1.8)	0	0
Periorbital oedema	1 (1.8)	1 (1.8)	0	0	0
Periorbital swelling	1 (1.8)	0	1 (1.8)	0	0
Vision blurred	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	44 (77.2)	10 (17.5)	17 (29.8)	15 (26.3)	2 (3.5)
Nausea	24 (42.1)	11 (19.3)	11 (19.3)	2 (3.5)	0
Vomiting	22 (38.6)	14 (24.6)	6 (10.5)	2 (3.5)	0
Diarrhoea	18 (31.6)	14 (24.6)	3 (5.3)	1 (1.8)	0
Constipation	12 (21.1)	6 (10.5)	6 (10.5)	0	0
Abdominal pain	10 (17.5)	3 (5.3)	5 (8.8)	2 (3.5)	0
Stomatitis	7 (12.3)	0	3 (5.3)	4 (7.0)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mouth haemorrhage	5 (8.8)	1 (1.8)	2 (3.5)	2 (3.5)	0
Haematemesis	4 (7.0)	4 (7.0)	0	0	0
Abdominal distension	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Gastrointestinal sounds abnormal	3 (5.3)	3 (5.3)	0	0	0
Gingival bleeding	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Abdominal compartment syndrome	2 (3.5)	0	0	0	2 (3.5)
Anal fissure	2 (3.5)	0	2 (3.5)	0	0
Ascites	2 (3.5)	2 (3.5)	0	0	0
Dry mouth	2 (3.5)	0	2 (3.5)	0	0
Gastrointestinal haemorrhage	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Gingival erythema	2 (3.5)	2 (3.5)	0	0	0
Neutropenic colitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Oral pain	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Pancreatitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Proctalgia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Abdominal pain upper	1 (1.8)	1 (1.8)	0	0	0
Anal fistula	1 (1.8)	0	0	1 (1.8)	0
Anal haemorrhage	1 (1.8)	1 (1.8)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal inflammation	1 (1.8)	0	0	1 (1.8)	0
Dysphagia	1 (1.8)	0	0	1 (1.8)	0
Gastrointestinal inflammation	1 (1.8)	0	1 (1.8)	0	0
Gastrooesophageal reflux disease	1 (1.8)	0	1 (1.8)	0	0
Gingivitis ulcerative	1 (1.8)	0	0	1 (1.8)	0
Haemoperitoneum	1 (1.8)	0	0	0	1 (1.8)
Ileus	1 (1.8)	0	1 (1.8)	0	0
Irritable bowel syndrome	1 (1.8)	0	1 (1.8)	0	0
Lip dry	1 (1.8)	0	1 (1.8)	0	0
Lip oedema	1 (1.8)	1 (1.8)	0	0	0
Lip pain	1 (1.8)	1 (1.8)	0	0	0
Lip ulceration	1 (1.8)	0	1 (1.8)	0	0
Melaena	1 (1.8)	0	0	1 (1.8)	0
Trichoglossia	1 (1.8)	0	1 (1.8)	0	0
Upper gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	41 (71.9)	16 (28.1)	11 (19.3)	10 (17.5)	4 (7.0)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	28 (49.1)	10 (17.5)	7 (12.3)	9 (15.8)	2 (3.5)
Fatigue	18 (31.6)	14 (24.6)	4 (7.0)	0	0
Chills	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Pain	7 (12.3)	0	5 (8.8)	2 (3.5)	0
Oedema peripheral	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Generalised oedema	5 (8.8)	2 (3.5)	2 (3.5)	1 (1.8)	0
Catheter site pain	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Face oedema	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Drug withdrawal syndrome	2 (3.5)	0	2 (3.5)	0	0
Malaise	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Multiple organ dysfunction syndrome	2 (3.5)	0	0	0	2 (3.5)
Vascular device occlusion	2 (3.5)	2 (3.5)	0	0	0
Asthenia	1 (1.8)	0	1 (1.8)	0	0
Catheter site dermatitis	1 (1.8)	1 (1.8)	0	0	0
Catheter site haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Chest discomfort	1 (1.8)	0	0	1 (1.8)	0
Complication associated with device	1 (1.8)	1 (1.8)	0	0	0
Crying	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Facial pain	1 (1.8)	0	1 (1.8)	0	0
Localised oedema	1 (1.8)	1 (1.8)	0	0	0
Non-cardiac chest pain	1 (1.8)	1 (1.8)	0	0	0
Oedema due to hepatic disease	1 (1.8)	0	1 (1.8)	0	0
Sluggishness	1 (1.8)	0	1 (1.8)	0	0
Swelling face	1 (1.8)	1 (1.8)	0	0	0
Systemic inflammatory response syndrome	1 (1.8)	0	0	1 (1.8)	0
Thirst	1 (1.8)	1 (1.8)	0	0	0
Xerosis	1 (1.8)	1 (1.8)	0	0	0
Hepatobiliary disorders					
-Total	14 (24.6)	5 (8.8)	4 (7.0)	3 (5.3)	2 (3.5)
Hyperbilirubinaemia	5 (8.8)	1 (1.8)	2 (3.5)	2 (3.5)	0
Hypertransaminasaemia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Gallbladder enlargement	2 (3.5)	2 (3.5)	0	0	0
Hepatomegaly	2 (3.5)	1 (1.8)	0	0	1 (1.8)
Biliary tract disorder	1 (1.8)	1 (1.8)	0	0	0
Cholelithiasis	1 (1.8)	1 (1.8)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholestasis	1 (1.8)	0	0	0	1 (1.8)
Drug-induced liver injury	1 (1.8)	0	0	1 (1.8)	0
Hepatic function abnormal	1 (1.8)	0	1 (1.8)	0	0
Hepatosplenomegaly	1 (1.8)	0	1 (1.8)	0	0
Ocular icterus	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	44 (77.2)	2 (3.5)	19 (33.3)	13 (22.8)	10 (17.5)
Cytokine release syndrome	36 (63.2)	4 (7.0)	12 (21.1)	10 (17.5)	10 (17.5)
Hypogammaglobulinaemia	20 (35.1)	1 (1.8)	16 (28.1)	3 (5.3)	0
Seasonal allergy	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Haemophagocytic lymphohistiocytosis	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Graft versus host disease	2 (3.5)	0	0	2 (3.5)	0
Allergy to immunoglobulin therapy	1 (1.8)	0	0	1 (1.8)	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0
Engraftment syndrome	1 (1.8)	0	0	1 (1.8)	0
Selective igg subclass deficiency	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	40 (70.2)	1 (1.8)	7 (12.3)	22 (38.6)	10 (17.5)
Upper respiratory tract infection	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0
Sinusitis	7 (12.3)	0	5 (8.8)	2 (3.5)	0
Rhinovirus infection	6 (10.5)	0	6 (10.5)	0	0
Staphylococcal bacteraemia	6 (10.5)	0	0	6 (10.5)	0
Staphylococcal infection	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)
Clostridium difficile infection	4 (7.0)	1 (1.8)	0	3 (5.3)	0
Conjunctivitis	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Oral herpes	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Acute sinusitis	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Candida infection	3 (5.3)	0	2 (3.5)	0	1 (1.8)
Catheter site infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Gastroenteritis viral	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Metapneumovirus infection	3 (5.3)	0	0	3 (5.3)	0
Otitis media	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Parainfluenzae virus infection	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Paronychia	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Pneumonia	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	3 (5.3)	0	0	0	3 (5.3)
Bacteraemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bronchitis	2 (3.5)	0	2 (3.5)	0	0
Ear infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Fungal skin infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Gastroenteritis	2 (3.5)	2 (3.5)	0	0	0
Herpes simplex	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Human herpesvirus 6 infection	2 (3.5)	0	0	2 (3.5)	0
Influenza	2 (3.5)	0	2 (3.5)	0	0
Klebsiella bacteraemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Localised infection	2 (3.5)	2 (3.5)	0	0	0
Oral candidiasis	2 (3.5)	0	2 (3.5)	0	0
Otitis externa	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Skin infection	2 (3.5)	0	2 (3.5)	0	0
Varicella zoster virus infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Adenovirus infection	1 (1.8)	0	0	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal abscess	1 (1.8)	0	0	1 (1.8)	0
Aspergillus infection	1 (1.8)	0	0	0	1 (1.8)
Atypical pneumonia	1 (1.8)	1 (1.8)	0	0	0
Bk virus infection	1 (1.8)	0	0	1 (1.8)	0
Bronchiolitis	1 (1.8)	0	0	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis	1 (1.8)	0	1 (1.8)	0	0
Cholecystitis infective	1 (1.8)	0	1 (1.8)	0	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Coronavirus infection	1 (1.8)	0	0	1 (1.8)	0
Covid-19	1 (1.8)	1 (1.8)	0	0	0
Cytomegalovirus infection reactivation	1 (1.8)	0	0	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	0	0	1 (1.8)
Encephalitis	1 (1.8)	0	0	0	1 (1.8)
Enterobacter infection	1 (1.8)	0	0	1 (1.8)	0
Folliculitis	1 (1.8)	0	1 (1.8)	0	0
Fungaemia	1 (1.8)	0	0	0	1 (1.8)
Fungal infection	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis clostridial	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis escherichia coli	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	1 (1.8)	0	0	0
Gastroenteritis salmonella	1 (1.8)	0	0	1 (1.8)	0
Gastrointestinal infection	1 (1.8)	1 (1.8)	0	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Granulicatella infection	1 (1.8)	0	0	1 (1.8)	0
Herpes zoster	1 (1.8)	0	1 (1.8)	0	0
Klebsiella infection	1 (1.8)	0	0	1 (1.8)	0
Mastoiditis	1 (1.8)	0	0	1 (1.8)	0
Meningitis pneumococcal	1 (1.8)	0	0	1 (1.8)	0
Nail infection	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Pharyngitis	1 (1.8)	0	0	1 (1.8)	0
Pharyngitis streptococcal	1 (1.8)	0	0	1 (1.8)	0
Pneumocystis jirovecii pneumonia	1 (1.8)	0	0	1 (1.8)	0
Pneumonia fungal	1 (1.8)	0	0	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia respiratory syncytial viral	1 (1.8)	0	0	1 (1.8)	0
Salmonellosis	1 (1.8)	0	1 (1.8)	0	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	0	0	1 (1.8)
Sinusitis fungal	1 (1.8)	0	0	1 (1.8)	0
Soft tissue infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	0	0	1 (1.8)	0
Stomatococcal infection	1 (1.8)	0	0	0	1 (1.8)
Syphilis	1 (1.8)	0	1 (1.8)	0	0
Systemic candida	1 (1.8)	0	0	1 (1.8)	0
Systemic mycosis	1 (1.8)	0	0	1 (1.8)	0
Tinea pedis	1 (1.8)	1 (1.8)	0	0	0
Urinary tract infection	1 (1.8)	0	1 (1.8)	0	0
Urinary tract infection pseudomonal	1 (1.8)	0	1 (1.8)	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	0	1 (1.8)	0
Vulval cellulitis	1 (1.8)	0	0	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	20 (35.1)	7 (12.3)	7 (12.3)	3 (5.3)	3 (5.3)
Infusion related reaction	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Transfusion reaction	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Procedural pain	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Contusion	2 (3.5)	2 (3.5)	0	0	0
Fall	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Skin abrasion	2 (3.5)	2 (3.5)	0	0	0
Wound	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Abdominal injury	1 (1.8)	1 (1.8)	0	0	0
Fibula fracture	1 (1.8)	0	1 (1.8)	0	0
Ligament sprain	1 (1.8)	1 (1.8)	0	0	0
Limb injury	1 (1.8)	0	1 (1.8)	0	0
Post-traumatic neck syndrome	1 (1.8)	0	1 (1.8)	0	0
Radius fracture	1 (1.8)	0	1 (1.8)	0	0
Scratch	1 (1.8)	1 (1.8)	0	0	0
Skin injury	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin wound	1 (1.8)	1 (1.8)	0	0	0
Tracheal obstruction	1 (1.8)	0	0	0	1 (1.8)
Transplant failure	1 (1.8)	0	0	0	1 (1.8)
Vasoplegia syndrome	1 (1.8)	0	0	0	1 (1.8)
Investigations					
-Total	40 (70.2)	1 (1.8)	3 (5.3)	13 (22.8)	23 (40.4)
Aspartate aminotransferase increased	20 (35.1)	2 (3.5)	5 (8.8)	9 (15.8)	4 (7.0)
Alanine aminotransferase increased	19 (33.3)	4 (7.0)	8 (14.0)	7 (12.3)	0
Neutrophil count decreased	18 (31.6)	1 (1.8)	2 (3.5)	3 (5.3)	12 (21.1)
Platelet count decreased	18 (31.6)	4 (7.0)	2 (3.5)	4 (7.0)	8 (14.0)
White blood cell count decreased	18 (31.6)	3 (5.3)	3 (5.3)	1 (1.8)	11 (19.3)
Lymphocyte count decreased	13 (22.8)	1 (1.8)	1 (1.8)	8 (14.0)	3 (5.3)
Blood bilirubin increased	12 (21.1)	1 (1.8)	2 (3.5)	9 (15.8)	0
International normalised ratio increased	10 (17.5)	6 (10.5)	4 (7.0)	0	0
Blood creatinine increased	7 (12.3)	2 (3.5)	1 (1.8)	3 (5.3)	1 (1.8)
Blood immunoglobulin a decreased	7 (12.3)	5 (8.8)	1 (1.8)	1 (1.8)	0
Blood immunoglobulin m decreased	7 (12.3)	4 (7.0)	1 (1.8)	2 (3.5)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
C-reactive protein increased	7 (12.3)	3 (5.3)	1 (1.8)	2 (3.5)	1 (1.8)
Serum ferritin increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)
Activated partial thromboplastin time prolonged	6 (10.5)	3 (5.3)	2 (3.5)	1 (1.8)	0
Blood lactate dehydrogenase increased	6 (10.5)	3 (5.3)	0	3 (5.3)	0
Weight increased	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Blood fibrinogen decreased	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)	0
Electrocardiogram qt prolonged	5 (8.8)	1 (1.8)	2 (3.5)	1 (1.8)	1 (1.8)
Fibrin d dimer increased	4 (7.0)	2 (3.5)	0	1 (1.8)	1 (1.8)
Blood fibrinogen increased	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Blood immunoglobulin g decreased	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Blood uric acid increased	3 (5.3)	2 (3.5)	0	0	1 (1.8)
Blood glucose increased	2 (3.5)	1 (1.8)	0	0	1 (1.8)
Blood phosphorus increased	2 (3.5)	0	2 (3.5)	0	0
Lipase increased	2 (3.5)	1 (1.8)	0	0	1 (1.8)
Oxygen saturation decreased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Urine output decreased	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Weight decreased	2 (3.5)	0	2 (3.5)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Amylase increased	1 (1.8)	1 (1.8)	0	0	0
Bacterial test positive	1 (1.8)	0	0	1 (1.8)	0
Blood alkaline phosphatase decreased	1 (1.8)	1 (1.8)	0	0	0
Blood alkaline phosphatase increased	1 (1.8)	1 (1.8)	0	0	0
Blood bicarbonate decreased	1 (1.8)	0	1 (1.8)	0	0
Blood creatine phosphokinase increased	1 (1.8)	0	0	0	1 (1.8)
Blood phosphorus decreased	1 (1.8)	0	0	1 (1.8)	0
Blood potassium decreased	1 (1.8)	0	0	0	1 (1.8)
Blood testosterone decreased	1 (1.8)	1 (1.8)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.8)	1 (1.8)	0	0	0
Blood urea increased	1 (1.8)	0	0	1 (1.8)	0
Breath sounds abnormal	1 (1.8)	0	1 (1.8)	0	0
Cardiac murmur	1 (1.8)	1 (1.8)	0	0	0
Coagulation test abnormal	1 (1.8)	1 (1.8)	0	0	0
Ejection fraction decreased	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram t wave abnormal	1 (1.8)	0	1 (1.8)	0	0
Enterovirus test positive	1 (1.8)	0	1 (1.8)	0	0
Eosinophil count decreased	1 (1.8)	1 (1.8)	0	0	0
Gamma-glutamyltransferase increased	1 (1.8)	0	0	1 (1.8)	0
Haematocrit decreased	1 (1.8)	1 (1.8)	0	0	0
Haemoglobin decreased	1 (1.8)	0	0	1 (1.8)	0
Haptoglobin decreased	1 (1.8)	1 (1.8)	0	0	0
Heart sounds abnormal	1 (1.8)	1 (1.8)	0	0	0
Red blood cell count decreased	1 (1.8)	1 (1.8)	0	0	0
Staphylococcus test positive	1 (1.8)	1 (1.8)	0	0	0
Troponin increased	1 (1.8)	0	0	1 (1.8)	0
Metabolism and nutrition disorders					
-Total	42 (73.7)	6 (10.5)	9 (15.8)	19 (33.3)	8 (14.0)
Decreased appetite	29 (50.9)	10 (17.5)	7 (12.3)	11 (19.3)	1 (1.8)
Hypokalaemia	17 (29.8)	3 (5.3)	4 (7.0)	8 (14.0)	2 (3.5)
Hypophosphataemia	17 (29.8)	3 (5.3)	7 (12.3)	7 (12.3)	0
Hypocalcaemia	16 (28.1)	2 (3.5)	10 (17.5)	4 (7.0)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoalbuminaemia	10 (17.5)	0	9 (15.8)	1 (1.8)	0
Hypervolaemia	9 (15.8)	1 (1.8)	2 (3.5)	6 (10.5)	0
Hyperuricaemia	8 (14.0)	7 (12.3)	0	1 (1.8)	0
Hyperglycaemia	6 (10.5)	0	3 (5.3)	3 (5.3)	0
Hyperphosphataemia	6 (10.5)	5 (8.8)	0	0	1 (1.8)
Hypomagnesaemia	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Metabolic acidosis	5 (8.8)	1 (1.8)	0	2 (3.5)	2 (3.5)
Hyperkalaemia	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Hypercalcaemia	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Hypertriglyceridaemia	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Hyponatraemia	3 (5.3)	3 (5.3)	0	0	0
Tumour lysis syndrome	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Acidosis	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Hyperchloraemia	2 (3.5)	2 (3.5)	0	0	0
Hypermagnesaemia	2 (3.5)	2 (3.5)	0	0	0
Hypernatraemia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Iron overload	2 (3.5)	0	2 (3.5)	0	0
Calcium deficiency	1 (1.8)	1 (1.8)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dehydration	1 (1.8)	0	1 (1.8)	0	0
Haemosiderosis	1 (1.8)	0	1 (1.8)	0	0
Hypercholesterolaemia	1 (1.8)	0	1 (1.8)	0	0
Hyperlactacidaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperlipidaemia	1 (1.8)	0	1 (1.8)	0	0
Hypoglycaemia	1 (1.8)	0	1 (1.8)	0	0
Hypophagia	1 (1.8)	0	1 (1.8)	0	0
Malnutrition	1 (1.8)	0	0	1 (1.8)	0
Metabolic syndrome	1 (1.8)	0	1 (1.8)	0	0
Obesity	1 (1.8)	0	0	1 (1.8)	0
Polydipsia	1 (1.8)	0	0	1 (1.8)	0
Vitamin d deficiency	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	31 (54.4)	11 (19.3)	11 (19.3)	8 (14.0)	1 (1.8)
Pain in extremity	15 (26.3)	7 (12.3)	5 (8.8)	3 (5.3)	0
Myalgia	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Arthralgia	8 (14.0)	3 (5.3)	4 (7.0)	1 (1.8)	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Back pain	7 (12.3)	1 (1.8)	3 (5.3)	3 (5.3)	0
Bone pain	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Joint effusion	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Neck pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Pain in jaw	2 (3.5)	0	0	2 (3.5)	0
Groin pain	1 (1.8)	1 (1.8)	0	0	0
Growth retardation	1 (1.8)	0	1 (1.8)	0	0
Haemarthrosis	1 (1.8)	0	0	1 (1.8)	0
Muscle rigidity	1 (1.8)	1 (1.8)	0	0	0
Muscle spasms	1 (1.8)	0	1 (1.8)	0	0
Muscular weakness	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal chest pain	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal pain	1 (1.8)	0	1 (1.8)	0	0
Myositis	1 (1.8)	0	1 (1.8)	0	0
Osteopenia	1 (1.8)	1 (1.8)	0	0	0
Rhabdomyolysis	1 (1.8)	0	0	0	1 (1.8)
Spinal pain	1 (1.8)	0	0	1 (1.8)	0
Synovitis	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.8)	0	1 (1.8)	0	0
Cancer pain	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	32 (56.1)	10 (17.5)	12 (21.1)	8 (14.0)	2 (3.5)
Headache	19 (33.3)	8 (14.0)	9 (15.8)	2 (3.5)	0
Somnolence	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Dizziness	5 (8.8)	5 (8.8)	0	0	0
Encephalopathy	5 (8.8)	1 (1.8)	1 (1.8)	3 (5.3)	0
Cognitive disorder	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Lethargy	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Tremor	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Seizure	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Dysgeusia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Neuropathy peripheral	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Aphasia	1 (1.8)	1 (1.8)	0	0	0
Cerebral haemorrhage	1 (1.8)	0	0	0	1 (1.8)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depressed level of consciousness	1 (1.8)	0	0	1 (1.8)	0
Disturbance in attention	1 (1.8)	1 (1.8)	0	0	0
Dysarthria	1 (1.8)	0	0	1 (1.8)	0
Extrapyramidal disorder	1 (1.8)	0	1 (1.8)	0	0
Generalised tonic-clonic seizure	1 (1.8)	0	1 (1.8)	0	0
Hypoaesthesia	1 (1.8)	1 (1.8)	0	0	0
Migraine	1 (1.8)	0	1 (1.8)	0	0
Monoparesis	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorder	1 (1.8)	0	0	1 (1.8)	0
Neurological decompensation	1 (1.8)	0	0	0	1 (1.8)
Paraesthesia	1 (1.8)	1 (1.8)	0	0	0
Posterior reversible encephalopathy syndrome	1 (1.8)	0	1 (1.8)	0	0
Psychiatric disorders					
-Total	29 (50.9)	9 (15.8)	11 (19.3)	9 (15.8)	0
Anxiety	10 (17.5)	2 (3.5)	6 (10.5)	2 (3.5)	0
Delirium	8 (14.0)	2 (3.5)	3 (5.3)	3 (5.3)	0
Agitation	6 (10.5)	3 (5.3)	3 (5.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	6 (10.5)	1 (1.8)	2 (3.5)	3 (5.3)	0
Confusional state	5 (8.8)	5 (8.8)	0	0	0
Insomnia	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Irritability	4 (7.0)	3 (5.3)	0	1 (1.8)	0
Affect lability	1 (1.8)	0	1 (1.8)	0	0
Automatism	1 (1.8)	1 (1.8)	0	0	0
Hallucination	1 (1.8)	1 (1.8)	0	0	0
Mood altered	1 (1.8)	1 (1.8)	0	0	0
Nightmare	1 (1.8)	1 (1.8)	0	0	0
Persistent depressive disorder	1 (1.8)	0	1 (1.8)	0	0
Restlessness	1 (1.8)	0	1 (1.8)	0	0
Sleep disorder	1 (1.8)	0	1 (1.8)	0	0
Social avoidant behaviour	1 (1.8)	0	1 (1.8)	0	0
Tearfulness	1 (1.8)	1 (1.8)	0	0	0
Tic	1 (1.8)	0	1 (1.8)	0	0
Renal and urinary disorders					
-Total	20 (35.1)	7 (12.3)	4 (7.0)	5 (8.8)	4 (7.0)
Acute kidney injury	13 (22.8)	5 (8.8)	2 (3.5)	3 (5.3)	3 (5.3)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysuria	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Haematuria	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Pollakiuria	2 (3.5)	0	2 (3.5)	0	0
Renal tubular necrosis	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Urinary retention	2 (3.5)	0	2 (3.5)	0	0
Anuria	1 (1.8)	1 (1.8)	0	0	0
Azotaemia	1 (1.8)	0	1 (1.8)	0	0
Bladder dilatation	1 (1.8)	0	1 (1.8)	0	0
Incontinence	1 (1.8)	0	1 (1.8)	0	0
Kidney enlargement	1 (1.8)	0	1 (1.8)	0	0
Micturition urgency	1 (1.8)	0	1 (1.8)	0	0
Renal failure	1 (1.8)	0	0	0	1 (1.8)
Renal mass	1 (1.8)	0	1 (1.8)	0	0
Renal pain	1 (1.8)	1 (1.8)	0	0	0
Renal tubular dysfunction	1 (1.8)	1 (1.8)	0	0	0
Urinary incontinence	1 (1.8)	0	1 (1.8)	0	0
Reproductive system and breast disorders					

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (8.8)	0	2 (3.5)	3 (5.3)	0
Dysmenorrhoea	1 (1.8)	0	1 (1.8)	0	0
Endometriosis	1 (1.8)	0	0	1 (1.8)	0
Perineal rash	1 (1.8)	0	1 (1.8)	0	0
Prostatitis	1 (1.8)	0	0	1 (1.8)	0
Vaginal haemorrhage	1 (1.8)	0	1 (1.8)	0	0
Vaginal ulceration	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	39 (68.4)	10 (17.5)	2 (3.5)	10 (17.5)	17 (29.8)
Cough	16 (28.1)	13 (22.8)	3 (5.3)	0	0
Hypoxia	15 (26.3)	0	2 (3.5)	10 (17.5)	3 (5.3)
Nasal congestion	11 (19.3)	9 (15.8)	2 (3.5)	0	0
Pulmonary oedema	10 (17.5)	2 (3.5)	3 (5.3)	3 (5.3)	2 (3.5)
Epistaxis	9 (15.8)	4 (7.0)	2 (3.5)	3 (5.3)	0
Respiratory failure	9 (15.8)	0	0	0	9 (15.8)
Tachypnoea	9 (15.8)	3 (5.3)	2 (3.5)	4 (7.0)	0
Dyspnoea	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	6 (10.5)	4 (7.0)	2 (3.5)	0	0
Pleural effusion	6 (10.5)	3 (5.3)	0	2 (3.5)	1 (1.8)
Rhinorrhoea	6 (10.5)	4 (7.0)	2 (3.5)	0	0
Acute respiratory distress syndrome	4 (7.0)	0	0	0	4 (7.0)
Respiratory distress	4 (7.0)	0	2 (3.5)	0	2 (3.5)
Atelectasis	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Rhinitis allergic	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Sleep apnoea syndrome	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Wheezing	2 (3.5)	0	2 (3.5)	0	0
Acute respiratory failure	1 (1.8)	0	0	1 (1.8)	0
Bradypnoea	1 (1.8)	0	0	1 (1.8)	0
Haemoptysis	1 (1.8)	0	1 (1.8)	0	0
Laryngeal oedema	1 (1.8)	0	0	0	1 (1.8)
Lung infiltration	1 (1.8)	0	0	1 (1.8)	0
Nasal discomfort	1 (1.8)	0	1 (1.8)	0	0
Nasal dryness	1 (1.8)	1 (1.8)	0	0	0
Oropharyngeal plaque	1 (1.8)	0	1 (1.8)	0	0
Paranasal sinus discomfort	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paranasal sinus inflammation	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal erythema	1 (1.8)	0	1 (1.8)	0	0
Pharyngeal exudate	1 (1.8)	0	1 (1.8)	0	0
Pharyngeal haemorrhage	1 (1.8)	0	1 (1.8)	0	0
Pharyngeal oedema	1 (1.8)	0	1 (1.8)	0	0
Pulmonary haemorrhage	1 (1.8)	0	0	0	1 (1.8)
Pulmonary mass	1 (1.8)	0	1 (1.8)	0	0
Respiratory acidosis	1 (1.8)	0	0	1 (1.8)	0
Skin and subcutaneous tissue disorders					
-Total	28 (49.1)	13 (22.8)	10 (17.5)	5 (8.8)	0
Rash	7 (12.3)	5 (8.8)	2 (3.5)	0	0
Dry skin	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Pruritus	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Erythema	4 (7.0)	4 (7.0)	0	0	0
Ingrowing nail	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Rash papular	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Blister	3 (5.3)	2 (3.5)	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eczema	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Hyperhidrosis	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Petechiae	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Rash maculo-papular	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Skin ulcer	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Skin discolouration	2 (3.5)	2 (3.5)	0	0	0
Decubitus ulcer	1 (1.8)	0	1 (1.8)	0	0
Dermatitis	1 (1.8)	1 (1.8)	0	0	0
Dermatitis diaper	1 (1.8)	0	1 (1.8)	0	0
Drug eruption	1 (1.8)	0	1 (1.8)	0	0
Miliaria	1 (1.8)	1 (1.8)	0	0	0
Night sweats	1 (1.8)	1 (1.8)	0	0	0
Purpura	1 (1.8)	1 (1.8)	0	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Scab	1 (1.8)	1 (1.8)	0	0	0
Skin hypopigmentation	1 (1.8)	1 (1.8)	0	0	0
Skin lesion	1 (1.8)	0	1 (1.8)	0	0

Region: US

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin necrosis	1 (1.8)	0	0	1 (1.8)	0
Vancomycin infusion reaction	1 (1.8)	0	0	1 (1.8)	0
Social circumstances					
-Total	1 (1.8)	0	1 (1.8)	0	0
Patient uncooperative	1 (1.8)	0	1 (1.8)	0	0
Surgical and medical procedures					
-Total	1 (1.8)	0	0	1 (1.8)	0
Thrombolysis	1 (1.8)	0	0	1 (1.8)	0
Vascular disorders					
-Total	33 (57.9)	3 (5.3)	8 (14.0)	13 (22.8)	9 (15.8)
Hypotension	25 (43.9)	1 (1.8)	4 (7.0)	11 (19.3)	9 (15.8)
Hypertension	15 (26.3)	3 (5.3)	9 (15.8)	3 (5.3)	0
Capillary leak syndrome	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Flushing	2 (3.5)	2 (3.5)	0	0	0
Peripheral ischaemia	2 (3.5)	0	2 (3.5)	0	0
Hot flush	1 (1.8)	1 (1.8)	0	0	0
Thrombosis	1 (1.8)	0	1 (1.8)	0	0
Venoocclusive disease	1 (1.8)	0	0	1 (1.8)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208k
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	1 (11.1)	1 (11.1)	7 (77.8)
Blood and lymphatic system disorders					
-Total	6 (66.7)	0	2 (22.2)	0	4 (44.4)
Neutropenia	3 (33.3)	0	0	0	3 (33.3)
Disseminated intravascular coagulation	2 (22.2)	0	2 (22.2)	0	0
Anaemia	1 (11.1)	0	1 (11.1)	0	0
B-cell aplasia	1 (11.1)	0	1 (11.1)	0	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Hypofibrinogenaemia	1 (11.1)	0	1 (11.1)	0	0
Leukopenia	1 (11.1)	0	0	0	1 (11.1)

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	3 (33.3)	2 (22.2)	0	0	1 (11.1)
Cardiac dysfunction	2 (22.2)	2 (22.2)	0	0	0
Cardiac failure	1 (11.1)	0	0	0	1 (11.1)
Gastrointestinal disorders					
-Total	7 (77.8)	2 (22.2)	4 (44.4)	1 (11.1)	0
Constipation	2 (22.2)	2 (22.2)	0	0	0
Nausea	2 (22.2)	2 (22.2)	0	0	0
Pancreatitis	2 (22.2)	0	2 (22.2)	0	0
Abdominal pain	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	0	1 (11.1)	0	0
Duodenal perforation	1 (11.1)	0	0	1 (11.1)	0
Enteritis	1 (11.1)	0	1 (11.1)	0	0
Enterocolitis	1 (11.1)	0	1 (11.1)	0	0
Gastritis	1 (11.1)	0	1 (11.1)	0	0
Haemorrhoids	1 (11.1)	0	1 (11.1)	0	0
Stomatitis	1 (11.1)	1 (11.1)	0	0	0

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Trichoglossia	1 (11.1)	1 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	1 (11.1)	1 (11.1)	0	0	0
Face oedema	1 (11.1)	1 (11.1)	0	0	0
Influenza like illness	1 (11.1)	1 (11.1)	0	0	0
Pain	1 (11.1)	1 (11.1)	0	0	0
Pyrexia	1 (11.1)	1 (11.1)	0	0	0
Hepatobiliary disorders					
-Total	4 (44.4)	0	1 (11.1)	2 (22.2)	1 (11.1)
Hepatic function abnormal	4 (44.4)	0	1 (11.1)	2 (22.2)	1 (11.1)
Immune system disorders					
-Total	7 (77.8)	0	2 (22.2)	2 (22.2)	3 (33.3)
Cytokine release syndrome	6 (66.7)	1 (11.1)	0	2 (22.2)	3 (33.3)
Hypogammaglobulinaemia	4 (44.4)	0	4 (44.4)	0	0
Infections and infestations					
-Total	9 (100)	3 (33.3)	1 (11.1)	4 (44.4)	1 (11.1)
Upper respiratory tract infection	2 (22.2)	0	0	2 (22.2)	0

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Bk virus infection	1 (11.1)	1 (11.1)	0	0	0
Encephalitis viral	1 (11.1)	0	0	0	1 (11.1)
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Meningitis bacterial	1 (11.1)	0	0	1 (11.1)	0
Nasopharyngitis	1 (11.1)	1 (11.1)	0	0	0
Otitis externa	1 (11.1)	0	1 (11.1)	0	0
Otitis media	1 (11.1)	0	1 (11.1)	0	0
Parainfluenzae virus infection	1 (11.1)	0	0	1 (11.1)	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	1 (11.1)	0
Respiratory syncytial virus infection	1 (11.1)	0	0	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	0	1 (11.1)	0
Sinusitis	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Tinea pedis	1 (11.1)	1 (11.1)	0	0	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0
Urinary tract infection viral	1 (11.1)	1 (11.1)	0	0	0

Region: Rest of World

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	5 (55.6)	0	0	0	5 (55.6)
White blood cell count decreased	4 (44.4)	0	0	0	4 (44.4)
Neutrophil count decreased	3 (33.3)	0	0	0	3 (33.3)
Serum ferritin increased	3 (33.3)	0	3 (33.3)	0	0
Blood fibrinogen decreased	2 (22.2)	0	2 (22.2)	0	0
Platelet count decreased	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Blood creatine phosphokinase increased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Tumour lysis syndrome	2 (22.2)	0	0	2 (22.2)	0
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)	0	0
Metabolic acidosis	1 (11.1)	0	0	0	1 (11.1)
Musculoskeletal and connective tissue disorders					
-Total	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Pain in extremity	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Arthralgia	1 (11.1)	1 (11.1)	0	0	0

Region: Rest of World

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	4 (44.4)	2 (22.2)	1 (11.1)	0	1 (11.1)
Headache	2 (22.2)	2 (22.2)	0	0	0
Haemorrhage intracranial	1 (11.1)	0	0	0	1 (11.1)
Seizure	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Anxiety	1 (11.1)	1 (11.1)	0	0	0
Renal and urinary disorders					
-Total	4 (44.4)	1 (11.1)	1 (11.1)	0	2 (22.2)
Acute kidney injury	2 (22.2)	0	0	0	2 (22.2)
Cystitis haemorrhagic	1 (11.1)	0	1 (11.1)	0	0
Haematuria	1 (11.1)	1 (11.1)	0	0	0
Proteinuria	1 (11.1)	1 (11.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Heavy menstrual bleeding	1 (11.1)	0	1 (11.1)	0	0

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	6 (66.7)	1 (11.1)	2 (22.2)	0	3 (33.3)
Hypoxia	3 (33.3)	0	0	0	3 (33.3)
Pleural effusion	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Epistaxis	1 (11.1)	1 (11.1)	0	0	0
Oropharyngeal pain	1 (11.1)	1 (11.1)	0	0	0
Upper respiratory tract inflammation	1 (11.1)	0	1 (11.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (55.6)	4 (44.4)	1 (11.1)	0	0
Pruritus	2 (22.2)	2 (22.2)	0	0	0
Dry skin	1 (11.1)	1 (11.1)	0	0	0
Erythema nodosum	1 (11.1)	1 (11.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (11.1)	1 (11.1)	0	0	0
Skin swelling	1 (11.1)	1 (11.1)	0	0	0
Skin ulcer	1 (11.1)	0	1 (11.1)	0	0
Vascular disorders					

Region: Rest of World

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Hypertension	1 (11.1)	0	1 (11.1)	0	0
Hypotension	1 (11.1)	0	0	0	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208l
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (100)	0	3 (5.2)	14 (24.1)	41 (70.7)
Blood and lymphatic system disorders					
-Total	40 (69.0)	1 (1.7)	4 (6.9)	24 (41.4)	11 (19.0)
Anaemia	23 (39.7)	2 (3.4)	6 (10.3)	15 (25.9)	0
Febrile neutropenia	22 (37.9)	0	0	21 (36.2)	1 (1.7)
Neutropenia	10 (17.2)	0	1 (1.7)	2 (3.4)	7 (12.1)
Thrombocytopenia	8 (13.8)	0	1 (1.7)	3 (5.2)	4 (6.9)
Leukopenia	5 (8.6)	0	0	1 (1.7)	4 (6.9)
Disseminated intravascular coagulation	4 (6.9)	0	3 (5.2)	1 (1.7)	0
Pancytopenia	4 (6.9)	0	0	3 (5.2)	1 (1.7)
Coagulopathy	2 (3.4)	1 (1.7)	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (3.4)	0	0	0	2 (3.4)
Splenomegaly	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Agranulocytosis	1 (1.7)	0	0	1 (1.7)	0
B-cell aplasia	1 (1.7)	0	1 (1.7)	0	0
Eosinophilia	1 (1.7)	0	1 (1.7)	0	0
Leukocytosis	1 (1.7)	0	1 (1.7)	0	0
Lymphadenopathy	1 (1.7)	0	1 (1.7)	0	0
Cardiac disorders					
-Total	17 (29.3)	5 (8.6)	4 (6.9)	7 (12.1)	1 (1.7)
Tachycardia	9 (15.5)	4 (6.9)	3 (5.2)	2 (3.4)	0
Left ventricular dysfunction	4 (6.9)	0	1 (1.7)	3 (5.2)	0
Pericardial effusion	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Bradycardia	1 (1.7)	1 (1.7)	0	0	0
Cardiac arrest	1 (1.7)	0	0	0	1 (1.7)
Cardiac dysfunction	1 (1.7)	1 (1.7)	0	0	0
Cardiac failure	1 (1.7)	0	0	1 (1.7)	0
Cardiac failure congestive	1 (1.7)	0	1 (1.7)	0	0
Mitral valve incompetence	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Right ventricular dysfunction	1 (1.7)	1 (1.7)	0	0	0
Sinus tachycardia	1 (1.7)	0	1 (1.7)	0	0
Tricuspid valve incompetence	1 (1.7)	1 (1.7)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Cerebral cavernous malformation	1 (1.7)	1 (1.7)	0	0	0
Ear and labyrinth disorders					
-Total	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Deafness unilateral	1 (1.7)	0	1 (1.7)	0	0
Ear pain	1 (1.7)	1 (1.7)	0	0	0
Vertigo	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					
-Total	5 (8.6)	0	5 (8.6)	0	0
Adrenal insufficiency	3 (5.2)	0	3 (5.2)	0	0
Hypothyroidism	2 (3.4)	0	2 (3.4)	0	0
Delayed puberty	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (20.7)	7 (12.1)	4 (6.9)	1 (1.7)	0
Eye pain	3 (5.2)	2 (3.4)	0	1 (1.7)	0
Cataract	2 (3.4)	2 (3.4)	0	0	0
Eyelid oedema	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Dry eye	1 (1.7)	1 (1.7)	0	0	0
Eye oedema	1 (1.7)	1 (1.7)	0	0	0
Hypermetropia	1 (1.7)	1 (1.7)	0	0	0
Mydriasis	1 (1.7)	0	1 (1.7)	0	0
Ocular hyperaemia	1 (1.7)	1 (1.7)	0	0	0
Periorbital swelling	1 (1.7)	0	1 (1.7)	0	0
Retinal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Vision blurred	1 (1.7)	1 (1.7)	0	0	0
Visual field defect	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	42 (72.4)	10 (17.2)	20 (34.5)	12 (20.7)	0
Nausea	20 (34.5)	10 (17.2)	9 (15.5)	1 (1.7)	0
Diarrhoea	19 (32.8)	11 (19.0)	6 (10.3)	2 (3.4)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	19 (32.8)	12 (20.7)	7 (12.1)	0	0
Abdominal pain	11 (19.0)	3 (5.2)	6 (10.3)	2 (3.4)	0
Constipation	10 (17.2)	5 (8.6)	5 (8.6)	0	0
Stomatitis	6 (10.3)	0	3 (5.2)	3 (5.2)	0
Abdominal pain upper	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Mouth haemorrhage	4 (6.9)	2 (3.4)	1 (1.7)	1 (1.7)	0
Gastrointestinal sounds abnormal	3 (5.2)	3 (5.2)	0	0	0
Pancreatitis	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Abdominal distension	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Ascites	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Gingival bleeding	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Haematemesis	2 (3.4)	2 (3.4)	0	0	0
Proctalgia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Trichoglossia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Abdominal rigidity	1 (1.7)	0	1 (1.7)	0	0
Anal erythema	1 (1.7)	1 (1.7)	0	0	0
Anal fissure	1 (1.7)	0	1 (1.7)	0	0
Anal fistula	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Anal inflammation	1 (1.7)	0	0	1 (1.7)	0
Dry mouth	1 (1.7)	0	1 (1.7)	0	0
Duodenal perforation	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	1 (1.7)	0	0	0
Enteritis	1 (1.7)	0	1 (1.7)	0	0
Enterocolitis	1 (1.7)	0	1 (1.7)	0	0
Gastritis	1 (1.7)	0	1 (1.7)	0	0
Gastrooesophageal reflux disease	1 (1.7)	0	1 (1.7)	0	0
Gingivitis ulcerative	1 (1.7)	0	0	1 (1.7)	0
Haemorrhoids	1 (1.7)	0	1 (1.7)	0	0
Lip dry	1 (1.7)	0	1 (1.7)	0	0
Lip oedema	1 (1.7)	1 (1.7)	0	0	0
Mouth swelling	1 (1.7)	1 (1.7)	0	0	0
Neutropenic colitis	1 (1.7)	0	0	1 (1.7)	0
Odynophagia	1 (1.7)	1 (1.7)	0	0	0
Oral disorder	1 (1.7)	1 (1.7)	0	0	0
Peritoneal haematoma	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	36 (62.1)	22 (37.9)	6 (10.3)	7 (12.1)	1 (1.7)
Pyrexia	23 (39.7)	12 (20.7)	4 (6.9)	6 (10.3)	1 (1.7)
Fatigue	10 (17.2)	9 (15.5)	1 (1.7)	0	0
Chills	6 (10.3)	4 (6.9)	2 (3.4)	0	0
Asthenia	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Face oedema	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Pain	4 (6.9)	1 (1.7)	1 (1.7)	2 (3.4)	0
Catheter site pain	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Generalised oedema	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Influenza like illness	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Localised oedema	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Non-cardiac chest pain	2 (3.4)	2 (3.4)	0	0	0
Oedema peripheral	2 (3.4)	2 (3.4)	0	0	0
Catheter site erythema	1 (1.7)	1 (1.7)	0	0	0
Chest discomfort	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Crying	1 (1.7)	0	1 (1.7)	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Malaise	1 (1.7)	0	1 (1.7)	0	0
Oedema due to hepatic disease	1 (1.7)	0	1 (1.7)	0	0
Sluggishness	1 (1.7)	0	1 (1.7)	0	0
Swelling face	1 (1.7)	1 (1.7)	0	0	0
Thirst	1 (1.7)	1 (1.7)	0	0	0
Vascular device occlusion	1 (1.7)	1 (1.7)	0	0	0
Xerosis	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	13 (22.4)	4 (6.9)	4 (6.9)	4 (6.9)	1 (1.7)
Hyperbilirubinaemia	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Hepatic cytolysis	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hepatic function abnormal	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Hepatomegaly	2 (3.4)	2 (3.4)	0	0	0
Cholelithiasis	1 (1.7)	0	1 (1.7)	0	0
Drug-induced liver injury	1 (1.7)	0	0	1 (1.7)	0
Hepatosplenomegaly	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Liver disorder	1 (1.7)	0	1 (1.7)	0	0
Immune system disorders					
-Total	45 (77.6)	1 (1.7)	15 (25.9)	18 (31.0)	11 (19.0)
Cytokine release syndrome	37 (63.8)	3 (5.2)	11 (19.0)	12 (20.7)	11 (19.0)
Hypogammaglobulinaemia	24 (41.4)	0	18 (31.0)	6 (10.3)	0
Graft versus host disease	3 (5.2)	0	0	3 (5.2)	0
Drug hypersensitivity	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Haemophagocytic lymphohistiocytosis	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Immunodeficiency	2 (3.4)	0	0	2 (3.4)	0
Seasonal allergy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Allergy to immunoglobulin therapy	1 (1.7)	1 (1.7)	0	0	0
Chronic graft versus host disease	1 (1.7)	0	1 (1.7)	0	0
Engraftment syndrome	1 (1.7)	0	0	1 (1.7)	0
Hypersensitivity	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	47 (81.0)	4 (6.9)	9 (15.5)	22 (37.9)	12 (20.7)
Upper respiratory tract infection	8 (13.8)	3 (5.2)	2 (3.4)	3 (5.2)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	7 (12.1)	3 (5.2)	4 (6.9)	0	0
Sinusitis	7 (12.1)	0	4 (6.9)	3 (5.2)	0
Gastroenteritis	6 (10.3)	3 (5.2)	1 (1.7)	2 (3.4)	0
Nasopharyngitis	6 (10.3)	4 (6.9)	2 (3.4)	0	0
Pneumonia	6 (10.3)	1 (1.7)	1 (1.7)	3 (5.2)	1 (1.7)
Oral herpes	5 (8.6)	1 (1.7)	2 (3.4)	2 (3.4)	0
Rhinovirus infection	5 (8.6)	0	4 (6.9)	1 (1.7)	0
Parainfluenzae virus infection	4 (6.9)	0	0	3 (5.2)	1 (1.7)
Paronychia	4 (6.9)	0	3 (5.2)	1 (1.7)	0
Bacteraemia	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Bronchopulmonary aspergillosis	3 (5.2)	0	0	2 (3.4)	1 (1.7)
Candida infection	3 (5.2)	0	2 (3.4)	0	1 (1.7)
Catheter site infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Device related infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Gingivitis	3 (5.2)	3 (5.2)	0	0	0
Herpes zoster	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Metapneumovirus infection	3 (5.2)	0	0	3 (5.2)	0
Oral candidiasis	3 (5.2)	0	3 (5.2)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Respiratory syncytial virus infection	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Rhinitis	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Sepsis	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Septic shock	3 (5.2)	0	0	0	3 (5.2)
Urinary tract infection	3 (5.2)	0	2 (3.4)	1 (1.7)	0
Cytomegalovirus infection reactivation	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Escherichia bacteraemia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Fungal infection	2 (3.4)	0	2 (3.4)	0	0
Human herpesvirus 6 infection	2 (3.4)	0	0	2 (3.4)	0
Influenza	2 (3.4)	0	2 (3.4)	0	0
Nail infection	2 (3.4)	2 (3.4)	0	0	0
Oral infection	2 (3.4)	0	2 (3.4)	0	0
Otitis externa	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pneumocystis jirovecii pneumonia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Respiratory tract infection	2 (3.4)	0	2 (3.4)	0	0
Skin infection	2 (3.4)	0	2 (3.4)	0	0
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (3.4)	0	0	2 (3.4)	0
Staphylococcal skin infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Tinea pedis	2 (3.4)	2 (3.4)	0	0	0
Varicella zoster virus infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Viral infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Adenovirus infection	1 (1.7)	0	0	1 (1.7)	0
Anal abscess	1 (1.7)	0	0	1 (1.7)	0
Bk virus infection	1 (1.7)	1 (1.7)	0	0	0
Bronchiolitis	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Cholecystitis infective	1 (1.7)	0	1 (1.7)	0	0
Clostridium difficile infection	1 (1.7)	0	0	1 (1.7)	0
Coronavirus infection	1 (1.7)	0	0	1 (1.7)	0
Covid-19	1 (1.7)	0	0	1 (1.7)	0
Cystitis	1 (1.7)	0	1 (1.7)	0	0
Device related bacteraemia	1 (1.7)	0	1 (1.7)	0	0
Device related sepsis	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (1.7)	0	0	1 (1.7)	0
Ear, nose and throat infection	1 (1.7)	0	1 (1.7)	0	0
Encephalitis	1 (1.7)	0	0	0	1 (1.7)
Encephalitis viral	1 (1.7)	0	0	1 (1.7)	0
Enterobacter infection	1 (1.7)	0	0	1 (1.7)	0
Epstein-barr virus infection	1 (1.7)	0	1 (1.7)	0	0
Fungaemia	1 (1.7)	0	0	0	1 (1.7)
Fungal pharyngitis	1 (1.7)	0	0	1 (1.7)	0
Fungal skin infection	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Granulicatella infection	1 (1.7)	0	0	1 (1.7)	0
Herpes simplex	1 (1.7)	0	0	1 (1.7)	0
Herpes virus infection	1 (1.7)	0	1 (1.7)	0	0
Klebsiella bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Klebsiella infection	1 (1.7)	0	0	1 (1.7)	0
Mastoiditis	1 (1.7)	0	0	1 (1.7)	0
Meningitis pneumococcal	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myringitis	1 (1.7)	1 (1.7)	0	0	0
Neutropenic infection	1 (1.7)	0	0	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Peritonitis	1 (1.7)	0	0	1 (1.7)	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Pneumonia viral	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	1 (1.7)	0	0
Salmonellosis	1 (1.7)	0	1 (1.7)	0	0
Soft tissue infection	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal sepsis	1 (1.7)	0	0	0	1 (1.7)
Stomatococcal infection	1 (1.7)	0	0	0	1 (1.7)
Streptococcal sepsis	1 (1.7)	0	1 (1.7)	0	0
Systemic candida	1 (1.7)	0	0	1 (1.7)	0
Urinary tract infection pseudomonal	1 (1.7)	0	1 (1.7)	0	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral skin infection	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	16 (27.6)	7 (12.1)	6 (10.3)	1 (1.7)	2 (3.4)
Infusion related reaction	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Fall	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Ligament sprain	2 (3.4)	2 (3.4)	0	0	0
Procedural pain	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Contusion	1 (1.7)	1 (1.7)	0	0	0
Extradural haematoma	1 (1.7)	0	1 (1.7)	0	0
Limb injury	1 (1.7)	0	1 (1.7)	0	0
Skin abrasion	1 (1.7)	1 (1.7)	0	0	0
Tracheal obstruction	1 (1.7)	0	0	0	1 (1.7)
Transfusion reaction	1 (1.7)	1 (1.7)	0	0	0
Transplant failure	1 (1.7)	0	0	0	1 (1.7)
Traumatic haematoma	1 (1.7)	0	1 (1.7)	0	0
Wound	1 (1.7)	1 (1.7)	0	0	0
Investigations					

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	40 (69.0)	1 (1.7)	4 (6.9)	13 (22.4)	22 (37.9)
Neutrophil count decreased	20 (34.5)	1 (1.7)	1 (1.7)	1 (1.7)	17 (29.3)
Platelet count decreased	18 (31.0)	4 (6.9)	0	5 (8.6)	9 (15.5)
White blood cell count decreased	18 (31.0)	2 (3.4)	0	0	16 (27.6)
Alanine aminotransferase increased	15 (25.9)	2 (3.4)	6 (10.3)	7 (12.1)	0
Lymphocyte count decreased	14 (24.1)	0	0	4 (6.9)	10 (17.2)
Aspartate aminotransferase increased	11 (19.0)	2 (3.4)	3 (5.2)	4 (6.9)	2 (3.4)
C-reactive protein increased	7 (12.1)	2 (3.4)	1 (1.7)	4 (6.9)	0
Blood bilirubin increased	6 (10.3)	0	1 (1.7)	5 (8.6)	0
Blood immunoglobulin a decreased	6 (10.3)	5 (8.6)	0	1 (1.7)	0
Blood immunoglobulin m decreased	5 (8.6)	4 (6.9)	0	1 (1.7)	0
Serum ferritin increased	5 (8.6)	1 (1.7)	3 (5.2)	1 (1.7)	0
Blood fibrinogen decreased	4 (6.9)	2 (3.4)	1 (1.7)	0	1 (1.7)
Activated partial thromboplastin time prolonged	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Blood creatinine increased	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Blood lactate dehydrogenase increased	3 (5.2)	2 (3.4)	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	3 (5.2)	1 (1.7)	0	1 (1.7)	1 (1.7)
International normalised ratio increased	3 (5.2)	3 (5.2)	0	0	0
Weight decreased	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Weight increased	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Blood fibrinogen increased	2 (3.4)	2 (3.4)	0	0	0
Blood glucose increased	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Immunoglobulins decreased	2 (3.4)	0	2 (3.4)	0	0
Blood alkaline phosphatase decreased	1 (1.7)	1 (1.7)	0	0	0
Blood creatine phosphokinase increased	1 (1.7)	0	0	1 (1.7)	0
Blood phosphorus decreased	1 (1.7)	0	0	1 (1.7)	0
Blood potassium decreased	1 (1.7)	0	0	0	1 (1.7)
Blood testosterone decreased	1 (1.7)	1 (1.7)	0	0	0
Blood urea increased	1 (1.7)	0	0	1 (1.7)	0
Bone density decreased	1 (1.7)	1 (1.7)	0	0	0
Breath sounds abnormal	1 (1.7)	0	1 (1.7)	0	0
Coagulation test abnormal	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	1 (1.7)	0	0	1 (1.7)	0
Enterovirus test positive	1 (1.7)	0	1 (1.7)	0	0
Eosinophil count decreased	1 (1.7)	1 (1.7)	0	0	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Gamma-glutamyltransferase increased	1 (1.7)	0	0	1 (1.7)	0
Haematocrit decreased	1 (1.7)	1 (1.7)	0	0	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Hepatitis b virus test positive	1 (1.7)	0	1 (1.7)	0	0
Oxygen saturation decreased	1 (1.7)	0	1 (1.7)	0	0
Prothrombin time prolonged	1 (1.7)	0	1 (1.7)	0	0
Red blood cell count decreased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	33 (56.9)	5 (8.6)	6 (10.3)	15 (25.9)	7 (12.1)
Decreased appetite	19 (32.8)	7 (12.1)	4 (6.9)	6 (10.3)	2 (3.4)
Hypokalaemia	16 (27.6)	3 (5.2)	2 (3.4)	9 (15.5)	2 (3.4)
Hypophosphataemia	12 (20.7)	3 (5.2)	4 (6.9)	4 (6.9)	1 (1.7)
Hypocalcaemia	7 (12.1)	2 (3.4)	2 (3.4)	3 (5.2)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	5 (8.6)	0	5 (8.6)	0	0
Hypervolaemia	4 (6.9)	1 (1.7)	1 (1.7)	2 (3.4)	0
Hypomagnesaemia	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Tumour lysis syndrome	4 (6.9)	0	0	2 (3.4)	2 (3.4)
Hyperglycaemia	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Hyperuricaemia	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Hypernatraemia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hypertriglyceridaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Iron overload	2 (3.4)	0	2 (3.4)	0	0
Malnutrition	2 (3.4)	0	0	2 (3.4)	0
Eating disorder symptom	1 (1.7)	0	1 (1.7)	0	0
Haemochromatosis	1 (1.7)	0	0	1 (1.7)	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hypercholesterolaemia	1 (1.7)	0	1 (1.7)	0	0
Hyperkalaemia	1 (1.7)	0	1 (1.7)	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperphosphataemia	1 (1.7)	1 (1.7)	0	0	0
Hyponatraemia	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophagia	1 (1.7)	0	1 (1.7)	0	0
Polydipsia	1 (1.7)	0	0	1 (1.7)	0
Vitamin d deficiency	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	29 (50.0)	11 (19.0)	13 (22.4)	5 (8.6)	0
Pain in extremity	13 (22.4)	5 (8.6)	7 (12.1)	1 (1.7)	0
Arthralgia	9 (15.5)	5 (8.6)	4 (6.9)	0	0
Back pain	9 (15.5)	2 (3.4)	4 (6.9)	3 (5.2)	0
Myalgia	5 (8.6)	3 (5.2)	2 (3.4)	0	0
Bone pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Growth retardation	2 (3.4)	0	2 (3.4)	0	0
Joint effusion	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Musculoskeletal chest pain	2 (3.4)	2 (3.4)	0	0	0
Pain in jaw	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Groin pain	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal pain	1 (1.7)	0	1 (1.7)	0	0
Myopathy	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neck pain	1 (1.7)	0	1 (1.7)	0	0
Osteonecrosis	1 (1.7)	1 (1.7)	0	0	0
Osteopenia	1 (1.7)	1 (1.7)	0	0	0
Spinal pain	1 (1.7)	0	0	1 (1.7)	0
Synovitis	1 (1.7)	0	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (6.9)	1 (1.7)	1 (1.7)	2 (3.4)	0
Skin papilloma	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Bone giant cell tumour benign	1 (1.7)	0	0	1 (1.7)	0
Myelodysplastic syndrome	1 (1.7)	0	0	1 (1.7)	0
Nervous system disorders					
-Total	31 (53.4)	11 (19.0)	9 (15.5)	8 (13.8)	3 (5.2)
Headache	17 (29.3)	9 (15.5)	5 (8.6)	3 (5.2)	0
Encephalopathy	5 (8.6)	1 (1.7)	2 (3.4)	2 (3.4)	0
Dizziness	4 (6.9)	4 (6.9)	0	0	0
Seizure	4 (6.9)	0	1 (1.7)	3 (5.2)	0
Tremor	3 (5.2)	3 (5.2)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysgeusia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Lethargy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Neuropathy peripheral	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Somnolence	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Amnesia	1 (1.7)	0	1 (1.7)	0	0
Aphasia	1 (1.7)	1 (1.7)	0	0	0
Autonomic neuropathy	1 (1.7)	0	0	1 (1.7)	0
Cerebral haemorrhage	1 (1.7)	0	0	0	1 (1.7)
Cognitive disorder	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	0	0	1 (1.7)	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	0	1 (1.7)	0	0
Haemorrhage intracranial	1 (1.7)	0	0	0	1 (1.7)
Hydrocephalus	1 (1.7)	0	0	0	1 (1.7)
Hyperaesthesia	1 (1.7)	1 (1.7)	0	0	0
Hypoaesthesia	1 (1.7)	1 (1.7)	0	0	0
Memory impairment	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorder	1 (1.7)	0	0	1 (1.7)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neuralgia	1 (1.7)	0	1 (1.7)	0	0
Paraesthesia	1 (1.7)	0	1 (1.7)	0	0
Psychiatric disorders					
-Total	24 (41.4)	8 (13.8)	14 (24.1)	2 (3.4)	0
Anxiety	11 (19.0)	4 (6.9)	6 (10.3)	1 (1.7)	0
Agitation	4 (6.9)	4 (6.9)	0	0	0
Confusional state	4 (6.9)	4 (6.9)	0	0	0
Insomnia	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Delirium	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Hallucination	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Irritability	2 (3.4)	2 (3.4)	0	0	0
Mental status changes	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Sleep disorder	2 (3.4)	0	2 (3.4)	0	0
Affect lability	1 (1.7)	0	1 (1.7)	0	0
Hallucination, visual	1 (1.7)	0	1 (1.7)	0	0
Mood altered	1 (1.7)	1 (1.7)	0	0	0
Nightmare	1 (1.7)	1 (1.7)	0	0	0
Restlessness	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social avoidant behaviour	1 (1.7)	0	1 (1.7)	0	0
Tearfulness	1 (1.7)	1 (1.7)	0	0	0
Tic	1 (1.7)	0	1 (1.7)	0	0
Renal and urinary disorders					
-Total	16 (27.6)	6 (10.3)	5 (8.6)	2 (3.4)	3 (5.2)
Acute kidney injury	6 (10.3)	3 (5.2)	1 (1.7)	0	2 (3.4)
Dysuria	2 (3.4)	2 (3.4)	0	0	0
Haematuria	2 (3.4)	2 (3.4)	0	0	0
Anuria	1 (1.7)	0	0	0	1 (1.7)
Cystitis haemorrhagic	1 (1.7)	0	1 (1.7)	0	0
Incontinence	1 (1.7)	0	1 (1.7)	0	0
Pollakiuria	1 (1.7)	0	1 (1.7)	0	0
Proteinuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	1 (1.7)	0	0
Renal tubular disorder	1 (1.7)	0	0	1 (1.7)	0
Renal tubular dysfunction	1 (1.7)	1 (1.7)	0	0	0
Renal tubular necrosis	1 (1.7)	0	0	1 (1.7)	0
Urinary incontinence	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract disorder	1 (1.7)	0	1 (1.7)	0	0
Reproductive system and breast disorders					
-Total	5 (8.6)	1 (1.7)	2 (3.4)	2 (3.4)	0
Endometriosis	1 (1.7)	0	0	1 (1.7)	0
Female genital tract fistula	1 (1.7)	1 (1.7)	0	0	0
Heavy menstrual bleeding	1 (1.7)	0	1 (1.7)	0	0
Prostatitis	1 (1.7)	0	0	1 (1.7)	0
Vaginal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	40 (69.0)	16 (27.6)	6 (10.3)	8 (13.8)	10 (17.2)
Cough	20 (34.5)	16 (27.6)	4 (6.9)	0	0
Hypoxia	11 (19.0)	0	4 (6.9)	4 (6.9)	3 (5.2)
Epistaxis	9 (15.5)	7 (12.1)	0	2 (3.4)	0
Nasal congestion	8 (13.8)	7 (12.1)	1 (1.7)	0	0
Pulmonary oedema	7 (12.1)	3 (5.2)	0	4 (6.9)	0
Pleural effusion	6 (10.3)	3 (5.2)	2 (3.4)	0	1 (1.7)
Tachypnoea	6 (10.3)	3 (5.2)	2 (3.4)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	5 (8.6)	4 (6.9)	1 (1.7)	0	0
Dyspnoea	4 (6.9)	1 (1.7)	1 (1.7)	2 (3.4)	0
Oropharyngeal pain	4 (6.9)	4 (6.9)	0	0	0
Respiratory failure	3 (5.2)	0	0	0	3 (5.2)
Acute respiratory distress syndrome	2 (3.4)	0	0	0	2 (3.4)
Atelectasis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pharyngeal erythema	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Respiratory distress	2 (3.4)	0	1 (1.7)	0	1 (1.7)
Bradypnoea	1 (1.7)	0	0	1 (1.7)	0
Bronchial oedema	1 (1.7)	1 (1.7)	0	0	0
Dyspnoea exertional	1 (1.7)	1 (1.7)	0	0	0
Laryngeal oedema	1 (1.7)	0	0	0	1 (1.7)
Lung disorder	1 (1.7)	1 (1.7)	0	0	0
Lung infiltration	1 (1.7)	0	0	1 (1.7)	0
Nasal dryness	1 (1.7)	1 (1.7)	0	0	0
Oropharyngeal plaque	1 (1.7)	0	1 (1.7)	0	0
Painful respiration	1 (1.7)	1 (1.7)	0	0	0
Paranasal sinus discomfort	1 (1.7)	0	1 (1.7)	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paranasal sinus inflammation	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal exudate	1 (1.7)	0	1 (1.7)	0	0
Pharyngeal oedema	1 (1.7)	0	1 (1.7)	0	0
Productive cough	1 (1.7)	1 (1.7)	0	0	0
Pulmonary haemorrhage	1 (1.7)	0	0	0	1 (1.7)
Pulmonary mass	1 (1.7)	0	1 (1.7)	0	0
Respiratory disorder	1 (1.7)	0	1 (1.7)	0	0
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Sleep apnoea syndrome	1 (1.7)	1 (1.7)	0	0	0
Wheezing	1 (1.7)	0	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	29 (50.0)	14 (24.1)	9 (15.5)	6 (10.3)	0
Pruritus	6 (10.3)	3 (5.2)	3 (5.2)	0	0
Rash	6 (10.3)	3 (5.2)	3 (5.2)	0	0
Dry skin	5 (8.6)	3 (5.2)	2 (3.4)	0	0
Rash papular	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Dermatitis atopic	3 (5.2)	2 (3.4)	0	1 (1.7)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash maculo-papular	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Eczema	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Erythema	2 (3.4)	2 (3.4)	0	0	0
Skin ulcer	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Acne	1 (1.7)	1 (1.7)	0	0	0
Blister	1 (1.7)	1 (1.7)	0	0	0
Decubitus ulcer	1 (1.7)	0	0	1 (1.7)	0
Dermatitis allergic	1 (1.7)	1 (1.7)	0	0	0
Erythema nodosum	1 (1.7)	1 (1.7)	0	0	0
Hangnail	1 (1.7)	1 (1.7)	0	0	0
Hyperhidrosis	1 (1.7)	0	1 (1.7)	0	0
Ingrowing nail	1 (1.7)	0	1 (1.7)	0	0
Night sweats	1 (1.7)	1 (1.7)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.7)	1 (1.7)	0	0	0
Papule	1 (1.7)	1 (1.7)	0	0	0
Pruritus allergic	1 (1.7)	0	1 (1.7)	0	0
Purpura	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (1.7)	0	0	1 (1.7)	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin discolouration	1 (1.7)	1 (1.7)	0	0	0
Skin lesion	1 (1.7)	0	1 (1.7)	0	0
Skin swelling	1 (1.7)	1 (1.7)	0	0	0
Urticaria	1 (1.7)	0	1 (1.7)	0	0
Vancomycin infusion reaction	1 (1.7)	0	0	1 (1.7)	0
Social circumstances					
-Total	1 (1.7)	0	1 (1.7)	0	0
Patient uncooperative	1 (1.7)	0	1 (1.7)	0	0
Vascular disorders					
-Total	21 (36.2)	5 (8.6)	6 (10.3)	6 (10.3)	4 (6.9)
Hypotension	13 (22.4)	2 (3.4)	3 (5.2)	4 (6.9)	4 (6.9)
Hypertension	9 (15.5)	3 (5.2)	5 (8.6)	1 (1.7)	0
Capillary leak syndrome	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Flushing	2 (3.4)	2 (3.4)	0	0	0
Haematoma	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Peripheral ischaemia	1 (1.7)	0	1 (1.7)	0	0
Venoocclusive disease	1 (1.7)	0	0	1 (1.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208l
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (92.5)	0	2 (5.0)	6 (15.0)	29 (72.5)
Blood and lymphatic system disorders					
-Total	27 (67.5)	0	5 (12.5)	13 (32.5)	9 (22.5)
Febrile neutropenia	17 (42.5)	0	0	15 (37.5)	2 (5.0)
Anaemia	15 (37.5)	3 (7.5)	5 (12.5)	6 (15.0)	1 (2.5)
Neutropenia	6 (15.0)	1 (2.5)	1 (2.5)	1 (2.5)	3 (7.5)
Thrombocytopenia	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Disseminated intravascular coagulation	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Coagulopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Splenomegaly	2 (5.0)	2 (5.0)	0	0	0
Hypercoagulation	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypofibrinogenaemia	1 (2.5)	0	1 (2.5)	0	0
Lymphadenopathy	1 (2.5)	1 (2.5)	0	0	0
Lymphocytosis	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	18 (45.0)	5 (12.5)	4 (10.0)	4 (10.0)	5 (12.5)
Tachycardia	12 (30.0)	3 (7.5)	5 (12.5)	3 (7.5)	1 (2.5)
Cardiac failure	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Bradycardia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cardiac arrest	2 (5.0)	0	0	0	2 (5.0)
Sinus tachycardia	2 (5.0)	2 (5.0)	0	0	0
Atrioventricular block first degree	1 (2.5)	0	1 (2.5)	0	0
Cardiac dysfunction	1 (2.5)	1 (2.5)	0	0	0
Left ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Sinus bradycardia	1 (2.5)	0	0	1 (2.5)	0
Ear and labyrinth disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Ear pruritus	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.0)	0	4 (10.0)	0	0
Adrenal insufficiency	3 (7.5)	0	3 (7.5)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Conjunctival haemorrhage	2 (5.0)	2 (5.0)	0	0	0
Ocular hyperaemia	2 (5.0)	2 (5.0)	0	0	0
Eyelid oedema	1 (2.5)	0	1 (2.5)	0	0
Periorbital oedema	1 (2.5)	1 (2.5)	0	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	30 (75.0)	10 (25.0)	10 (25.0)	8 (20.0)	2 (5.0)
Nausea	13 (32.5)	4 (10.0)	7 (17.5)	2 (5.0)	0
Vomiting	11 (27.5)	8 (20.0)	1 (2.5)	2 (5.0)	0
Constipation	9 (22.5)	4 (10.0)	5 (12.5)	0	0
Diarrhoea	8 (20.0)	6 (15.0)	2 (5.0)	0	0
Abdominal pain	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Stomatitis	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Abdominal compartment syndrome	2 (5.0)	0	0	0	2 (5.0)
Gastrointestinal haemorrhage	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Gingival erythema	2 (5.0)	2 (5.0)	0	0	0
Haematemesis	2 (5.0)	2 (5.0)	0	0	0
Ileus	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Mouth haemorrhage	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Oral pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal distension	1 (2.5)	0	1 (2.5)	0	0
Anal fissure	1 (2.5)	0	1 (2.5)	0	0
Ascites	1 (2.5)	1 (2.5)	0	0	0
Dry mouth	1 (2.5)	0	1 (2.5)	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal inflammation	1 (2.5)	0	1 (2.5)	0	0
Gingival bleeding	1 (2.5)	1 (2.5)	0	0	0
Haemoperitoneum	1 (2.5)	0	0	0	1 (2.5)
Irritable bowel syndrome	1 (2.5)	0	1 (2.5)	0	0
Lip pain	1 (2.5)	1 (2.5)	0	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip ulceration	1 (2.5)	0	1 (2.5)	0	0
Melaena	1 (2.5)	0	0	1 (2.5)	0
Neutropenic colitis	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	27 (67.5)	7 (17.5)	10 (25.0)	6 (15.0)	4 (10.0)
Pyrexia	20 (50.0)	6 (15.0)	8 (20.0)	5 (12.5)	1 (2.5)
Fatigue	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Oedema peripheral	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Pain	4 (10.0)	0	4 (10.0)	0	0
Chills	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Generalised oedema	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Multiple organ dysfunction syndrome	3 (7.5)	0	0	0	3 (7.5)
Catheter site pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Drug withdrawal syndrome	2 (5.0)	0	2 (5.0)	0	0
Catheter site dermatitis	1 (2.5)	1 (2.5)	0	0	0
Catheter site haemorrhage	1 (2.5)	1 (2.5)	0	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Complication associated with device	1 (2.5)	1 (2.5)	0	0	0
Localised oedema	1 (2.5)	1 (2.5)	0	0	0
Malaise	1 (2.5)	1 (2.5)	0	0	0
Systemic inflammatory response syndrome	1 (2.5)	0	0	1 (2.5)	0
Vascular device occlusion	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	11 (27.5)	3 (7.5)	4 (10.0)	2 (5.0)	2 (5.0)
Hepatic function abnormal	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hyperbilirubinaemia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hypertransaminasaemia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Gallbladder enlargement	2 (5.0)	2 (5.0)	0	0	0
Biliary tract disorder	1 (2.5)	1 (2.5)	0	0	0
Cholelithiasis	1 (2.5)	1 (2.5)	0	0	0
Cholestasis	1 (2.5)	0	0	0	1 (2.5)
Hepatomegaly	1 (2.5)	0	0	0	1 (2.5)
Ocular icterus	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	28 (70.0)	1 (2.5)	9 (22.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	24 (60.0)	2 (5.0)	7 (17.5)	5 (12.5)	10 (25.0)
Hypogammaglobulinaemia	12 (30.0)	2 (5.0)	8 (20.0)	2 (5.0)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Seasonal allergy	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Immunodeficiency	2 (5.0)	0	0	2 (5.0)	0
Allergy to immunoglobulin therapy	1 (2.5)	0	0	1 (2.5)	0
Chronic graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	29 (72.5)	2 (5.0)	4 (10.0)	15 (37.5)	8 (20.0)
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Staphylococcal bacteraemia	5 (12.5)	0	0	5 (12.5)	0
Staphylococcal infection	5 (12.5)	0	3 (7.5)	1 (2.5)	1 (2.5)
Pneumonia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Rhinovirus infection	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised infection	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Parainfluenzae virus infection	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Acute sinusitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Bacteraemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Bronchitis	2 (5.0)	0	2 (5.0)	0	0
Conjunctivitis	2 (5.0)	0	2 (5.0)	0	0
Ear infection	2 (5.0)	0	2 (5.0)	0	0
Gastroenteritis viral	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Sinusitis	2 (5.0)	0	2 (5.0)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Aspergillus infection	1 (2.5)	0	0	0	1 (2.5)
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Bronchiolitis	1 (2.5)	0	0	1 (2.5)	0
Candida infection	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Covid-19	1 (2.5)	1 (2.5)	0	0	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Disseminated trichosporonosis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	0	0	1 (2.5)
Enterovirus infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal skin infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (2.5)	0	0	0	1 (2.5)
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Paronychia	1 (2.5)	1 (2.5)	0	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Vulval cellulitis	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	11 (27.5)	2 (5.0)	6 (15.0)	2 (5.0)	1 (2.5)
Transfusion reaction	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Infusion related reaction	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Procedural pain	2 (5.0)	0	2 (5.0)	0	0
Wound	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal injury	1 (2.5)	1 (2.5)	0	0	0
Contusion	1 (2.5)	1 (2.5)	0	0	0
Fibula fracture	1 (2.5)	0	1 (2.5)	0	0
Post-traumatic neck syndrome	1 (2.5)	0	1 (2.5)	0	0
Radius fracture	1 (2.5)	0	1 (2.5)	0	0
Scratch	1 (2.5)	1 (2.5)	0	0	0
Skin abrasion	1 (2.5)	1 (2.5)	0	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin injury	1 (2.5)	0	1 (2.5)	0	0
Skin wound	1 (2.5)	1 (2.5)	0	0	0
Vasoplegia syndrome	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	26 (65.0)	0	2 (5.0)	7 (17.5)	17 (42.5)
White blood cell count decreased	14 (35.0)	1 (2.5)	3 (7.5)	1 (2.5)	9 (22.5)
Aspartate aminotransferase increased	10 (25.0)	0	2 (5.0)	6 (15.0)	2 (5.0)
Platelet count decreased	10 (25.0)	2 (5.0)	2 (5.0)	1 (2.5)	5 (12.5)
Lymphocyte count decreased	9 (22.5)	1 (2.5)	1 (2.5)	5 (12.5)	2 (5.0)
Neutrophil count decreased	9 (22.5)	0	1 (2.5)	2 (5.0)	6 (15.0)
Alanine aminotransferase increased	7 (17.5)	3 (7.5)	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	7 (17.5)	1 (2.5)	1 (2.5)	5 (12.5)	0
International normalised ratio increased	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Serum ferritin increased	6 (15.0)	1 (2.5)	2 (5.0)	2 (5.0)	1 (2.5)
Blood creatinine increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)
Blood fibrinogen decreased	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Blood immunoglobulin g decreased	4 (10.0)	1 (2.5)	3 (7.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	4 (10.0)	1 (2.5)	0	3 (7.5)	0
C-reactive protein increased	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
Electrocardiogram qt prolonged	4 (10.0)	1 (2.5)	2 (5.0)	0	1 (2.5)
Activated partial thromboplastin time prolonged	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Fibrin d dimer increased	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Weight increased	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Amylase increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Blood immunoglobulin m decreased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Blood phosphorus increased	2 (5.0)	0	2 (5.0)	0	0
Lipase increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Oxygen saturation decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Urine output decreased	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Bacterial test positive	1 (2.5)	0	0	1 (2.5)	0
Blood alkaline phosphatase increased	1 (2.5)	1 (2.5)	0	0	0
Blood bicarbonate decreased	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (2.5)	0	0	0	1 (2.5)
Blood fibrinogen increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin a decreased	1 (2.5)	0	1 (2.5)	0	0
Blood thyroid stimulating hormone increased	1 (2.5)	1 (2.5)	0	0	0
Blood uric acid increased	1 (2.5)	1 (2.5)	0	0	0
Cardiac murmur	1 (2.5)	1 (2.5)	0	0	0
Ejection fraction decreased	1 (2.5)	0	1 (2.5)	0	0
Electrocardiogram t wave abnormal	1 (2.5)	0	1 (2.5)	0	0
Gamma-glutamyltransferase increased	1 (2.5)	0	0	1 (2.5)	0
Haptoglobin decreased	1 (2.5)	1 (2.5)	0	0	0
Heart sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Staphylococcus test positive	1 (2.5)	1 (2.5)	0	0	0
Troponin increased	1 (2.5)	0	0	1 (2.5)	0
Weight decreased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	26 (65.0)	3 (7.5)	5 (12.5)	11 (27.5)	7 (17.5)

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	15 (37.5)	5 (12.5)	4 (10.0)	6 (15.0)	0
Hypocalcaemia	11 (27.5)	0	8 (20.0)	3 (7.5)	0
Hypokalaemia	9 (22.5)	1 (2.5)	3 (7.5)	4 (10.0)	1 (2.5)
Hypophosphataemia	9 (22.5)	0	4 (10.0)	5 (12.5)	0
Hypoalbuminaemia	7 (17.5)	0	6 (15.0)	1 (2.5)	0
Hyperglycaemia	6 (15.0)	0	3 (7.5)	3 (7.5)	0
Hyperuricaemia	6 (15.0)	5 (12.5)	0	1 (2.5)	0
Metabolic acidosis	6 (15.0)	1 (2.5)	0	2 (5.0)	3 (7.5)
Hyperphosphataemia	5 (12.5)	4 (10.0)	0	0	1 (2.5)
Hypervolaemia	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Hypercalcaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hyperkalaemia	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Hyponatraemia	3 (7.5)	2 (5.0)	0	0	1 (2.5)
Acidosis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Calcium deficiency	1 (2.5)	1 (2.5)	0	0	0
Dehydration	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemosiderosis	1 (2.5)	0	1 (2.5)	0	0
Hyperchloraemia	1 (2.5)	1 (2.5)	0	0	0
Hyperlactacidaemia	1 (2.5)	1 (2.5)	0	0	0
Hyperlipidaemia	1 (2.5)	0	1 (2.5)	0	0
Hypermagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Hypernatraemia	1 (2.5)	0	0	0	1 (2.5)
Hypertriglyceridaemia	1 (2.5)	0	0	0	1 (2.5)
Hypoglycaemia	1 (2.5)	0	1 (2.5)	0	0
Metabolic syndrome	1 (2.5)	0	1 (2.5)	0	0
Obesity	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	19 (47.5)	7 (17.5)	6 (15.0)	5 (12.5)	1 (2.5)
Pain in extremity	10 (25.0)	4 (10.0)	4 (10.0)	2 (5.0)	0
Myalgia	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Arthralgia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Back pain	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Bone pain	2 (5.0)	0	2 (5.0)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Muscular weakness	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Haemarthrosis	1 (2.5)	0	0	1 (2.5)	0
Muscle rigidity	1 (2.5)	1 (2.5)	0	0	0
Muscle spasms	1 (2.5)	0	1 (2.5)	0	0
Myositis	1 (2.5)	0	1 (2.5)	0	0
Neck pain	1 (2.5)	1 (2.5)	0	0	0
Pain in jaw	1 (2.5)	0	0	1 (2.5)	0
Rhabdomyolysis	1 (2.5)	0	0	0	1 (2.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	1 (2.5)	0	0
Cancer pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	24 (60.0)	6 (15.0)	11 (27.5)	5 (12.5)	2 (5.0)
Headache	15 (37.5)	7 (17.5)	8 (20.0)	0	0
Encephalopathy	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Somnolence	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Cognitive disorder	3 (7.5)	0	1 (2.5)	2 (5.0)	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Lethargy	2 (5.0)	2 (5.0)	0	0	0
Seizure	2 (5.0)	0	2 (5.0)	0	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Dysgeusia	1 (2.5)	1 (2.5)	0	0	0
Extrapyramidal disorder	1 (2.5)	0	1 (2.5)	0	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Migraine	1 (2.5)	0	1 (2.5)	0	0
Monoparesis	1 (2.5)	0	1 (2.5)	0	0
Neurological decompensation	1 (2.5)	0	0	0	1 (2.5)
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Posterior reversible encephalopathy syndrome	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	17 (42.5)	5 (12.5)	4 (10.0)	8 (20.0)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anxiety	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Delirium	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Mental status changes	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Agitation	3 (7.5)	0	3 (7.5)	0	0
Confusional state	3 (7.5)	3 (7.5)	0	0	0
Insomnia	2 (5.0)	0	2 (5.0)	0	0
Irritability	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Automatism	1 (2.5)	1 (2.5)	0	0	0
Persistent depressive disorder	1 (2.5)	0	1 (2.5)	0	0
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	14 (35.0)	4 (10.0)	2 (5.0)	4 (10.0)	4 (10.0)
Acute kidney injury	9 (22.5)	2 (5.0)	1 (2.5)	3 (7.5)	3 (7.5)
Dysuria	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Haematuria	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Urinary retention	2 (5.0)	0	2 (5.0)	0	0
Anuria	1 (2.5)	1 (2.5)	0	0	0
Azotaemia	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bladder dilatation	1 (2.5)	0	1 (2.5)	0	0
Kidney enlargement	1 (2.5)	0	1 (2.5)	0	0
Micturition urgency	1 (2.5)	0	1 (2.5)	0	0
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Renal failure	1 (2.5)	0	0	0	1 (2.5)
Renal mass	1 (2.5)	0	1 (2.5)	0	0
Renal pain	1 (2.5)	1 (2.5)	0	0	0
Renal tubular necrosis	1 (2.5)	0	0	0	1 (2.5)
Reproductive system and breast disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Dysmenorrhoea	1 (2.5)	0	1 (2.5)	0	0
Perineal rash	1 (2.5)	0	1 (2.5)	0	0
Vaginal ulceration	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (55.0)	3 (7.5)	2 (5.0)	5 (12.5)	12 (30.0)
Hypoxia	10 (25.0)	0	1 (2.5)	6 (15.0)	3 (7.5)
Pulmonary oedema	7 (17.5)	0	3 (7.5)	2 (5.0)	2 (5.0)

Prior SCT therapy: No

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	7 (17.5)	0	0	0	7 (17.5)
Cough	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Oropharyngeal pain	6 (15.0)	4 (10.0)	2 (5.0)	0	0
Dyspnoea	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Pleural effusion	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Tachypnoea	4 (10.0)	0	0	3 (7.5)	1 (2.5)
Epistaxis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Nasal congestion	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Acute respiratory distress syndrome	2 (5.0)	0	0	0	2 (5.0)
Respiratory distress	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Acute respiratory failure	1 (2.5)	0	0	1 (2.5)	0
Atelectasis	1 (2.5)	0	0	1 (2.5)	0
Bronchospasm	1 (2.5)	0	1 (2.5)	0	0
Haemoptysis	1 (2.5)	0	1 (2.5)	0	0
Nasal discomfort	1 (2.5)	0	1 (2.5)	0	0
Pharyngeal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Respiratory acidosis	1 (2.5)	0	0	1 (2.5)	0
Rhinitis allergic	1 (2.5)	0	1 (2.5)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinorrhoea	1 (2.5)	0	1 (2.5)	0	0
Sleep apnoea syndrome	1 (2.5)	0	1 (2.5)	0	0
Upper respiratory tract inflammation	1 (2.5)	0	1 (2.5)	0	0
Wheezing	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (47.5)	8 (20.0)	9 (22.5)	2 (5.0)	0
Pruritus	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Dry skin	4 (10.0)	4 (10.0)	0	0	0
Erythema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Rash	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Ingrowing nail	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Petechiae	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Blister	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Hyperhidrosis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Skin ulcer	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Decubitus ulcer	1 (2.5)	0	1 (2.5)	0	0
Dermatitis	1 (2.5)	1 (2.5)	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dermatitis diaper	1 (2.5)	0	1 (2.5)	0	0
Drug eruption	1 (2.5)	0	1 (2.5)	0	0
Eczema	1 (2.5)	1 (2.5)	0	0	0
Miliaria	1 (2.5)	1 (2.5)	0	0	0
Photosensitivity reaction	1 (2.5)	0	1 (2.5)	0	0
Rash erythematous	1 (2.5)	1 (2.5)	0	0	0
Rash maculo-papular	1 (2.5)	1 (2.5)	0	0	0
Scab	1 (2.5)	1 (2.5)	0	0	0
Skin discolouration	1 (2.5)	1 (2.5)	0	0	0
Skin hypopigmentation	1 (2.5)	1 (2.5)	0	0	0
Skin necrosis	1 (2.5)	0	0	1 (2.5)	0
Surgical and medical procedures					
-Total	1 (2.5)	0	0	1 (2.5)	0
Thrombolysis	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	22 (55.0)	0	5 (12.5)	10 (25.0)	7 (17.5)
Hypotension	17 (42.5)	0	3 (7.5)	8 (20.0)	6 (15.0)
Hypertension	10 (25.0)	1 (2.5)	5 (12.5)	4 (10.0)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peripheral ischaemia	1 (2.5)	0	1 (2.5)	0	0
Thrombosis	1 (2.5)	0	1 (2.5)	0	0
Venoocclusive disease	1 (2.5)	0	0	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208m
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	2 (11.8)	5 (29.4)	10 (58.8)
Blood and lymphatic system disorders					
-Total	13 (76.5)	1 (5.9)	2 (11.8)	8 (47.1)	2 (11.8)
Febrile neutropenia	9 (52.9)	0	0	9 (52.9)	0
Anaemia	8 (47.1)	3 (17.6)	5 (29.4)	0	0
Neutropenia	2 (11.8)	0	0	0	2 (11.8)
Disseminated intravascular coagulation	1 (5.9)	0	1 (5.9)	0	0
Hypofibrinogenaemia	1 (5.9)	0	1 (5.9)	0	0
Leukopenia	1 (5.9)	0	0	0	1 (5.9)
Splenomegaly	1 (5.9)	1 (5.9)	0	0	0
Cardiac disorders					

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (41.2)	6 (35.3)	0	1 (5.9)	0
Tachycardia	6 (35.3)	6 (35.3)	0	0	0
Cardiac dysfunction	1 (5.9)	1 (5.9)	0	0	0
Left ventricular dysfunction	1 (5.9)	0	0	1 (5.9)	0
Congenital, familial and genetic disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Cerebral cavernous malformation	1 (5.9)	1 (5.9)	0	0	0
Ear and labyrinth disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Deafness unilateral	1 (5.9)	0	1 (5.9)	0	0
Ear pain	1 (5.9)	1 (5.9)	0	0	0
Eye disorders					
-Total	4 (23.5)	4 (23.5)	0	0	0
Ocular hyperaemia	2 (11.8)	2 (11.8)	0	0	0
Cataract	1 (5.9)	1 (5.9)	0	0	0
Vision blurred	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	12 (70.6)	2 (11.8)	7 (41.2)	3 (17.6)	0
Nausea	9 (52.9)	6 (35.3)	3 (17.6)	0	0
Vomiting	7 (41.2)	4 (23.5)	3 (17.6)	0	0
Diarrhoea	5 (29.4)	5 (29.4)	0	0	0
Abdominal pain	4 (23.5)	1 (5.9)	2 (11.8)	1 (5.9)	0
Constipation	3 (17.6)	3 (17.6)	0	0	0
Haematemesis	2 (11.8)	2 (11.8)	0	0	0
Neutropenic colitis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Proctalgia	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Stomatitis	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Anal fissure	1 (5.9)	0	1 (5.9)	0	0
Anal fistula	1 (5.9)	0	0	1 (5.9)	0
Anal haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Duodenal perforation	1 (5.9)	0	0	1 (5.9)	0
Enteritis	1 (5.9)	0	1 (5.9)	0	0
Enterocolitis	1 (5.9)	0	1 (5.9)	0	0
Gastritis	1 (5.9)	0	1 (5.9)	0	0
Gastrointestinal sounds abnormal	1 (5.9)	1 (5.9)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrooesophageal reflux disease	1 (5.9)	0	1 (5.9)	0	0
Gingival bleeding	1 (5.9)	1 (5.9)	0	0	0
Haemorrhoids	1 (5.9)	0	1 (5.9)	0	0
Lip oedema	1 (5.9)	1 (5.9)	0	0	0
Trichoglossia	1 (5.9)	1 (5.9)	0	0	0
General disorders and administration site conditions					
-Total	8 (47.1)	7 (41.2)	1 (5.9)	0	0
Fatigue	7 (41.2)	6 (35.3)	1 (5.9)	0	0
Pyrexia	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Catheter site dermatitis	1 (5.9)	1 (5.9)	0	0	0
Catheter site haemorrhage	1 (5.9)	1 (5.9)	0	0	0
Chills	1 (5.9)	1 (5.9)	0	0	0
Generalised oedema	1 (5.9)	1 (5.9)	0	0	0
Non-cardiac chest pain	1 (5.9)	1 (5.9)	0	0	0
Oedema peripheral	1 (5.9)	1 (5.9)	0	0	0
Vascular device occlusion	1 (5.9)	1 (5.9)	0	0	0
Xerosis	1 (5.9)	1 (5.9)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	5 (29.4)	2 (11.8)	1 (5.9)	1 (5.9)	1 (5.9)
Hepatic function abnormal	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Drug-induced liver injury	1 (5.9)	0	0	1 (5.9)	0
Hepatomegaly	1 (5.9)	1 (5.9)	0	0	0
Ocular icterus	1 (5.9)	1 (5.9)	0	0	0
Immune system disorders					
-Total	13 (76.5)	0	7 (41.2)	5 (29.4)	1 (5.9)
Cytokine release syndrome	11 (64.7)	0	5 (29.4)	5 (29.4)	1 (5.9)
Hypogammaglobulinaemia	6 (35.3)	0	6 (35.3)	0	0
Infections and infestations					
-Total	11 (64.7)	2 (11.8)	1 (5.9)	7 (41.2)	1 (5.9)
Acute sinusitis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Catheter site infection	2 (11.8)	0	0	2 (11.8)	0
Tinea pedis	2 (11.8)	2 (11.8)	0	0	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Anal abscess	1 (5.9)	0	0	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	0	0	1 (5.9)

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Conjunctivitis	1 (5.9)	0	1 (5.9)	0	0
Ear infection	1 (5.9)	0	0	1 (5.9)	0
Epstein-barr virus infection	1 (5.9)	0	1 (5.9)	0	0
Fungal pharyngitis	1 (5.9)	0	0	1 (5.9)	0
Fungal skin infection	1 (5.9)	0	0	1 (5.9)	0
Gastroenteritis	1 (5.9)	1 (5.9)	0	0	0
Herpes zoster	1 (5.9)	0	1 (5.9)	0	0
Influenza	1 (5.9)	0	1 (5.9)	0	0
Nasopharyngitis	1 (5.9)	1 (5.9)	0	0	0
Oral herpes	1 (5.9)	1 (5.9)	0	0	0
Otitis externa	1 (5.9)	0	1 (5.9)	0	0
Otitis media	1 (5.9)	0	1 (5.9)	0	0
Paronychia	1 (5.9)	0	1 (5.9)	0	0
Peritonitis	1 (5.9)	0	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	1 (5.9)	0
Sinusitis	1 (5.9)	0	1 (5.9)	0	0
Skin infection	1 (5.9)	0	1 (5.9)	0	0
Staphylococcal abscess	1 (5.9)	0	0	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Staphylococcal infection	1 (5.9)	0	0	1 (5.9)	0
Systemic mycosis	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection viral	1 (5.9)	1 (5.9)	0	0	0
Varicella zoster virus infection	1 (5.9)	0	0	1 (5.9)	0
Vascular device infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Transfusion reaction	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Contusion	1 (5.9)	1 (5.9)	0	0	0
Infusion related reaction	1 (5.9)	1 (5.9)	0	0	0
Procedural pain	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	11 (64.7)	1 (5.9)	0	4 (23.5)	6 (35.3)
Neutrophil count decreased	9 (52.9)	1 (5.9)	2 (11.8)	1 (5.9)	5 (29.4)
Platelet count decreased	9 (52.9)	4 (23.5)	1 (5.9)	4 (23.5)	0
White blood cell count decreased	9 (52.9)	2 (11.8)	2 (11.8)	0	5 (29.4)

Eligibility for SCT: Yes

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (41.2)	0	1 (5.9)	4 (23.5)	2 (11.8)
Blood immunoglobulin a decreased	6 (35.3)	5 (29.4)	0	1 (5.9)	0
International normalised ratio increased	6 (35.3)	5 (29.4)	1 (5.9)	0	0
Alanine aminotransferase increased	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Aspartate aminotransferase increased	5 (29.4)	0	1 (5.9)	4 (23.5)	0
Blood immunoglobulin m decreased	5 (29.4)	4 (23.5)	0	1 (5.9)	0
Blood bilirubin increased	4 (23.5)	1 (5.9)	0	3 (17.6)	0
Blood fibrinogen decreased	4 (23.5)	3 (17.6)	1 (5.9)	0	0
Activated partial thromboplastin time prolonged	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Serum ferritin increased	2 (11.8)	0	2 (11.8)	0	0
Weight increased	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Blood creatine phosphokinase increased	1 (5.9)	0	0	1 (5.9)	0
Blood creatinine increased	1 (5.9)	0	0	1 (5.9)	0
Blood fibrinogen increased	1 (5.9)	1 (5.9)	0	0	0
Blood lactate dehydrogenase increased	1 (5.9)	1 (5.9)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood uric acid increased	1 (5.9)	1 (5.9)	0	0	0
C-reactive protein increased	1 (5.9)	1 (5.9)	0	0	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Haemoglobin decreased	1 (5.9)	0	0	1 (5.9)	0
Metabolism and nutrition disorders					
-Total	10 (58.8)	2 (11.8)	2 (11.8)	6 (35.3)	0
Decreased appetite	8 (47.1)	4 (23.5)	2 (11.8)	2 (11.8)	0
Hyperphosphataemia	3 (17.6)	3 (17.6)	0	0	0
Hypokalaemia	3 (17.6)	0	0	3 (17.6)	0
Hyperuricaemia	2 (11.8)	2 (11.8)	0	0	0
Hypophosphataemia	2 (11.8)	0	0	2 (11.8)	0
Dehydration	1 (5.9)	0	1 (5.9)	0	0
Hypertriglyceridaemia	1 (5.9)	0	0	1 (5.9)	0
Hypoalbuminaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Metabolic acidosis	1 (5.9)	1 (5.9)	0	0	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	9 (52.9)	7 (41.2)	2 (11.8)	0	0
Pain in extremity	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Myalgia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Arthralgia	3 (17.6)	3 (17.6)	0	0	0
Nervous system disorders					
-Total	9 (52.9)	7 (41.2)	1 (5.9)	0	1 (5.9)
Headache	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Dizziness	1 (5.9)	1 (5.9)	0	0	0
Haemorrhage intracranial	1 (5.9)	0	0	0	1 (5.9)
Hypoaesthesia	1 (5.9)	1 (5.9)	0	0	0
Lethargy	1 (5.9)	1 (5.9)	0	0	0
Neuropathy peripheral	1 (5.9)	1 (5.9)	0	0	0
Tremor	1 (5.9)	1 (5.9)	0	0	0
Psychiatric disorders					
-Total	6 (35.3)	4 (23.5)	1 (5.9)	1 (5.9)	0
Anxiety	2 (11.8)	1 (5.9)	1 (5.9)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	2 (11.8)	2 (11.8)	0	0	0
Mental status changes	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Agitation	1 (5.9)	1 (5.9)	0	0	0
Irritability	1 (5.9)	1 (5.9)	0	0	0
Renal and urinary disorders					
-Total	6 (35.3)	2 (11.8)	2 (11.8)	1 (5.9)	1 (5.9)
Acute kidney injury	1 (5.9)	0	0	0	1 (5.9)
Cystitis haemorrhagic	1 (5.9)	0	1 (5.9)	0	0
Dysuria	1 (5.9)	1 (5.9)	0	0	0
Micturition urgency	1 (5.9)	0	1 (5.9)	0	0
Pollakiuria	1 (5.9)	0	1 (5.9)	0	0
Renal tubular dysfunction	1 (5.9)	1 (5.9)	0	0	0
Renal tubular necrosis	1 (5.9)	0	0	1 (5.9)	0
Reproductive system and breast disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Prostatitis	1 (5.9)	0	0	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders					

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	10 (58.8)	4 (23.5)	2 (11.8)	2 (11.8)	2 (11.8)
Cough	5 (29.4)	5 (29.4)	0	0	0
Rhinorrhoea	4 (23.5)	4 (23.5)	0	0	0
Hypoxia	3 (17.6)	0	1 (5.9)	1 (5.9)	1 (5.9)
Nasal congestion	3 (17.6)	3 (17.6)	0	0	0
Oropharyngeal pain	3 (17.6)	3 (17.6)	0	0	0
Epistaxis	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Pleural effusion	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Tachypnoea	2 (11.8)	2 (11.8)	0	0	0
Dyspnoea	1 (5.9)	1 (5.9)	0	0	0
Laryngeal oedema	1 (5.9)	0	0	0	1 (5.9)
Paranasal sinus inflammation	1 (5.9)	1 (5.9)	0	0	0
Respiratory distress	1 (5.9)	0	1 (5.9)	0	0
Sleep apnoea syndrome	1 (5.9)	1 (5.9)	0	0	0
Upper respiratory tract inflammation	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (52.9)	6 (35.3)	2 (11.8)	1 (5.9)	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Rash papular	3 (17.6)	3 (17.6)	0	0	0
Eczema	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Pruritus	2 (11.8)	2 (11.8)	0	0	0
Skin ulcer	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Blister	1 (5.9)	1 (5.9)	0	0	0
Dermatitis	1 (5.9)	1 (5.9)	0	0	0
Erythema nodosum	1 (5.9)	1 (5.9)	0	0	0
Rash maculo-papular	1 (5.9)	1 (5.9)	0	0	0
Rash pruritic	1 (5.9)	1 (5.9)	0	0	0
Skin swelling	1 (5.9)	1 (5.9)	0	0	0
Vascular disorders					
-Total	4 (23.5)	2 (11.8)	0	1 (5.9)	1 (5.9)
Hypotension	3 (17.6)	1 (5.9)	0	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	1 (5.9)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208m
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (96.3)	0	3 (3.7)	15 (18.5)	60 (74.1)
Blood and lymphatic system disorders					
-Total	54 (66.7)	0	7 (8.6)	29 (35.8)	18 (22.2)
Anaemia	30 (37.0)	2 (2.5)	6 (7.4)	21 (25.9)	1 (1.2)
Febrile neutropenia	30 (37.0)	0	0	27 (33.3)	3 (3.7)
Neutropenia	14 (17.3)	1 (1.2)	2 (2.5)	3 (3.7)	8 (9.9)
Thrombocytopenia	13 (16.0)	0	1 (1.2)	5 (6.2)	7 (8.6)
Disseminated intravascular coagulation	7 (8.6)	0	4 (4.9)	3 (3.7)	0
Coagulopathy	5 (6.2)	1 (1.2)	2 (2.5)	2 (2.5)	0
Leukopenia	4 (4.9)	0	0	1 (1.2)	3 (3.7)
Pancytopenia	4 (4.9)	0	0	3 (3.7)	1 (1.2)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Lymphadenopathy	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Lymphopenia	2 (2.5)	0	0	0	2 (2.5)
Agranulocytosis	1 (1.2)	0	0	1 (1.2)	0
B-cell aplasia	1 (1.2)	0	1 (1.2)	0	0
Eosinophilia	1 (1.2)	0	1 (1.2)	0	0
Hypercoagulation	1 (1.2)	0	1 (1.2)	0	0
Leukocytosis	1 (1.2)	0	1 (1.2)	0	0
Lymphocytosis	1 (1.2)	0	1 (1.2)	0	0
Cardiac disorders					
-Total	28 (34.6)	4 (4.9)	8 (9.9)	10 (12.3)	6 (7.4)
Tachycardia	15 (18.5)	1 (1.2)	8 (9.9)	5 (6.2)	1 (1.2)
Cardiac failure	4 (4.9)	0	0	2 (2.5)	2 (2.5)
Left ventricular dysfunction	4 (4.9)	0	1 (1.2)	3 (3.7)	0
Bradycardia	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Cardiac arrest	3 (3.7)	0	0	0	3 (3.7)
Sinus tachycardia	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Pericardial effusion	2 (2.5)	1 (1.2)	0	1 (1.2)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Atrioventricular block first degree	1 (1.2)	0	1 (1.2)	0	0
Cardiac dysfunction	1 (1.2)	1 (1.2)	0	0	0
Cardiac failure congestive	1 (1.2)	0	1 (1.2)	0	0
Mitral valve incompetence	1 (1.2)	1 (1.2)	0	0	0
Right ventricular dysfunction	1 (1.2)	1 (1.2)	0	0	0
Sinus bradycardia	1 (1.2)	0	0	1 (1.2)	0
Tricuspid valve incompetence	1 (1.2)	1 (1.2)	0	0	0
Ear and labyrinth disorders					
-Total	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Ear pruritus	1 (1.2)	1 (1.2)	0	0	0
Vertigo	1 (1.2)	0	1 (1.2)	0	0
Endocrine disorders					
-Total	9 (11.1)	0	9 (11.1)	0	0
Adrenal insufficiency	6 (7.4)	0	6 (7.4)	0	0
Hypothyroidism	3 (3.7)	0	3 (3.7)	0	0
Delayed puberty	1 (1.2)	0	1 (1.2)	0	0
Eye disorders					
-Total	13 (16.0)	7 (8.6)	5 (6.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Eyelid oedema	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Conjunctival haemorrhage	2 (2.5)	2 (2.5)	0	0	0
Visual impairment	2 (2.5)	2 (2.5)	0	0	0
Cataract	1 (1.2)	1 (1.2)	0	0	0
Dry eye	1 (1.2)	1 (1.2)	0	0	0
Eye oedema	1 (1.2)	1 (1.2)	0	0	0
Hypermetropia	1 (1.2)	1 (1.2)	0	0	0
Mydriasis	1 (1.2)	0	1 (1.2)	0	0
Ocular hyperaemia	1 (1.2)	1 (1.2)	0	0	0
Periorbital oedema	1 (1.2)	1 (1.2)	0	0	0
Periorbital swelling	1 (1.2)	0	1 (1.2)	0	0
Retinal haemorrhage	1 (1.2)	0	1 (1.2)	0	0
Visual field defect	1 (1.2)	0	1 (1.2)	0	0
Gastrointestinal disorders					
-Total	60 (74.1)	18 (22.2)	23 (28.4)	17 (21.0)	2 (2.5)
Nausea	24 (29.6)	8 (9.9)	13 (16.0)	3 (3.7)	0
Vomiting	23 (28.4)	16 (19.8)	5 (6.2)	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	22 (27.2)	12 (14.8)	8 (9.9)	2 (2.5)	0
Constipation	16 (19.8)	6 (7.4)	10 (12.3)	0	0
Abdominal pain	13 (16.0)	4 (4.9)	8 (9.9)	1 (1.2)	0
Stomatitis	9 (11.1)	0	5 (6.2)	4 (4.9)	0
Mouth haemorrhage	6 (7.4)	2 (2.5)	2 (2.5)	2 (2.5)	0
Pancreatitis	6 (7.4)	1 (1.2)	3 (3.7)	2 (2.5)	0
Abdominal pain upper	4 (4.9)	3 (3.7)	1 (1.2)	0	0
Abdominal distension	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Ascites	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Abdominal compartment syndrome	2 (2.5)	0	0	0	2 (2.5)
Dry mouth	2 (2.5)	0	2 (2.5)	0	0
Gastrointestinal haemorrhage	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Gastrointestinal sounds abnormal	2 (2.5)	2 (2.5)	0	0	0
Gingival bleeding	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Gingival erythema	2 (2.5)	2 (2.5)	0	0	0
Haematemesis	2 (2.5)	2 (2.5)	0	0	0
Ileus	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Oral pain	2 (2.5)	0	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (1.2)	0	1 (1.2)	0	0
Anal erythema	1 (1.2)	1 (1.2)	0	0	0
Anal fissure	1 (1.2)	0	1 (1.2)	0	0
Anal inflammation	1 (1.2)	0	0	1 (1.2)	0
Dyspepsia	1 (1.2)	1 (1.2)	0	0	0
Dysphagia	1 (1.2)	0	0	1 (1.2)	0
Gastrointestinal inflammation	1 (1.2)	0	1 (1.2)	0	0
Gingivitis ulcerative	1 (1.2)	0	0	1 (1.2)	0
Haemoperitoneum	1 (1.2)	0	0	0	1 (1.2)
Irritable bowel syndrome	1 (1.2)	0	1 (1.2)	0	0
Lip dry	1 (1.2)	0	1 (1.2)	0	0
Lip pain	1 (1.2)	1 (1.2)	0	0	0
Lip ulceration	1 (1.2)	0	1 (1.2)	0	0
Melaena	1 (1.2)	0	0	1 (1.2)	0
Mouth swelling	1 (1.2)	1 (1.2)	0	0	0
Odynophagia	1 (1.2)	1 (1.2)	0	0	0
Oral disorder	1 (1.2)	1 (1.2)	0	0	0
Peritoneal haematoma	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Trichoglossia	1 (1.2)	0	1 (1.2)	0	0
Upper gastrointestinal haemorrhage	1 (1.2)	1 (1.2)	0	0	0
General disorders and administration site conditions					
-Total	55 (67.9)	22 (27.2)	15 (18.5)	13 (16.0)	5 (6.2)
Pyrexia	40 (49.4)	16 (19.8)	11 (13.6)	11 (13.6)	2 (2.5)
Fatigue	12 (14.8)	9 (11.1)	3 (3.7)	0	0
Chills	8 (9.9)	4 (4.9)	4 (4.9)	0	0
Face oedema	8 (9.9)	5 (6.2)	2 (2.5)	1 (1.2)	0
Pain	8 (9.9)	1 (1.2)	5 (6.2)	2 (2.5)	0
Oedema peripheral	7 (8.6)	5 (6.2)	1 (1.2)	1 (1.2)	0
Catheter site pain	5 (6.2)	2 (2.5)	2 (2.5)	1 (1.2)	0
Generalised oedema	5 (6.2)	1 (1.2)	3 (3.7)	1 (1.2)	0
Asthenia	4 (4.9)	3 (3.7)	1 (1.2)	0	0
Localised oedema	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Multiple organ dysfunction syndrome	3 (3.7)	0	0	0	3 (3.7)
Drug withdrawal syndrome	2 (2.5)	0	2 (2.5)	0	0
Influenza like illness	2 (2.5)	1 (1.2)	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Catheter site erythema	1 (1.2)	1 (1.2)	0	0	0
Chest discomfort	1 (1.2)	0	0	1 (1.2)	0
Complication associated with device	1 (1.2)	1 (1.2)	0	0	0
Crying	1 (1.2)	0	1 (1.2)	0	0
Facial pain	1 (1.2)	0	1 (1.2)	0	0
Non-cardiac chest pain	1 (1.2)	1 (1.2)	0	0	0
Oedema due to hepatic disease	1 (1.2)	0	1 (1.2)	0	0
Sluggishness	1 (1.2)	0	1 (1.2)	0	0
Swelling face	1 (1.2)	1 (1.2)	0	0	0
Systemic inflammatory response syndrome	1 (1.2)	0	0	1 (1.2)	0
Thirst	1 (1.2)	1 (1.2)	0	0	0
Vascular device occlusion	1 (1.2)	1 (1.2)	0	0	0
Hepatobiliary disorders					
-Total	19 (23.5)	5 (6.2)	7 (8.6)	5 (6.2)	2 (2.5)
Hyperbilirubinaemia	6 (7.4)	1 (1.2)	3 (3.7)	2 (2.5)	0
Hepatic function abnormal	3 (3.7)	0	1 (1.2)	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Cholelithiasis	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Gallbladder enlargement	2 (2.5)	2 (2.5)	0	0	0
Hepatic cytolysis	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Hepatomegaly	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Biliary tract disorder	1 (1.2)	1 (1.2)	0	0	0
Cholestasis	1 (1.2)	0	0	0	1 (1.2)
Hepatosplenomegaly	1 (1.2)	0	1 (1.2)	0	0
Liver disorder	1 (1.2)	0	1 (1.2)	0	0
Immune system disorders					
-Total	60 (74.1)	2 (2.5)	17 (21.0)	20 (24.7)	21 (25.9)
Cytokine release syndrome	50 (61.7)	5 (6.2)	13 (16.0)	12 (14.8)	20 (24.7)
Hypogammaglobulinaemia	30 (37.0)	2 (2.5)	20 (24.7)	8 (9.9)	0
Haemophagocytic lymphohistiocytosis	6 (7.4)	1 (1.2)	1 (1.2)	2 (2.5)	2 (2.5)
Seasonal allergy	5 (6.2)	2 (2.5)	3 (3.7)	0	0
Immunodeficiency	4 (4.9)	0	0	4 (4.9)	0
Graft versus host disease	3 (3.7)	0	0	3 (3.7)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Chronic graft versus host disease	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Drug hypersensitivity	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Engraftment syndrome	1 (1.2)	0	0	1 (1.2)	0
Hypersensitivity	1 (1.2)	1 (1.2)	0	0	0
Selective igg subclass deficiency	1 (1.2)	0	1 (1.2)	0	0
Infections and infestations					
-Total	65 (80.2)	4 (4.9)	12 (14.8)	30 (37.0)	19 (23.5)
Upper respiratory tract infection	12 (14.8)	4 (4.9)	6 (7.4)	2 (2.5)	0
Pneumonia	9 (11.1)	1 (1.2)	2 (2.5)	3 (3.7)	3 (3.7)
Rhinovirus infection	9 (11.1)	0	7 (8.6)	2 (2.5)	0
Conjunctivitis	8 (9.9)	3 (3.7)	5 (6.2)	0	0
Sinusitis	8 (9.9)	0	5 (6.2)	3 (3.7)	0
Nasopharyngitis	7 (8.6)	4 (4.9)	3 (3.7)	0	0
Parainfluenzae virus infection	7 (8.6)	1 (1.2)	1 (1.2)	4 (4.9)	1 (1.2)
Gastroenteritis	6 (7.4)	3 (3.7)	1 (1.2)	2 (2.5)	0
Staphylococcal bacteraemia	6 (7.4)	0	0	6 (7.4)	0
Staphylococcal infection	6 (7.4)	0	3 (3.7)	2 (2.5)	1 (1.2)

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	5 (6.2)	0	1 (1.2)	3 (3.7)	1 (1.2)
Oral herpes	5 (6.2)	0	3 (3.7)	2 (2.5)	0
Candida infection	4 (4.9)	0	3 (3.7)	0	1 (1.2)
Clostridium difficile infection	4 (4.9)	1 (1.2)	0	3 (3.7)	0
Nail infection	4 (4.9)	3 (3.7)	1 (1.2)	0	0
Otitis media	4 (4.9)	0	3 (3.7)	1 (1.2)	0
Paronychia	4 (4.9)	1 (1.2)	2 (2.5)	1 (1.2)	0
Sepsis	4 (4.9)	0	0	1 (1.2)	3 (3.7)
Bronchitis	3 (3.7)	0	3 (3.7)	0	0
Bronchopulmonary aspergillosis	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Device related infection	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Escherichia bacteraemia	3 (3.7)	0	0	2 (2.5)	1 (1.2)
Gastroenteritis viral	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Gingivitis	3 (3.7)	3 (3.7)	0	0	0
Herpes zoster	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Localised infection	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Metapneumovirus infection	3 (3.7)	0	0	3 (3.7)	0
Oral candidiasis	3 (3.7)	0	3 (3.7)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Respiratory tract infection	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Rhinitis	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Septic shock	3 (3.7)	0	0	0	3 (3.7)
Urinary tract infection	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Adenovirus infection	2 (2.5)	0	0	2 (2.5)	0
Bk virus infection	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Bronchiolitis	2 (2.5)	0	0	2 (2.5)	0
Covid-19	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Cytomegalovirus infection reactivation	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Ear infection	2 (2.5)	0	2 (2.5)	0	0
Encephalitis	2 (2.5)	0	0	0	2 (2.5)
Encephalitis viral	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Fungal infection	2 (2.5)	0	2 (2.5)	0	0
Herpes simplex	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Human herpesvirus 6 infection	2 (2.5)	0	0	2 (2.5)	0
Influenza	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Klebsiella bacteraemia	2 (2.5)	0	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.5)	0	2 (2.5)	0	0
Otitis externa	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Pneumocystis jirovecii pneumonia	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Pneumonia fungal	2 (2.5)	0	0	2 (2.5)	0
Skin infection	2 (2.5)	0	2 (2.5)	0	0
Staphylococcal skin infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Viral infection	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Acute sinusitis	1 (1.2)	0	1 (1.2)	0	0
Atypical pneumonia	1 (1.2)	1 (1.2)	0	0	0
Catheter site infection	1 (1.2)	0	1 (1.2)	0	0
Cellulitis	1 (1.2)	0	1 (1.2)	0	0
Cholecystitis infective	1 (1.2)	0	1 (1.2)	0	0
Clostridium difficile colitis	1 (1.2)	0	0	1 (1.2)	0
Coronavirus infection	1 (1.2)	0	0	1 (1.2)	0
Covid-19 pneumonia	1 (1.2)	0	0	0	1 (1.2)
Cystitis	1 (1.2)	0	1 (1.2)	0	0
Device related bacteraemia	1 (1.2)	0	1 (1.2)	0	0
Device related sepsis	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated trichosporonosis	1 (1.2)	0	0	0	1 (1.2)
Ear, nose and throat infection	1 (1.2)	0	1 (1.2)	0	0
Enterobacter infection	1 (1.2)	0	0	1 (1.2)	0
Enterovirus infection	1 (1.2)	0	0	1 (1.2)	0
Folliculitis	1 (1.2)	0	1 (1.2)	0	0
Fungaemia	1 (1.2)	0	0	0	1 (1.2)
Fungal skin infection	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis clostridial	1 (1.2)	0	1 (1.2)	0	0
Gastroenteritis escherichia coli	1 (1.2)	0	0	1 (1.2)	0
Gastroenteritis norovirus	1 (1.2)	1 (1.2)	0	0	0
Gastroenteritis salmonella	1 (1.2)	0	0	1 (1.2)	0
Gastrointestinal infection	1 (1.2)	1 (1.2)	0	0	0
Granulicatella infection	1 (1.2)	0	0	1 (1.2)	0
Herpes virus infection	1 (1.2)	0	1 (1.2)	0	0
Klebsiella infection	1 (1.2)	0	0	1 (1.2)	0
Mastoiditis	1 (1.2)	0	0	1 (1.2)	0
Meningitis bacterial	1 (1.2)	0	0	1 (1.2)	0
Meningitis pneumococcal	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.2)	1 (1.2)	0	0	0
Myringitis	1 (1.2)	1 (1.2)	0	0	0
Neutropenic infection	1 (1.2)	0	0	1 (1.2)	0
Ophthalmic herpes zoster	1 (1.2)	0	1 (1.2)	0	0
Otitis media acute	1 (1.2)	0	1 (1.2)	0	0
Pharyngitis	1 (1.2)	0	0	1 (1.2)	0
Pharyngitis streptococcal	1 (1.2)	0	0	1 (1.2)	0
Pneumonia respiratory syncytial viral	1 (1.2)	0	0	1 (1.2)	0
Pneumonia viral	1 (1.2)	0	0	1 (1.2)	0
Respiratory tract infection viral	1 (1.2)	0	1 (1.2)	0	0
Salmonellosis	1 (1.2)	0	1 (1.2)	0	0
Serratia sepsis	1 (1.2)	0	0	0	1 (1.2)
Sialoadenitis	1 (1.2)	0	0	1 (1.2)	0
Sinusitis fungal	1 (1.2)	0	0	1 (1.2)	0
Soft tissue infection	1 (1.2)	0	0	1 (1.2)	0
Staphylococcal sepsis	1 (1.2)	0	0	0	1 (1.2)
Stomatococcal infection	1 (1.2)	0	0	0	1 (1.2)
Streptococcal sepsis	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Syphilis	1 (1.2)	0	1 (1.2)	0	0
Systemic candida	1 (1.2)	0	0	1 (1.2)	0
Urinary tract infection pseudomonal	1 (1.2)	0	1 (1.2)	0	0
Varicella zoster virus infection	1 (1.2)	0	1 (1.2)	0	0
Viral haemorrhagic cystitis	1 (1.2)	0	0	1 (1.2)	0
Viral skin infection	1 (1.2)	1 (1.2)	0	0	0
Viral upper respiratory tract infection	1 (1.2)	0	0	1 (1.2)	0
Vulval cellulitis	1 (1.2)	0	0	1 (1.2)	0
Injury, poisoning and procedural complications					
-Total	24 (29.6)	7 (8.6)	11 (13.6)	3 (3.7)	3 (3.7)
Infusion related reaction	5 (6.2)	1 (1.2)	3 (3.7)	1 (1.2)	0
Fall	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Procedural pain	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Wound	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Ligament sprain	2 (2.5)	2 (2.5)	0	0	0
Skin abrasion	2 (2.5)	2 (2.5)	0	0	0
Transfusion reaction	2 (2.5)	0	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal injury	1 (1.2)	1 (1.2)	0	0	0
Contusion	1 (1.2)	1 (1.2)	0	0	0
Extradural haematoma	1 (1.2)	0	1 (1.2)	0	0
Fibula fracture	1 (1.2)	0	1 (1.2)	0	0
Limb injury	1 (1.2)	0	1 (1.2)	0	0
Post-traumatic neck syndrome	1 (1.2)	0	1 (1.2)	0	0
Radius fracture	1 (1.2)	0	1 (1.2)	0	0
Scratch	1 (1.2)	1 (1.2)	0	0	0
Skin injury	1 (1.2)	0	1 (1.2)	0	0
Skin wound	1 (1.2)	1 (1.2)	0	0	0
Tracheal obstruction	1 (1.2)	0	0	0	1 (1.2)
Transplant failure	1 (1.2)	0	0	0	1 (1.2)
Traumatic haematoma	1 (1.2)	0	1 (1.2)	0	0
Vasoplegia syndrome	1 (1.2)	0	0	0	1 (1.2)
Investigations					
-Total	55 (67.9)	0	6 (7.4)	16 (19.8)	33 (40.7)
White blood cell count decreased	23 (28.4)	1 (1.2)	1 (1.2)	1 (1.2)	20 (24.7)
Neutrophil count decreased	20 (24.7)	0	0	2 (2.5)	18 (22.2)

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	19 (23.5)	2 (2.5)	1 (1.2)	2 (2.5)	14 (17.3)
Alanine aminotransferase increased	17 (21.0)	5 (6.2)	5 (6.2)	7 (8.6)	0
Aspartate aminotransferase increased	16 (19.8)	2 (2.5)	4 (4.9)	6 (7.4)	4 (4.9)
Lymphocyte count decreased	16 (19.8)	1 (1.2)	0	5 (6.2)	10 (12.3)
C-reactive protein increased	10 (12.3)	2 (2.5)	2 (2.5)	5 (6.2)	1 (1.2)
Blood bilirubin increased	9 (11.1)	0	2 (2.5)	7 (8.6)	0
Serum ferritin increased	9 (11.1)	2 (2.5)	3 (3.7)	3 (3.7)	1 (1.2)
Blood creatinine increased	6 (7.4)	2 (2.5)	1 (1.2)	2 (2.5)	1 (1.2)
Blood lactate dehydrogenase increased	6 (7.4)	2 (2.5)	1 (1.2)	3 (3.7)	0
Blood fibrinogen decreased	4 (4.9)	0	2 (2.5)	1 (1.2)	1 (1.2)
Blood immunoglobulin g decreased	4 (4.9)	1 (1.2)	3 (3.7)	0	0
Electrocardiogram qt prolonged	4 (4.9)	0	2 (2.5)	1 (1.2)	1 (1.2)
Fibrin d dimer increased	4 (4.9)	2 (2.5)	0	1 (1.2)	1 (1.2)
International normalised ratio increased	4 (4.9)	1 (1.2)	3 (3.7)	0	0
Weight decreased	4 (4.9)	0	2 (2.5)	2 (2.5)	0
Weight increased	4 (4.9)	2 (2.5)	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Blood uric acid increased	3 (3.7)	1 (1.2)	0	1 (1.2)	1 (1.2)
Oxygen saturation decreased	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Amylase increased	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Blood fibrinogen increased	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Blood glucose increased	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Blood immunoglobulin m decreased	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Blood phosphorus increased	2 (2.5)	0	2 (2.5)	0	0
Gamma-glutamyltransferase increased	2 (2.5)	0	0	2 (2.5)	0
Immunoglobulins decreased	2 (2.5)	0	2 (2.5)	0	0
Lipase increased	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Urine output decreased	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Bacterial test positive	1 (1.2)	0	0	1 (1.2)	0
Blood alkaline phosphatase decreased	1 (1.2)	1 (1.2)	0	0	0
Blood alkaline phosphatase increased	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (1.2)	0	1 (1.2)	0	0
Blood creatine phosphokinase increased	1 (1.2)	0	0	0	1 (1.2)
Blood immunoglobulin a decreased	1 (1.2)	0	1 (1.2)	0	0
Blood phosphorus decreased	1 (1.2)	0	0	1 (1.2)	0
Blood potassium decreased	1 (1.2)	0	0	0	1 (1.2)
Blood testosterone decreased	1 (1.2)	1 (1.2)	0	0	0
Blood thyroid stimulating hormone increased	1 (1.2)	1 (1.2)	0	0	0
Blood urea increased	1 (1.2)	0	0	1 (1.2)	0
Bone density decreased	1 (1.2)	1 (1.2)	0	0	0
Breath sounds abnormal	1 (1.2)	0	1 (1.2)	0	0
Cardiac murmur	1 (1.2)	1 (1.2)	0	0	0
Coagulation test abnormal	1 (1.2)	1 (1.2)	0	0	0
Ejection fraction decreased	1 (1.2)	0	1 (1.2)	0	0
Electrocardiogram t wave abnormal	1 (1.2)	0	1 (1.2)	0	0
Enterovirus test positive	1 (1.2)	0	1 (1.2)	0	0
Eosinophil count decreased	1 (1.2)	1 (1.2)	0	0	0
Haematocrit decreased	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haptoglobin decreased	1 (1.2)	1 (1.2)	0	0	0
Heart sounds abnormal	1 (1.2)	1 (1.2)	0	0	0
Hepatitis b virus test positive	1 (1.2)	0	1 (1.2)	0	0
Prothrombin time prolonged	1 (1.2)	0	1 (1.2)	0	0
Red blood cell count decreased	1 (1.2)	1 (1.2)	0	0	0
Staphylococcus test positive	1 (1.2)	1 (1.2)	0	0	0
Troponin increased	1 (1.2)	0	0	1 (1.2)	0
Metabolism and nutrition disorders					
-Total	49 (60.5)	6 (7.4)	9 (11.1)	20 (24.7)	14 (17.3)
Decreased appetite	26 (32.1)	8 (9.9)	6 (7.4)	10 (12.3)	2 (2.5)
Hypokalaemia	22 (27.2)	4 (4.9)	5 (6.2)	10 (12.3)	3 (3.7)
Hypophosphataemia	19 (23.5)	3 (3.7)	8 (9.9)	7 (8.6)	1 (1.2)
Hypocalcaemia	18 (22.2)	2 (2.5)	10 (12.3)	6 (7.4)	0
Hypoalbuminaemia	11 (13.6)	0	10 (12.3)	1 (1.2)	0
Hyperglycaemia	9 (11.1)	0	4 (4.9)	5 (6.2)	0
Hypervolaemia	9 (11.1)	1 (1.2)	2 (2.5)	6 (7.4)	0
Hypomagnesaemia	8 (9.9)	6 (7.4)	2 (2.5)	0	0
Hyperuricaemia	7 (8.6)	5 (6.2)	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	5 (6.2)	0	0	2 (2.5)	3 (3.7)
Tumour lysis syndrome	5 (6.2)	0	0	3 (3.7)	2 (2.5)
Hyperkalaemia	4 (4.9)	0	1 (1.2)	2 (2.5)	1 (1.2)
Hyponatraemia	4 (4.9)	3 (3.7)	0	0	1 (1.2)
Hypercalcaemia	3 (3.7)	0	1 (1.2)	1 (1.2)	1 (1.2)
Hypernatraemia	3 (3.7)	1 (1.2)	0	1 (1.2)	1 (1.2)
Hyperphosphataemia	3 (3.7)	2 (2.5)	0	0	1 (1.2)
Acidosis	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Hyperchloraemia	2 (2.5)	2 (2.5)	0	0	0
Hypermagnesaemia	2 (2.5)	2 (2.5)	0	0	0
Hypertriglyceridaemia	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Iron overload	2 (2.5)	0	2 (2.5)	0	0
Malnutrition	2 (2.5)	0	0	2 (2.5)	0
Calcium deficiency	1 (1.2)	1 (1.2)	0	0	0
Eating disorder symptom	1 (1.2)	0	1 (1.2)	0	0
Haemochromatosis	1 (1.2)	0	0	1 (1.2)	0
Haemosiderosis	1 (1.2)	0	1 (1.2)	0	0
Hypercholesterolaemia	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlactacidaemia	1 (1.2)	1 (1.2)	0	0	0
Hyperlipidaemia	1 (1.2)	0	1 (1.2)	0	0
Hypoglycaemia	1 (1.2)	0	1 (1.2)	0	0
Hypophagia	1 (1.2)	0	1 (1.2)	0	0
Metabolic syndrome	1 (1.2)	0	1 (1.2)	0	0
Obesity	1 (1.2)	0	0	1 (1.2)	0
Polydipsia	1 (1.2)	0	0	1 (1.2)	0
Vitamin d deficiency	1 (1.2)	1 (1.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	39 (48.1)	11 (13.6)	17 (21.0)	10 (12.3)	1 (1.2)
Pain in extremity	18 (22.2)	5 (6.2)	10 (12.3)	3 (3.7)	0
Back pain	12 (14.8)	2 (2.5)	6 (7.4)	4 (4.9)	0
Arthralgia	10 (12.3)	3 (3.7)	6 (7.4)	1 (1.2)	0
Myalgia	6 (7.4)	4 (4.9)	2 (2.5)	0	0
Bone pain	4 (4.9)	1 (1.2)	3 (3.7)	0	0
Pain in jaw	3 (3.7)	1 (1.2)	0	2 (2.5)	0
Growth retardation	2 (2.5)	0	2 (2.5)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint effusion	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Muscular weakness	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Musculoskeletal chest pain	2 (2.5)	2 (2.5)	0	0	0
Neck pain	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Groin pain	1 (1.2)	1 (1.2)	0	0	0
Haemarthrosis	1 (1.2)	0	0	1 (1.2)	0
Muscle rigidity	1 (1.2)	1 (1.2)	0	0	0
Muscle spasms	1 (1.2)	0	1 (1.2)	0	0
Musculoskeletal pain	1 (1.2)	0	1 (1.2)	0	0
Myopathy	1 (1.2)	0	0	1 (1.2)	0
Myositis	1 (1.2)	0	1 (1.2)	0	0
Osteonecrosis	1 (1.2)	1 (1.2)	0	0	0
Osteopenia	1 (1.2)	1 (1.2)	0	0	0
Rhabdomyolysis	1 (1.2)	0	0	0	1 (1.2)
Spinal pain	1 (1.2)	0	0	1 (1.2)	0
Synovitis	1 (1.2)	0	1 (1.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.2)	1 (1.2)	2 (2.5)	2 (2.5)	0
Skin papilloma	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Bone giant cell tumour benign	1 (1.2)	0	0	1 (1.2)	0
Cancer pain	1 (1.2)	0	1 (1.2)	0	0
Myelodysplastic syndrome	1 (1.2)	0	0	1 (1.2)	0
Nervous system disorders					
-Total	46 (56.8)	10 (12.3)	19 (23.5)	13 (16.0)	4 (4.9)
Headache	27 (33.3)	12 (14.8)	12 (14.8)	3 (3.7)	0
Encephalopathy	9 (11.1)	1 (1.2)	3 (3.7)	5 (6.2)	0
Seizure	6 (7.4)	0	3 (3.7)	3 (3.7)	0
Somnolence	6 (7.4)	2 (2.5)	2 (2.5)	2 (2.5)	0
Tremor	5 (6.2)	4 (4.9)	1 (1.2)	0	0
Cognitive disorder	4 (4.9)	0	2 (2.5)	2 (2.5)	0
Dizziness	4 (4.9)	4 (4.9)	0	0	0
Dysgeusia	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Lethargy	3 (3.7)	2 (2.5)	1 (1.2)	0	0
Cerebral haemorrhage	2 (2.5)	0	0	0	2 (2.5)
Dysarthria	2 (2.5)	0	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Paraesthesia	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Amnesia	1 (1.2)	0	1 (1.2)	0	0
Aphasia	1 (1.2)	1 (1.2)	0	0	0
Autonomic neuropathy	1 (1.2)	0	0	1 (1.2)	0
Depressed level of consciousness	1 (1.2)	0	0	1 (1.2)	0
Disturbance in attention	1 (1.2)	1 (1.2)	0	0	0
Extrapyramidal disorder	1 (1.2)	0	1 (1.2)	0	0
Generalised tonic-clonic seizure	1 (1.2)	0	1 (1.2)	0	0
Hydrocephalus	1 (1.2)	0	0	0	1 (1.2)
Hyperaesthesia	1 (1.2)	1 (1.2)	0	0	0
Memory impairment	1 (1.2)	0	1 (1.2)	0	0
Migraine	1 (1.2)	0	1 (1.2)	0	0
Monoparesis	1 (1.2)	0	1 (1.2)	0	0
Nervous system disorder	1 (1.2)	0	0	1 (1.2)	0
Neuralgia	1 (1.2)	0	1 (1.2)	0	0
Neurological decompensation	1 (1.2)	0	0	0	1 (1.2)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Posterior reversible encephalopathy syndrome	1 (1.2)	0	1 (1.2)	0	0
Psychiatric disorders					
-Total	35 (43.2)	9 (11.1)	17 (21.0)	9 (11.1)	0
Anxiety	14 (17.3)	3 (3.7)	8 (9.9)	3 (3.7)	0
Delirium	8 (9.9)	2 (2.5)	3 (3.7)	3 (3.7)	0
Agitation	6 (7.4)	3 (3.7)	3 (3.7)	0	0
Insomnia	6 (7.4)	2 (2.5)	4 (4.9)	0	0
Confusional state	5 (6.2)	5 (6.2)	0	0	0
Mental status changes	4 (4.9)	0	2 (2.5)	2 (2.5)	0
Hallucination	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Irritability	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Sleep disorder	3 (3.7)	0	3 (3.7)	0	0
Affect lability	1 (1.2)	0	1 (1.2)	0	0
Automatism	1 (1.2)	1 (1.2)	0	0	0
Hallucination, visual	1 (1.2)	0	1 (1.2)	0	0
Mood altered	1 (1.2)	1 (1.2)	0	0	0
Nightmare	1 (1.2)	1 (1.2)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Persistent depressive disorder	1 (1.2)	0	1 (1.2)	0	0
Restlessness	1 (1.2)	0	1 (1.2)	0	0
Social avoidant behaviour	1 (1.2)	0	1 (1.2)	0	0
Tearfulness	1 (1.2)	1 (1.2)	0	0	0
Tic	1 (1.2)	0	1 (1.2)	0	0
Renal and urinary disorders					
-Total	24 (29.6)	8 (9.9)	5 (6.2)	5 (6.2)	6 (7.4)
Acute kidney injury	14 (17.3)	5 (6.2)	2 (2.5)	3 (3.7)	4 (4.9)
Dysuria	4 (4.9)	3 (3.7)	1 (1.2)	0	0
Haematuria	4 (4.9)	3 (3.7)	0	1 (1.2)	0
Anuria	2 (2.5)	1 (1.2)	0	0	1 (1.2)
Renal failure	2 (2.5)	0	1 (1.2)	0	1 (1.2)
Urinary retention	2 (2.5)	0	2 (2.5)	0	0
Azotaemia	1 (1.2)	0	1 (1.2)	0	0
Bladder dilatation	1 (1.2)	0	1 (1.2)	0	0
Incontinence	1 (1.2)	0	1 (1.2)	0	0
Kidney enlargement	1 (1.2)	0	1 (1.2)	0	0
Pollakiuria	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proteinuria	1 (1.2)	1 (1.2)	0	0	0
Renal mass	1 (1.2)	0	1 (1.2)	0	0
Renal pain	1 (1.2)	1 (1.2)	0	0	0
Renal tubular disorder	1 (1.2)	0	0	1 (1.2)	0
Renal tubular necrosis	1 (1.2)	0	0	0	1 (1.2)
Urinary incontinence	1 (1.2)	0	1 (1.2)	0	0
Urinary tract disorder	1 (1.2)	0	1 (1.2)	0	0
Reproductive system and breast disorders					
-Total	6 (7.4)	1 (1.2)	3 (3.7)	2 (2.5)	0
Dysmenorrhoea	1 (1.2)	0	1 (1.2)	0	0
Endometriosis	1 (1.2)	0	0	1 (1.2)	0
Female genital tract fistula	1 (1.2)	1 (1.2)	0	0	0
Heavy menstrual bleeding	1 (1.2)	0	1 (1.2)	0	0
Perineal rash	1 (1.2)	0	1 (1.2)	0	0
Vaginal haemorrhage	1 (1.2)	0	1 (1.2)	0	0
Vaginal ulceration	1 (1.2)	0	0	1 (1.2)	0
Respiratory, thoracic and mediastinal disorders					

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	52 (64.2)	15 (18.5)	6 (7.4)	11 (13.6)	20 (24.7)
Cough	21 (25.9)	16 (19.8)	5 (6.2)	0	0
Hypoxia	18 (22.2)	0	4 (4.9)	9 (11.1)	5 (6.2)
Pulmonary oedema	14 (17.3)	3 (3.7)	3 (3.7)	6 (7.4)	2 (2.5)
Epistaxis	10 (12.3)	6 (7.4)	2 (2.5)	2 (2.5)	0
Respiratory failure	10 (12.3)	0	0	0	10 (12.3)
Nasal congestion	8 (9.9)	6 (7.4)	2 (2.5)	0	0
Pleural effusion	8 (9.9)	3 (3.7)	2 (2.5)	2 (2.5)	1 (1.2)
Tachypnoea	8 (9.9)	1 (1.2)	2 (2.5)	4 (4.9)	1 (1.2)
Dyspnoea	7 (8.6)	0	2 (2.5)	3 (3.7)	2 (2.5)
Oropharyngeal pain	7 (8.6)	5 (6.2)	2 (2.5)	0	0
Acute respiratory distress syndrome	4 (4.9)	0	0	0	4 (4.9)
Atelectasis	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Respiratory distress	3 (3.7)	0	1 (1.2)	0	2 (2.5)
Pharyngeal erythema	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Rhinitis allergic	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Rhinorrhoea	2 (2.5)	0	2 (2.5)	0	0
Wheezing	2 (2.5)	0	2 (2.5)	0	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory failure	1 (1.2)	0	0	1 (1.2)	0
Bradypnoea	1 (1.2)	0	0	1 (1.2)	0
Bronchial oedema	1 (1.2)	1 (1.2)	0	0	0
Bronchospasm	1 (1.2)	0	1 (1.2)	0	0
Dyspnoea exertional	1 (1.2)	1 (1.2)	0	0	0
Haemoptysis	1 (1.2)	0	1 (1.2)	0	0
Lung disorder	1 (1.2)	1 (1.2)	0	0	0
Lung infiltration	1 (1.2)	0	0	1 (1.2)	0
Nasal discomfort	1 (1.2)	0	1 (1.2)	0	0
Nasal dryness	1 (1.2)	1 (1.2)	0	0	0
Oropharyngeal plaque	1 (1.2)	0	1 (1.2)	0	0
Painful respiration	1 (1.2)	1 (1.2)	0	0	0
Paranasal sinus discomfort	1 (1.2)	0	1 (1.2)	0	0
Pharyngeal exudate	1 (1.2)	0	1 (1.2)	0	0
Pharyngeal haemorrhage	1 (1.2)	0	1 (1.2)	0	0
Pharyngeal oedema	1 (1.2)	0	1 (1.2)	0	0
Productive cough	1 (1.2)	1 (1.2)	0	0	0
Pulmonary haemorrhage	1 (1.2)	0	0	0	1 (1.2)

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary mass	1 (1.2)	0	1 (1.2)	0	0
Respiratory acidosis	1 (1.2)	0	0	1 (1.2)	0
Respiratory disorder	1 (1.2)	0	1 (1.2)	0	0
Sleep apnoea syndrome	1 (1.2)	0	1 (1.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	39 (48.1)	16 (19.8)	16 (19.8)	7 (8.6)	0
Rash	10 (12.3)	5 (6.2)	5 (6.2)	0	0
Pruritus	9 (11.1)	3 (3.7)	6 (7.4)	0	0
Dry skin	6 (7.4)	5 (6.2)	1 (1.2)	0	0
Erythema	6 (7.4)	5 (6.2)	1 (1.2)	0	0
Ingrowing nail	4 (4.9)	1 (1.2)	3 (3.7)	0	0
Dermatitis atopic	3 (3.7)	2 (2.5)	0	1 (1.2)	0
Hyperhidrosis	3 (3.7)	1 (1.2)	2 (2.5)	0	0
Petechiae	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Rash maculo-papular	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Blister	2 (2.5)	1 (1.2)	1 (1.2)	0	0
Decubitus ulcer	2 (2.5)	0	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin discolouration	2 (2.5)	2 (2.5)	0	0	0
Skin ulcer	2 (2.5)	1 (1.2)	0	1 (1.2)	0
Acne	1 (1.2)	1 (1.2)	0	0	0
Dermatitis allergic	1 (1.2)	1 (1.2)	0	0	0
Dermatitis diaper	1 (1.2)	0	1 (1.2)	0	0
Drug eruption	1 (1.2)	0	1 (1.2)	0	0
Eczema	1 (1.2)	1 (1.2)	0	0	0
Hangnail	1 (1.2)	1 (1.2)	0	0	0
Miliaria	1 (1.2)	1 (1.2)	0	0	0
Night sweats	1 (1.2)	1 (1.2)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.2)	1 (1.2)	0	0	0
Papule	1 (1.2)	1 (1.2)	0	0	0
Photosensitivity reaction	1 (1.2)	0	1 (1.2)	0	0
Pruritus allergic	1 (1.2)	0	1 (1.2)	0	0
Purpura	1 (1.2)	1 (1.2)	0	0	0
Rash erythematous	1 (1.2)	1 (1.2)	0	0	0
Rash macular	1 (1.2)	0	0	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	1 (1.2)	0	1 (1.2)	0	0
Rash vesicular	1 (1.2)	1 (1.2)	0	0	0
Scab	1 (1.2)	1 (1.2)	0	0	0
Skin hypopigmentation	1 (1.2)	1 (1.2)	0	0	0
Skin lesion	1 (1.2)	0	1 (1.2)	0	0
Skin necrosis	1 (1.2)	0	0	1 (1.2)	0
Urticaria	1 (1.2)	0	1 (1.2)	0	0
Vancomycin infusion reaction	1 (1.2)	0	0	1 (1.2)	0
Social circumstances					
-Total	1 (1.2)	0	1 (1.2)	0	0
Patient uncooperative	1 (1.2)	0	1 (1.2)	0	0
Surgical and medical procedures					
-Total	1 (1.2)	0	0	1 (1.2)	0
Thrombolysis	1 (1.2)	0	0	1 (1.2)	0
Vascular disorders					
-Total	39 (48.1)	3 (3.7)	11 (13.6)	15 (18.5)	10 (12.3)
Hypotension	27 (33.3)	1 (1.2)	6 (7.4)	11 (13.6)	9 (11.1)
Hypertension	18 (22.2)	3 (3.7)	10 (12.3)	5 (6.2)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Capillary leak syndrome	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Flushing	2 (2.5)	2 (2.5)	0	0	0
Peripheral ischaemia	2 (2.5)	0	2 (2.5)	0	0
Venoocclusive disease	2 (2.5)	0	0	1 (1.2)	1 (1.2)
Haematoma	1 (1.2)	1 (1.2)	0	0	0
Hot flush	1 (1.2)	1 (1.2)	0	0	0
Thrombosis	1 (1.2)	0	1 (1.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208n
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	0	3 (10.7)	10 (35.7)	14 (50.0)
Blood and lymphatic system disorders					
-Total	20 (71.4)	0	4 (14.3)	9 (32.1)	7 (25.0)
Anaemia	11 (39.3)	3 (10.7)	2 (7.1)	6 (21.4)	0
Febrile neutropenia	11 (39.3)	0	0	10 (35.7)	1 (3.6)
Thrombocytopenia	6 (21.4)	0	1 (3.6)	3 (10.7)	2 (7.1)
Neutropenia	5 (17.9)	0	1 (3.6)	1 (3.6)	3 (10.7)
Disseminated intravascular coagulation	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Leukopenia	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Pancytopenia	2 (7.1)	0	0	2 (7.1)	0
B-cell aplasia	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coagulopathy	1 (3.6)	0	0	1 (3.6)	0
Hypercoagulation	1 (3.6)	0	1 (3.6)	0	0
Leukocytosis	1 (3.6)	0	1 (3.6)	0	0
Lymphadenopathy	1 (3.6)	1 (3.6)	0	0	0
Lymphocytosis	1 (3.6)	0	1 (3.6)	0	0
Cardiac disorders					
-Total	8 (28.6)	3 (10.7)	2 (7.1)	2 (7.1)	1 (3.6)
Tachycardia	6 (21.4)	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)
Left ventricular dysfunction	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Sinus bradycardia	1 (3.6)	0	0	1 (3.6)	0
Endocrine disorders					
-Total	4 (14.3)	0	4 (14.3)	0	0
Adrenal insufficiency	2 (7.1)	0	2 (7.1)	0	0
Hypothyroidism	2 (7.1)	0	2 (7.1)	0	0
Delayed puberty	1 (3.6)	0	1 (3.6)	0	0
Eye disorders					
-Total	6 (21.4)	5 (17.9)	1 (3.6)	0	0
Ocular hyperaemia	3 (10.7)	3 (10.7)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Dry eye	1 (3.6)	1 (3.6)	0	0	0
Eye pain	1 (3.6)	1 (3.6)	0	0	0
Eyelid oedema	1 (3.6)	0	1 (3.6)	0	0
Gastrointestinal disorders					
-Total	22 (78.6)	9 (32.1)	8 (28.6)	5 (17.9)	0
Diarrhoea	11 (39.3)	8 (28.6)	3 (10.7)	0	0
Nausea	10 (35.7)	3 (10.7)	5 (17.9)	2 (7.1)	0
Vomiting	10 (35.7)	7 (25.0)	2 (7.1)	1 (3.6)	0
Constipation	7 (25.0)	7 (25.0)	0	0	0
Abdominal pain	5 (17.9)	3 (10.7)	2 (7.1)	0	0
Stomatitis	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Ascites	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Pancreatitis	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Abdominal distension	1 (3.6)	0	1 (3.6)	0	0
Abdominal pain upper	1 (3.6)	1 (3.6)	0	0	0
Anal fissure	1 (3.6)	0	1 (3.6)	0	0
Dyspepsia	1 (3.6)	1 (3.6)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival bleeding	1 (3.6)	1 (3.6)	0	0	0
Ileus	1 (3.6)	0	0	1 (3.6)	0
Irritable bowel syndrome	1 (3.6)	0	1 (3.6)	0	0
Lip pain	1 (3.6)	1 (3.6)	0	0	0
Lip ulceration	1 (3.6)	0	1 (3.6)	0	0
Melaena	1 (3.6)	0	0	1 (3.6)	0
Mouth haemorrhage	1 (3.6)	0	1 (3.6)	0	0
Peritoneal haematoma	1 (3.6)	1 (3.6)	0	0	0
Trichoglossia	1 (3.6)	0	1 (3.6)	0	0
General disorders and administration site conditions					
-Total	20 (71.4)	8 (28.6)	7 (25.0)	2 (7.1)	3 (10.7)
Pyrexia	14 (50.0)	6 (21.4)	6 (21.4)	1 (3.6)	1 (3.6)
Fatigue	5 (17.9)	3 (10.7)	2 (7.1)	0	0
Face oedema	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Pain	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Chills	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Influenza like illness	2 (7.1)	1 (3.6)	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	2 (7.1)	0	0	0	2 (7.1)
Oedema peripheral	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Catheter site dermatitis	1 (3.6)	1 (3.6)	0	0	0
Catheter site pain	1 (3.6)	1 (3.6)	0	0	0
Drug withdrawal syndrome	1 (3.6)	0	1 (3.6)	0	0
Generalised oedema	1 (3.6)	0	1 (3.6)	0	0
Localised oedema	1 (3.6)	0	1 (3.6)	0	0
Systemic inflammatory response syndrome	1 (3.6)	0	0	1 (3.6)	0
Hepatobiliary disorders					
-Total	4 (14.3)	2 (7.1)	1 (3.6)	0	1 (3.6)
Cholelithiasis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Cholestasis	1 (3.6)	0	0	0	1 (3.6)
Gallbladder enlargement	1 (3.6)	1 (3.6)	0	0	0
Hepatic cytolysis	1 (3.6)	1 (3.6)	0	0	0
Ocular icterus	1 (3.6)	1 (3.6)	0	0	0
Immune system disorders					
-Total	24 (85.7)	1 (3.6)	12 (42.9)	6 (21.4)	5 (17.9)

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	18 (64.3)	3 (10.7)	8 (28.6)	3 (10.7)	4 (14.3)
Hypogammaglobulinaemia	16 (57.1)	1 (3.6)	12 (42.9)	3 (10.7)	0
Haemophagocytic lymphohistiocytosis	2 (7.1)	0	0	0	2 (7.1)
Immunodeficiency	2 (7.1)	0	0	2 (7.1)	0
Seasonal allergy	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Chronic graft versus host disease	1 (3.6)	0	0	1 (3.6)	0
Infections and infestations					
-Total	23 (82.1)	2 (7.1)	9 (32.1)	8 (28.6)	4 (14.3)
Upper respiratory tract infection	7 (25.0)	3 (10.7)	2 (7.1)	2 (7.1)	0
Conjunctivitis	5 (17.9)	2 (7.1)	3 (10.7)	0	0
Sinusitis	5 (17.9)	0	4 (14.3)	1 (3.6)	0
Rhinovirus infection	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Staphylococcal bacteraemia	4 (14.3)	0	0	4 (14.3)	0
Parainfluenzae virus infection	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Pneumonia	3 (10.7)	0	1 (3.6)	1 (3.6)	1 (3.6)
Respiratory syncytial virus infection	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Clostridium difficile infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	2 (7.1)	0	0	0	2 (7.1)
Localised infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Otitis media	2 (7.1)	0	2 (7.1)	0	0
Bronchopulmonary aspergillosis	1 (3.6)	0	0	0	1 (3.6)
Catheter site infection	1 (3.6)	0	1 (3.6)	0	0
Cellulitis	1 (3.6)	0	1 (3.6)	0	0
Clostridium difficile colitis	1 (3.6)	0	0	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	0	0	1 (3.6)
Device related bacteraemia	1 (3.6)	0	1 (3.6)	0	0
Device related infection	1 (3.6)	0	1 (3.6)	0	0
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Ear, nose and throat infection	1 (3.6)	0	1 (3.6)	0	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Epstein-barr virus infection	1 (3.6)	0	1 (3.6)	0	0
Fungal infection	1 (3.6)	0	1 (3.6)	0	0
Fungal skin infection	1 (3.6)	0	1 (3.6)	0	0
Gastroenteritis	1 (3.6)	0	0	1 (3.6)	0
Gastroenteritis escherichia coli	1 (3.6)	0	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (3.6)	0	0	1 (3.6)	0
Gastrointestinal infection	1 (3.6)	1 (3.6)	0	0	0
Gingivitis	1 (3.6)	1 (3.6)	0	0	0
Herpes zoster	1 (3.6)	0	0	1 (3.6)	0
Influenza	1 (3.6)	0	0	0	1 (3.6)
Metapneumovirus infection	1 (3.6)	0	0	1 (3.6)	0
Molluscum contagiosum	1 (3.6)	1 (3.6)	0	0	0
Nail infection	1 (3.6)	1 (3.6)	0	0	0
Nasopharyngitis	1 (3.6)	0	1 (3.6)	0	0
Neutropenic infection	1 (3.6)	0	0	1 (3.6)	0
Otitis externa	1 (3.6)	0	1 (3.6)	0	0
Otitis media acute	1 (3.6)	0	1 (3.6)	0	0
Paronychia	1 (3.6)	0	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	0	1 (3.6)	0
Respiratory tract infection	1 (3.6)	0	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	0	1 (3.6)	0	0
Rhinitis	1 (3.6)	0	1 (3.6)	0	0
Sepsis	1 (3.6)	0	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Staphylococcal skin infection	1 (3.6)	0	0	1 (3.6)	0
Tinea pedis	1 (3.6)	1 (3.6)	0	0	0
Urinary tract infection	1 (3.6)	0	1 (3.6)	0	0
Varicella zoster virus infection	1 (3.6)	0	1 (3.6)	0	0
Viral haemorrhagic cystitis	1 (3.6)	0	0	1 (3.6)	0
Vulval cellulitis	1 (3.6)	0	0	1 (3.6)	0
Injury, poisoning and procedural complications					
-Total	8 (28.6)	4 (14.3)	2 (7.1)	1 (3.6)	1 (3.6)
Infusion related reaction	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Abdominal injury	1 (3.6)	1 (3.6)	0	0	0
Fibula fracture	1 (3.6)	0	1 (3.6)	0	0
Scratch	1 (3.6)	1 (3.6)	0	0	0
Skin abrasion	1 (3.6)	1 (3.6)	0	0	0
Skin injury	1 (3.6)	0	1 (3.6)	0	0
Skin wound	1 (3.6)	1 (3.6)	0	0	0
Vasoplegia syndrome	1 (3.6)	0	0	0	1 (3.6)

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (3.6)	0	0	1 (3.6)	0
Investigations					
-Total	18 (64.3)	0	2 (7.1)	7 (25.0)	9 (32.1)
Neutrophil count decreased	9 (32.1)	0	1 (3.6)	2 (7.1)	6 (21.4)
White blood cell count decreased	9 (32.1)	1 (3.6)	2 (7.1)	1 (3.6)	5 (17.9)
Lymphocyte count decreased	7 (25.0)	0	0	5 (17.9)	2 (7.1)
Platelet count decreased	7 (25.0)	2 (7.1)	1 (3.6)	0	4 (14.3)
Alanine aminotransferase increased	6 (21.4)	2 (7.1)	2 (7.1)	2 (7.1)	0
Aspartate aminotransferase increased	5 (17.9)	1 (3.6)	2 (7.1)	1 (3.6)	1 (3.6)
C-reactive protein increased	4 (14.3)	1 (3.6)	0	3 (10.7)	0
Serum ferritin increased	4 (14.3)	1 (3.6)	1 (3.6)	2 (7.1)	0
Blood bilirubin increased	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Blood immunoglobulin g decreased	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Blood immunoglobulin m decreased	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
International normalised ratio increased	3 (10.7)	3 (10.7)	0	0	0
Activated partial thromboplastin time prolonged	2 (7.1)	1 (3.6)	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Blood lactate dehydrogenase increased	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Blood phosphorus increased	2 (7.1)	0	2 (7.1)	0	0
Electrocardiogram qt prolonged	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Fibrin d dimer increased	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Lipase increased	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Oxygen saturation decreased	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Amylase increased	1 (3.6)	1 (3.6)	0	0	0
Bacterial test positive	1 (3.6)	0	0	1 (3.6)	0
Blood creatine phosphokinase increased	1 (3.6)	0	0	0	1 (3.6)
Blood creatinine increased	1 (3.6)	0	0	1 (3.6)	0
Blood fibrinogen decreased	1 (3.6)	0	1 (3.6)	0	0
Blood fibrinogen increased	1 (3.6)	1 (3.6)	0	0	0
Blood testosterone decreased	1 (3.6)	1 (3.6)	0	0	0
Electrocardiogram t wave abnormal	1 (3.6)	0	1 (3.6)	0	0
Troponin increased	1 (3.6)	0	0	1 (3.6)	0
Weight decreased	1 (3.6)	0	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (3.6)	1 (3.6)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (57.1)	2 (7.1)	5 (17.9)	5 (17.9)	4 (14.3)
Decreased appetite	10 (35.7)	4 (14.3)	3 (10.7)	2 (7.1)	1 (3.6)
Hypophosphataemia	7 (25.0)	0	4 (14.3)	3 (10.7)	0
Hypocalcaemia	6 (21.4)	0	4 (14.3)	2 (7.1)	0
Hypokalaemia	6 (21.4)	1 (3.6)	0	3 (10.7)	2 (7.1)
Hyperuricaemia	3 (10.7)	3 (10.7)	0	0	0
Hypomagnesaemia	3 (10.7)	3 (10.7)	0	0	0
Hyperglycaemia	2 (7.1)	0	0	2 (7.1)	0
Hypertriglyceridaemia	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Hypervolaemia	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Hypoalbuminaemia	2 (7.1)	0	2 (7.1)	0	0
Calcium deficiency	1 (3.6)	1 (3.6)	0	0	0
Dehydration	1 (3.6)	0	1 (3.6)	0	0
Haemochromatosis	1 (3.6)	0	0	1 (3.6)	0
Haemosiderosis	1 (3.6)	0	1 (3.6)	0	0
Hypercalcaemia	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypercholesterolaemia	1 (3.6)	0	1 (3.6)	0	0
Hyperkalaemia	1 (3.6)	0	1 (3.6)	0	0
Hyperlactacidaemia	1 (3.6)	1 (3.6)	0	0	0
Hypernatraemia	1 (3.6)	0	0	0	1 (3.6)
Hyperphosphataemia	1 (3.6)	1 (3.6)	0	0	0
Iron overload	1 (3.6)	0	1 (3.6)	0	0
Malnutrition	1 (3.6)	0	0	1 (3.6)	0
Metabolic acidosis	1 (3.6)	1 (3.6)	0	0	0
Obesity	1 (3.6)	0	0	1 (3.6)	0
Tumour lysis syndrome	1 (3.6)	0	0	1 (3.6)	0
Vitamin d deficiency	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (42.9)	4 (14.3)	5 (17.9)	2 (7.1)	1 (3.6)
Pain in extremity	6 (21.4)	4 (14.3)	2 (7.1)	0	0
Back pain	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Arthralgia	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Growth retardation	2 (7.1)	0	2 (7.1)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Groin pain	1 (3.6)	1 (3.6)	0	0	0
Haemarthrosis	1 (3.6)	0	0	1 (3.6)	0
Joint effusion	1 (3.6)	0	1 (3.6)	0	0
Myositis	1 (3.6)	0	1 (3.6)	0	0
Osteopenia	1 (3.6)	1 (3.6)	0	0	0
Rhabdomyolysis	1 (3.6)	0	0	0	1 (3.6)
Synovitis	1 (3.6)	0	1 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.6)	0	0	1 (3.6)	0
Bone giant cell tumour benign	1 (3.6)	0	0	1 (3.6)	0
Nervous system disorders					
-Total	15 (53.6)	5 (17.9)	5 (17.9)	4 (14.3)	1 (3.6)
Headache	9 (32.1)	6 (21.4)	2 (7.1)	1 (3.6)	0
Seizure	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Cognitive disorder	2 (7.1)	0	2 (7.1)	0	0
Encephalopathy	2 (7.1)	0	0	2 (7.1)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Autonomic neuropathy	1 (3.6)	0	0	1 (3.6)	0
Cerebral haemorrhage	1 (3.6)	0	0	0	1 (3.6)
Dysarthria	1 (3.6)	0	1 (3.6)	0	0
Dysgeusia	1 (3.6)	1 (3.6)	0	0	0
Lethargy	1 (3.6)	1 (3.6)	0	0	0
Memory impairment	1 (3.6)	0	1 (3.6)	0	0
Monoparesis	1 (3.6)	0	1 (3.6)	0	0
Neuropathy peripheral	1 (3.6)	0	1 (3.6)	0	0
Somnolence	1 (3.6)	1 (3.6)	0	0	0
Tremor	1 (3.6)	1 (3.6)	0	0	0
Psychiatric disorders					
-Total	12 (42.9)	6 (21.4)	4 (14.3)	2 (7.1)	0
Anxiety	5 (17.9)	2 (7.1)	2 (7.1)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Insomnia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Irritability	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Sleep disorder	2 (7.1)	0	2 (7.1)	0	0
Persistent depressive disorder	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	6 (21.4)	3 (10.7)	0	1 (3.6)	2 (7.1)
Dysuria	3 (10.7)	3 (10.7)	0	0	0
Acute kidney injury	1 (3.6)	0	0	0	1 (3.6)
Anuria	1 (3.6)	0	0	0	1 (3.6)
Bladder dilatation	1 (3.6)	0	1 (3.6)	0	0
Renal pain	1 (3.6)	1 (3.6)	0	0	0
Renal tubular disorder	1 (3.6)	0	0	1 (3.6)	0
Renal tubular necrosis	1 (3.6)	0	0	0	1 (3.6)
Urinary retention	1 (3.6)	0	1 (3.6)	0	0
Reproductive system and breast disorders					
-Total	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Endometriosis	1 (3.6)	0	0	1 (3.6)	0
Heavy menstrual bleeding	1 (3.6)	0	1 (3.6)	0	0
Vaginal ulceration	1 (3.6)	0	0	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (60.7)	7 (25.0)	4 (14.3)	2 (7.1)	4 (14.3)

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	7 (25.0)	4 (14.3)	3 (10.7)	0	0
Nasal congestion	5 (17.9)	4 (14.3)	1 (3.6)	0	0
Pleural effusion	4 (14.3)	0	2 (7.1)	1 (3.6)	1 (3.6)
Epistaxis	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Hypoxia	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Pulmonary oedema	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Acute respiratory distress syndrome	2 (7.1)	0	0	0	2 (7.1)
Dyspnoea	2 (7.1)	0	0	0	2 (7.1)
Rhinitis allergic	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Rhinorrhoea	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Tachypnoea	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Atelectasis	1 (3.6)	0	0	1 (3.6)	0
Bronchospasm	1 (3.6)	0	1 (3.6)	0	0
Dyspnoea exertional	1 (3.6)	1 (3.6)	0	0	0
Lung disorder	1 (3.6)	1 (3.6)	0	0	0
Nasal dryness	1 (3.6)	1 (3.6)	0	0	0
Oropharyngeal pain	1 (3.6)	0	1 (3.6)	0	0
Pharyngeal erythema	1 (3.6)	1 (3.6)	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory acidosis	1 (3.6)	0	0	1 (3.6)	0
Sleep apnoea syndrome	1 (3.6)	0	1 (3.6)	0	0
Wheezing	1 (3.6)	0	1 (3.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (53.6)	9 (32.1)	4 (14.3)	2 (7.1)	0
Rash	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Erythema	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Pruritus	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Dry skin	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Rash maculo-papular	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Skin ulcer	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Acne	1 (3.6)	1 (3.6)	0	0	0
Decubitus ulcer	1 (3.6)	0	1 (3.6)	0	0
Dermatitis	1 (3.6)	1 (3.6)	0	0	0
Dermatitis allergic	1 (3.6)	1 (3.6)	0	0	0
Eczema	1 (3.6)	1 (3.6)	0	0	0
Ingrowing nail	1 (3.6)	0	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Miliaria	1 (3.6)	1 (3.6)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (3.6)	1 (3.6)	0	0	0
Petechiae	1 (3.6)	0	0	1 (3.6)	0
Rash papular	1 (3.6)	1 (3.6)	0	0	0
Skin discolouration	1 (3.6)	1 (3.6)	0	0	0
Skin necrosis	1 (3.6)	0	0	1 (3.6)	0
Vascular disorders					
-Total	13 (46.4)	2 (7.1)	5 (17.9)	5 (17.9)	1 (3.6)
Hypotension	9 (32.1)	2 (7.1)	3 (10.7)	3 (10.7)	1 (3.6)
Hypertension	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Capillary leak syndrome	1 (3.6)	0	0	1 (3.6)	0
Flushing	1 (3.6)	1 (3.6)	0	0	0
Peripheral ischaemia	1 (3.6)	0	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208n
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (97.1)	0	2 (2.9)	10 (14.3)	56 (80.0)
Blood and lymphatic system disorders					
-Total	47 (67.1)	1 (1.4)	5 (7.1)	28 (40.0)	13 (18.6)
Febrile neutropenia	28 (40.0)	0	0	26 (37.1)	2 (2.9)
Anaemia	27 (38.6)	2 (2.9)	9 (12.9)	15 (21.4)	1 (1.4)
Neutropenia	11 (15.7)	1 (1.4)	1 (1.4)	2 (2.9)	7 (10.0)
Thrombocytopenia	7 (10.0)	0	0	2 (2.9)	5 (7.1)
Disseminated intravascular coagulation	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Coagulopathy	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Splenomegaly	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Leukopenia	2 (2.9)	0	0	0	2 (2.9)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (2.9)	0	0	0	2 (2.9)
Pancytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Agranulocytosis	1 (1.4)	0	0	1 (1.4)	0
Eosinophilia	1 (1.4)	0	1 (1.4)	0	0
Hypofibrinogenaemia	1 (1.4)	0	1 (1.4)	0	0
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Cardiac disorders					
-Total	27 (38.6)	7 (10.0)	6 (8.6)	9 (12.9)	5 (7.1)
Tachycardia	15 (21.4)	4 (5.7)	7 (10.0)	4 (5.7)	0
Cardiac failure	4 (5.7)	0	0	2 (2.9)	2 (2.9)
Bradycardia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Cardiac arrest	3 (4.3)	0	0	0	3 (4.3)
Left ventricular dysfunction	3 (4.3)	0	0	3 (4.3)	0
Sinus tachycardia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Cardiac dysfunction	2 (2.9)	2 (2.9)	0	0	0
Pericardial effusion	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Atrioventricular block first degree	1 (1.4)	0	1 (1.4)	0	0
Cardiac failure congestive	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mitral valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Right ventricular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Tricuspid valve incompetence	1 (1.4)	1 (1.4)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Cerebral cavernous malformation	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Ear pain	1 (1.4)	1 (1.4)	0	0	0
Ear pruritus	1 (1.4)	1 (1.4)	0	0	0
Vertigo	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	5 (7.1)	0	5 (7.1)	0	0
Adrenal insufficiency	4 (5.7)	0	4 (5.7)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (15.7)	6 (8.6)	4 (5.7)	1 (1.4)	0
Cataract	2 (2.9)	2 (2.9)	0	0	0
Eye pain	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Eyelid oedema	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Visual impairment	2 (2.9)	2 (2.9)	0	0	0
Conjunctival haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Eye oedema	1 (1.4)	1 (1.4)	0	0	0
Hypermetropia	1 (1.4)	1 (1.4)	0	0	0
Mydriasis	1 (1.4)	0	1 (1.4)	0	0
Periorbital oedema	1 (1.4)	1 (1.4)	0	0	0
Periorbital swelling	1 (1.4)	0	1 (1.4)	0	0
Retinal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Vision blurred	1 (1.4)	1 (1.4)	0	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	50 (71.4)	11 (15.7)	22 (31.4)	15 (21.4)	2 (2.9)
Nausea	23 (32.9)	11 (15.7)	11 (15.7)	1 (1.4)	0
Vomiting	20 (28.6)	13 (18.6)	6 (8.6)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	16 (22.9)	9 (12.9)	5 (7.1)	2 (2.9)	0
Abdominal pain	12 (17.1)	2 (2.9)	8 (11.4)	2 (2.9)	0
Constipation	12 (17.1)	2 (2.9)	10 (14.3)	0	0
Stomatitis	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Mouth haemorrhage	5 (7.1)	2 (2.9)	1 (1.4)	2 (2.9)	0
Haematemesis	4 (5.7)	4 (5.7)	0	0	0
Pancreatitis	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Abdominal pain upper	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Gastrointestinal sounds abnormal	3 (4.3)	3 (4.3)	0	0	0
Abdominal compartment syndrome	2 (2.9)	0	0	0	2 (2.9)
Abdominal distension	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Dry mouth	2 (2.9)	0	2 (2.9)	0	0
Gastrointestinal haemorrhage	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Gingival bleeding	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Gingival erythema	2 (2.9)	2 (2.9)	0	0	0
Neutropenic colitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Oral pain	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Proctalgia	2 (2.9)	1 (1.4)	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal rigidity	1 (1.4)	0	1 (1.4)	0	0
Anal erythema	1 (1.4)	1 (1.4)	0	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal fistula	1 (1.4)	0	0	1 (1.4)	0
Anal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Anal inflammation	1 (1.4)	0	0	1 (1.4)	0
Ascites	1 (1.4)	1 (1.4)	0	0	0
Duodenal perforation	1 (1.4)	0	0	1 (1.4)	0
Dysphagia	1 (1.4)	0	0	1 (1.4)	0
Enteritis	1 (1.4)	0	1 (1.4)	0	0
Enterocolitis	1 (1.4)	0	1 (1.4)	0	0
Gastritis	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal inflammation	1 (1.4)	0	1 (1.4)	0	0
Gastrooesophageal reflux disease	1 (1.4)	0	1 (1.4)	0	0
Gingivitis ulcerative	1 (1.4)	0	0	1 (1.4)	0
Haemoperitoneum	1 (1.4)	0	0	0	1 (1.4)
Haemorrhoids	1 (1.4)	0	1 (1.4)	0	0
Ileus	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip dry	1 (1.4)	0	1 (1.4)	0	0
Lip oedema	1 (1.4)	1 (1.4)	0	0	0
Mouth swelling	1 (1.4)	1 (1.4)	0	0	0
Odynophagia	1 (1.4)	1 (1.4)	0	0	0
Oral disorder	1 (1.4)	1 (1.4)	0	0	0
Trichoglossia	1 (1.4)	1 (1.4)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	43 (61.4)	21 (30.0)	9 (12.9)	11 (15.7)	2 (2.9)
Pyrexia	29 (41.4)	12 (17.1)	6 (8.6)	10 (14.3)	1 (1.4)
Fatigue	14 (20.0)	12 (17.1)	2 (2.9)	0	0
Chills	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Oedema peripheral	6 (8.6)	5 (7.1)	1 (1.4)	0	0
Generalised oedema	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Pain	5 (7.1)	0	3 (4.3)	2 (2.9)	0
Asthenia	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Catheter site pain	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	4 (5.7)	4 (5.7)	0	0	0
Localised oedema	2 (2.9)	2 (2.9)	0	0	0
Malaise	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Non-cardiac chest pain	2 (2.9)	2 (2.9)	0	0	0
Vascular device occlusion	2 (2.9)	2 (2.9)	0	0	0
Catheter site erythema	1 (1.4)	1 (1.4)	0	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Chest discomfort	1 (1.4)	0	0	1 (1.4)	0
Complication associated with device	1 (1.4)	1 (1.4)	0	0	0
Crying	1 (1.4)	0	1 (1.4)	0	0
Drug withdrawal syndrome	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Multiple organ dysfunction syndrome	1 (1.4)	0	0	0	1 (1.4)
Oedema due to hepatic disease	1 (1.4)	0	1 (1.4)	0	0
Sluggishness	1 (1.4)	0	1 (1.4)	0	0
Swelling face	1 (1.4)	1 (1.4)	0	0	0
Thirst	1 (1.4)	1 (1.4)	0	0	0
Xerosis	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	20 (28.6)	5 (7.1)	7 (10.0)	6 (8.6)	2 (2.9)
Hyperbilirubinaemia	6 (8.6)	1 (1.4)	3 (4.3)	2 (2.9)	0
Hepatic function abnormal	5 (7.1)	0	2 (2.9)	2 (2.9)	1 (1.4)
Hepatomegaly	3 (4.3)	2 (2.9)	0	0	1 (1.4)
Hypertransaminasaemia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Biliary tract disorder	1 (1.4)	1 (1.4)	0	0	0
Drug-induced liver injury	1 (1.4)	0	0	1 (1.4)	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic cytolysis	1 (1.4)	0	0	1 (1.4)	0
Hepatosplenomegaly	1 (1.4)	0	1 (1.4)	0	0
Liver disorder	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	49 (70.0)	1 (1.4)	12 (17.1)	19 (27.1)	17 (24.3)
Cytokine release syndrome	43 (61.4)	2 (2.9)	10 (14.3)	14 (20.0)	17 (24.3)
Hypogammaglobulinaemia	20 (28.6)	1 (1.4)	14 (20.0)	5 (7.1)	0
Haemophagocytic lymphohistiocytosis	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	3 (4.3)	0	0	3 (4.3)	0
Seasonal allergy	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Allergy to immunoglobulin therapy	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Drug hypersensitivity	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Immunodeficiency	2 (2.9)	0	0	2 (2.9)	0
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Engraftment syndrome	1 (1.4)	0	0	1 (1.4)	0
Hypersensitivity	1 (1.4)	1 (1.4)	0	0	0
Selective igg subclass deficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	53 (75.7)	4 (5.7)	4 (5.7)	29 (41.4)	16 (22.9)
Nasopharyngitis	7 (10.0)	5 (7.1)	2 (2.9)	0	0
Pneumonia	7 (10.0)	1 (1.4)	1 (1.4)	3 (4.3)	2 (2.9)
Staphylococcal infection	7 (10.0)	0	3 (4.3)	3 (4.3)	1 (1.4)
Upper respiratory tract infection	7 (10.0)	2 (2.9)	4 (5.7)	1 (1.4)	0
Gastroenteritis	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Oral herpes	6 (8.6)	1 (1.4)	3 (4.3)	2 (2.9)	0
Bacteraemia	5 (7.1)	0	1 (1.4)	3 (4.3)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	5 (7.1)	0	5 (7.1)	0	0
Candida infection	4 (5.7)	0	3 (4.3)	0	1 (1.4)
Conjunctivitis	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Parainfluenzae virus infection	4 (5.7)	0	1 (1.4)	2 (2.9)	1 (1.4)
Paronychia	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Sinusitis	4 (5.7)	0	2 (2.9)	2 (2.9)	0
Acute sinusitis	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Bronchitis	3 (4.3)	0	3 (4.3)	0	0
Escherichia bacteraemia	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Gastroenteritis viral	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Herpes zoster	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Nail infection	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Oral candidiasis	3 (4.3)	0	3 (4.3)	0	0
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Sepsis	3 (4.3)	0	0	0	3 (4.3)
Septic shock	3 (4.3)	0	0	0	3 (4.3)
Staphylococcal bacteraemia	3 (4.3)	0	0	3 (4.3)	0
Adenovirus infection	2 (2.9)	0	0	2 (2.9)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Bronchiolitis	2 (2.9)	0	0	2 (2.9)	0
Bronchopulmonary aspergillosis	2 (2.9)	0	0	2 (2.9)	0
Catheter site infection	2 (2.9)	0	0	2 (2.9)	0
Clostridium difficile infection	2 (2.9)	0	0	2 (2.9)	0
Covid-19	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Cytomegalovirus infection reactivation	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Ear infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Encephalitis viral	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Gingivitis	2 (2.9)	2 (2.9)	0	0	0
Herpes simplex	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	2 (2.9)	0	0	2 (2.9)	0
Influenza	2 (2.9)	0	2 (2.9)	0	0
Klebsiella bacteraemia	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0
Oral infection	2 (2.9)	0	2 (2.9)	0	0
Otitis externa	2 (2.9)	0	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	2 (2.9)	0	0	2 (2.9)	0
Respiratory tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Rhinitis	2 (2.9)	2 (2.9)	0	0	0
Skin infection	2 (2.9)	0	2 (2.9)	0	0
Urinary tract infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Anal abscess	1 (1.4)	0	0	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	0	0	1 (1.4)
Atypical pneumonia	1 (1.4)	1 (1.4)	0	0	0
Cholecystitis infective	1 (1.4)	0	1 (1.4)	0	0
Coronavirus infection	1 (1.4)	0	0	1 (1.4)	0
Cystitis	1 (1.4)	0	1 (1.4)	0	0
Device related sepsis	1 (1.4)	0	0	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	0	0	1 (1.4)
Enterobacter infection	1 (1.4)	0	0	1 (1.4)	0
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungaemia	1 (1.4)	0	0	0	1 (1.4)
Fungal infection	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Fungal skin infection	1 (1.4)	0	0	1 (1.4)	0
Gastroenteritis clostridial	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	1 (1.4)	0	0	0
Granulicatella infection	1 (1.4)	0	0	1 (1.4)	0
Herpes virus infection	1 (1.4)	0	1 (1.4)	0	0
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0	0	0
Mastoiditis	1 (1.4)	0	0	1 (1.4)	0
Meningitis bacterial	1 (1.4)	0	0	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	0	0	1 (1.4)	0
Myringitis	1 (1.4)	1 (1.4)	0	0	0
Ophthalmic herpes zoster	1 (1.4)	0	1 (1.4)	0	0
Peritonitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis	1 (1.4)	0	0	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	0	0	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	0	0	1 (1.4)
Pneumonia respiratory syncytial viral	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.4)	0	0	1 (1.4)	0
Salmonellosis	1 (1.4)	0	1 (1.4)	0	0
Serratia sepsis	1 (1.4)	0	0	0	1 (1.4)
Sialoadenitis	1 (1.4)	0	0	1 (1.4)	0
Sinusitis fungal	1 (1.4)	0	0	1 (1.4)	0
Soft tissue infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	0	1 (1.4)	0	0
Stomatococcal infection	1 (1.4)	0	0	0	1 (1.4)
Streptococcal sepsis	1 (1.4)	0	1 (1.4)	0	0
Syphilis	1 (1.4)	0	1 (1.4)	0	0
Systemic candida	1 (1.4)	0	0	1 (1.4)	0
Systemic mycosis	1 (1.4)	0	0	1 (1.4)	0
Tinea pedis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection pseudomonal	1 (1.4)	0	1 (1.4)	0	0
Urinary tract infection viral	1 (1.4)	1 (1.4)	0	0	0
Varicella zoster virus infection	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Viral skin infection	1 (1.4)	1 (1.4)	0	0	0
Viral upper respiratory tract infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	19 (27.1)	5 (7.1)	10 (14.3)	2 (2.9)	2 (2.9)
Procedural pain	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Transfusion reaction	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Fall	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Infusion related reaction	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Contusion	2 (2.9)	2 (2.9)	0	0	0
Ligament sprain	2 (2.9)	2 (2.9)	0	0	0
Wound	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Extradural haematoma	1 (1.4)	0	1 (1.4)	0	0
Limb injury	1 (1.4)	0	1 (1.4)	0	0
Post-traumatic neck syndrome	1 (1.4)	0	1 (1.4)	0	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal obstruction	1 (1.4)	0	0	0	1 (1.4)
Transplant failure	1 (1.4)	0	0	0	1 (1.4)
Traumatic haematoma	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	48 (68.6)	1 (1.4)	4 (5.7)	13 (18.6)	30 (42.9)
White blood cell count decreased	23 (32.9)	2 (2.9)	1 (1.4)	0	20 (28.6)
Platelet count decreased	21 (30.0)	4 (5.7)	1 (1.4)	6 (8.6)	10 (14.3)
Neutrophil count decreased	20 (28.6)	1 (1.4)	1 (1.4)	1 (1.4)	17 (24.3)
Alanine aminotransferase increased	16 (22.9)	3 (4.3)	6 (8.6)	7 (10.0)	0
Aspartate aminotransferase increased	16 (22.9)	1 (1.4)	3 (4.3)	9 (12.9)	3 (4.3)
Lymphocyte count decreased	16 (22.9)	1 (1.4)	1 (1.4)	4 (5.7)	10 (14.3)
Blood bilirubin increased	10 (14.3)	1 (1.4)	1 (1.4)	8 (11.4)	0
Blood fibrinogen decreased	7 (10.0)	3 (4.3)	2 (2.9)	1 (1.4)	1 (1.4)
C-reactive protein increased	7 (10.0)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.4)
International normalised ratio increased	7 (10.0)	3 (4.3)	4 (5.7)	0	0
Serum ferritin increased	7 (10.0)	1 (1.4)	4 (5.7)	1 (1.4)	1 (1.4)
Blood creatinine increased	6 (8.6)	2 (2.9)	1 (1.4)	2 (2.9)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (7.1)	4 (5.7)	0	1 (1.4)	0
Blood lactate dehydrogenase increased	5 (7.1)	2 (2.9)	1 (1.4)	2 (2.9)	0
Weight increased	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Activated partial thromboplastin time prolonged	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Blood immunoglobulin m decreased	4 (5.7)	3 (4.3)	0	1 (1.4)	0
Blood uric acid increased	4 (5.7)	2 (2.9)	0	1 (1.4)	1 (1.4)
Electrocardiogram qt prolonged	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Weight decreased	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Blood fibrinogen increased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Blood glucose increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Fibrin d dimer increased	2 (2.9)	1 (1.4)	0	0	1 (1.4)
Gamma-glutamyltransferase increased	2 (2.9)	0	0	2 (2.9)	0
Immunoglobulins decreased	2 (2.9)	0	2 (2.9)	0	0
Urine output decreased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Amylase increased	1 (1.4)	0	0	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase decreased	1 (1.4)	1 (1.4)	0	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	1 (1.4)	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus decreased	1 (1.4)	0	0	1 (1.4)	0
Blood potassium decreased	1 (1.4)	0	0	0	1 (1.4)
Blood thyroid stimulating hormone increased	1 (1.4)	1 (1.4)	0	0	0
Blood urea increased	1 (1.4)	0	0	1 (1.4)	0
Bone density decreased	1 (1.4)	1 (1.4)	0	0	0
Breath sounds abnormal	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Coagulation test abnormal	1 (1.4)	1 (1.4)	0	0	0
Ejection fraction decreased	1 (1.4)	0	1 (1.4)	0	0
Enterovirus test positive	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophil count decreased	1 (1.4)	1 (1.4)	0	0	0
Haematocrit decreased	1 (1.4)	1 (1.4)	0	0	0
Haemoglobin decreased	1 (1.4)	0	0	1 (1.4)	0
Haptoglobin decreased	1 (1.4)	1 (1.4)	0	0	0
Heart sounds abnormal	1 (1.4)	1 (1.4)	0	0	0
Hepatitis b virus test positive	1 (1.4)	0	1 (1.4)	0	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0
Prothrombin time prolonged	1 (1.4)	0	1 (1.4)	0	0
Red blood cell count decreased	1 (1.4)	1 (1.4)	0	0	0
Staphylococcus test positive	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	43 (61.4)	6 (8.6)	6 (8.6)	21 (30.0)	10 (14.3)
Decreased appetite	24 (34.3)	8 (11.4)	5 (7.1)	10 (14.3)	1 (1.4)
Hypokalaemia	19 (27.1)	3 (4.3)	5 (7.1)	10 (14.3)	1 (1.4)
Hypophosphataemia	14 (20.0)	3 (4.3)	4 (5.7)	6 (8.6)	1 (1.4)
Hypocalcaemia	12 (17.1)	2 (2.9)	6 (8.6)	4 (5.7)	0
Hypoalbuminaemia	10 (14.3)	0	9 (12.9)	1 (1.4)	0
Hyperglycaemia	7 (10.0)	0	4 (5.7)	3 (4.3)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	7 (10.0)	0	2 (2.9)	5 (7.1)	0
Hyperuricaemia	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	6 (8.6)	4 (5.7)	2 (2.9)	0	0
Hyperphosphataemia	5 (7.1)	4 (5.7)	0	0	1 (1.4)
Metabolic acidosis	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Tumour lysis syndrome	5 (7.1)	0	0	3 (4.3)	2 (2.9)
Hyponatraemia	4 (5.7)	3 (4.3)	0	0	1 (1.4)
Hyperkalaemia	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Acidosis	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hypercalcaemia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Hyperchloraemia	2 (2.9)	2 (2.9)	0	0	0
Hypermagnesaemia	2 (2.9)	2 (2.9)	0	0	0
Hypernatraemia	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Eating disorder symptom	1 (1.4)	0	1 (1.4)	0	0
Hyperlipidaemia	1 (1.4)	0	1 (1.4)	0	0
Hypertriglyceridaemia	1 (1.4)	0	0	1 (1.4)	0
Hypoglycaemia	1 (1.4)	0	1 (1.4)	0	0
Hypophagia	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (1.4)	0	1 (1.4)	0	0
Malnutrition	1 (1.4)	0	0	1 (1.4)	0
Metabolic syndrome	1 (1.4)	0	1 (1.4)	0	0
Polydipsia	1 (1.4)	0	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					
-Total	36 (51.4)	14 (20.0)	14 (20.0)	8 (11.4)	0
Pain in extremity	17 (24.3)	5 (7.1)	9 (12.9)	3 (4.3)	0
Arthralgia	11 (15.7)	6 (8.6)	5 (7.1)	0	0
Back pain	9 (12.9)	0	6 (8.6)	3 (4.3)	0
Myalgia	8 (11.4)	5 (7.1)	3 (4.3)	0	0
Bone pain	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Pain in jaw	3 (4.3)	1 (1.4)	0	2 (2.9)	0
Muscular weakness	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Musculoskeletal chest pain	2 (2.9)	2 (2.9)	0	0	0
Neck pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Joint effusion	1 (1.4)	0	0	1 (1.4)	0
Muscle rigidity	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Muscle spasms	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal pain	1 (1.4)	0	1 (1.4)	0	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Osteonecrosis	1 (1.4)	1 (1.4)	0	0	0
Spinal pain	1 (1.4)	0	0	1 (1.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Skin papilloma	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Cancer pain	1 (1.4)	0	1 (1.4)	0	0
Myelodysplastic syndrome	1 (1.4)	0	0	1 (1.4)	0
Nervous system disorders					
-Total	40 (57.1)	12 (17.1)	15 (21.4)	9 (12.9)	4 (5.7)
Headache	23 (32.9)	10 (14.3)	11 (15.7)	2 (2.9)	0
Encephalopathy	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Dizziness	5 (7.1)	5 (7.1)	0	0	0
Somnolence	5 (7.1)	1 (1.4)	2 (2.9)	2 (2.9)	0
Tremor	5 (7.1)	4 (5.7)	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lethargy	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Seizure	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Cognitive disorder	2 (2.9)	0	0	2 (2.9)	0
Dysgeusia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Paraesthesia	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Amnesia	1 (1.4)	0	1 (1.4)	0	0
Aphasia	1 (1.4)	1 (1.4)	0	0	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Depressed level of consciousness	1 (1.4)	0	0	1 (1.4)	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysarthria	1 (1.4)	0	0	1 (1.4)	0
Extrapyramidal disorder	1 (1.4)	0	1 (1.4)	0	0
Generalised tonic-clonic seizure	1 (1.4)	0	1 (1.4)	0	0
Haemorrhage intracranial	1 (1.4)	0	0	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	0	0	1 (1.4)
Hyperaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Migraine	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorder	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neurological decompensation	1 (1.4)	0	0	0	1 (1.4)
Posterior reversible encephalopathy syndrome	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	29 (41.4)	7 (10.0)	14 (20.0)	8 (11.4)	0
Anxiety	11 (15.7)	2 (2.9)	7 (10.0)	2 (2.9)	0
Delirium	8 (11.4)	2 (2.9)	3 (4.3)	3 (4.3)	0
Agitation	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Mental status changes	6 (8.6)	1 (1.4)	2 (2.9)	3 (4.3)	0
Confusional state	5 (7.1)	5 (7.1)	0	0	0
Insomnia	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Hallucination	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Affect lability	1 (1.4)	0	1 (1.4)	0	0
Automatism	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination, visual	1 (1.4)	0	1 (1.4)	0	0
Mood altered	1 (1.4)	1 (1.4)	0	0	0
Nightmare	1 (1.4)	1 (1.4)	0	0	0
Restlessness	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Social avoidant behaviour	1 (1.4)	0	1 (1.4)	0	0
Tearfulness	1 (1.4)	1 (1.4)	0	0	0
Tic	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	24 (34.3)	7 (10.0)	7 (10.0)	5 (7.1)	5 (7.1)
Acute kidney injury	14 (20.0)	5 (7.1)	2 (2.9)	3 (4.3)	4 (5.7)
Haematuria	4 (5.7)	3 (4.3)	0	1 (1.4)	0
Dysuria	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Pollakiuria	2 (2.9)	0	2 (2.9)	0	0
Renal failure	2 (2.9)	0	1 (1.4)	0	1 (1.4)
Anuria	1 (1.4)	1 (1.4)	0	0	0
Azotaemia	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Incontinence	1 (1.4)	0	1 (1.4)	0	0
Kidney enlargement	1 (1.4)	0	1 (1.4)	0	0
Micturition urgency	1 (1.4)	0	1 (1.4)	0	0
Proteinuria	1 (1.4)	1 (1.4)	0	0	0
Renal mass	1 (1.4)	0	1 (1.4)	0	0
Renal tubular dysfunction	1 (1.4)	1 (1.4)	0	0	0
Renal tubular necrosis	1 (1.4)	0	0	1 (1.4)	0
Urinary incontinence	1 (1.4)	0	1 (1.4)	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Urinary tract disorder	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Dysmenorrhoea	1 (1.4)	0	1 (1.4)	0	0
Female genital tract fistula	1 (1.4)	1 (1.4)	0	0	0
Perineal rash	1 (1.4)	0	1 (1.4)	0	0
Prostatitis	1 (1.4)	0	0	1 (1.4)	0
Vaginal haemorrhage	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	45 (64.3)	12 (17.1)	4 (5.7)	11 (15.7)	18 (25.7)
Cough	19 (27.1)	17 (24.3)	2 (2.9)	0	0
Hypoxia	18 (25.7)	0	4 (5.7)	8 (11.4)	6 (8.6)
Pulmonary oedema	11 (15.7)	2 (2.9)	3 (4.3)	4 (5.7)	2 (2.9)
Respiratory failure	10 (14.3)	0	0	0	10 (14.3)
Epistaxis	9 (12.9)	5 (7.1)	1 (1.4)	3 (4.3)	0
Oropharyngeal pain	9 (12.9)	8 (11.4)	1 (1.4)	0	0
Tachypnoea	8 (11.4)	3 (4.3)	2 (2.9)	3 (4.3)	0
Dyspnoea	6 (8.6)	1 (1.4)	2 (2.9)	3 (4.3)	0
Nasal congestion	6 (8.6)	5 (7.1)	1 (1.4)	0	0
Pleural effusion	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Respiratory distress	4 (5.7)	0	2 (2.9)	0	2 (2.9)
Rhinorrhoea	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Acute respiratory distress syndrome	2 (2.9)	0	0	0	2 (2.9)
Atelectasis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Acute respiratory failure	1 (1.4)	0	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradypnoea	1 (1.4)	0	0	1 (1.4)	0
Bronchial oedema	1 (1.4)	1 (1.4)	0	0	0
Haemoptysis	1 (1.4)	0	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	0	0	1 (1.4)
Lung infiltration	1 (1.4)	0	0	1 (1.4)	0
Nasal discomfort	1 (1.4)	0	1 (1.4)	0	0
Oropharyngeal plaque	1 (1.4)	0	1 (1.4)	0	0
Painful respiration	1 (1.4)	1 (1.4)	0	0	0
Paranasal sinus discomfort	1 (1.4)	0	1 (1.4)	0	0
Paranasal sinus inflammation	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal erythema	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal exudate	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Pharyngeal oedema	1 (1.4)	0	1 (1.4)	0	0
Productive cough	1 (1.4)	1 (1.4)	0	0	0
Pulmonary haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory disorder	1 (1.4)	0	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep apnoea syndrome	1 (1.4)	1 (1.4)	0	0	0
Upper respiratory tract inflammation	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	33 (47.1)	13 (18.6)	14 (20.0)	6 (8.6)	0
Pruritus	8 (11.4)	3 (4.3)	5 (7.1)	0	0
Dry skin	7 (10.0)	6 (8.6)	1 (1.4)	0	0
Rash	6 (8.6)	2 (2.9)	4 (5.7)	0	0
Blister	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Dermatitis atopic	3 (4.3)	2 (2.9)	0	1 (1.4)	0
Erythema	3 (4.3)	3 (4.3)	0	0	0
Hyperhidrosis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Ingrowing nail	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Rash papular	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Eczema	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Petechiae	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Rash maculo-papular	2 (2.9)	1 (1.4)	0	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin ulcer	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Dermatitis diaper	1 (1.4)	0	1 (1.4)	0	0
Drug eruption	1 (1.4)	0	1 (1.4)	0	0
Erythema nodosum	1 (1.4)	1 (1.4)	0	0	0
Hangnail	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Photosensitivity reaction	1 (1.4)	0	1 (1.4)	0	0
Pruritus allergic	1 (1.4)	0	1 (1.4)	0	0
Purpura	1 (1.4)	1 (1.4)	0	0	0
Rash erythematous	1 (1.4)	1 (1.4)	0	0	0
Rash macular	1 (1.4)	0	0	1 (1.4)	0
Rash pruritic	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Scab	1 (1.4)	1 (1.4)	0	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin hypopigmentation	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin lesion	1 (1.4)	0	1 (1.4)	0	0
Skin swelling	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vancomycin infusion reaction	1 (1.4)	0	0	1 (1.4)	0
Social circumstances					
-Total	1 (1.4)	0	1 (1.4)	0	0
Patient uncooperative	1 (1.4)	0	1 (1.4)	0	0
Surgical and medical procedures					
-Total	1 (1.4)	0	0	1 (1.4)	0
Thrombolysis	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	30 (42.9)	3 (4.3)	6 (8.6)	11 (15.7)	10 (14.3)
Hypotension	21 (30.0)	0	3 (4.3)	9 (12.9)	9 (12.9)
Hypertension	15 (21.4)	4 (5.7)	8 (11.4)	3 (4.3)	0
Venoocclusive disease	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Capillary leak syndrome	1 (1.4)	0	1 (1.4)	0	0
Flushing	1 (1.4)	1 (1.4)	0	0	0
Haematoma	1 (1.4)	1 (1.4)	0	0	0

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Peripheral ischaemia	1 (1.4)	0	1 (1.4)	0	0
Thrombosis	1 (1.4)	0	1 (1.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208o
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	1 (9.1)	3 (27.3)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Anaemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
B-cell aplasia	1 (9.1)	0	1 (9.1)	0	0
Disseminated intravascular coagulation	1 (9.1)	0	0	1 (9.1)	0
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Leukopenia	1 (9.1)	0	0	0	1 (9.1)
Pancytopenia	1 (9.1)	0	0	1 (9.1)	0
Thrombocytopenia	1 (9.1)	0	1 (9.1)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Left ventricular dysfunction	1 (9.1)	0	1 (9.1)	0	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0	0	0
Endocrine disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Hypothyroidism	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Retinal haemorrhage	1 (9.1)	0	1 (9.1)	0	0
Visual field defect	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	7 (63.6)	3 (27.3)	3 (27.3)	1 (9.1)	0
Constipation	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Nausea	2 (18.2)	0	2 (18.2)	0	0
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Abdominal rigidity	1 (9.1)	0	1 (9.1)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (9.1)	1 (9.1)	0	0	0
Pancreatitis	1 (9.1)	0	0	1 (9.1)	0
Peritoneal haematoma	1 (9.1)	1 (9.1)	0	0	0
Trichoglossia	1 (9.1)	0	1 (9.1)	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	7 (63.6)	5 (45.5)	2 (18.2)	0	0
Pyrexia	6 (54.5)	5 (45.5)	1 (9.1)	0	0
Pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Asthenia	1 (9.1)	1 (9.1)	0	0	0
Face oedema	1 (9.1)	1 (9.1)	0	0	0
Influenza like illness	1 (9.1)	1 (9.1)	0	0	0
Hepatobiliary disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hepatic cytolysis	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Immune system disorders					
-Total	8 (72.7)	0	4 (36.4)	3 (27.3)	1 (9.1)

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	7 (63.6)	1 (9.1)	3 (27.3)	3 (27.3)	0
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Seasonal allergy	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	9 (81.8)	0	5 (45.5)	3 (27.3)	1 (9.1)
Sinusitis	3 (27.3)	0	3 (27.3)	0	0
Paronychia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Catheter site infection	1 (9.1)	0	1 (9.1)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Device related bacteraemia	1 (9.1)	0	1 (9.1)	0	0
Device related infection	1 (9.1)	0	0	1 (9.1)	0
Encephalitis	1 (9.1)	0	0	0	1 (9.1)
Fungal skin infection	1 (9.1)	0	1 (9.1)	0	0
Herpes zoster	1 (9.1)	0	1 (9.1)	0	0
Parainfluenzae virus infection	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory syncytial virus infection	1 (9.1)	0	0	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (9.1)	1 (9.1)	0	0	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal skin infection	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	1 (9.1)	0	0
Varicella zoster virus infection	1 (9.1)	0	1 (9.1)	0	0
Viral haemorrhagic cystitis	1 (9.1)	0	0	1 (9.1)	0
Injury, poisoning and procedural complications					
-Total	1 (9.1)	1 (9.1)	0	0	0
Infusion related reaction	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	8 (72.7)	0	1 (9.1)	2 (18.2)	5 (45.5)
Alanine aminotransferase increased	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Platelet count decreased	4 (36.4)	0	0	0	4 (36.4)
White blood cell count decreased	3 (27.3)	0	0	0	3 (27.3)

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Blood bilirubin increased	1 (9.1)	0	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)
Blood fibrinogen increased	1 (9.1)	1 (9.1)	0	0	0
Blood testosterone decreased	1 (9.1)	1 (9.1)	0	0	0
Blood uric acid increased	1 (9.1)	0	0	1 (9.1)	0
C-reactive protein increased	1 (9.1)	0	0	1 (9.1)	0
Gamma-glutamyltransferase increased	1 (9.1)	0	0	1 (9.1)	0
Serum ferritin increased	1 (9.1)	0	0	1 (9.1)	0
Weight decreased	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	4 (36.4)	0	2 (18.2)	0	2 (18.2)
Hypophosphataemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Decreased appetite	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Haemochromatosis	1 (9.1)	0	0	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercholesterolaemia	1 (9.1)	0	1 (9.1)	0	0
Hypertriglyceridaemia	1 (9.1)	0	1 (9.1)	0	0
Hypervolaemia	1 (9.1)	1 (9.1)	0	0	0
Hypokalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Iron overload	1 (9.1)	0	1 (9.1)	0	0
Vitamin d deficiency	1 (9.1)	1 (9.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Groin pain	1 (9.1)	1 (9.1)	0	0	0
Joint effusion	1 (9.1)	0	1 (9.1)	0	0
Synovitis	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	5 (45.5)	1 (9.1)	2 (18.2)	1 (9.1)	1 (9.1)
Headache	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Autonomic neuropathy	1 (9.1)	0	0	1 (9.1)	0
Cerebral haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Dysarthria	1 (9.1)	0	1 (9.1)	0	0
Memory impairment	1 (9.1)	0	1 (9.1)	0	0
Neuralgia	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Anxiety	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Confusional state	1 (9.1)	1 (9.1)	0	0	0
Insomnia	1 (9.1)	0	1 (9.1)	0	0
Sleep disorder	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Renal tubular disorder	1 (9.1)	0	0	1 (9.1)	0
Reproductive system and breast disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Endometriosis	1 (9.1)	0	0	1 (9.1)	0
Heavy menstrual bleeding	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	3 (27.3)	2 (18.2)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Epistaxis	1 (9.1)	1 (9.1)	0	0	0
Lung disorder	1 (9.1)	1 (9.1)	0	0	0
Nasal congestion	1 (9.1)	1 (9.1)	0	0	0
Nasal dryness	1 (9.1)	1 (9.1)	0	0	0
Pleural effusion	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (54.5)	5 (45.5)	1 (9.1)	0	0
Pruritus	2 (18.2)	2 (18.2)	0	0	0
Acne	1 (9.1)	1 (9.1)	0	0	0
Dermatitis allergic	1 (9.1)	1 (9.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (9.1)	1 (9.1)	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Photosensitivity reaction	1 (9.1)	0	1 (9.1)	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Hypertension	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hypotension	2 (18.2)	1 (9.1)	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208o
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	84 (96.6)	0	4 (4.6)	17 (19.5)	63 (72.4)
Blood and lymphatic system disorders					
-Total	62 (71.3)	1 (1.1)	8 (9.2)	36 (41.4)	17 (19.5)
Febrile neutropenia	38 (43.7)	0	0	35 (40.2)	3 (3.4)
Anaemia	36 (41.4)	5 (5.7)	10 (11.5)	20 (23.0)	1 (1.1)
Neutropenia	14 (16.1)	1 (1.1)	2 (2.3)	3 (3.4)	8 (9.2)
Thrombocytopenia	12 (13.8)	0	0	5 (5.7)	7 (8.0)
Disseminated intravascular coagulation	7 (8.0)	0	5 (5.7)	2 (2.3)	0
Coagulopathy	5 (5.7)	1 (1.1)	2 (2.3)	2 (2.3)	0
Leukopenia	4 (4.6)	0	0	1 (1.1)	3 (3.4)
Splenomegaly	4 (4.6)	3 (3.4)	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Lymphadenopathy	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Lymphopenia	2 (2.3)	0	0	0	2 (2.3)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
Eosinophilia	1 (1.1)	0	1 (1.1)	0	0
Hypercoagulation	1 (1.1)	0	1 (1.1)	0	0
Hypofibrinogenaemia	1 (1.1)	0	1 (1.1)	0	0
Leukocytosis	1 (1.1)	0	1 (1.1)	0	0
Lymphocytosis	1 (1.1)	0	1 (1.1)	0	0
Cardiac disorders					
-Total	33 (37.9)	9 (10.3)	7 (8.0)	11 (12.6)	6 (6.9)
Tachycardia	21 (24.1)	7 (8.0)	8 (9.2)	5 (5.7)	1 (1.1)
Cardiac failure	4 (4.6)	0	0	2 (2.3)	2 (2.3)
Left ventricular dysfunction	4 (4.6)	0	0	4 (4.6)	0
Bradycardia	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Cardiac arrest	3 (3.4)	0	0	0	3 (3.4)
Cardiac dysfunction	2 (2.3)	2 (2.3)	0	0	0
Pericardial effusion	2 (2.3)	1 (1.1)	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinus tachycardia	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Atrioventricular block first degree	1 (1.1)	0	1 (1.1)	0	0
Cardiac failure congestive	1 (1.1)	0	1 (1.1)	0	0
Mitral valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Right ventricular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Sinus bradycardia	1 (1.1)	0	0	1 (1.1)	0
Tricuspid valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.1)	1 (1.1)	0	0	0
Cerebral cavernous malformation	1 (1.1)	1 (1.1)	0	0	0
Ear and labyrinth disorders					
-Total	4 (4.6)	2 (2.3)	2 (2.3)	0	0
Deafness unilateral	1 (1.1)	0	1 (1.1)	0	0
Ear pain	1 (1.1)	1 (1.1)	0	0	0
Ear pruritus	1 (1.1)	1 (1.1)	0	0	0
Vertigo	1 (1.1)	0	1 (1.1)	0	0
Endocrine disorders					

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (8.0)	0	7 (8.0)	0	0
Adrenal insufficiency	5 (5.7)	0	5 (5.7)	0	0
Hypothyroidism	2 (2.3)	0	2 (2.3)	0	0
Delayed puberty	1 (1.1)	0	1 (1.1)	0	0
Eye disorders					
-Total	16 (18.4)	11 (12.6)	4 (4.6)	1 (1.1)	0
Eye pain	3 (3.4)	2 (2.3)	0	1 (1.1)	0
Eyelid oedema	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Ocular hyperaemia	3 (3.4)	3 (3.4)	0	0	0
Cataract	2 (2.3)	2 (2.3)	0	0	0
Conjunctival haemorrhage	2 (2.3)	2 (2.3)	0	0	0
Visual impairment	2 (2.3)	2 (2.3)	0	0	0
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eye oedema	1 (1.1)	1 (1.1)	0	0	0
Hypermetropia	1 (1.1)	1 (1.1)	0	0	0
Mydriasis	1 (1.1)	0	1 (1.1)	0	0
Periorbital oedema	1 (1.1)	1 (1.1)	0	0	0
Periorbital swelling	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vision blurred	1 (1.1)	1 (1.1)	0	0	0
Gastrointestinal disorders					
-Total	65 (74.7)	17 (19.5)	27 (31.0)	19 (21.8)	2 (2.3)
Nausea	31 (35.6)	14 (16.1)	14 (16.1)	3 (3.4)	0
Vomiting	29 (33.3)	19 (21.8)	8 (9.2)	2 (2.3)	0
Diarrhoea	26 (29.9)	16 (18.4)	8 (9.2)	2 (2.3)	0
Abdominal pain	16 (18.4)	4 (4.6)	10 (11.5)	2 (2.3)	0
Constipation	15 (17.2)	7 (8.0)	8 (9.2)	0	0
Stomatitis	11 (12.6)	1 (1.1)	5 (5.7)	5 (5.7)	0
Mouth haemorrhage	6 (6.9)	2 (2.3)	2 (2.3)	2 (2.3)	0
Pancreatitis	5 (5.7)	1 (1.1)	3 (3.4)	1 (1.1)	0
Abdominal pain upper	4 (4.6)	3 (3.4)	1 (1.1)	0	0
Haematemesis	4 (4.6)	4 (4.6)	0	0	0
Abdominal distension	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Ascites	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Gastrointestinal sounds abnormal	3 (3.4)	3 (3.4)	0	0	0
Gingival bleeding	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Abdominal compartment syndrome	2 (2.3)	0	0	0	2 (2.3)

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	2 (2.3)	0	2 (2.3)	0	0
Dry mouth	2 (2.3)	0	2 (2.3)	0	0
Gastrointestinal haemorrhage	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Gingival erythema	2 (2.3)	2 (2.3)	0	0	0
Ileus	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Neutropenic colitis	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Oral pain	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Proctalgia	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Anal erythema	1 (1.1)	1 (1.1)	0	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0
Anal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0
Duodenal perforation	1 (1.1)	0	0	1 (1.1)	0
Dyspepsia	1 (1.1)	1 (1.1)	0	0	0
Dysphagia	1 (1.1)	0	0	1 (1.1)	0
Enteritis	1 (1.1)	0	1 (1.1)	0	0
Enterocolitis	1 (1.1)	0	1 (1.1)	0	0
Gastritis	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal inflammation	1 (1.1)	0	1 (1.1)	0	0
Gastrooesophageal reflux disease	1 (1.1)	0	1 (1.1)	0	0
Gingivitis ulcerative	1 (1.1)	0	0	1 (1.1)	0
Haemoperitoneum	1 (1.1)	0	0	0	1 (1.1)
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Irritable bowel syndrome	1 (1.1)	0	1 (1.1)	0	0
Lip dry	1 (1.1)	0	1 (1.1)	0	0
Lip oedema	1 (1.1)	1 (1.1)	0	0	0
Lip pain	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Melaena	1 (1.1)	0	0	1 (1.1)	0
Mouth swelling	1 (1.1)	1 (1.1)	0	0	0
Odynophagia	1 (1.1)	1 (1.1)	0	0	0
Oral disorder	1 (1.1)	1 (1.1)	0	0	0
Trichoglossia	1 (1.1)	1 (1.1)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
General disorders and administration site conditions					

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	56 (64.4)	24 (27.6)	14 (16.1)	13 (14.9)	5 (5.7)
Pyrexia	37 (42.5)	13 (14.9)	11 (12.6)	11 (12.6)	2 (2.3)
Fatigue	19 (21.8)	15 (17.2)	4 (4.6)	0	0
Chills	9 (10.3)	5 (5.7)	4 (4.6)	0	0
Oedema peripheral	8 (9.2)	6 (6.9)	1 (1.1)	1 (1.1)	0
Face oedema	7 (8.0)	4 (4.6)	2 (2.3)	1 (1.1)	0
Generalised oedema	6 (6.9)	2 (2.3)	3 (3.4)	1 (1.1)	0
Pain	6 (6.9)	0	4 (4.6)	2 (2.3)	0
Catheter site pain	5 (5.7)	2 (2.3)	2 (2.3)	1 (1.1)	0
Asthenia	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Localised oedema	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Multiple organ dysfunction syndrome	3 (3.4)	0	0	0	3 (3.4)
Drug withdrawal syndrome	2 (2.3)	0	2 (2.3)	0	0
Malaise	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Non-cardiac chest pain	2 (2.3)	2 (2.3)	0	0	0
Vascular device occlusion	2 (2.3)	2 (2.3)	0	0	0
Catheter site dermatitis	1 (1.1)	1 (1.1)	0	0	0
Catheter site erythema	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Chest discomfort	1 (1.1)	0	0	1 (1.1)	0
Complication associated with device	1 (1.1)	1 (1.1)	0	0	0
Crying	1 (1.1)	0	1 (1.1)	0	0
Facial pain	1 (1.1)	0	1 (1.1)	0	0
Influenza like illness	1 (1.1)	0	1 (1.1)	0	0
Oedema due to hepatic disease	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0
Swelling face	1 (1.1)	1 (1.1)	0	0	0
Systemic inflammatory response syndrome	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Xerosis	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	22 (25.3)	6 (6.9)	8 (9.2)	5 (5.7)	3 (3.4)
Hyperbilirubinaemia	6 (6.9)	1 (1.1)	3 (3.4)	2 (2.3)	0
Hepatic function abnormal	5 (5.7)	0	2 (2.3)	2 (2.3)	1 (1.1)
Hepatomegaly	3 (3.4)	2 (2.3)	0	0	1 (1.1)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertransaminasaemia	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Cholelithiasis	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Gallbladder enlargement	2 (2.3)	2 (2.3)	0	0	0
Biliary tract disorder	1 (1.1)	1 (1.1)	0	0	0
Cholestasis	1 (1.1)	0	0	0	1 (1.1)
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Liver disorder	1 (1.1)	0	1 (1.1)	0	0
Ocular icterus	1 (1.1)	1 (1.1)	0	0	0
Immune system disorders					
-Total	65 (74.7)	2 (2.3)	20 (23.0)	22 (25.3)	21 (24.1)
Cytokine release syndrome	55 (63.2)	4 (4.6)	15 (17.2)	16 (18.4)	20 (23.0)
Hypogammaglobulinaemia	29 (33.3)	1 (1.1)	23 (26.4)	5 (5.7)	0
Haemophagocytic lymphohistiocytosis	6 (6.9)	1 (1.1)	1 (1.1)	2 (2.3)	2 (2.3)
Immunodeficiency	4 (4.6)	0	0	4 (4.6)	0
Seasonal allergy	4 (4.6)	2 (2.3)	2 (2.3)	0	0
Graft versus host disease	3 (3.4)	0	0	3 (3.4)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Allergy to immunoglobulin therapy	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Chronic graft versus host disease	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Engraftment syndrome	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	1 (1.1)	0	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	67 (77.0)	6 (6.9)	8 (9.2)	34 (39.1)	19 (21.8)
Upper respiratory tract infection	13 (14.9)	5 (5.7)	6 (6.9)	2 (2.3)	0
Pneumonia	9 (10.3)	1 (1.1)	1 (1.1)	4 (4.6)	3 (3.4)
Conjunctivitis	8 (9.2)	3 (3.4)	5 (5.7)	0	0
Nasopharyngitis	8 (9.2)	5 (5.7)	3 (3.4)	0	0
Rhinovirus infection	8 (9.2)	0	7 (8.0)	1 (1.1)	0
Gastroenteritis	7 (8.0)	4 (4.6)	1 (1.1)	2 (2.3)	0
Staphylococcal bacteraemia	7 (8.0)	0	0	7 (8.0)	0
Oral herpes	6 (6.9)	1 (1.1)	3 (3.4)	2 (2.3)	0
Parainfluenzae virus infection	6 (6.9)	1 (1.1)	1 (1.1)	3 (3.4)	1 (1.1)
Sinusitis	6 (6.9)	0	3 (3.4)	3 (3.4)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	6 (6.9)	0	2 (2.3)	3 (3.4)	1 (1.1)
Bacteraemia	5 (5.7)	0	1 (1.1)	3 (3.4)	1 (1.1)
Otitis media	5 (5.7)	0	4 (4.6)	1 (1.1)	0
Candida infection	4 (4.6)	0	3 (3.4)	0	1 (1.1)
Clostridium difficile infection	4 (4.6)	1 (1.1)	0	3 (3.4)	0
Nail infection	4 (4.6)	3 (3.4)	1 (1.1)	0	0
Acute sinusitis	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Bronchitis	3 (3.4)	0	3 (3.4)	0	0
Bronchopulmonary aspergillosis	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Ear infection	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Escherichia bacteraemia	3 (3.4)	0	0	2 (2.3)	1 (1.1)
Gastroenteritis viral	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Gingivitis	3 (3.4)	3 (3.4)	0	0	0
Herpes zoster	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Influenza	3 (3.4)	0	2 (2.3)	0	1 (1.1)
Localised infection	3 (3.4)	2 (2.3)	0	1 (1.1)	0
Metapneumovirus infection	3 (3.4)	0	0	3 (3.4)	0
Oral candidiasis	3 (3.4)	0	3 (3.4)	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Paronychia	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Sepsis	3 (3.4)	0	0	0	3 (3.4)
Septic shock	3 (3.4)	0	0	0	3 (3.4)
Skin infection	3 (3.4)	0	3 (3.4)	0	0
Adenovirus infection	2 (2.3)	0	0	2 (2.3)	0
Bk virus infection	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Bronchiolitis	2 (2.3)	0	0	2 (2.3)	0
Catheter site infection	2 (2.3)	0	0	2 (2.3)	0
Covid-19	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Device related infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Encephalitis viral	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Fungal infection	2 (2.3)	0	2 (2.3)	0	0
Herpes simplex	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.3)	0	0	2 (2.3)	0
Klebsiella bacteraemia	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Oral infection	2 (2.3)	0	2 (2.3)	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Pneumonia fungal	2 (2.3)	0	0	2 (2.3)	0
Respiratory syncytial virus infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Respiratory tract infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Rhinitis	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Tinea pedis	2 (2.3)	2 (2.3)	0	0	0
Urinary tract infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Clostridium difficile colitis	1 (1.1)	0	0	1 (1.1)	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cystitis	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Folliculitis	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Fungal skin infection	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal infection	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Peritonitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)
Staphylococcal skin infection	1 (1.1)	0	1 (1.1)	0	0
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Varicella zoster virus infection	1 (1.1)	0	0	1 (1.1)	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Vulval cellulitis	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	26 (29.9)	8 (9.2)	12 (13.8)	3 (3.4)	3 (3.4)
Infusion related reaction	5 (5.7)	1 (1.1)	3 (3.4)	1 (1.1)	0
Procedural pain	4 (4.6)	1 (1.1)	2 (2.3)	1 (1.1)	0
Transfusion reaction	4 (4.6)	1 (1.1)	2 (2.3)	1 (1.1)	0
Fall	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Wound	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Contusion	2 (2.3)	2 (2.3)	0	0	0
Ligament sprain	2 (2.3)	2 (2.3)	0	0	0
Skin abrasion	2 (2.3)	2 (2.3)	0	0	0
Abdominal injury	1 (1.1)	1 (1.1)	0	0	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Fibula fracture	1 (1.1)	0	1 (1.1)	0	0
Limb injury	1 (1.1)	0	1 (1.1)	0	0
Post-traumatic neck syndrome	1 (1.1)	0	1 (1.1)	0	0
Radius fracture	1 (1.1)	0	1 (1.1)	0	0
Scratch	1 (1.1)	1 (1.1)	0	0	0
Skin injury	1 (1.1)	0	1 (1.1)	0	0
Skin wound	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Transplant failure	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Vasoplegia syndrome	1 (1.1)	0	0	0	1 (1.1)
Investigations					
-Total	58 (66.7)	1 (1.1)	5 (5.7)	18 (20.7)	34 (39.1)
White blood cell count decreased	29 (33.3)	3 (3.4)	3 (3.4)	1 (1.1)	22 (25.3)
Neutrophil count decreased	27 (31.0)	1 (1.1)	2 (2.3)	3 (3.4)	21 (24.1)
Platelet count decreased	24 (27.6)	6 (6.9)	2 (2.3)	6 (6.9)	10 (11.5)
Lymphocyte count decreased	21 (24.1)	1 (1.1)	1 (1.1)	9 (10.3)	10 (11.5)
Aspartate aminotransferase increased	20 (23.0)	1 (1.1)	5 (5.7)	10 (11.5)	4 (4.6)
Alanine aminotransferase increased	18 (20.7)	3 (3.4)	7 (8.0)	8 (9.2)	0
Blood bilirubin increased	12 (13.8)	1 (1.1)	2 (2.3)	9 (10.3)	0
C-reactive protein increased	10 (11.5)	3 (3.4)	2 (2.3)	4 (4.6)	1 (1.1)
International normalised ratio increased	10 (11.5)	6 (6.9)	4 (4.6)	0	0
Serum ferritin increased	10 (11.5)	2 (2.3)	5 (5.7)	2 (2.3)	1 (1.1)
Blood creatinine increased	7 (8.0)	2 (2.3)	1 (1.1)	3 (3.4)	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	7 (8.0)	3 (3.4)	3 (3.4)	1 (1.1)	0
Blood immunoglobulin a decreased	7 (8.0)	5 (5.7)	1 (1.1)	1 (1.1)	0
Blood immunoglobulin m decreased	7 (8.0)	4 (4.6)	1 (1.1)	2 (2.3)	0
Blood lactate dehydrogenase increased	7 (8.0)	3 (3.4)	1 (1.1)	3 (3.4)	0
Activated partial thromboplastin time prolonged	6 (6.9)	3 (3.4)	2 (2.3)	1 (1.1)	0
Weight increased	6 (6.9)	2 (2.3)	2 (2.3)	2 (2.3)	0
Electrocardiogram qt prolonged	5 (5.7)	1 (1.1)	2 (2.3)	1 (1.1)	1 (1.1)
Blood immunoglobulin g decreased	4 (4.6)	1 (1.1)	3 (3.4)	0	0
Fibrin d dimer increased	4 (4.6)	2 (2.3)	0	1 (1.1)	1 (1.1)
Blood uric acid increased	3 (3.4)	2 (2.3)	0	0	1 (1.1)
Oxygen saturation decreased	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Weight decreased	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Amylase increased	2 (2.3)	1 (1.1)	0	0	1 (1.1)
Blood creatine phosphokinase increased	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Blood fibrinogen increased	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Blood glucose increased	2 (2.3)	1 (1.1)	0	0	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood phosphorus increased	2 (2.3)	0	2 (2.3)	0	0
Immunoglobulins decreased	2 (2.3)	0	2 (2.3)	0	0
Lipase increased	2 (2.3)	1 (1.1)	0	0	1 (1.1)
Urine output decreased	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Bacterial test positive	1 (1.1)	0	0	1 (1.1)	0
Blood alkaline phosphatase decreased	1 (1.1)	1 (1.1)	0	0	0
Blood alkaline phosphatase increased	1 (1.1)	1 (1.1)	0	0	0
Blood bicarbonate decreased	1 (1.1)	0	1 (1.1)	0	0
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0
Blood potassium decreased	1 (1.1)	0	0	0	1 (1.1)
Blood thyroid stimulating hormone increased	1 (1.1)	1 (1.1)	0	0	0
Blood urea increased	1 (1.1)	0	0	1 (1.1)	0
Bone density decreased	1 (1.1)	1 (1.1)	0	0	0
Breath sounds abnormal	1 (1.1)	0	1 (1.1)	0	0
Cardiac murmur	1 (1.1)	1 (1.1)	0	0	0
Coagulation test abnormal	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ejection fraction decreased	1 (1.1)	0	1 (1.1)	0	0
Electrocardiogram t wave abnormal	1 (1.1)	0	1 (1.1)	0	0
Enterovirus test positive	1 (1.1)	0	1 (1.1)	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Gamma-glutamyltransferase increased	1 (1.1)	0	0	1 (1.1)	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0
Haptoglobin decreased	1 (1.1)	1 (1.1)	0	0	0
Heart sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Hepatitis b virus test positive	1 (1.1)	0	1 (1.1)	0	0
Prothrombin time prolonged	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Staphylococcus test positive	1 (1.1)	1 (1.1)	0	0	0
Troponin increased	1 (1.1)	0	0	1 (1.1)	0
Metabolism and nutrition disorders					
-Total	55 (63.2)	8 (9.2)	9 (10.3)	26 (29.9)	12 (13.8)
Decreased appetite	32 (36.8)	11 (12.6)	8 (9.2)	12 (13.8)	1 (1.1)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	24 (27.6)	4 (4.6)	5 (5.7)	12 (13.8)	3 (3.4)
Hypocalcaemia	18 (20.7)	2 (2.3)	10 (11.5)	6 (6.9)	0
Hypophosphataemia	18 (20.7)	3 (3.4)	6 (6.9)	9 (10.3)	0
Hypoalbuminaemia	12 (13.8)	0	11 (12.6)	1 (1.1)	0
Hyperglycaemia	9 (10.3)	0	4 (4.6)	5 (5.7)	0
Hyperuricaemia	9 (10.3)	7 (8.0)	1 (1.1)	1 (1.1)	0
Hypervolaemia	8 (9.2)	0	2 (2.3)	6 (6.9)	0
Hypomagnesaemia	8 (9.2)	6 (6.9)	2 (2.3)	0	0
Hyperphosphataemia	6 (6.9)	5 (5.7)	0	0	1 (1.1)
Metabolic acidosis	6 (6.9)	1 (1.1)	0	2 (2.3)	3 (3.4)
Tumour lysis syndrome	6 (6.9)	0	0	4 (4.6)	2 (2.3)
Hyperkalaemia	4 (4.6)	0	1 (1.1)	2 (2.3)	1 (1.1)
Hyponatraemia	4 (4.6)	3 (3.4)	0	0	1 (1.1)
Hypercalcaemia	3 (3.4)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hypernatraemia	3 (3.4)	1 (1.1)	0	1 (1.1)	1 (1.1)
Acidosis	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Hyperchloraemia	2 (2.3)	2 (2.3)	0	0	0
Hypermagnesaemia	2 (2.3)	2 (2.3)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Malnutrition	2 (2.3)	0	0	2 (2.3)	0
Calcium deficiency	1 (1.1)	1 (1.1)	0	0	0
Dehydration	1 (1.1)	0	1 (1.1)	0	0
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Haemosiderosis	1 (1.1)	0	1 (1.1)	0	0
Hyperlactacidaemia	1 (1.1)	1 (1.1)	0	0	0
Hyperlipidaemia	1 (1.1)	0	1 (1.1)	0	0
Hypoglycaemia	1 (1.1)	0	1 (1.1)	0	0
Hypophagia	1 (1.1)	0	1 (1.1)	0	0
Iron overload	1 (1.1)	0	1 (1.1)	0	0
Metabolic syndrome	1 (1.1)	0	1 (1.1)	0	0
Obesity	1 (1.1)	0	0	1 (1.1)	0
Polydipsia	1 (1.1)	0	0	1 (1.1)	0
Musculoskeletal and connective tissue disorders					
-Total	45 (51.7)	17 (19.5)	17 (19.5)	10 (11.5)	1 (1.1)
Pain in extremity	23 (26.4)	9 (10.3)	11 (12.6)	3 (3.4)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	12 (13.8)	6 (6.9)	5 (5.7)	1 (1.1)	0
Back pain	10 (11.5)	1 (1.1)	5 (5.7)	4 (4.6)	0
Myalgia	10 (11.5)	6 (6.9)	4 (4.6)	0	0
Bone pain	4 (4.6)	1 (1.1)	3 (3.4)	0	0
Pain in jaw	3 (3.4)	1 (1.1)	0	2 (2.3)	0
Growth retardation	2 (2.3)	0	2 (2.3)	0	0
Muscular weakness	2 (2.3)	1 (1.1)	0	1 (1.1)	0
Musculoskeletal chest pain	2 (2.3)	2 (2.3)	0	0	0
Neck pain	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Haemarthrosis	1 (1.1)	0	0	1 (1.1)	0
Joint effusion	1 (1.1)	0	0	1 (1.1)	0
Muscle rigidity	1 (1.1)	1 (1.1)	0	0	0
Muscle spasms	1 (1.1)	0	1 (1.1)	0	0
Musculoskeletal pain	1 (1.1)	0	1 (1.1)	0	0
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Myositis	1 (1.1)	0	1 (1.1)	0	0
Osteonecrosis	1 (1.1)	1 (1.1)	0	0	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhabdomyolysis	1 (1.1)	0	0	0	1 (1.1)
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (5.7)	1 (1.1)	2 (2.3)	2 (2.3)	0
Skin papilloma	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Bone giant cell tumour benign	1 (1.1)	0	0	1 (1.1)	0
Cancer pain	1 (1.1)	0	1 (1.1)	0	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Nervous system disorders					
-Total	50 (57.5)	16 (18.4)	18 (20.7)	12 (13.8)	4 (4.6)
Headache	29 (33.3)	15 (17.2)	12 (13.8)	2 (2.3)	0
Encephalopathy	9 (10.3)	1 (1.1)	3 (3.4)	5 (5.7)	0
Somnolence	6 (6.9)	2 (2.3)	2 (2.3)	2 (2.3)	0
Tremor	6 (6.9)	5 (5.7)	1 (1.1)	0	0
Dizziness	5 (5.7)	5 (5.7)	0	0	0
Cognitive disorder	4 (4.6)	0	2 (2.3)	2 (2.3)	0
Lethargy	4 (4.6)	3 (3.4)	1 (1.1)	0	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	4 (4.6)	0	2 (2.3)	2 (2.3)	0
Dysgeusia	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Neuropathy peripheral	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Paraesthesia	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0
Cerebral haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Dysarthria	1 (1.1)	0	0	1 (1.1)	0
Extrapyramidal disorder	1 (1.1)	0	1 (1.1)	0	0
Generalised tonic-clonic seizure	1 (1.1)	0	1 (1.1)	0	0
Haemorrhage intracranial	1 (1.1)	0	0	0	1 (1.1)
Hydrocephalus	1 (1.1)	0	0	0	1 (1.1)
Hyperaesthesia	1 (1.1)	1 (1.1)	0	0	0
Hypoaesthesia	1 (1.1)	1 (1.1)	0	0	0
Migraine	1 (1.1)	0	1 (1.1)	0	0
Monoparesis	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorder	1 (1.1)	0	0	1 (1.1)	0
Neurological decompensation	1 (1.1)	0	0	0	1 (1.1)
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	37 (42.5)	11 (12.6)	16 (18.4)	10 (11.5)	0
Anxiety	14 (16.1)	3 (3.4)	8 (9.2)	3 (3.4)	0
Delirium	8 (9.2)	2 (2.3)	3 (3.4)	3 (3.4)	0
Agitation	7 (8.0)	4 (4.6)	3 (3.4)	0	0
Confusional state	6 (6.9)	6 (6.9)	0	0	0
Mental status changes	6 (6.9)	1 (1.1)	2 (2.3)	3 (3.4)	0
Insomnia	5 (5.7)	2 (2.3)	3 (3.4)	0	0
Irritability	4 (4.6)	3 (3.4)	0	1 (1.1)	0
Hallucination	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Sleep disorder	2 (2.3)	0	2 (2.3)	0	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Automatism	1 (1.1)	1 (1.1)	0	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mood altered	1 (1.1)	1 (1.1)	0	0	0
Nightmare	1 (1.1)	1 (1.1)	0	0	0
Persistent depressive disorder	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tearfulness	1 (1.1)	1 (1.1)	0	0	0
Tic	1 (1.1)	0	1 (1.1)	0	0
Renal and urinary disorders					
-Total	29 (33.3)	10 (11.5)	7 (8.0)	5 (5.7)	7 (8.0)
Acute kidney injury	15 (17.2)	5 (5.7)	2 (2.3)	3 (3.4)	5 (5.7)
Dysuria	5 (5.7)	4 (4.6)	1 (1.1)	0	0
Haematuria	4 (4.6)	3 (3.4)	0	1 (1.1)	0
Anuria	2 (2.3)	1 (1.1)	0	0	1 (1.1)
Pollakiuria	2 (2.3)	0	2 (2.3)	0	0
Renal failure	2 (2.3)	0	1 (1.1)	0	1 (1.1)
Renal tubular necrosis	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Urinary retention	2 (2.3)	0	2 (2.3)	0	0
Azotaemia	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bladder dilatation	1 (1.1)	0	1 (1.1)	0	0
Cystitis haemorrhagic	1 (1.1)	0	1 (1.1)	0	0
Incontinence	1 (1.1)	0	1 (1.1)	0	0
Kidney enlargement	1 (1.1)	0	1 (1.1)	0	0
Micturition urgency	1 (1.1)	0	1 (1.1)	0	0
Proteinuria	1 (1.1)	1 (1.1)	0	0	0
Renal mass	1 (1.1)	0	1 (1.1)	0	0
Renal pain	1 (1.1)	1 (1.1)	0	0	0
Renal tubular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Urinary incontinence	1 (1.1)	0	1 (1.1)	0	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0
Reproductive system and breast disorders					
-Total	5 (5.7)	1 (1.1)	2 (2.3)	2 (2.3)	0
Dysmenorrhoea	1 (1.1)	0	1 (1.1)	0	0
Female genital tract fistula	1 (1.1)	1 (1.1)	0	0	0
Perineal rash	1 (1.1)	0	1 (1.1)	0	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Vaginal ulceration	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	57 (65.5)	16 (18.4)	6 (6.9)	13 (14.9)	22 (25.3)
Cough	25 (28.7)	21 (24.1)	4 (4.6)	0	0
Hypoxia	21 (24.1)	0	5 (5.7)	10 (11.5)	6 (6.9)
Pulmonary oedema	14 (16.1)	3 (3.4)	3 (3.4)	6 (6.9)	2 (2.3)
Epistaxis	11 (12.6)	6 (6.9)	2 (2.3)	3 (3.4)	0
Nasal congestion	10 (11.5)	8 (9.2)	2 (2.3)	0	0
Oropharyngeal pain	10 (11.5)	8 (9.2)	2 (2.3)	0	0
Respiratory failure	10 (11.5)	0	0	0	10 (11.5)
Tachypnoea	10 (11.5)	3 (3.4)	2 (2.3)	4 (4.6)	1 (1.1)
Pleural effusion	9 (10.3)	4 (4.6)	2 (2.3)	2 (2.3)	1 (1.1)
Dyspnoea	8 (9.2)	1 (1.1)	2 (2.3)	3 (3.4)	2 (2.3)
Rhinorrhoea	6 (6.9)	4 (4.6)	2 (2.3)	0	0
Acute respiratory distress syndrome	4 (4.6)	0	0	0	4 (4.6)
Respiratory distress	4 (4.6)	0	2 (2.3)	0	2 (2.3)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Atelectasis	3 (3.4)	0	1 (1.1)	2 (2.3)	0
Pharyngeal erythema	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Rhinitis allergic	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Sleep apnoea syndrome	2 (2.3)	1 (1.1)	1 (1.1)	0	0
Wheezing	2 (2.3)	0	2 (2.3)	0	0
Acute respiratory failure	1 (1.1)	0	0	1 (1.1)	0
Bradypnoea	1 (1.1)	0	0	1 (1.1)	0
Bronchial oedema	1 (1.1)	1 (1.1)	0	0	0
Bronchospasm	1 (1.1)	0	1 (1.1)	0	0
Dyspnoea exertional	1 (1.1)	1 (1.1)	0	0	0
Haemoptysis	1 (1.1)	0	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	0	0	1 (1.1)
Lung infiltration	1 (1.1)	0	0	1 (1.1)	0
Nasal discomfort	1 (1.1)	0	1 (1.1)	0	0
Oropharyngeal plaque	1 (1.1)	0	1 (1.1)	0	0
Painful respiration	1 (1.1)	1 (1.1)	0	0	0
Paranasal sinus discomfort	1 (1.1)	0	1 (1.1)	0	0
Paranasal sinus inflammation	1 (1.1)	1 (1.1)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngeal exudate	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal oedema	1 (1.1)	0	1 (1.1)	0	0
Productive cough	1 (1.1)	1 (1.1)	0	0	0
Pulmonary haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Pulmonary mass	1 (1.1)	0	1 (1.1)	0	0
Respiratory acidosis	1 (1.1)	0	0	1 (1.1)	0
Respiratory disorder	1 (1.1)	0	1 (1.1)	0	0
Upper respiratory tract inflammation	1 (1.1)	0	1 (1.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	42 (48.3)	17 (19.5)	17 (19.5)	8 (9.2)	0
Dry skin	9 (10.3)	7 (8.0)	2 (2.3)	0	0
Pruritus	9 (10.3)	3 (3.4)	6 (6.9)	0	0
Rash	9 (10.3)	4 (4.6)	5 (5.7)	0	0
Erythema	6 (6.9)	5 (5.7)	1 (1.1)	0	0
Ingrowing nail	4 (4.6)	1 (1.1)	3 (3.4)	0	0
Rash maculo-papular	4 (4.6)	2 (2.3)	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash papular	4 (4.6)	3 (3.4)	1 (1.1)	0	0
Skin ulcer	4 (4.6)	2 (2.3)	1 (1.1)	1 (1.1)	0
Blister	3 (3.4)	2 (2.3)	1 (1.1)	0	0
Dermatitis atopic	3 (3.4)	2 (2.3)	0	1 (1.1)	0
Eczema	3 (3.4)	2 (2.3)	0	1 (1.1)	0
Hyperhidrosis	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Petechiae	3 (3.4)	1 (1.1)	1 (1.1)	1 (1.1)	0
Decubitus ulcer	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Skin discolouration	2 (2.3)	2 (2.3)	0	0	0
Dermatitis	1 (1.1)	1 (1.1)	0	0	0
Dermatitis diaper	1 (1.1)	0	1 (1.1)	0	0
Drug eruption	1 (1.1)	0	1 (1.1)	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Hangnail	1 (1.1)	1 (1.1)	0	0	0
Miliaria	1 (1.1)	1 (1.1)	0	0	0
Night sweats	1 (1.1)	1 (1.1)	0	0	0
Papule	1 (1.1)	1 (1.1)	0	0	0
Pruritus allergic	1 (1.1)	0	1 (1.1)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Purpura	1 (1.1)	1 (1.1)	0	0	0
Rash erythematous	1 (1.1)	1 (1.1)	0	0	0
Rash macular	1 (1.1)	0	0	1 (1.1)	0
Rash pruritic	1 (1.1)	1 (1.1)	0	0	0
Rash vesicular	1 (1.1)	1 (1.1)	0	0	0
Scab	1 (1.1)	1 (1.1)	0	0	0
Skin hypopigmentation	1 (1.1)	1 (1.1)	0	0	0
Skin lesion	1 (1.1)	0	1 (1.1)	0	0
Skin necrosis	1 (1.1)	0	0	1 (1.1)	0
Skin swelling	1 (1.1)	1 (1.1)	0	0	0
Urticaria	1 (1.1)	0	1 (1.1)	0	0
Vancomycin infusion reaction	1 (1.1)	0	0	1 (1.1)	0
Social circumstances					
-Total	1 (1.1)	0	1 (1.1)	0	0
Patient uncooperative	1 (1.1)	0	1 (1.1)	0	0
Surgical and medical procedures					
-Total	1 (1.1)	0	0	1 (1.1)	0
Thrombolysis	1 (1.1)	0	0	1 (1.1)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	39 (44.8)	4 (4.6)	9 (10.3)	15 (17.2)	11 (12.6)
Hypotension	28 (32.2)	1 (1.1)	5 (5.7)	12 (13.8)	10 (11.5)
Hypertension	17 (19.5)	4 (4.6)	9 (10.3)	4 (4.6)	0
Capillary leak syndrome	2 (2.3)	0	1 (1.1)	1 (1.1)	0
Flushing	2 (2.3)	2 (2.3)	0	0	0
Peripheral ischaemia	2 (2.3)	0	2 (2.3)	0	0
Venoocclusive disease	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Haematoma	1 (1.1)	1 (1.1)	0	0	0
Hot flush	1 (1.1)	1 (1.1)	0	0	0
Thrombosis	1 (1.1)	0	1 (1.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208p
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	0	7 (100)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	1 (14.3)	4 (57.1)	0
Anaemia	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Febrile neutropenia	3 (42.9)	0	0	3 (42.9)	0
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)	0	0
Neutropenia	1 (14.3)	1 (14.3)	0	0	0
Splenomegaly	1 (14.3)	1 (14.3)	0	0	0
Cardiac disorders					
-Total	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Tachycardia	2 (28.6)	0	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (14.3)	0	1 (14.3)	0	0
Ear and labyrinth disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Ear pruritus	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypothyroidism	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Conjunctival haemorrhage	2 (28.6)	2 (28.6)	0	0	0
Ocular hyperaemia	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	1 (14.3)	2 (28.6)	2 (28.6)	1 (14.3)
Constipation	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Diarrhoea	3 (42.9)	3 (42.9)	0	0	0
Vomiting	2 (28.6)	2 (28.6)	0	0	0
Abdominal compartment syndrome	1 (14.3)	0	0	0	1 (14.3)

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (14.3)	0	1 (14.3)	0	0
Duodenal perforation	1 (14.3)	0	0	1 (14.3)	0
Dysphagia	1 (14.3)	0	0	1 (14.3)	0
Enterocolitis	1 (14.3)	0	1 (14.3)	0	0
Gastritis	1 (14.3)	0	1 (14.3)	0	0
Gingival erythema	1 (14.3)	1 (14.3)	0	0	0
Nausea	1 (14.3)	0	1 (14.3)	0	0
Oral pain	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	4 (57.1)	2 (28.6)	2 (28.6)	0	0
Pyrexia	3 (42.9)	3 (42.9)	0	0	0
Face oedema	2 (28.6)	2 (28.6)	0	0	0
Fatigue	2 (28.6)	2 (28.6)	0	0	0
Generalised oedema	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Catheter site pain	1 (14.3)	0	1 (14.3)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Complication associated with device	1 (14.3)	1 (14.3)	0	0	0
Localised oedema	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Hepatic function abnormal	1 (14.3)	0	0	0	1 (14.3)
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)	0	0
Hypertransaminasaemia	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	6 (85.7)	1 (14.3)	1 (14.3)	1 (14.3)	3 (42.9)
Cytokine release syndrome	6 (85.7)	2 (28.6)	1 (14.3)	0	3 (42.9)
Hypogammaglobulinaemia	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Haemophagocytic lymphohistiocytosis	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	7 (100)	0	2 (28.6)	5 (71.4)	0
Upper respiratory tract infection	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Otitis media	2 (28.6)	0	2 (28.6)	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (14.3)	0	0	1 (14.3)	0
Bronchitis	1 (14.3)	0	1 (14.3)	0	0
Cellulitis	1 (14.3)	0	1 (14.3)	0	0
Ear infection	1 (14.3)	0	1 (14.3)	0	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Folliculitis	1 (14.3)	0	1 (14.3)	0	0
Gastroenteritis viral	1 (14.3)	0	1 (14.3)	0	0
Metapneumovirus infection	1 (14.3)	0	0	1 (14.3)	0
Nail infection	1 (14.3)	0	1 (14.3)	0	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Paronychia	1 (14.3)	1 (14.3)	0	0	0
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)	0	0
Pneumonia respiratory syncytial viral	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	1 (14.3)	0	0
Sinusitis	1 (14.3)	0	1 (14.3)	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Abdominal injury	1 (14.3)	1 (14.3)	0	0	0
Contusion	1 (14.3)	1 (14.3)	0	0	0
Skin abrasion	1 (14.3)	1 (14.3)	0	0	0
Transfusion reaction	1 (14.3)	0	1 (14.3)	0	0
Wound	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	6 (85.7)	0	0	0	6 (85.7)
Neutrophil count decreased	4 (57.1)	0	0	1 (14.3)	3 (42.9)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Lymphocyte count decreased	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Platelet count decreased	3 (42.9)	0	1 (14.3)	0	2 (28.6)
Alanine aminotransferase increased	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Blood creatinine increased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Serum ferritin increased	2 (28.6)	0	2 (28.6)	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urine output decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Weight increased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Activated partial thromboplastin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bicarbonate decreased	1 (14.3)	0	1 (14.3)	0	0
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatine phosphokinase increased	1 (14.3)	0	0	1 (14.3)	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin a decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin g decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	0	0	1 (14.3)	0
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
C-reactive protein increased	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	0	1 (14.3)	0	0
Oxygen saturation decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (85.7)	0	2 (28.6)	3 (42.9)	1 (14.3)
Hypocalcaemia	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Hypokalaemia	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Hypophosphataemia	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Decreased appetite	2 (28.6)	0	0	2 (28.6)	0
Hyperphosphataemia	2 (28.6)	2 (28.6)	0	0	0
Hypoalbuminaemia	2 (28.6)	0	2 (28.6)	0	0
Hypercalcaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperchloraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperglycaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperlipidaemia	1 (14.3)	0	1 (14.3)	0	0
Hypermagnesaemia	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (14.3)	0	1 (14.3)	0	0
Hyponatraemia	1 (14.3)	1 (14.3)	0	0	0
Metabolic acidosis	1 (14.3)	0	0	0	1 (14.3)
Metabolic syndrome	1 (14.3)	0	1 (14.3)	0	0
Obesity	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	3 (42.9)	0	0	0
Bone pain	1 (14.3)	1 (14.3)	0	0	0
Muscle rigidity	1 (14.3)	1 (14.3)	0	0	0
Myalgia	1 (14.3)	1 (14.3)	0	0	0
Pain in extremity	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Cerebral haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Encephalopathy	1 (14.3)	0	0	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised tonic-clonic seizure	1 (14.3)	0	1 (14.3)	0	0
Haemorrhage intracranial	1 (14.3)	0	0	0	1 (14.3)
Headache	1 (14.3)	0	1 (14.3)	0	0
Somnolence	1 (14.3)	0	0	1 (14.3)	0
Tremor	1 (14.3)	0	1 (14.3)	0	0
Psychiatric disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Automatism	1 (14.3)	1 (14.3)	0	0	0
Confusional state	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Insomnia	1 (14.3)	0	1 (14.3)	0	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Acute kidney injury	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Anuria	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Azotaemia	1 (14.3)	0	1 (14.3)	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Dysmenorrhoea	1 (14.3)	0	1 (14.3)	0	0
Perineal rash	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	1 (14.3)	1 (14.3)	2 (28.6)	2 (28.6)
Hypoxia	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Cough	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Pleural effusion	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Epistaxis	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Nasal congestion	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Pulmonary oedema	2 (28.6)	0	2 (28.6)	0	0
Dyspnoea	1 (14.3)	0	1 (14.3)	0	0
Nasal discomfort	1 (14.3)	0	1 (14.3)	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pharyngeal haemorrhage	1 (14.3)	0	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (14.3)	0	1 (14.3)	0	0
Rhinitis allergic	1 (14.3)	0	1 (14.3)	0	0
Rhinorrhoea	1 (14.3)	0	1 (14.3)	0	0
Sleep apnoea syndrome	1 (14.3)	0	1 (14.3)	0	0
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Wheezing	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (85.7)	3 (42.9)	3 (42.9)	0	0
Rash	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Blister	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Erythema	2 (28.6)	2 (28.6)	0	0	0
Dermatitis diaper	1 (14.3)	0	1 (14.3)	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Eczema	1 (14.3)	1 (14.3)	0	0	0
Ingrowing nail	1 (14.3)	0	1 (14.3)	0	0
Miliaria	1 (14.3)	1 (14.3)	0	0	0
Petechiae	1 (14.3)	0	1 (14.3)	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	1 (14.3)	1 (14.3)	0	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Scab	1 (14.3)	1 (14.3)	0	0	0
Skin discolouration	1 (14.3)	1 (14.3)	0	0	0
Skin swelling	1 (14.3)	1 (14.3)	0	0	0
Skin ulcer	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	4 (57.1)	1 (14.3)	0	1 (14.3)	2 (28.6)
Hypertension	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Hypotension	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Thrombosis	1 (14.3)	0	1 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208p
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	88 (96.7)	0	5 (5.5)	20 (22.0)	63 (69.2)
Blood and lymphatic system disorders					
-Total	62 (68.1)	1 (1.1)	8 (8.8)	33 (36.3)	20 (22.0)
Febrile neutropenia	36 (39.6)	0	0	33 (36.3)	3 (3.3)
Anaemia	35 (38.5)	5 (5.5)	10 (11.0)	19 (20.9)	1 (1.1)
Neutropenia	15 (16.5)	0	2 (2.2)	3 (3.3)	10 (11.0)
Thrombocytopenia	13 (14.3)	0	1 (1.1)	5 (5.5)	7 (7.7)
Disseminated intravascular coagulation	6 (6.6)	0	3 (3.3)	3 (3.3)	0
Coagulopathy	5 (5.5)	1 (1.1)	2 (2.2)	2 (2.2)	0
Leukopenia	5 (5.5)	0	0	1 (1.1)	4 (4.4)
Pancytopenia	4 (4.4)	0	0	3 (3.3)	1 (1.1)

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Splenomegaly	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Lymphadenopathy	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Lymphopenia	2 (2.2)	0	0	0	2 (2.2)
Agranulocytosis	1 (1.1)	0	0	1 (1.1)	0
B-cell aplasia	1 (1.1)	0	1 (1.1)	0	0
Eosinophilia	1 (1.1)	0	1 (1.1)	0	0
Hypercoagulation	1 (1.1)	0	1 (1.1)	0	0
Hypofibrinogenaemia	1 (1.1)	0	1 (1.1)	0	0
Leukocytosis	1 (1.1)	0	1 (1.1)	0	0
Lymphocytosis	1 (1.1)	0	1 (1.1)	0	0
Cardiac disorders					
-Total	32 (35.2)	10 (11.0)	6 (6.6)	10 (11.0)	6 (6.6)
Tachycardia	19 (20.9)	7 (7.7)	7 (7.7)	4 (4.4)	1 (1.1)
Left ventricular dysfunction	5 (5.5)	0	1 (1.1)	4 (4.4)	0
Cardiac failure	4 (4.4)	0	0	2 (2.2)	2 (2.2)
Cardiac arrest	3 (3.3)	0	0	0	3 (3.3)
Sinus tachycardia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Bradycardia	2 (2.2)	2 (2.2)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac dysfunction	2 (2.2)	2 (2.2)	0	0	0
Pericardial effusion	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Atrioventricular block first degree	1 (1.1)	0	1 (1.1)	0	0
Cardiac failure congestive	1 (1.1)	0	1 (1.1)	0	0
Mitral valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Right ventricular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Sinus bradycardia	1 (1.1)	0	0	1 (1.1)	0
Tricuspid valve incompetence	1 (1.1)	1 (1.1)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (1.1)	1 (1.1)	0	0	0
Cerebral cavernous malformation	1 (1.1)	1 (1.1)	0	0	0
Ear and labyrinth disorders					
-Total	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Deafness unilateral	1 (1.1)	0	1 (1.1)	0	0
Ear pain	1 (1.1)	1 (1.1)	0	0	0
Vertigo	1 (1.1)	0	1 (1.1)	0	0
Endocrine disorders					

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (8.8)	0	8 (8.8)	0	0
Adrenal insufficiency	6 (6.6)	0	6 (6.6)	0	0
Hypothyroidism	2 (2.2)	0	2 (2.2)	0	0
Delayed puberty	1 (1.1)	0	1 (1.1)	0	0
Eye disorders					
-Total	15 (16.5)	9 (9.9)	5 (5.5)	1 (1.1)	0
Eye pain	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Eyelid oedema	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Cataract	2 (2.2)	2 (2.2)	0	0	0
Ocular hyperaemia	2 (2.2)	2 (2.2)	0	0	0
Visual impairment	2 (2.2)	2 (2.2)	0	0	0
Dry eye	1 (1.1)	1 (1.1)	0	0	0
Eye oedema	1 (1.1)	1 (1.1)	0	0	0
Hypermetropia	1 (1.1)	1 (1.1)	0	0	0
Mydriasis	1 (1.1)	0	1 (1.1)	0	0
Periorbital swelling	1 (1.1)	0	1 (1.1)	0	0
Retinal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Vision blurred	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual field defect	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal disorders					
-Total	66 (72.5)	19 (20.9)	28 (30.8)	18 (19.8)	1 (1.1)
Nausea	32 (35.2)	14 (15.4)	15 (16.5)	3 (3.3)	0
Vomiting	28 (30.8)	18 (19.8)	8 (8.8)	2 (2.2)	0
Diarrhoea	24 (26.4)	14 (15.4)	8 (8.8)	2 (2.2)	0
Abdominal pain	17 (18.7)	5 (5.5)	10 (11.0)	2 (2.2)	0
Constipation	16 (17.6)	7 (7.7)	9 (9.9)	0	0
Stomatitis	10 (11.0)	1 (1.1)	4 (4.4)	5 (5.5)	0
Mouth haemorrhage	6 (6.6)	2 (2.2)	2 (2.2)	2 (2.2)	0
Pancreatitis	6 (6.6)	1 (1.1)	3 (3.3)	2 (2.2)	0
Abdominal pain upper	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Haematemesis	4 (4.4)	4 (4.4)	0	0	0
Abdominal distension	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Ascites	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Gastrointestinal sounds abnormal	3 (3.3)	3 (3.3)	0	0	0
Gingival bleeding	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Dry mouth	2 (2.2)	0	2 (2.2)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Ileus	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Neutropenic colitis	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Proctalgia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Trichoglossia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
Abdominal rigidity	1 (1.1)	0	1 (1.1)	0	0
Anal erythema	1 (1.1)	1 (1.1)	0	0	0
Anal fissure	1 (1.1)	0	1 (1.1)	0	0
Anal fistula	1 (1.1)	0	0	1 (1.1)	0
Anal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
Anal inflammation	1 (1.1)	0	0	1 (1.1)	0
Dyspepsia	1 (1.1)	1 (1.1)	0	0	0
Enteritis	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal inflammation	1 (1.1)	0	1 (1.1)	0	0
Gastrooesophageal reflux disease	1 (1.1)	0	1 (1.1)	0	0
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
Gingivitis ulcerative	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (1.1)	0	0	0	1 (1.1)
Haemorrhoids	1 (1.1)	0	1 (1.1)	0	0
Irritable bowel syndrome	1 (1.1)	0	1 (1.1)	0	0
Lip dry	1 (1.1)	0	1 (1.1)	0	0
Lip oedema	1 (1.1)	1 (1.1)	0	0	0
Lip pain	1 (1.1)	1 (1.1)	0	0	0
Lip ulceration	1 (1.1)	0	1 (1.1)	0	0
Melaena	1 (1.1)	0	0	1 (1.1)	0
Mouth swelling	1 (1.1)	1 (1.1)	0	0	0
Odynophagia	1 (1.1)	1 (1.1)	0	0	0
Oral disorder	1 (1.1)	1 (1.1)	0	0	0
Oral pain	1 (1.1)	0	0	1 (1.1)	0
Peritoneal haematoma	1 (1.1)	1 (1.1)	0	0	0
Upper gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0	0	0
General disorders and administration site conditions					
-Total	59 (64.8)	27 (29.7)	14 (15.4)	13 (14.3)	5 (5.5)
Pyrexia	40 (44.0)	15 (16.5)	12 (13.2)	11 (12.1)	2 (2.2)

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	17 (18.7)	13 (14.3)	4 (4.4)	0	0
Chills	8 (8.8)	4 (4.4)	4 (4.4)	0	0
Oedema peripheral	8 (8.8)	6 (6.6)	1 (1.1)	1 (1.1)	0
Pain	8 (8.8)	1 (1.1)	5 (5.5)	2 (2.2)	0
Face oedema	6 (6.6)	3 (3.3)	2 (2.2)	1 (1.1)	0
Asthenia	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Catheter site pain	4 (4.4)	2 (2.2)	1 (1.1)	1 (1.1)	0
Generalised oedema	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Multiple organ dysfunction syndrome	3 (3.3)	0	0	0	3 (3.3)
Drug withdrawal syndrome	2 (2.2)	0	2 (2.2)	0	0
Influenza like illness	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Localised oedema	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Malaise	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Non-cardiac chest pain	2 (2.2)	2 (2.2)	0	0	0
Vascular device occlusion	2 (2.2)	2 (2.2)	0	0	0
Catheter site dermatitis	1 (1.1)	1 (1.1)	0	0	0
Catheter site erythema	1 (1.1)	1 (1.1)	0	0	0
Catheter site haemorrhage	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chest discomfort	1 (1.1)	0	0	1 (1.1)	0
Crying	1 (1.1)	0	1 (1.1)	0	0
Facial pain	1 (1.1)	0	1 (1.1)	0	0
Oedema due to hepatic disease	1 (1.1)	0	1 (1.1)	0	0
Sluggishness	1 (1.1)	0	1 (1.1)	0	0
Swelling face	1 (1.1)	1 (1.1)	0	0	0
Systemic inflammatory response syndrome	1 (1.1)	0	0	1 (1.1)	0
Thirst	1 (1.1)	1 (1.1)	0	0	0
Xerosis	1 (1.1)	1 (1.1)	0	0	0
Hepatobiliary disorders					
-Total	22 (24.2)	7 (7.7)	7 (7.7)	6 (6.6)	2 (2.2)
Hyperbilirubinaemia	5 (5.5)	1 (1.1)	2 (2.2)	2 (2.2)	0
Hepatic function abnormal	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Hepatomegaly	3 (3.3)	2 (2.2)	0	0	1 (1.1)
Cholelithiasis	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Gallbladder enlargement	2 (2.2)	2 (2.2)	0	0	0
Hepatic cytolysis	2 (2.2)	1 (1.1)	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertransaminasaemia	2 (2.2)	2 (2.2)	0	0	0
Biliary tract disorder	1 (1.1)	1 (1.1)	0	0	0
Cholestasis	1 (1.1)	0	0	0	1 (1.1)
Drug-induced liver injury	1 (1.1)	0	0	1 (1.1)	0
Hepatosplenomegaly	1 (1.1)	0	1 (1.1)	0	0
Liver disorder	1 (1.1)	0	1 (1.1)	0	0
Ocular icterus	1 (1.1)	1 (1.1)	0	0	0
Immune system disorders					
-Total	67 (73.6)	1 (1.1)	23 (25.3)	24 (26.4)	19 (20.9)
Cytokine release syndrome	55 (60.4)	3 (3.3)	17 (18.7)	17 (18.7)	18 (19.8)
Hypogammaglobulinaemia	33 (36.3)	2 (2.2)	24 (26.4)	7 (7.7)	0
Haemophagocytic lymphohistiocytosis	5 (5.5)	1 (1.1)	0	2 (2.2)	2 (2.2)
Immunodeficiency	4 (4.4)	0	0	4 (4.4)	0
Seasonal allergy	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Graft versus host disease	3 (3.3)	0	0	3 (3.3)	0
Allergy to immunoglobulin therapy	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Chronic graft versus host disease	2 (2.2)	0	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug hypersensitivity	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Engraftment syndrome	1 (1.1)	0	0	1 (1.1)	0
Hypersensitivity	1 (1.1)	1 (1.1)	0	0	0
Selective igg subclass deficiency	1 (1.1)	0	1 (1.1)	0	0
Infections and infestations					
-Total	69 (75.8)	6 (6.6)	11 (12.1)	32 (35.2)	20 (22.0)
Upper respiratory tract infection	10 (11.0)	4 (4.4)	4 (4.4)	2 (2.2)	0
Conjunctivitis	9 (9.9)	3 (3.3)	6 (6.6)	0	0
Pneumonia	9 (9.9)	1 (1.1)	1 (1.1)	4 (4.4)	3 (3.3)
Rhinovirus infection	8 (8.8)	0	6 (6.6)	2 (2.2)	0
Sinusitis	8 (8.8)	0	5 (5.5)	3 (3.3)	0
Gastroenteritis	7 (7.7)	4 (4.4)	1 (1.1)	2 (2.2)	0
Nasopharyngitis	7 (7.7)	4 (4.4)	3 (3.3)	0	0
Parainfluenzae virus infection	7 (7.7)	1 (1.1)	1 (1.1)	4 (4.4)	1 (1.1)
Staphylococcal bacteraemia	7 (7.7)	0	0	7 (7.7)	0
Oral herpes	6 (6.6)	1 (1.1)	3 (3.3)	2 (2.2)	0
Staphylococcal infection	6 (6.6)	0	2 (2.2)	3 (3.3)	1 (1.1)
Bacteraemia	5 (5.5)	0	1 (1.1)	3 (3.3)	1 (1.1)

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida infection	4 (4.4)	0	3 (3.3)	0	1 (1.1)
Clostridium difficile infection	4 (4.4)	1 (1.1)	0	3 (3.3)	0
Herpes zoster	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Paronychia	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Sepsis	4 (4.4)	0	0	1 (1.1)	3 (3.3)
Acute sinusitis	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Bronchopulmonary aspergillosis	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Catheter site infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Device related infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Gingivitis	3 (3.3)	3 (3.3)	0	0	0
Influenza	3 (3.3)	0	2 (2.2)	0	1 (1.1)
Localised infection	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Nail infection	3 (3.3)	3 (3.3)	0	0	0
Oral candidiasis	3 (3.3)	0	3 (3.3)	0	0
Otitis media	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Respiratory syncytial virus infection	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Respiratory tract infection	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Rhinitis	3 (3.3)	2 (2.2)	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	3 (3.3)	0	0	0	3 (3.3)
Urinary tract infection	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Adenovirus infection	2 (2.2)	0	0	2 (2.2)	0
Bk virus infection	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Bronchitis	2 (2.2)	0	2 (2.2)	0	0
Covid-19	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Cytomegalovirus infection reactivation	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Ear infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Encephalitis	2 (2.2)	0	0	0	2 (2.2)
Encephalitis viral	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Escherichia bacteraemia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Fungal infection	2 (2.2)	0	2 (2.2)	0	0
Fungal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Herpes simplex	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	2 (2.2)	0	0	2 (2.2)	0
Klebsiella bacteraemia	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Metapneumovirus infection	2 (2.2)	0	0	2 (2.2)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral infection	2 (2.2)	0	2 (2.2)	0	0
Otitis externa	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Pneumonia fungal	2 (2.2)	0	0	2 (2.2)	0
Skin infection	2 (2.2)	0	2 (2.2)	0	0
Staphylococcal skin infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Tinea pedis	2 (2.2)	2 (2.2)	0	0	0
Varicella zoster virus infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Viral infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Anal abscess	1 (1.1)	0	0	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	0	0	1 (1.1)
Atypical pneumonia	1 (1.1)	1 (1.1)	0	0	0
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Cholecystitis infective	1 (1.1)	0	1 (1.1)	0	0
Clostridium difficile colitis	1 (1.1)	0	0	1 (1.1)	0
Coronavirus infection	1 (1.1)	0	0	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	0	0	1 (1.1)
Cystitis	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Device related sepsis	1 (1.1)	0	0	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	0	0	1 (1.1)
Ear, nose and throat infection	1 (1.1)	0	1 (1.1)	0	0
Enterobacter infection	1 (1.1)	0	0	1 (1.1)	0
Enterovirus infection	1 (1.1)	0	0	1 (1.1)	0
Epstein-barr virus infection	1 (1.1)	0	1 (1.1)	0	0
Fungaemia	1 (1.1)	0	0	0	1 (1.1)
Fungal pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis clostridial	1 (1.1)	0	1 (1.1)	0	0
Gastroenteritis escherichia coli	1 (1.1)	0	0	1 (1.1)	0
Gastroenteritis norovirus	1 (1.1)	1 (1.1)	0	0	0
Gastroenteritis salmonella	1 (1.1)	0	0	1 (1.1)	0
Gastrointestinal infection	1 (1.1)	1 (1.1)	0	0	0
Granulicatella infection	1 (1.1)	0	0	1 (1.1)	0
Herpes virus infection	1 (1.1)	0	1 (1.1)	0	0
Klebsiella infection	1 (1.1)	0	0	1 (1.1)	0
Mastoiditis	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (1.1)	0	0	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	0	0	1 (1.1)	0
Molluscum contagiosum	1 (1.1)	1 (1.1)	0	0	0
Myringitis	1 (1.1)	1 (1.1)	0	0	0
Neutropenic infection	1 (1.1)	0	0	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	1 (1.1)	0	0
Otitis media acute	1 (1.1)	0	1 (1.1)	0	0
Pharyngitis	1 (1.1)	0	0	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	0	0	1 (1.1)	0
Pneumonia viral	1 (1.1)	0	0	1 (1.1)	0
Respiratory tract infection viral	1 (1.1)	0	1 (1.1)	0	0
Salmonellosis	1 (1.1)	0	1 (1.1)	0	0
Serratia sepsis	1 (1.1)	0	0	0	1 (1.1)
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Sinusitis fungal	1 (1.1)	0	0	1 (1.1)	0
Soft tissue infection	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	0	0	1 (1.1)

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatococcal infection	1 (1.1)	0	0	0	1 (1.1)
Streptococcal sepsis	1 (1.1)	0	1 (1.1)	0	0
Syphilis	1 (1.1)	0	1 (1.1)	0	0
Systemic candida	1 (1.1)	0	0	1 (1.1)	0
Systemic mycosis	1 (1.1)	0	0	1 (1.1)	0
Urinary tract infection pseudomonal	1 (1.1)	0	1 (1.1)	0	0
Urinary tract infection viral	1 (1.1)	1 (1.1)	0	0	0
Vascular device infection	1 (1.1)	0	0	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	0	0	1 (1.1)	0
Viral skin infection	1 (1.1)	1 (1.1)	0	0	0
Viral upper respiratory tract infection	1 (1.1)	0	0	1 (1.1)	0
Vulval cellulitis	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	24 (26.4)	8 (8.8)	10 (11.0)	3 (3.3)	3 (3.3)
Infusion related reaction	6 (6.6)	2 (2.2)	3 (3.3)	1 (1.1)	0
Procedural pain	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Fall	3 (3.3)	1 (1.1)	2 (2.2)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Ligament sprain	2 (2.2)	2 (2.2)	0	0	0
Wound	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Contusion	1 (1.1)	1 (1.1)	0	0	0
Extradural haematoma	1 (1.1)	0	1 (1.1)	0	0
Fibula fracture	1 (1.1)	0	1 (1.1)	0	0
Limb injury	1 (1.1)	0	1 (1.1)	0	0
Post-traumatic neck syndrome	1 (1.1)	0	1 (1.1)	0	0
Radius fracture	1 (1.1)	0	1 (1.1)	0	0
Scratch	1 (1.1)	1 (1.1)	0	0	0
Skin abrasion	1 (1.1)	1 (1.1)	0	0	0
Skin injury	1 (1.1)	0	1 (1.1)	0	0
Skin wound	1 (1.1)	1 (1.1)	0	0	0
Tracheal obstruction	1 (1.1)	0	0	0	1 (1.1)
Transplant failure	1 (1.1)	0	0	0	1 (1.1)
Traumatic haematoma	1 (1.1)	0	1 (1.1)	0	0
Vasoplegia syndrome	1 (1.1)	0	0	0	1 (1.1)
Investigations					

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	60 (65.9)	1 (1.1)	6 (6.6)	20 (22.0)	33 (36.3)
White blood cell count decreased	28 (30.8)	3 (3.3)	3 (3.3)	1 (1.1)	21 (23.1)
Neutrophil count decreased	25 (27.5)	1 (1.1)	2 (2.2)	2 (2.2)	20 (22.0)
Platelet count decreased	25 (27.5)	6 (6.6)	1 (1.1)	6 (6.6)	12 (13.2)
Alanine aminotransferase increased	20 (22.0)	5 (5.5)	7 (7.7)	8 (8.8)	0
Aspartate aminotransferase increased	20 (22.0)	2 (2.2)	5 (5.5)	10 (11.0)	3 (3.3)
Lymphocyte count decreased	20 (22.0)	1 (1.1)	1 (1.1)	7 (7.7)	11 (12.1)
Blood bilirubin increased	12 (13.2)	1 (1.1)	2 (2.2)	9 (9.9)	0
C-reactive protein increased	10 (11.0)	2 (2.2)	2 (2.2)	5 (5.5)	1 (1.1)
International normalised ratio increased	9 (9.9)	6 (6.6)	3 (3.3)	0	0
Serum ferritin increased	9 (9.9)	2 (2.2)	3 (3.3)	3 (3.3)	1 (1.1)
Blood fibrinogen decreased	7 (7.7)	3 (3.3)	2 (2.2)	1 (1.1)	1 (1.1)
Blood immunoglobulin a decreased	6 (6.6)	5 (5.5)	0	1 (1.1)	0
Blood immunoglobulin m decreased	6 (6.6)	4 (4.4)	1 (1.1)	1 (1.1)	0
Blood lactate dehydrogenase increased	6 (6.6)	2 (2.2)	1 (1.1)	3 (3.3)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	5 (5.5)	3 (3.3)	1 (1.1)	1 (1.1)	0
Blood creatinine increased	5 (5.5)	2 (2.2)	1 (1.1)	2 (2.2)	0
Electrocardiogram qt prolonged	5 (5.5)	1 (1.1)	2 (2.2)	1 (1.1)	1 (1.1)
Fibrin d dimer increased	4 (4.4)	2 (2.2)	0	1 (1.1)	1 (1.1)
Weight decreased	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Weight increased	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Blood fibrinogen increased	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Blood immunoglobulin g decreased	3 (3.3)	0	3 (3.3)	0	0
Blood uric acid increased	3 (3.3)	1 (1.1)	0	1 (1.1)	1 (1.1)
Amylase increased	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Blood glucose increased	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Blood phosphorus increased	2 (2.2)	0	2 (2.2)	0	0
Gamma-glutamyltransferase increased	2 (2.2)	0	0	2 (2.2)	0
Immunoglobulins decreased	2 (2.2)	0	2 (2.2)	0	0
Lipase increased	2 (2.2)	1 (1.1)	0	0	1 (1.1)
Oxygen saturation decreased	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Bacterial test positive	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase decreased	1 (1.1)	1 (1.1)	0	0	0
Blood alkaline phosphatase increased	1 (1.1)	1 (1.1)	0	0	0
Blood creatine phosphokinase increased	1 (1.1)	0	0	0	1 (1.1)
Blood phosphorus decreased	1 (1.1)	0	0	1 (1.1)	0
Blood potassium decreased	1 (1.1)	0	0	0	1 (1.1)
Blood testosterone decreased	1 (1.1)	1 (1.1)	0	0	0
Blood urea increased	1 (1.1)	0	0	1 (1.1)	0
Bone density decreased	1 (1.1)	1 (1.1)	0	0	0
Breath sounds abnormal	1 (1.1)	0	1 (1.1)	0	0
Coagulation test abnormal	1 (1.1)	1 (1.1)	0	0	0
Ejection fraction decreased	1 (1.1)	0	1 (1.1)	0	0
Electrocardiogram t wave abnormal	1 (1.1)	0	1 (1.1)	0	0
Enterovirus test positive	1 (1.1)	0	1 (1.1)	0	0
Eosinophil count decreased	1 (1.1)	1 (1.1)	0	0	0
Haematocrit decreased	1 (1.1)	1 (1.1)	0	0	0
Haemoglobin decreased	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haptoglobin decreased	1 (1.1)	1 (1.1)	0	0	0
Heart sounds abnormal	1 (1.1)	1 (1.1)	0	0	0
Hepatitis b virus test positive	1 (1.1)	0	1 (1.1)	0	0
Prothrombin time prolonged	1 (1.1)	0	1 (1.1)	0	0
Red blood cell count decreased	1 (1.1)	1 (1.1)	0	0	0
Staphylococcus test positive	1 (1.1)	1 (1.1)	0	0	0
Troponin increased	1 (1.1)	0	0	1 (1.1)	0
Metabolism and nutrition disorders					
-Total	53 (58.2)	8 (8.8)	9 (9.9)	23 (25.3)	13 (14.3)
Decreased appetite	32 (35.2)	12 (13.2)	8 (8.8)	10 (11.0)	2 (2.2)
Hypokalaemia	22 (24.2)	2 (2.2)	5 (5.5)	12 (13.2)	3 (3.3)
Hypophosphataemia	18 (19.8)	2 (2.2)	6 (6.6)	9 (9.9)	1 (1.1)
Hypocalcaemia	14 (15.4)	1 (1.1)	7 (7.7)	6 (6.6)	0
Hypoalbuminaemia	10 (11.0)	0	9 (9.9)	1 (1.1)	0
Hyperuricaemia	9 (9.9)	7 (7.7)	1 (1.1)	1 (1.1)	0
Hypomagnesaemia	9 (9.9)	7 (7.7)	2 (2.2)	0	0
Hyperglycaemia	8 (8.8)	0	4 (4.4)	4 (4.4)	0
Hypervolaemia	8 (8.8)	1 (1.1)	1 (1.1)	6 (6.6)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	5 (5.5)	1 (1.1)	0	2 (2.2)	2 (2.2)
Tumour lysis syndrome	5 (5.5)	0	0	3 (3.3)	2 (2.2)
Hyperphosphataemia	4 (4.4)	3 (3.3)	0	0	1 (1.1)
Hyperkalaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hypernatraemia	3 (3.3)	1 (1.1)	0	1 (1.1)	1 (1.1)
Hypertriglyceridaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hyponatraemia	3 (3.3)	2 (2.2)	0	0	1 (1.1)
Acidosis	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Hypercalcaemia	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Iron overload	2 (2.2)	0	2 (2.2)	0	0
Malnutrition	2 (2.2)	0	0	2 (2.2)	0
Calcium deficiency	1 (1.1)	1 (1.1)	0	0	0
Dehydration	1 (1.1)	0	1 (1.1)	0	0
Eating disorder symptom	1 (1.1)	0	1 (1.1)	0	0
Haemochromatosis	1 (1.1)	0	0	1 (1.1)	0
Haemosiderosis	1 (1.1)	0	1 (1.1)	0	0
Hyperchloraemia	1 (1.1)	1 (1.1)	0	0	0
Hypercholesterolaemia	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperlactacidaemia	1 (1.1)	1 (1.1)	0	0	0
Hypermagnesaemia	1 (1.1)	1 (1.1)	0	0	0
Hypoglycaemia	1 (1.1)	0	1 (1.1)	0	0
Hypophagia	1 (1.1)	0	1 (1.1)	0	0
Polydipsia	1 (1.1)	0	0	1 (1.1)	0
Vitamin d deficiency	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	45 (49.5)	15 (16.5)	19 (20.9)	10 (11.0)	1 (1.1)
Pain in extremity	22 (24.2)	8 (8.8)	11 (12.1)	3 (3.3)	0
Arthralgia	13 (14.3)	6 (6.6)	6 (6.6)	1 (1.1)	0
Back pain	12 (13.2)	2 (2.2)	6 (6.6)	4 (4.4)	0
Myalgia	9 (9.9)	5 (5.5)	4 (4.4)	0	0
Bone pain	3 (3.3)	0	3 (3.3)	0	0
Pain in jaw	3 (3.3)	1 (1.1)	0	2 (2.2)	0
Growth retardation	2 (2.2)	0	2 (2.2)	0	0
Joint effusion	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Muscular weakness	2 (2.2)	1 (1.1)	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	2 (2.2)	2 (2.2)	0	0	0
Neck pain	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Groin pain	1 (1.1)	1 (1.1)	0	0	0
Haemarthrosis	1 (1.1)	0	0	1 (1.1)	0
Muscle spasms	1 (1.1)	0	1 (1.1)	0	0
Musculoskeletal pain	1 (1.1)	0	1 (1.1)	0	0
Myopathy	1 (1.1)	0	0	1 (1.1)	0
Myositis	1 (1.1)	0	1 (1.1)	0	0
Osteonecrosis	1 (1.1)	1 (1.1)	0	0	0
Osteopenia	1 (1.1)	1 (1.1)	0	0	0
Rhabdomyolysis	1 (1.1)	0	0	0	1 (1.1)
Spinal pain	1 (1.1)	0	0	1 (1.1)	0
Synovitis	1 (1.1)	0	1 (1.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	5 (5.5)	1 (1.1)	2 (2.2)	2 (2.2)	0
Skin papilloma	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Bone giant cell tumour benign	1 (1.1)	0	0	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cancer pain	1 (1.1)	0	1 (1.1)	0	0
Myelodysplastic syndrome	1 (1.1)	0	0	1 (1.1)	0
Nervous system disorders					
-Total	52 (57.1)	17 (18.7)	20 (22.0)	12 (13.2)	3 (3.3)
Headache	31 (34.1)	16 (17.6)	12 (13.2)	3 (3.3)	0
Encephalopathy	8 (8.8)	1 (1.1)	3 (3.3)	4 (4.4)	0
Seizure	6 (6.6)	0	3 (3.3)	3 (3.3)	0
Somnolence	5 (5.5)	2 (2.2)	2 (2.2)	1 (1.1)	0
Tremor	5 (5.5)	5 (5.5)	0	0	0
Cognitive disorder	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Dizziness	4 (4.4)	4 (4.4)	0	0	0
Lethargy	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Dysgeusia	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Neuropathy peripheral	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Dysarthria	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Paraesthesia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Amnesia	1 (1.1)	0	1 (1.1)	0	0
Aphasia	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Autonomic neuropathy	1 (1.1)	0	0	1 (1.1)	0
Cerebral haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Depressed level of consciousness	1 (1.1)	0	0	1 (1.1)	0
Disturbance in attention	1 (1.1)	1 (1.1)	0	0	0
Extrapyramidal disorder	1 (1.1)	0	1 (1.1)	0	0
Hydrocephalus	1 (1.1)	0	0	0	1 (1.1)
Hyperaesthesia	1 (1.1)	1 (1.1)	0	0	0
Hypoaesthesia	1 (1.1)	1 (1.1)	0	0	0
Memory impairment	1 (1.1)	0	1 (1.1)	0	0
Migraine	1 (1.1)	0	1 (1.1)	0	0
Monoparesis	1 (1.1)	0	1 (1.1)	0	0
Nervous system disorder	1 (1.1)	0	0	1 (1.1)	0
Neuralgia	1 (1.1)	0	1 (1.1)	0	0
Neurological decompensation	1 (1.1)	0	0	0	1 (1.1)
Posterior reversible encephalopathy syndrome	1 (1.1)	0	1 (1.1)	0	0
Psychiatric disorders					
-Total	39 (42.9)	12 (13.2)	18 (19.8)	9 (9.9)	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	16 (17.6)	4 (4.4)	9 (9.9)	3 (3.3)	0
Delirium	7 (7.7)	2 (2.2)	2 (2.2)	3 (3.3)	0
Agitation	6 (6.6)	4 (4.4)	2 (2.2)	0	0
Confusional state	6 (6.6)	6 (6.6)	0	0	0
Insomnia	5 (5.5)	2 (2.2)	3 (3.3)	0	0
Mental status changes	5 (5.5)	1 (1.1)	2 (2.2)	2 (2.2)	0
Hallucination	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Irritability	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Sleep disorder	3 (3.3)	0	3 (3.3)	0	0
Affect lability	1 (1.1)	0	1 (1.1)	0	0
Hallucination, visual	1 (1.1)	0	1 (1.1)	0	0
Mood altered	1 (1.1)	1 (1.1)	0	0	0
Nightmare	1 (1.1)	1 (1.1)	0	0	0
Persistent depressive disorder	1 (1.1)	0	1 (1.1)	0	0
Restlessness	1 (1.1)	0	1 (1.1)	0	0
Social avoidant behaviour	1 (1.1)	0	1 (1.1)	0	0
Tearfulness	1 (1.1)	1 (1.1)	0	0	0
Tic	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders					
-Total	27 (29.7)	10 (11.0)	7 (7.7)	5 (5.5)	5 (5.5)
Acute kidney injury	12 (13.2)	5 (5.5)	2 (2.2)	2 (2.2)	3 (3.3)
Dysuria	5 (5.5)	4 (4.4)	1 (1.1)	0	0
Haematuria	4 (4.4)	3 (3.3)	0	1 (1.1)	0
Pollakiuria	2 (2.2)	0	2 (2.2)	0	0
Renal failure	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Renal tubular necrosis	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Urinary retention	2 (2.2)	0	2 (2.2)	0	0
Anuria	1 (1.1)	0	0	0	1 (1.1)
Bladder dilatation	1 (1.1)	0	1 (1.1)	0	0
Cystitis haemorrhagic	1 (1.1)	0	1 (1.1)	0	0
Incontinence	1 (1.1)	0	1 (1.1)	0	0
Kidney enlargement	1 (1.1)	0	1 (1.1)	0	0
Micturition urgency	1 (1.1)	0	1 (1.1)	0	0
Proteinuria	1 (1.1)	1 (1.1)	0	0	0
Renal mass	1 (1.1)	0	1 (1.1)	0	0
Renal pain	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular disorder	1 (1.1)	0	0	1 (1.1)	0
Renal tubular dysfunction	1 (1.1)	1 (1.1)	0	0	0
Urinary incontinence	1 (1.1)	0	1 (1.1)	0	0
Urinary tract disorder	1 (1.1)	0	1 (1.1)	0	0
Reproductive system and breast disorders					
-Total	6 (6.6)	1 (1.1)	2 (2.2)	3 (3.3)	0
Endometriosis	1 (1.1)	0	0	1 (1.1)	0
Female genital tract fistula	1 (1.1)	1 (1.1)	0	0	0
Heavy menstrual bleeding	1 (1.1)	0	1 (1.1)	0	0
Prostatitis	1 (1.1)	0	0	1 (1.1)	0
Vaginal haemorrhage	1 (1.1)	0	1 (1.1)	0	0
Vaginal ulceration	1 (1.1)	0	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	56 (61.5)	18 (19.8)	7 (7.7)	11 (12.1)	20 (22.0)
Cough	23 (25.3)	19 (20.9)	4 (4.4)	0	0
Hypoxia	17 (18.7)	0	5 (5.5)	8 (8.8)	4 (4.4)
Pulmonary oedema	12 (13.2)	3 (3.3)	1 (1.1)	6 (6.6)	2 (2.2)

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	10 (11.0)	6 (6.6)	1 (1.1)	3 (3.3)	0
Respiratory failure	10 (11.0)	0	0	0	10 (11.0)
Nasal congestion	9 (9.9)	8 (8.8)	1 (1.1)	0	0
Oropharyngeal pain	9 (9.9)	8 (8.8)	1 (1.1)	0	0
Tachypnoea	9 (9.9)	3 (3.3)	2 (2.2)	3 (3.3)	1 (1.1)
Dyspnoea	7 (7.7)	1 (1.1)	1 (1.1)	3 (3.3)	2 (2.2)
Pleural effusion	7 (7.7)	2 (2.2)	3 (3.3)	1 (1.1)	1 (1.1)
Rhinorrhoea	5 (5.5)	4 (4.4)	1 (1.1)	0	0
Acute respiratory distress syndrome	4 (4.4)	0	0	0	4 (4.4)
Atelectasis	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Respiratory distress	3 (3.3)	0	1 (1.1)	0	2 (2.2)
Pharyngeal erythema	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Acute respiratory failure	1 (1.1)	0	0	1 (1.1)	0
Bradypnoea	1 (1.1)	0	0	1 (1.1)	0
Bronchial oedema	1 (1.1)	1 (1.1)	0	0	0
Bronchospasm	1 (1.1)	0	1 (1.1)	0	0
Dyspnoea exertional	1 (1.1)	1 (1.1)	0	0	0
Haemoptysis	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (1.1)	0	0	0	1 (1.1)
Lung disorder	1 (1.1)	1 (1.1)	0	0	0
Lung infiltration	1 (1.1)	0	0	1 (1.1)	0
Nasal dryness	1 (1.1)	1 (1.1)	0	0	0
Oropharyngeal plaque	1 (1.1)	0	1 (1.1)	0	0
Painful respiration	1 (1.1)	1 (1.1)	0	0	0
Paranasal sinus discomfort	1 (1.1)	0	1 (1.1)	0	0
Paranasal sinus inflammation	1 (1.1)	1 (1.1)	0	0	0
Pharyngeal exudate	1 (1.1)	0	1 (1.1)	0	0
Pharyngeal oedema	1 (1.1)	0	1 (1.1)	0	0
Productive cough	1 (1.1)	1 (1.1)	0	0	0
Pulmonary haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Pulmonary mass	1 (1.1)	0	1 (1.1)	0	0
Respiratory acidosis	1 (1.1)	0	0	1 (1.1)	0
Respiratory disorder	1 (1.1)	0	1 (1.1)	0	0
Rhinitis allergic	1 (1.1)	1 (1.1)	0	0	0
Sleep apnoea syndrome	1 (1.1)	1 (1.1)	0	0	0
Upper respiratory tract inflammation	1 (1.1)	0	1 (1.1)	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (1.1)	0	1 (1.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	42 (46.2)	19 (20.9)	15 (16.5)	8 (8.8)	0
Pruritus	11 (12.1)	5 (5.5)	6 (6.6)	0	0
Dry skin	8 (8.8)	6 (6.6)	2 (2.2)	0	0
Rash	7 (7.7)	3 (3.3)	4 (4.4)	0	0
Erythema	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Rash papular	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Dermatitis atopic	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Hyperhidrosis	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Ingrowing nail	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Rash maculo-papular	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Skin ulcer	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Decubitus ulcer	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Eczema	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Petechiae	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Acne	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blister	1 (1.1)	1 (1.1)	0	0	0
Dermatitis	1 (1.1)	1 (1.1)	0	0	0
Dermatitis allergic	1 (1.1)	1 (1.1)	0	0	0
Drug eruption	1 (1.1)	0	1 (1.1)	0	0
Erythema nodosum	1 (1.1)	1 (1.1)	0	0	0
Hangnail	1 (1.1)	1 (1.1)	0	0	0
Night sweats	1 (1.1)	1 (1.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (1.1)	1 (1.1)	0	0	0
Papule	1 (1.1)	1 (1.1)	0	0	0
Photosensitivity reaction	1 (1.1)	0	1 (1.1)	0	0
Pruritus allergic	1 (1.1)	0	1 (1.1)	0	0
Purpura	1 (1.1)	1 (1.1)	0	0	0
Rash macular	1 (1.1)	0	0	1 (1.1)	0
Rash pruritic	1 (1.1)	1 (1.1)	0	0	0
Rash vesicular	1 (1.1)	1 (1.1)	0	0	0
Skin discolouration	1 (1.1)	1 (1.1)	0	0	0
Skin hypopigmentation	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

	All patients N=91				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin lesion	1 (1.1)	0	1 (1.1)	0	0
Skin necrosis	1 (1.1)	0	0	1 (1.1)	0
Urticaria	1 (1.1)	0	1 (1.1)	0	0
Vancomycin infusion reaction	1 (1.1)	0	0	1 (1.1)	0
Social circumstances					
-Total	1 (1.1)	0	1 (1.1)	0	0
Patient uncooperative	1 (1.1)	0	1 (1.1)	0	0
Surgical and medical procedures					
-Total	1 (1.1)	0	0	1 (1.1)	0
Thrombolysis	1 (1.1)	0	0	1 (1.1)	0
Vascular disorders					
-Total	39 (42.9)	4 (4.4)	11 (12.1)	15 (16.5)	9 (9.9)
Hypotension	27 (29.7)	2 (2.2)	6 (6.6)	11 (12.1)	8 (8.8)
Hypertension	16 (17.6)	2 (2.2)	9 (9.9)	5 (5.5)	0
Capillary leak syndrome	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Flushing	2 (2.2)	2 (2.2)	0	0	0
Peripheral ischaemia	2 (2.2)	0	2 (2.2)	0	0
Venoocclusive disease	2 (2.2)	0	0	1 (1.1)	1 (1.1)

Down syndrome: No

Primary system organ class Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematoma	1 (1.1)	1 (1.1)	0	0	0
Hot flush	1 (1.1)	1 (1.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208q
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	1 (2.5)	6 (15.0)	33 (82.5)
Blood and lymphatic system disorders					
-Total	32 (80.0)	0	4 (10.0)	16 (40.0)	12 (30.0)
Anaemia	17 (42.5)	1 (2.5)	3 (7.5)	13 (32.5)	0
Febrile neutropenia	16 (40.0)	0	0	15 (37.5)	1 (2.5)
Neutropenia	12 (30.0)	0	1 (2.5)	2 (5.0)	9 (22.5)
Thrombocytopenia	6 (15.0)	0	0	1 (2.5)	5 (12.5)
Disseminated intravascular coagulation	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Leukopenia	4 (10.0)	0	0	1 (2.5)	3 (7.5)
Coagulopathy	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Lymphadenopathy	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	2 (5.0)	0	0	0	2 (5.0)
Pancytopenia	2 (5.0)	0	0	2 (5.0)	0
B-cell aplasia	1 (2.5)	0	1 (2.5)	0	0
Eosinophilia	1 (2.5)	0	1 (2.5)	0	0
Hypercoagulation	1 (2.5)	0	1 (2.5)	0	0
Hypofibrinogenaemia	1 (2.5)	0	1 (2.5)	0	0
Splenomegaly	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	11 (27.5)	4 (10.0)	3 (7.5)	2 (5.0)	2 (5.0)
Tachycardia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Cardiac dysfunction	2 (5.0)	2 (5.0)	0	0	0
Left ventricular dysfunction	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinus tachycardia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cardiac arrest	1 (2.5)	0	0	0	1 (2.5)
Cardiac failure	1 (2.5)	0	0	0	1 (2.5)
Cardiac failure congestive	1 (2.5)	0	1 (2.5)	0	0
Mitral valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Pericardial effusion	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (2.5)	1 (2.5)	0	0	0
Tricuspid valve incompetence	1 (2.5)	1 (2.5)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Cerebral cavernous malformation	1 (2.5)	1 (2.5)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Deafness unilateral	1 (2.5)	0	1 (2.5)	0	0
Endocrine disorders					
-Total	3 (7.5)	0	3 (7.5)	0	0
Adrenal insufficiency	2 (5.0)	0	2 (5.0)	0	0
Hypothyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Cataract	2 (5.0)	2 (5.0)	0	0	0
Eye oedema	1 (2.5)	1 (2.5)	0	0	0
Eye pain	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermetropia	1 (2.5)	1 (2.5)	0	0	0
Mydriasis	1 (2.5)	0	1 (2.5)	0	0
Periorbital swelling	1 (2.5)	0	1 (2.5)	0	0
Retinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Visual field defect	1 (2.5)	0	1 (2.5)	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	30 (75.0)	11 (27.5)	12 (30.0)	7 (17.5)	0
Diarrhoea	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Nausea	12 (30.0)	6 (15.0)	4 (10.0)	2 (5.0)	0
Vomiting	12 (30.0)	7 (17.5)	5 (12.5)	0	0
Abdominal pain	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Constipation	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Stomatitis	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Mouth haemorrhage	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Pancreatitis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Abdominal distension	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Abdominal pain upper	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Gastrointestinal sounds abnormal	2 (5.0)	2 (5.0)	0	0	0
Abdominal rigidity	1 (2.5)	0	1 (2.5)	0	0
Anal erythema	1 (2.5)	1 (2.5)	0	0	0
Anal fistula	1 (2.5)	0	0	1 (2.5)	0
Anal inflammation	1 (2.5)	0	0	1 (2.5)	0
Dyspepsia	1 (2.5)	1 (2.5)	0	0	0
Enteritis	1 (2.5)	0	1 (2.5)	0	0
Enterocolitis	1 (2.5)	0	1 (2.5)	0	0
Gastrooesophageal reflux disease	1 (2.5)	0	1 (2.5)	0	0
Gingival bleeding	1 (2.5)	0	1 (2.5)	0	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Gingivitis ulcerative	1 (2.5)	0	0	1 (2.5)	0
Haemorrhoids	1 (2.5)	0	1 (2.5)	0	0
Ileus	1 (2.5)	0	0	1 (2.5)	0
Lip dry	1 (2.5)	0	1 (2.5)	0	0
Mouth swelling	1 (2.5)	1 (2.5)	0	0	0
Odynophagia	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral disorder	1 (2.5)	1 (2.5)	0	0	0
Peritoneal haematoma	1 (2.5)	1 (2.5)	0	0	0
Proctalgia	1 (2.5)	0	0	1 (2.5)	0
Trichoglossia	1 (2.5)	1 (2.5)	0	0	0
Upper gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	25 (62.5)	15 (37.5)	4 (10.0)	4 (10.0)	2 (5.0)
Pyrexia	17 (42.5)	9 (22.5)	4 (10.0)	3 (7.5)	1 (2.5)
Chills	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Asthenia	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Fatigue	4 (10.0)	4 (10.0)	0	0	0
Oedema peripheral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Pain	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Generalised oedema	2 (5.0)	0	2 (5.0)	0	0
Influenza like illness	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Localised oedema	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	2 (5.0)	2 (5.0)	0	0	0
Catheter site pain	1 (2.5)	0	0	1 (2.5)	0
Chest discomfort	1 (2.5)	0	0	1 (2.5)	0
Crying	1 (2.5)	0	1 (2.5)	0	0
Facial pain	1 (2.5)	0	1 (2.5)	0	0
Malaise	1 (2.5)	0	1 (2.5)	0	0
Multiple organ dysfunction syndrome	1 (2.5)	0	0	0	1 (2.5)
Sluggishness	1 (2.5)	0	1 (2.5)	0	0
Swelling face	1 (2.5)	1 (2.5)	0	0	0
Thirst	1 (2.5)	1 (2.5)	0	0	0
Vascular device occlusion	1 (2.5)	1 (2.5)	0	0	0
Xerosis	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	12 (30.0)	3 (7.5)	4 (10.0)	4 (10.0)	1 (2.5)
Hepatic function abnormal	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hepatic cytolysis	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hyperbilirubinaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Cholelithiasis	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug-induced liver injury	1 (2.5)	0	0	1 (2.5)	0
Hepatomegaly	1 (2.5)	1 (2.5)	0	0	0
Hepatosplenomegaly	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	35 (87.5)	1 (2.5)	7 (17.5)	16 (40.0)	11 (27.5)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	18 (45.0)	1 (2.5)	10 (25.0)	7 (17.5)	0
Immunodeficiency	4 (10.0)	0	0	4 (10.0)	0
Chronic graft versus host disease	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Drug hypersensitivity	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Hypersensitivity	1 (2.5)	1 (2.5)	0	0	0
Seasonal allergy	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	38 (95.0)	5 (12.5)	5 (12.5)	19 (47.5)	9 (22.5)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	7 (17.5)	4 (10.0)	1 (2.5)	2 (5.0)	0
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Parainfluenzae virus infection	5 (12.5)	1 (2.5)	0	3 (7.5)	1 (2.5)
Pneumonia	5 (12.5)	0	1 (2.5)	2 (5.0)	2 (5.0)
Conjunctivitis	4 (10.0)	0	4 (10.0)	0	0
Herpes zoster	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Oral herpes	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Sinusitis	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Bacteraemia	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Bronchopulmonary aspergillosis	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Gingivitis	3 (7.5)	3 (7.5)	0	0	0
Otitis media	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Paronychia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Respiratory tract infection	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Rhinitis	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rhinovirus infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Candida infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	2 (5.0)	0	0	2 (5.0)	0
Cytomegalovirus infection reactivation	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Device related infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Ear infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Encephalitis viral	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Escherichia bacteraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Human herpesvirus 6 infection	2 (5.0)	0	0	2 (5.0)	0
Influenza	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Localised infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Nail infection	2 (5.0)	2 (5.0)	0	0	0
Oral candidiasis	2 (5.0)	0	2 (5.0)	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sepsis	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Staphylococcal skin infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tinea pedis	2 (5.0)	2 (5.0)	0	0	0
Urinary tract infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Anal abscess	1 (2.5)	0	0	1 (2.5)	0
Bk virus infection	1 (2.5)	1 (2.5)	0	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile infection	1 (2.5)	0	0	1 (2.5)	0
Covid-19 pneumonia	1 (2.5)	0	0	0	1 (2.5)
Cystitis	1 (2.5)	0	1 (2.5)	0	0
Device related bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Device related sepsis	1 (2.5)	0	0	1 (2.5)	0
Ear, nose and throat infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Enterobacter infection	1 (2.5)	0	0	1 (2.5)	0
Enterovirus infection	1 (2.5)	0	0	1 (2.5)	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	0	0	1 (2.5)	0
Granulicatella infection	1 (2.5)	0	0	1 (2.5)	0
Herpes simplex	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Mastoiditis	1 (2.5)	0	0	1 (2.5)	0
Meningitis bacterial	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	0	1 (2.5)	0
Molluscum contagiosum	1 (2.5)	1 (2.5)	0	0	0
Myringitis	1 (2.5)	1 (2.5)	0	0	0
Neutropenic infection	1 (2.5)	0	0	1 (2.5)	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia viral	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	0	1 (2.5)	0
Respiratory tract infection viral	1 (2.5)	0	1 (2.5)	0	0
Septic shock	1 (2.5)	0	0	0	1 (2.5)
Sialoadenitis	1 (2.5)	0	0	1 (2.5)	0
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Soft tissue infection	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	0	0	1 (2.5)	0
Stomatococcal infection	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic candida	1 (2.5)	0	0	1 (2.5)	0
Urinary tract infection viral	1 (2.5)	1 (2.5)	0	0	0
Varicella zoster virus infection	1 (2.5)	0	0	1 (2.5)	0
Vascular device infection	1 (2.5)	0	0	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	0	0	1 (2.5)	0
Viral infection	1 (2.5)	0	0	1 (2.5)	0
Viral skin infection	1 (2.5)	1 (2.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	8 (20.0)	3 (7.5)	4 (10.0)	0	1 (2.5)
Fall	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Infusion related reaction	2 (5.0)	0	2 (5.0)	0	0
Ligament sprain	2 (5.0)	2 (5.0)	0	0	0
Procedural pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Extradural haematoma	1 (2.5)	0	1 (2.5)	0	0
Radius fracture	1 (2.5)	0	1 (2.5)	0	0
Transplant failure	1 (2.5)	0	0	0	1 (2.5)
Traumatic haematoma	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (2.5)	1 (2.5)	0	0	0
Investigations					
-Total	30 (75.0)	0	2 (5.0)	7 (17.5)	21 (52.5)
White blood cell count decreased	17 (42.5)	0	0	0	17 (42.5)
Neutrophil count decreased	15 (37.5)	1 (2.5)	0	1 (2.5)	13 (32.5)
Platelet count decreased	14 (35.0)	3 (7.5)	0	3 (7.5)	8 (20.0)
Lymphocyte count decreased	11 (27.5)	0	0	2 (5.0)	9 (22.5)
Alanine aminotransferase increased	9 (22.5)	2 (5.0)	2 (5.0)	5 (12.5)	0
Aspartate aminotransferase increased	6 (15.0)	1 (2.5)	0	4 (10.0)	1 (2.5)
Serum ferritin increased	6 (15.0)	2 (5.0)	4 (10.0)	0	0
C-reactive protein increased	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Blood bilirubin increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Weight increased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Blood creatinine increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)	0	0
Blood glucose increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0	0	0
Gamma-glutamyltransferase increased	2 (5.0)	0	0	2 (5.0)	0
Weight decreased	2 (5.0)	0	0	2 (5.0)	0
Amylase increased	1 (2.5)	0	0	0	1 (2.5)
Blood alkaline phosphatase increased	1 (2.5)	1 (2.5)	0	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	1 (2.5)	0
Blood fibrinogen increased	1 (2.5)	1 (2.5)	0	0	0
Blood immunoglobulin g decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Blood phosphorus decreased	1 (2.5)	0	0	1 (2.5)	0
Blood potassium decreased	1 (2.5)	0	0	0	1 (2.5)
Bone density decreased	1 (2.5)	1 (2.5)	0	0	0
Breath sounds abnormal	1 (2.5)	0	1 (2.5)	0	0
Eosinophil count decreased	1 (2.5)	1 (2.5)	0	0	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematocrit decreased	1 (2.5)	1 (2.5)	0	0	0
Haemoglobin decreased	1 (2.5)	0	0	1 (2.5)	0
Hepatitis b virus test positive	1 (2.5)	0	1 (2.5)	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0	0	0
Oxygen saturation decreased	1 (2.5)	0	0	1 (2.5)	0
Prothrombin time prolonged	1 (2.5)	0	1 (2.5)	0	0
Red blood cell count decreased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					
-Total	22 (55.0)	3 (7.5)	3 (7.5)	11 (27.5)	5 (12.5)
Decreased appetite	11 (27.5)	5 (12.5)	2 (5.0)	2 (5.0)	2 (5.0)
Hypokalaemia	9 (22.5)	2 (5.0)	0	6 (15.0)	1 (2.5)
Hypophosphataemia	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hyperglycaemia	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Hypocalcaemia	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	3 (7.5)	2 (5.0)	0	0	1 (2.5)
Hypermagnesaemia	2 (5.0)	2 (5.0)	0	0	0
Hyperuricaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Acidosis	1 (2.5)	0	0	1 (2.5)	0
Haemochromatosis	1 (2.5)	0	0	1 (2.5)	0
Hypernatraemia	1 (2.5)	1 (2.5)	0	0	0
Hypervolaemia	1 (2.5)	0	1 (2.5)	0	0
Hypophagia	1 (2.5)	0	1 (2.5)	0	0
Iron overload	1 (2.5)	0	1 (2.5)	0	0
Malnutrition	1 (2.5)	0	0	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	0	0	1 (2.5)
Polydipsia	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	22 (55.0)	9 (22.5)	7 (17.5)	6 (15.0)	0
Pain in extremity	10 (25.0)	2 (5.0)	6 (15.0)	2 (5.0)	0
Arthralgia	8 (20.0)	6 (15.0)	2 (5.0)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Bone pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Musculoskeletal chest pain	2 (5.0)	2 (5.0)	0	0	0
Pain in jaw	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Growth retardation	1 (2.5)	0	1 (2.5)	0	0
Joint effusion	1 (2.5)	0	0	1 (2.5)	0
Muscular weakness	1 (2.5)	1 (2.5)	0	0	0
Myopathy	1 (2.5)	0	0	1 (2.5)	0
Neck pain	1 (2.5)	0	1 (2.5)	0	0
Spinal pain	1 (2.5)	0	0	1 (2.5)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Skin papilloma	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Bone giant cell tumour benign	1 (2.5)	0	0	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	0	0	1 (2.5)	0
Nervous system disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (60.0)	10 (25.0)	9 (22.5)	4 (10.0)	1 (2.5)
Headache	14 (35.0)	9 (22.5)	4 (10.0)	1 (2.5)	0
Dizziness	3 (7.5)	3 (7.5)	0	0	0
Dysgeusia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Seizure	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Somnolence	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Tremor	3 (7.5)	3 (7.5)	0	0	0
Lethargy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Neuropathy peripheral	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Amnesia	1 (2.5)	0	1 (2.5)	0	0
Aphasia	1 (2.5)	1 (2.5)	0	0	0
Autonomic neuropathy	1 (2.5)	0	0	1 (2.5)	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Depressed level of consciousness	1 (2.5)	0	0	1 (2.5)	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	1 (2.5)	0	0
Hyperaesthesia	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoaesthesia	1 (2.5)	1 (2.5)	0	0	0
Memory impairment	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	13 (32.5)	2 (5.0)	9 (22.5)	2 (5.0)	0
Anxiety	7 (17.5)	3 (7.5)	3 (7.5)	1 (2.5)	0
Agitation	3 (7.5)	3 (7.5)	0	0	0
Hallucination	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Delirium	2 (5.0)	0	2 (5.0)	0	0
Sleep disorder	2 (5.0)	0	2 (5.0)	0	0
Affect lability	1 (2.5)	0	1 (2.5)	0	0
Hallucination, visual	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Mood altered	1 (2.5)	1 (2.5)	0	0	0
Nightmare	1 (2.5)	1 (2.5)	0	0	0
Restlessness	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Social avoidant behaviour	1 (2.5)	0	1 (2.5)	0	0
Tearfulness	1 (2.5)	1 (2.5)	0	0	0
Renal and urinary disorders					
-Total	13 (32.5)	2 (5.0)	5 (12.5)	3 (7.5)	3 (7.5)
Acute kidney injury	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Haematuria	2 (5.0)	2 (5.0)	0	0	0
Anuria	1 (2.5)	0	0	0	1 (2.5)
Cystitis haemorrhagic	1 (2.5)	0	1 (2.5)	0	0
Dysuria	1 (2.5)	1 (2.5)	0	0	0
Incontinence	1 (2.5)	0	1 (2.5)	0	0
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Proteinuria	1 (2.5)	1 (2.5)	0	0	0
Renal failure	1 (2.5)	0	1 (2.5)	0	0
Renal tubular disorder	1 (2.5)	0	0	1 (2.5)	0
Renal tubular necrosis	1 (2.5)	0	0	1 (2.5)	0
Urinary incontinence	1 (2.5)	0	1 (2.5)	0	0
Urinary tract disorder	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Female genital tract fistula	1 (2.5)	1 (2.5)	0	0	0
Heavy menstrual bleeding	1 (2.5)	0	1 (2.5)	0	0
Prostatitis	1 (2.5)	0	0	1 (2.5)	0
Vaginal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (70.0)	9 (22.5)	5 (12.5)	8 (20.0)	6 (15.0)
Cough	15 (37.5)	13 (32.5)	2 (5.0)	0	0
Hypoxia	10 (25.0)	0	3 (7.5)	4 (10.0)	3 (7.5)
Epistaxis	7 (17.5)	6 (15.0)	0	1 (2.5)	0
Oropharyngeal pain	5 (12.5)	5 (12.5)	0	0	0
Pleural effusion	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Pulmonary oedema	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Dyspnoea	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Nasal congestion	4 (10.0)	4 (10.0)	0	0	0
Tachypnoea	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal erythema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Acute respiratory failure	1 (2.5)	0	0	1 (2.5)	0
Atelectasis	1 (2.5)	0	1 (2.5)	0	0
Bronchial oedema	1 (2.5)	1 (2.5)	0	0	0
Bronchospasm	1 (2.5)	0	1 (2.5)	0	0
Dyspnoea exertional	1 (2.5)	1 (2.5)	0	0	0
Laryngeal oedema	1 (2.5)	0	0	0	1 (2.5)
Lung disorder	1 (2.5)	1 (2.5)	0	0	0
Lung infiltration	1 (2.5)	0	0	1 (2.5)	0
Oropharyngeal plaque	1 (2.5)	0	1 (2.5)	0	0
Painful respiration	1 (2.5)	1 (2.5)	0	0	0
Paranasal sinus discomfort	1 (2.5)	0	1 (2.5)	0	0
Paranasal sinus inflammation	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal exudate	1 (2.5)	0	1 (2.5)	0	0
Pharyngeal oedema	1 (2.5)	0	1 (2.5)	0	0
Pulmonary mass	1 (2.5)	0	1 (2.5)	0	0
Respiratory disorder	1 (2.5)	0	1 (2.5)	0	0
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (2.5)	1 (2.5)	0	0	0
Sleep apnoea syndrome	1 (2.5)	1 (2.5)	0	0	0
Upper respiratory tract inflammation	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	25 (62.5)	14 (35.0)	6 (15.0)	5 (12.5)	0
Dry skin	4 (10.0)	4 (10.0)	0	0	0
Dermatitis atopic	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rash	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rash maculo-papular	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Erythema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Hyperhidrosis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Skin ulcer	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Acne	1 (2.5)	1 (2.5)	0	0	0
Decubitus ulcer	1 (2.5)	0	0	1 (2.5)	0
Dermatitis allergic	1 (2.5)	1 (2.5)	0	0	0
Eczema	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema nodosum	1 (2.5)	1 (2.5)	0	0	0
Hangnail	1 (2.5)	1 (2.5)	0	0	0
Ingrowing nail	1 (2.5)	1 (2.5)	0	0	0
Night sweats	1 (2.5)	1 (2.5)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.5)	1 (2.5)	0	0	0
Photosensitivity reaction	1 (2.5)	0	1 (2.5)	0	0
Purpura	1 (2.5)	1 (2.5)	0	0	0
Rash macular	1 (2.5)	0	0	1 (2.5)	0
Rash papular	1 (2.5)	0	1 (2.5)	0	0
Rash vesicular	1 (2.5)	1 (2.5)	0	0	0
Skin hypopigmentation	1 (2.5)	1 (2.5)	0	0	0
Skin lesion	1 (2.5)	0	1 (2.5)	0	0
Skin swelling	1 (2.5)	1 (2.5)	0	0	0
Social circumstances					
-Total	1 (2.5)	0	1 (2.5)	0	0
Patient uncooperative	1 (2.5)	0	1 (2.5)	0	0
Vascular disorders					

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	13 (32.5)	4 (10.0)	2 (5.0)	4 (10.0)	3 (7.5)
Hypotension	7 (17.5)	1 (2.5)	1 (2.5)	3 (7.5)	2 (5.0)
Hypertension	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Flushing	1 (2.5)	1 (2.5)	0	0	0
Hot flush	1 (2.5)	1 (2.5)	0	0	0
Venoocclusive disease	1 (2.5)	0	0	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208q
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	3 (7.5)	9 (22.5)	28 (70.0)
Blood and lymphatic system disorders					
-Total	29 (72.5)	1 (2.5)	5 (12.5)	17 (42.5)	6 (15.0)
Febrile neutropenia	20 (50.0)	0	0	19 (47.5)	1 (2.5)
Anaemia	19 (47.5)	4 (10.0)	8 (20.0)	6 (15.0)	1 (2.5)
Thrombocytopenia	7 (17.5)	0	1 (2.5)	4 (10.0)	2 (5.0)
Neutropenia	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
Disseminated intravascular coagulation	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Splenomegaly	3 (7.5)	3 (7.5)	0	0	0
Coagulopathy	2 (5.0)	0	2 (5.0)	0	0
Agranulocytosis	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukocytosis	1 (2.5)	0	1 (2.5)	0	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Lymphocytosis	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	19 (47.5)	6 (15.0)	4 (10.0)	5 (12.5)	4 (10.0)
Tachycardia	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)
Bradycardia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Cardiac arrest	2 (5.0)	0	0	0	2 (5.0)
Cardiac failure	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Left ventricular dysfunction	2 (5.0)	0	0	2 (5.0)	0
Atrioventricular block first degree	1 (2.5)	0	1 (2.5)	0	0
Pericardial effusion	1 (2.5)	0	0	1 (2.5)	0
Sinus bradycardia	1 (2.5)	0	0	1 (2.5)	0
Sinus tachycardia	1 (2.5)	1 (2.5)	0	0	0
Ear and labyrinth disorders					
-Total	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Ear pain	1 (2.5)	1 (2.5)	0	0	0
Ear pruritus	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vertigo	1 (2.5)	0	1 (2.5)	0	0
Endocrine disorders					
-Total	6 (15.0)	0	6 (15.0)	0	0
Adrenal insufficiency	4 (10.0)	0	4 (10.0)	0	0
Hypothyroidism	2 (5.0)	0	2 (5.0)	0	0
Delayed puberty	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	10 (25.0)	7 (17.5)	2 (5.0)	1 (2.5)	0
Eyelid oedema	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Ocular hyperaemia	3 (7.5)	3 (7.5)	0	0	0
Conjunctival haemorrhage	2 (5.0)	2 (5.0)	0	0	0
Eye pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Dry eye	1 (2.5)	1 (2.5)	0	0	0
Periorbital oedema	1 (2.5)	1 (2.5)	0	0	0
Vision blurred	1 (2.5)	1 (2.5)	0	0	0
Visual impairment	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	37 (92.5)	8 (20.0)	18 (45.0)	10 (25.0)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	21 (52.5)	8 (20.0)	12 (30.0)	1 (2.5)	0
Vomiting	18 (45.0)	13 (32.5)	3 (7.5)	2 (5.0)	0
Diarrhoea	15 (37.5)	11 (27.5)	2 (5.0)	2 (5.0)	0
Constipation	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Abdominal pain	9 (22.5)	4 (10.0)	4 (10.0)	1 (2.5)	0
Stomatitis	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Haematemesis	3 (7.5)	3 (7.5)	0	0	0
Mouth haemorrhage	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Pancreatitis	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Abdominal pain upper	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Anal fissure	2 (5.0)	0	2 (5.0)	0	0
Dry mouth	2 (5.0)	0	2 (5.0)	0	0
Gingival bleeding	2 (5.0)	2 (5.0)	0	0	0
Neutropenic colitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Oral pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal compartment syndrome	1 (2.5)	0	0	0	1 (2.5)
Abdominal distension	1 (2.5)	0	1 (2.5)	0	0
Anal haemorrhage	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (2.5)	1 (2.5)	0	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal inflammation	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Gingival erythema	1 (2.5)	1 (2.5)	0	0	0
Ileus	1 (2.5)	0	1 (2.5)	0	0
Irritable bowel syndrome	1 (2.5)	0	1 (2.5)	0	0
Lip oedema	1 (2.5)	1 (2.5)	0	0	0
Lip pain	1 (2.5)	1 (2.5)	0	0	0
Lip ulceration	1 (2.5)	0	1 (2.5)	0	0
Melaena	1 (2.5)	0	0	1 (2.5)	0
Proctalgia	1 (2.5)	1 (2.5)	0	0	0
Trichoglossia	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	33 (82.5)	13 (32.5)	11 (27.5)	6 (15.0)	3 (7.5)
Pyrexia	23 (57.5)	9 (22.5)	7 (17.5)	6 (15.0)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	15 (37.5)	11 (27.5)	4 (10.0)	0	0
Oedema peripheral	5 (12.5)	5 (12.5)	0	0	0
Chills	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Pain	4 (10.0)	0	4 (10.0)	0	0
Catheter site pain	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Generalised oedema	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Drug withdrawal syndrome	2 (5.0)	0	2 (5.0)	0	0
Multiple organ dysfunction syndrome	2 (5.0)	0	0	0	2 (5.0)
Catheter site dermatitis	1 (2.5)	1 (2.5)	0	0	0
Catheter site erythema	1 (2.5)	1 (2.5)	0	0	0
Catheter site haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Complication associated with device	1 (2.5)	1 (2.5)	0	0	0
Localised oedema	1 (2.5)	1 (2.5)	0	0	0
Malaise	1 (2.5)	1 (2.5)	0	0	0
Oedema due to hepatic disease	1 (2.5)	0	1 (2.5)	0	0
Systemic inflammatory response syndrome	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device occlusion	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	11 (27.5)	4 (10.0)	4 (10.0)	1 (2.5)	2 (5.0)
Hyperbilirubinaemia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hypertransaminasaemia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Gallbladder enlargement	2 (5.0)	2 (5.0)	0	0	0
Hepatomegaly	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Biliary tract disorder	1 (2.5)	1 (2.5)	0	0	0
Cholelithiasis	1 (2.5)	1 (2.5)	0	0	0
Cholestasis	1 (2.5)	0	0	0	1 (2.5)
Hepatic function abnormal	1 (2.5)	0	1 (2.5)	0	0
Liver disorder	1 (2.5)	0	1 (2.5)	0	0
Ocular icterus	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	37 (92.5)	1 (2.5)	17 (42.5)	8 (20.0)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Hypogammaglobulinaemia	18 (45.0)	1 (2.5)	16 (40.0)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Seasonal allergy	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Allergy to immunoglobulin therapy	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Engraftment syndrome	1 (2.5)	0	0	1 (2.5)	0
Graft versus host disease	1 (2.5)	0	0	1 (2.5)	0
Selective igg subclass deficiency	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	28 (70.0)	1 (2.5)	7 (17.5)	15 (37.5)	5 (12.5)
Rhinovirus infection	6 (15.0)	0	6 (15.0)	0	0
Upper respiratory tract infection	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Conjunctivitis	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Sinusitis	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Staphylococcal bacteraemia	5 (12.5)	0	0	5 (12.5)	0
Pneumonia	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Clostridium difficile infection	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Staphylococcal infection	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Bacteraemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	2 (5.0)	0	0	2 (5.0)	0
Bronchitis	2 (5.0)	0	2 (5.0)	0	0
Candida infection	2 (5.0)	0	2 (5.0)	0	0
Covid-19	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Gastroenteritis viral	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Metapneumovirus infection	2 (5.0)	0	0	2 (5.0)	0
Nail infection	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oral herpes	2 (5.0)	0	2 (5.0)	0	0
Otitis media	2 (5.0)	0	2 (5.0)	0	0
Parainfluenzae virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Paronychia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Pneumocystis jirovecii pneumonia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Septic shock	2 (5.0)	0	0	0	2 (5.0)
Skin infection	2 (5.0)	0	2 (5.0)	0	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Adenovirus infection	1 (2.5)	0	0	1 (2.5)	0
Atypical pneumonia	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Catheter site infection	1 (2.5)	0	1 (2.5)	0	0
Cellulitis	1 (2.5)	0	1 (2.5)	0	0
Cholecystitis infective	1 (2.5)	0	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Coronavirus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Ear infection	1 (2.5)	0	1 (2.5)	0	0
Encephalitis	1 (2.5)	0	0	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Folliculitis	1 (2.5)	0	1 (2.5)	0	0
Fungal infection	1 (2.5)	0	1 (2.5)	0	0
Fungal skin infection	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis clostridial	1 (2.5)	0	1 (2.5)	0	0
Gastroenteritis escherichia coli	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis norovirus	1 (2.5)	1 (2.5)	0	0	0
Gastroenteritis salmonella	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal infection	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes simplex	1 (2.5)	0	1 (2.5)	0	0
Herpes virus infection	1 (2.5)	0	1 (2.5)	0	0
Influenza	1 (2.5)	0	1 (2.5)	0	0
Klebsiella bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Localised infection	1 (2.5)	1 (2.5)	0	0	0
Meningitis pneumococcal	1 (2.5)	0	0	1 (2.5)	0
Nasopharyngitis	1 (2.5)	1 (2.5)	0	0	0
Ophthalmic herpes zoster	1 (2.5)	0	1 (2.5)	0	0
Oral candidiasis	1 (2.5)	0	1 (2.5)	0	0
Oral infection	1 (2.5)	0	1 (2.5)	0	0
Otitis externa	1 (2.5)	0	1 (2.5)	0	0
Otitis media acute	1 (2.5)	0	1 (2.5)	0	0
Pharyngitis	1 (2.5)	0	0	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	0	0	1 (2.5)	0
Salmonellosis	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis fungal	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	0	0	1 (2.5)
Streptococcal sepsis	1 (2.5)	0	1 (2.5)	0	0
Syphilis	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection pseudomonal	1 (2.5)	0	1 (2.5)	0	0
Varicella zoster virus infection	1 (2.5)	0	1 (2.5)	0	0
Viral infection	1 (2.5)	0	1 (2.5)	0	0
Viral upper respiratory tract infection	1 (2.5)	0	0	1 (2.5)	0
Vulval cellulitis	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	19 (47.5)	6 (15.0)	8 (20.0)	3 (7.5)	2 (5.0)
Infusion related reaction	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Transfusion reaction	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Contusion	2 (5.0)	2 (5.0)	0	0	0
Procedural pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Skin abrasion	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Wound	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal injury	1 (2.5)	1 (2.5)	0	0	0
Fall	1 (2.5)	0	1 (2.5)	0	0
Fibula fracture	1 (2.5)	0	1 (2.5)	0	0
Limb injury	1 (2.5)	0	1 (2.5)	0	0
Post-traumatic neck syndrome	1 (2.5)	0	1 (2.5)	0	0
Scratch	1 (2.5)	1 (2.5)	0	0	0
Skin injury	1 (2.5)	0	1 (2.5)	0	0
Skin wound	1 (2.5)	1 (2.5)	0	0	0
Tracheal obstruction	1 (2.5)	0	0	0	1 (2.5)
Vasoplegia syndrome	1 (2.5)	0	0	0	1 (2.5)
Investigations					
-Total	33 (82.5)	1 (2.5)	4 (10.0)	12 (30.0)	16 (40.0)
Aspartate aminotransferase increased	14 (35.0)	1 (2.5)	5 (12.5)	6 (15.0)	2 (5.0)
White blood cell count decreased	14 (35.0)	2 (5.0)	3 (7.5)	1 (2.5)	8 (20.0)
Neutrophil count decreased	13 (32.5)	0	2 (5.0)	2 (5.0)	9 (22.5)
Platelet count decreased	13 (32.5)	3 (7.5)	2 (5.0)	3 (7.5)	5 (12.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	12 (30.0)	2 (5.0)	6 (15.0)	4 (10.0)	0
Lymphocyte count decreased	11 (27.5)	0	1 (2.5)	7 (17.5)	3 (7.5)
Blood bilirubin increased	10 (25.0)	1 (2.5)	1 (2.5)	8 (20.0)	0
International normalised ratio increased	9 (22.5)	5 (12.5)	4 (10.0)	0	0
Activated partial thromboplastin time prolonged	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Blood fibrinogen decreased	6 (15.0)	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
C-reactive protein increased	6 (15.0)	1 (2.5)	1 (2.5)	3 (7.5)	1 (2.5)
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Blood lactate dehydrogenase increased	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Electrocardiogram qt prolonged	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Serum ferritin increased	5 (12.5)	0	1 (2.5)	3 (7.5)	1 (2.5)
Blood creatinine increased	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Blood uric acid increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)
Blood immunoglobulin g decreased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Fibrin d dimer increased	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Weight increased	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Blood fibrinogen increased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Blood phosphorus increased	2 (5.0)	0	2 (5.0)	0	0
Lipase increased	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Oxygen saturation decreased	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Urine output decreased	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Weight decreased	2 (5.0)	0	2 (5.0)	0	0
Amylase increased	1 (2.5)	1 (2.5)	0	0	0
Bacterial test positive	1 (2.5)	0	0	1 (2.5)	0
Blood alkaline phosphatase decreased	1 (2.5)	1 (2.5)	0	0	0
Blood bicarbonate decreased	1 (2.5)	0	1 (2.5)	0	0
Blood creatine phosphokinase increased	1 (2.5)	0	0	0	1 (2.5)
Blood testosterone decreased	1 (2.5)	1 (2.5)	0	0	0
Blood thyroid stimulating hormone increased	1 (2.5)	1 (2.5)	0	0	0
Blood urea increased	1 (2.5)	0	0	1 (2.5)	0
Cardiac murmur	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coagulation test abnormal	1 (2.5)	1 (2.5)	0	0	0
Ejection fraction decreased	1 (2.5)	0	1 (2.5)	0	0
Electrocardiogram t wave abnormal	1 (2.5)	0	1 (2.5)	0	0
Enterovirus test positive	1 (2.5)	0	1 (2.5)	0	0
Haptoglobin decreased	1 (2.5)	1 (2.5)	0	0	0
Heart sounds abnormal	1 (2.5)	1 (2.5)	0	0	0
Immunoglobulins decreased	1 (2.5)	0	1 (2.5)	0	0
Staphylococcus test positive	1 (2.5)	1 (2.5)	0	0	0
Troponin increased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	34 (85.0)	5 (12.5)	8 (20.0)	13 (32.5)	8 (20.0)
Decreased appetite	23 (57.5)	7 (17.5)	6 (15.0)	10 (25.0)	0
Hypokalaemia	16 (40.0)	2 (5.0)	5 (12.5)	7 (17.5)	2 (5.0)
Hypophosphataemia	14 (35.0)	2 (5.0)	5 (12.5)	6 (15.0)	1 (2.5)
Hypocalcaemia	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Hypervolaemia	8 (20.0)	1 (2.5)	1 (2.5)	6 (15.0)	0
Hyperuricaemia	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Hyperphosphataemia	6 (15.0)	5 (12.5)	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypomagnesaemia	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Hypercalcaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hyperkalaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hypertriglyceridaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Metabolic acidosis	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Tumour lysis syndrome	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Hyperchloraemia	2 (5.0)	2 (5.0)	0	0	0
Hypernatraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Acidosis	1 (2.5)	0	0	0	1 (2.5)
Calcium deficiency	1 (2.5)	1 (2.5)	0	0	0
Dehydration	1 (2.5)	0	1 (2.5)	0	0
Eating disorder symptom	1 (2.5)	0	1 (2.5)	0	0
Haemosiderosis	1 (2.5)	0	1 (2.5)	0	0
Hypercholesterolaemia	1 (2.5)	0	1 (2.5)	0	0
Hyperlactacidaemia	1 (2.5)	1 (2.5)	0	0	0
Hyperlipidaemia	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoglycaemia	1 (2.5)	0	1 (2.5)	0	0
Hyponatraemia	1 (2.5)	1 (2.5)	0	0	0
Iron overload	1 (2.5)	0	1 (2.5)	0	0
Malnutrition	1 (2.5)	0	0	1 (2.5)	0
Metabolic syndrome	1 (2.5)	0	1 (2.5)	0	0
Obesity	1 (2.5)	0	0	1 (2.5)	0
Vitamin d deficiency	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	26 (65.0)	9 (22.5)	12 (30.0)	4 (10.0)	1 (2.5)
Pain in extremity	13 (32.5)	7 (17.5)	5 (12.5)	1 (2.5)	0
Arthralgia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Back pain	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Myalgia	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Bone pain	2 (5.0)	0	2 (5.0)	0	0
Groin pain	1 (2.5)	1 (2.5)	0	0	0
Growth retardation	1 (2.5)	0	1 (2.5)	0	0
Haemarthrosis	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint effusion	1 (2.5)	0	1 (2.5)	0	0
Muscle rigidity	1 (2.5)	1 (2.5)	0	0	0
Muscle spasms	1 (2.5)	0	1 (2.5)	0	0
Muscular weakness	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal pain	1 (2.5)	0	1 (2.5)	0	0
Myositis	1 (2.5)	0	1 (2.5)	0	0
Neck pain	1 (2.5)	1 (2.5)	0	0	0
Osteonecrosis	1 (2.5)	1 (2.5)	0	0	0
Osteopenia	1 (2.5)	1 (2.5)	0	0	0
Pain in jaw	1 (2.5)	0	0	1 (2.5)	0
Rhabdomyolysis	1 (2.5)	0	0	0	1 (2.5)
Synovitis	1 (2.5)	0	1 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	1 (2.5)	0	0
Cancer pain	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	28 (70.0)	7 (17.5)	11 (27.5)	7 (17.5)	3 (7.5)

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	18 (45.0)	7 (17.5)	9 (22.5)	2 (5.0)	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Cognitive disorder	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Seizure	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Somnolence	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Tremor	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Dizziness	2 (5.0)	2 (5.0)	0	0	0
Lethargy	2 (5.0)	2 (5.0)	0	0	0
Cerebral haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Dysarthria	1 (2.5)	0	0	1 (2.5)	0
Extrapyramidal disorder	1 (2.5)	0	1 (2.5)	0	0
Generalised tonic-clonic seizure	1 (2.5)	0	1 (2.5)	0	0
Hydrocephalus	1 (2.5)	0	0	0	1 (2.5)
Migraine	1 (2.5)	0	1 (2.5)	0	0
Monoparesis	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorder	1 (2.5)	0	0	1 (2.5)	0
Neuralgia	1 (2.5)	0	1 (2.5)	0	0
Neurological decompensation	1 (2.5)	0	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Posterior reversible encephalopathy syndrome	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	27 (67.5)	11 (27.5)	9 (22.5)	7 (17.5)	0
Anxiety	9 (22.5)	1 (2.5)	6 (15.0)	2 (5.0)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Insomnia	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Mental status changes	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Irritability	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Automatism	1 (2.5)	1 (2.5)	0	0	0
Persistent depressive disorder	1 (2.5)	0	1 (2.5)	0	0
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Tic	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (35.0)	5 (12.5)	2 (5.0)	3 (7.5)	4 (10.0)
Acute kidney injury	7 (17.5)	1 (2.5)	1 (2.5)	2 (5.0)	3 (7.5)
Dysuria	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Haematuria	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Urinary retention	2 (5.0)	0	2 (5.0)	0	0
Anuria	1 (2.5)	1 (2.5)	0	0	0
Azotaemia	1 (2.5)	0	1 (2.5)	0	0
Bladder dilatation	1 (2.5)	0	1 (2.5)	0	0
Kidney enlargement	1 (2.5)	0	1 (2.5)	0	0
Micturition urgency	1 (2.5)	0	1 (2.5)	0	0
Pollakiuria	1 (2.5)	0	1 (2.5)	0	0
Renal failure	1 (2.5)	0	0	0	1 (2.5)
Renal mass	1 (2.5)	0	1 (2.5)	0	0
Renal pain	1 (2.5)	1 (2.5)	0	0	0
Renal tubular dysfunction	1 (2.5)	1 (2.5)	0	0	0
Renal tubular necrosis	1 (2.5)	0	0	0	1 (2.5)
Reproductive system and breast disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Dysmenorrhoea	1 (2.5)	0	1 (2.5)	0	0
Endometriosis	1 (2.5)	0	0	1 (2.5)	0
Perineal rash	1 (2.5)	0	1 (2.5)	0	0
Vaginal ulceration	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	30 (75.0)	10 (25.0)	3 (7.5)	5 (12.5)	12 (30.0)
Cough	11 (27.5)	8 (20.0)	3 (7.5)	0	0
Hypoxia	11 (27.5)	0	2 (5.0)	6 (15.0)	3 (7.5)
Pulmonary oedema	8 (20.0)	2 (5.0)	3 (7.5)	2 (5.0)	1 (2.5)
Nasal congestion	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Respiratory failure	6 (15.0)	0	0	0	6 (15.0)
Epistaxis	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Oropharyngeal pain	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Pleural effusion	5 (12.5)	2 (5.0)	0	2 (5.0)	1 (2.5)
Rhinorrhoea	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Tachypnoea	5 (12.5)	3 (7.5)	0	2 (5.0)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	4 (10.0)	0	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory distress	4 (10.0)	0	2 (5.0)	0	2 (5.0)
Acute respiratory distress syndrome	3 (7.5)	0	0	0	3 (7.5)
Atelectasis	2 (5.0)	0	0	2 (5.0)	0
Rhinitis allergic	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Wheezing	2 (5.0)	0	2 (5.0)	0	0
Bradypnoea	1 (2.5)	0	0	1 (2.5)	0
Haemoptysis	1 (2.5)	0	1 (2.5)	0	0
Nasal discomfort	1 (2.5)	0	1 (2.5)	0	0
Nasal dryness	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Productive cough	1 (2.5)	1 (2.5)	0	0	0
Respiratory acidosis	1 (2.5)	0	0	1 (2.5)	0
Sleep apnoea syndrome	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	23 (57.5)	8 (20.0)	12 (30.0)	3 (7.5)	0
Pruritus	8 (20.0)	3 (7.5)	5 (12.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Dry skin	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Erythema	4 (10.0)	4 (10.0)	0	0	0
Blister	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Ingrowing nail	3 (7.5)	0	3 (7.5)	0	0
Petechiae	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Rash papular	3 (7.5)	3 (7.5)	0	0	0
Eczema	2 (5.0)	2 (5.0)	0	0	0
Skin discolouration	2 (5.0)	2 (5.0)	0	0	0
Skin ulcer	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Decubitus ulcer	1 (2.5)	0	1 (2.5)	0	0
Dermatitis	1 (2.5)	1 (2.5)	0	0	0
Dermatitis diaper	1 (2.5)	0	1 (2.5)	0	0
Drug eruption	1 (2.5)	0	1 (2.5)	0	0
Hyperhidrosis	1 (2.5)	0	1 (2.5)	0	0
Miliaria	1 (2.5)	1 (2.5)	0	0	0
Papule	1 (2.5)	1 (2.5)	0	0	0
Pruritus allergic	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	1 (2.5)	1 (2.5)	0	0	0
Rash maculo-papular	1 (2.5)	1 (2.5)	0	0	0
Rash pruritic	1 (2.5)	1 (2.5)	0	0	0
Scab	1 (2.5)	1 (2.5)	0	0	0
Skin necrosis	1 (2.5)	0	0	1 (2.5)	0
Urticaria	1 (2.5)	0	1 (2.5)	0	0
Vancomycin infusion reaction	1 (2.5)	0	0	1 (2.5)	0
Surgical and medical procedures					
-Total	1 (2.5)	0	0	1 (2.5)	0
Thrombolysis	1 (2.5)	0	0	1 (2.5)	0
Vascular disorders					
-Total	25 (62.5)	1 (2.5)	8 (20.0)	9 (22.5)	7 (17.5)
Hypotension	19 (47.5)	1 (2.5)	5 (12.5)	6 (15.0)	7 (17.5)
Hypertension	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Capillary leak syndrome	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Peripheral ischaemia	2 (5.0)	0	2 (5.0)	0	0
Flushing	1 (2.5)	1 (2.5)	0	0	0
Haematoma	1 (2.5)	1 (2.5)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Thrombosis	1 (2.5)	0	1 (2.5)	0	0
Venoocclusive disease	1 (2.5)	0	0	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208q
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	1 (5.6)	5 (27.8)	9 (50.0)
Blood and lymphatic system disorders					
-Total	6 (33.3)	0	0	4 (22.2)	2 (11.1)
Febrile neutropenia	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Anaemia	2 (11.1)	0	0	2 (11.1)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Cardiac disorders					
-Total	5 (27.8)	0	1 (5.6)	4 (22.2)	0
Tachycardia	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	5 (27.8)	1 (5.6)	0	3 (16.7)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	0	0	1 (5.6)
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
Duodenal perforation	1 (5.6)	0	0	1 (5.6)	0
Gastritis	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Haemoperitoneum	1 (5.6)	0	0	0	1 (5.6)
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	5 (27.8)	1 (5.6)	1 (5.6)	3 (16.7)	0
Pyrexia	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Catheter site pain	1 (5.6)	1 (5.6)	0	0	0
Generalised oedema	1 (5.6)	0	0	1 (5.6)	0
Pain	1 (5.6)	0	1 (5.6)	0	0
Hepatobiliary disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	0	0	1 (5.6)	0
Hyperbilirubinaemia	1 (5.6)	0	0	1 (5.6)	0
Immune system disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Graft versus host disease	1 (5.6)	0	0	1 (5.6)	0
Infections and infestations					
-Total	10 (55.6)	0	1 (5.6)	3 (16.7)	6 (33.3)
Acute sinusitis	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Disseminated trichosporonosis	1 (5.6)	0	0	0	1 (5.6)
Epstein-barr virus infection	1 (5.6)	0	1 (5.6)	0	0
Fungaemia	1 (5.6)	0	0	0	1 (5.6)
Fungal skin infection	1 (5.6)	0	0	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Peritonitis	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Sepsis	1 (5.6)	0	0	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	0	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (5.6)	0	0	0	1 (5.6)
Systemic mycosis	1 (5.6)	0	0	1 (5.6)	0
Investigations					
-Total	3 (16.7)	0	0	1 (5.6)	2 (11.1)
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0	0	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
C-reactive protein increased	1 (5.6)	0	0	1 (5.6)	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Hyperkalaemia	1 (5.6)	0	0	1 (5.6)	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	1 (5.6)	0	1 (5.6)	0	0
Tumour lysis syndrome	1 (5.6)	0	0	0	1 (5.6)
Nervous system disorders					
-Total	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	0	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	0	0	1 (5.6)
Psychiatric disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Mental status changes	1 (5.6)	0	0	1 (5.6)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (22.2)	0	0	0	4 (22.2)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	0	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary haemorrhage	1 (5.6)	0	0	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Tachypnoea	1 (5.6)	0	1 (5.6)	0	0
Vascular disorders					
-Total	5 (27.8)	0	1 (5.6)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	1 (5.6)	0	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	1 (12.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders					
-Total	6 (75.0)	0	1 (12.5)	3 (37.5)	2 (25.0)
Anaemia	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Febrile neutropenia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Coagulopathy	1 (12.5)	0	0	1 (12.5)	0
Disseminated intravascular coagulation	1 (12.5)	0	0	1 (12.5)	0
Lymphocytosis	1 (12.5)	0	1 (12.5)	0	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Sinus tachycardia	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Eyelid oedema	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	6 (75.0)	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)
Abdominal pain	2 (25.0)	2 (25.0)	0	0	0
Nausea	2 (25.0)	2 (25.0)	0	0	0
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Abdominal distension	1 (12.5)	0	1 (12.5)	0	0
Ascites	1 (12.5)	1 (12.5)	0	0	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
Irritable bowel syndrome	1 (12.5)	0	1 (12.5)	0	0
Melaena	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	1 (12.5)	0	1 (12.5)	0	0
Stomatitis	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	2 (25.0)	2 (25.0)	1 (12.5)
Pyrexia	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Fatigue	2 (25.0)	2 (25.0)	0	0	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Face oedema	1 (12.5)	0	1 (12.5)	0	0
Generalised oedema	1 (12.5)	0	1 (12.5)	0	0
Multiple organ dysfunction syndrome	1 (12.5)	0	0	0	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Systemic inflammatory response syndrome	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cholelithiasis	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholestasis	1 (12.5)	0	0	0	1 (12.5)
Gallbladder enlargement	1 (12.5)	1 (12.5)	0	0	0
Immune system disorders					
-Total	6 (75.0)	0	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Hypogammaglobulinaemia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Seasonal allergy	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0	0	0
Otitis externa	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)	0	0
Vulval cellulitis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					
-Total	3 (37.5)	0	2 (25.0)	0	1 (12.5)
Fibula fracture	1 (12.5)	0	1 (12.5)	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Skin injury	1 (12.5)	0	1 (12.5)	0	0
Skin wound	1 (12.5)	1 (12.5)	0	0	0
Vasoplegia syndrome	1 (12.5)	0	0	0	1 (12.5)
Wound	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	4 (50.0)	0	0	1 (12.5)	3 (37.5)
Neutrophil count decreased	3 (37.5)	0	0	1 (12.5)	2 (25.0)
White blood cell count decreased	3 (37.5)	1 (12.5)	1 (12.5)	0	1 (12.5)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Blood creatinine increased	2 (25.0)	2 (25.0)	0	0	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Blood alkaline phosphatase increased	1 (12.5)	1 (12.5)	0	0	0
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0
Blood creatine phosphokinase increased	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Electrocardiogram qt prolonged	1 (12.5)	0	1 (12.5)	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Lipase increased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	0	1 (12.5)	0	0
Metabolism and nutrition disorders					
-Total	7 (87.5)	1 (12.5)	1 (12.5)	4 (50.0)	1 (12.5)
Decreased appetite	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Hypocalcaemia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Hypophosphataemia	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Hyperuricaemia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Hypoalbuminaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Acidosis	1 (12.5)	0	0	1 (12.5)	0
Haemosiderosis	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperglycaemia	1 (12.5)	0	1 (12.5)	0	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperlactacidaemia	1 (12.5)	1 (12.5)	0	0	0
Hypermagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypernatraemia	1 (12.5)	0	0	0	1 (12.5)
Hypokalaemia	1 (12.5)	0	0	0	1 (12.5)
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hyponatraemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Myalgia	1 (12.5)	1 (12.5)	0	0	0
Myositis	1 (12.5)	0	1 (12.5)	0	0
Rhabdomyolysis	1 (12.5)	0	0	0	1 (12.5)
Nervous system disorders					
-Total	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Headache	4 (50.0)	3 (37.5)	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Monoparesis	1 (12.5)	0	1 (12.5)	0	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Tremor	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Confusional state	1 (12.5)	1 (12.5)	0	0	0
Irritability	1 (12.5)	0	0	1 (12.5)	0
Persistent depressive disorder	1 (12.5)	0	1 (12.5)	0	0
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Acute kidney injury	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Bladder dilatation	1 (12.5)	0	1 (12.5)	0	0
Dysuria	1 (12.5)	1 (12.5)	0	0	0
Renal tubular necrosis	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Reproductive system and breast disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Vaginal ulceration	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (75.0)	2 (25.0)	0	1 (12.5)	3 (37.5)
Nasal congestion	2 (25.0)	2 (25.0)	0	0	0
Oropharyngeal pain	2 (25.0)	2 (25.0)	0	0	0
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Tachypnoea	2 (25.0)	0	0	2 (25.0)	0
Acute respiratory distress syndrome	1 (12.5)	0	0	0	1 (12.5)
Acute respiratory failure	1 (12.5)	0	0	1 (12.5)	0
Atelectasis	1 (12.5)	0	0	1 (12.5)	0
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)
Hypoxia	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory acidosis	1 (12.5)	0	0	1 (12.5)	0
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	0	1 (12.5)	0
Dry skin	2 (25.0)	2 (25.0)	0	0	0
Rash	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Decubitus ulcer	1 (12.5)	0	1 (12.5)	0	0
Erythema	1 (12.5)	1 (12.5)	0	0	0
Hyperhidrosis	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Petechiae	1 (12.5)	0	0	1 (12.5)	0
Pruritus	1 (12.5)	0	1 (12.5)	0	0
Skin hypopigmentation	1 (12.5)	1 (12.5)	0	0	0
Skin necrosis	1 (12.5)	0	0	1 (12.5)	0
Skin ulcer	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Hypotension	4 (50.0)	0	0	3 (37.5)	1 (12.5)

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (12.5)	0	0	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (90.0)	0	2 (6.7)	7 (23.3)	18 (60.0)
Blood and lymphatic system disorders					
-Total	18 (60.0)	1 (3.3)	4 (13.3)	7 (23.3)	6 (20.0)
Anaemia	10 (33.3)	2 (6.7)	3 (10.0)	5 (16.7)	0
Febrile neutropenia	9 (30.0)	0	0	8 (26.7)	1 (3.3)
Neutropenia	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Thrombocytopenia	4 (13.3)	0	0	2 (6.7)	2 (6.7)
Coagulopathy	2 (6.7)	0	2 (6.7)	0	0
Disseminated intravascular coagulation	2 (6.7)	0	2 (6.7)	0	0
Lymphadenopathy	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Hypercoagulation	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Pancytopenia	1 (3.3)	0	0	1 (3.3)	0
Splenomegaly	1 (3.3)	1 (3.3)	0	0	0
Cardiac disorders					
-Total	10 (33.3)	1 (3.3)	2 (6.7)	5 (16.7)	2 (6.7)
Tachycardia	7 (23.3)	2 (6.7)	3 (10.0)	2 (6.7)	0
Left ventricular dysfunction	3 (10.0)	0	0	3 (10.0)	0
Bradycardia	2 (6.7)	2 (6.7)	0	0	0
Cardiac failure	2 (6.7)	0	0	0	2 (6.7)
Atrioventricular block first degree	1 (3.3)	0	1 (3.3)	0	0
Sinus bradycardia	1 (3.3)	0	0	1 (3.3)	0
Ear and labyrinth disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Ear pain	1 (3.3)	1 (3.3)	0	0	0
Endocrine disorders					
-Total	4 (13.3)	0	4 (13.3)	0	0
Adrenal insufficiency	3 (10.0)	0	3 (10.0)	0	0
Hypothyroidism	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	2 (6.7)	2 (6.7)	0	0	0
Ocular hyperaemia	2 (6.7)	2 (6.7)	0	0	0
Conjunctival haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	21 (70.0)	5 (16.7)	9 (30.0)	6 (20.0)	1 (3.3)
Vomiting	12 (40.0)	9 (30.0)	2 (6.7)	1 (3.3)	0
Nausea	11 (36.7)	3 (10.0)	6 (20.0)	2 (6.7)	0
Constipation	7 (23.3)	3 (10.0)	4 (13.3)	0	0
Diarrhoea	7 (23.3)	6 (20.0)	1 (3.3)	0	0
Abdominal pain	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	0
Anal fissure	2 (6.7)	0	2 (6.7)	0	0
Dry mouth	2 (6.7)	0	2 (6.7)	0	0
Gastrointestinal haemorrhage	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Ileus	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Pancreatitis	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Stomatitis	2 (6.7)	0	0	2 (6.7)	0
Abdominal compartment syndrome	1 (3.3)	0	0	0	1 (3.3)

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	1 (3.3)	1 (3.3)	0	0	0
Anal haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal sounds abnormal	1 (3.3)	1 (3.3)	0	0	0
Gingival bleeding	1 (3.3)	1 (3.3)	0	0	0
Haematemesis	1 (3.3)	1 (3.3)	0	0	0
Lip pain	1 (3.3)	1 (3.3)	0	0	0
Lip ulceration	1 (3.3)	0	1 (3.3)	0	0
Mouth haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Neutropenic colitis	1 (3.3)	0	0	1 (3.3)	0
Proctalgia	1 (3.3)	1 (3.3)	0	0	0
General disorders and administration site conditions					
-Total	17 (56.7)	6 (20.0)	4 (13.3)	4 (13.3)	3 (10.0)
Pyrexia	12 (40.0)	5 (16.7)	3 (10.0)	3 (10.0)	1 (3.3)
Oedema peripheral	5 (16.7)	4 (13.3)	0	1 (3.3)	0
Fatigue	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Chills	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Face oedema	3 (10.0)	2 (6.7)	0	1 (3.3)	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	3 (10.0)	0	3 (10.0)	0	0
Drug withdrawal syndrome	2 (6.7)	0	2 (6.7)	0	0
Multiple organ dysfunction syndrome	2 (6.7)	0	0	0	2 (6.7)
Catheter site dermatitis	1 (3.3)	1 (3.3)	0	0	0
Catheter site pain	1 (3.3)	0	1 (3.3)	0	0
Generalised oedema	1 (3.3)	0	1 (3.3)	0	0
Oedema due to hepatic disease	1 (3.3)	0	1 (3.3)	0	0
Hepatobiliary disorders					
-Total	7 (23.3)	3 (10.0)	2 (6.7)	2 (6.7)	0
Hepatic function abnormal	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Hyperbilirubinaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Biliary tract disorder	1 (3.3)	1 (3.3)	0	0	0
Gallbladder enlargement	1 (3.3)	1 (3.3)	0	0	0
Hepatomegaly	1 (3.3)	1 (3.3)	0	0	0
Hypertransaminasaemia	1 (3.3)	1 (3.3)	0	0	0
Ocular icterus	1 (3.3)	1 (3.3)	0	0	0
Immune system disorders					
-Total	20 (66.7)	1 (3.3)	7 (23.3)	5 (16.7)	7 (23.3)

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	15 (50.0)	1 (3.3)	4 (13.3)	4 (13.3)	6 (20.0)
Hypogammaglobulinaemia	10 (33.3)	1 (3.3)	8 (26.7)	1 (3.3)	0
Haemophagocytic lymphohistiocytosis	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Allergy to immunoglobulin therapy	1 (3.3)	0	0	1 (3.3)	0
Chronic graft versus host disease	1 (3.3)	0	0	1 (3.3)	0
Engraftment syndrome	1 (3.3)	0	0	1 (3.3)	0
Graft versus host disease	1 (3.3)	0	0	1 (3.3)	0
Immunodeficiency	1 (3.3)	0	0	1 (3.3)	0
Infections and infestations					
-Total	20 (66.7)	2 (6.7)	5 (16.7)	9 (30.0)	4 (13.3)
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Clostridium difficile infection	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Parainfluenzae virus infection	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Staphylococcal bacteraemia	3 (10.0)	0	0	3 (10.0)	0
Acute sinusitis	2 (6.7)	0	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Klebsiella bacteraemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Nasopharyngitis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Pneumonia	2 (6.7)	0	0	0	2 (6.7)
Atypical pneumonia	1 (3.3)	1 (3.3)	0	0	0
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Candida infection	1 (3.3)	0	1 (3.3)	0	0
Cellulitis	1 (3.3)	0	1 (3.3)	0	0
Cholecystitis infective	1 (3.3)	0	1 (3.3)	0	0
Coronavirus infection	1 (3.3)	0	0	1 (3.3)	0
Covid-19 pneumonia	1 (3.3)	0	0	0	1 (3.3)
Cystitis	1 (3.3)	0	1 (3.3)	0	0
Ear infection	1 (3.3)	0	1 (3.3)	0	0
Encephalitis viral	1 (3.3)	0	0	0	1 (3.3)
Enterovirus infection	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Fungal skin infection	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis viral	1 (3.3)	1 (3.3)	0	0	0
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Meningitis bacterial	1 (3.3)	0	0	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	0	0	1 (3.3)	0
Molluscum contagiosum	1 (3.3)	1 (3.3)	0	0	0
Otitis media	1 (3.3)	0	1 (3.3)	0	0
Otitis media acute	1 (3.3)	0	1 (3.3)	0	0
Pharyngitis streptococcal	1 (3.3)	0	0	1 (3.3)	0
Pneumonia fungal	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal infection	1 (3.3)	0	1 (3.3)	0	0
Systemic mycosis	1 (3.3)	0	0	1 (3.3)	0
Tinea pedis	1 (3.3)	1 (3.3)	0	0	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	8 (26.7)	4 (13.3)	2 (6.7)	2 (6.7)	0
Transfusion reaction	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Abdominal injury	1 (3.3)	1 (3.3)	0	0	0
Contusion	1 (3.3)	1 (3.3)	0	0	0
Infusion related reaction	1 (3.3)	0	0	1 (3.3)	0
Post-traumatic neck syndrome	1 (3.3)	0	1 (3.3)	0	0
Scratch	1 (3.3)	1 (3.3)	0	0	0
Skin abrasion	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	19 (63.3)	1 (3.3)	1 (3.3)	6 (20.0)	11 (36.7)
White blood cell count decreased	10 (33.3)	1 (3.3)	1 (3.3)	1 (3.3)	7 (23.3)
Aspartate aminotransferase increased	8 (26.7)	0	2 (6.7)	5 (16.7)	1 (3.3)
Platelet count decreased	8 (26.7)	3 (10.0)	1 (3.3)	1 (3.3)	3 (10.0)
Lymphocyte count decreased	7 (23.3)	0	0	3 (10.0)	4 (13.3)
Blood bilirubin increased	6 (20.0)	0	1 (3.3)	5 (16.7)	0
Neutrophil count decreased	6 (20.0)	0	0	1 (3.3)	5 (16.7)

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (16.7)	1 (3.3)	4 (13.3)	0	0
Serum ferritin increased	5 (16.7)	1 (3.3)	2 (6.7)	1 (3.3)	1 (3.3)
Blood fibrinogen decreased	4 (13.3)	2 (6.7)	2 (6.7)	0	0
C-reactive protein increased	4 (13.3)	1 (3.3)	0	2 (6.7)	1 (3.3)
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood immunoglobulin a decreased	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood immunoglobulin g decreased	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Blood immunoglobulin m decreased	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Blood lactate dehydrogenase increased	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Electrocardiogram qt prolonged	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Fibrin d dimer increased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
International normalised ratio increased	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Oxygen saturation decreased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Amylase increased	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Blood creatinine increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Blood phosphorus increased	2 (6.7)	0	2 (6.7)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	2 (6.7)	2 (6.7)	0	0	0
Weight increased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Bacterial test positive	1 (3.3)	0	0	1 (3.3)	0
Blood alkaline phosphatase decreased	1 (3.3)	1 (3.3)	0	0	0
Blood fibrinogen increased	1 (3.3)	0	1 (3.3)	0	0
Blood urea increased	1 (3.3)	0	0	1 (3.3)	0
Coagulation test abnormal	1 (3.3)	1 (3.3)	0	0	0
Electrocardiogram t wave abnormal	1 (3.3)	0	1 (3.3)	0	0
Heart sounds abnormal	1 (3.3)	1 (3.3)	0	0	0
Lipase increased	1 (3.3)	1 (3.3)	0	0	0
Staphylococcus test positive	1 (3.3)	1 (3.3)	0	0	0
Troponin increased	1 (3.3)	0	0	1 (3.3)	0
Urine output decreased	1 (3.3)	0	0	1 (3.3)	0
Weight decreased	1 (3.3)	0	1 (3.3)	0	0
Metabolism and nutrition disorders					
-Total	16 (53.3)	2 (6.7)	2 (6.7)	7 (23.3)	5 (16.7)
Decreased appetite	10 (33.3)	2 (6.7)	1 (3.3)	7 (23.3)	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	7 (23.3)	1 (3.3)	4 (13.3)	2 (6.7)	0
Hypokalaemia	6 (20.0)	1 (3.3)	3 (10.0)	2 (6.7)	0
Hyperglycaemia	5 (16.7)	0	2 (6.7)	3 (10.0)	0
Hypervolaemia	5 (16.7)	0	0	5 (16.7)	0
Hypophosphataemia	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hypoalbuminaemia	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Hyperphosphataemia	3 (10.0)	3 (10.0)	0	0	0
Hyperuricaemia	3 (10.0)	3 (10.0)	0	0	0
Hypomagnesaemia	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Metabolic acidosis	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Hypercalcaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Hypertriglyceridaemia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Tumour lysis syndrome	2 (6.7)	0	0	2 (6.7)	0
Acidosis	1 (3.3)	0	0	0	1 (3.3)
Calcium deficiency	1 (3.3)	1 (3.3)	0	0	0
Dehydration	1 (3.3)	0	1 (3.3)	0	0
Hyperkalaemia	1 (3.3)	0	0	1 (3.3)	0
Hypoglycaemia	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (3.3)	0	0	0	1 (3.3)
Obesity	1 (3.3)	0	0	1 (3.3)	0
Musculoskeletal and connective tissue disorders					
-Total	12 (40.0)	6 (20.0)	4 (13.3)	2 (6.7)	0
Pain in extremity	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Arthralgia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Bone pain	2 (6.7)	0	2 (6.7)	0	0
Back pain	1 (3.3)	0	1 (3.3)	0	0
Haemarthrosis	1 (3.3)	0	0	1 (3.3)	0
Muscle spasms	1 (3.3)	0	1 (3.3)	0	0
Muscular weakness	1 (3.3)	1 (3.3)	0	0	0
Myalgia	1 (3.3)	1 (3.3)	0	0	0
Neck pain	1 (3.3)	1 (3.3)	0	0	0
Pain in jaw	1 (3.3)	0	0	1 (3.3)	0
Nervous system disorders					
-Total	13 (43.3)	6 (20.0)	3 (10.0)	2 (6.7)	2 (6.7)
Headache	4 (13.3)	3 (10.0)	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Cognitive disorder	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Lethargy	2 (6.7)	2 (6.7)	0	0	0
Cerebral haemorrhage	1 (3.3)	0	0	0	1 (3.3)
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Dysarthria	1 (3.3)	0	0	1 (3.3)	0
Dysgeusia	1 (3.3)	1 (3.3)	0	0	0
Extrapyramidal disorder	1 (3.3)	0	1 (3.3)	0	0
Migraine	1 (3.3)	0	1 (3.3)	0	0
Neurological decompensation	1 (3.3)	0	0	0	1 (3.3)
Paraesthesia	1 (3.3)	1 (3.3)	0	0	0
Seizure	1 (3.3)	0	1 (3.3)	0	0
Somnolence	1 (3.3)	0	0	1 (3.3)	0
Psychiatric disorders					
-Total	11 (36.7)	5 (16.7)	2 (6.7)	4 (13.3)	0
Delirium	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Anxiety	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Agitation	2 (6.7)	0	2 (6.7)	0	0

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	2 (6.7)	2 (6.7)	0	0	0
Insomnia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Irritability	2 (6.7)	2 (6.7)	0	0	0
Mental status changes	1 (3.3)	0	1 (3.3)	0	0
Renal and urinary disorders					
-Total	9 (30.0)	4 (13.3)	1 (3.3)	1 (3.3)	3 (10.0)
Acute kidney injury	4 (13.3)	1 (3.3)	0	1 (3.3)	2 (6.7)
Dysuria	1 (3.3)	1 (3.3)	0	0	0
Haematuria	1 (3.3)	1 (3.3)	0	0	0
Renal failure	1 (3.3)	0	0	0	1 (3.3)
Renal pain	1 (3.3)	1 (3.3)	0	0	0
Renal tubular dysfunction	1 (3.3)	1 (3.3)	0	0	0
Urinary retention	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (56.7)	4 (13.3)	1 (3.3)	3 (10.0)	9 (30.0)
Cough	7 (23.3)	7 (23.3)	0	0	0
Hypoxia	7 (23.3)	0	1 (3.3)	3 (10.0)	3 (10.0)

Number of previous relapses: 1

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	7 (23.3)	2 (6.7)	2 (6.7)	2 (6.7)	1 (3.3)
Pleural effusion	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Respiratory failure	4 (13.3)	0	0	0	4 (13.3)
Epistaxis	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Respiratory distress	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Tachypnoea	3 (10.0)	2 (6.7)	0	0	1 (3.3)
Oropharyngeal pain	2 (6.7)	0	2 (6.7)	0	0
Rhinitis allergic	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Acute respiratory distress syndrome	1 (3.3)	0	0	0	1 (3.3)
Atelectasis	1 (3.3)	0	0	1 (3.3)	0
Bradypnoea	1 (3.3)	0	0	1 (3.3)	0
Bronchospasm	1 (3.3)	0	1 (3.3)	0	0
Dyspnoea	1 (3.3)	0	0	0	1 (3.3)
Nasal congestion	1 (3.3)	1 (3.3)	0	0	0
Rhinorrhoea	1 (3.3)	1 (3.3)	0	0	0
Sleep apnoea syndrome	1 (3.3)	0	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	16 (53.3)	8 (26.7)	6 (20.0)	2 (6.7)	0
Pruritus	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Blister	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Dry skin	2 (6.7)	2 (6.7)	0	0	0
Erythema	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Rash papular	2 (6.7)	2 (6.7)	0	0	0
Skin discolouration	2 (6.7)	2 (6.7)	0	0	0
Dermatitis	1 (3.3)	1 (3.3)	0	0	0
Dermatitis allergic	1 (3.3)	1 (3.3)	0	0	0
Dermatitis atopic	1 (3.3)	1 (3.3)	0	0	0
Hyperhidrosis	1 (3.3)	0	1 (3.3)	0	0
Ingrowing nail	1 (3.3)	0	1 (3.3)	0	0
Miliaria	1 (3.3)	1 (3.3)	0	0	0
Petechiae	1 (3.3)	1 (3.3)	0	0	0
Rash	1 (3.3)	1 (3.3)	0	0	0
Rash maculo-papular	1 (3.3)	1 (3.3)	0	0	0
Rash pruritic	1 (3.3)	1 (3.3)	0	0	0
Rash vesicular	1 (3.3)	1 (3.3)	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Scab	1 (3.3)	1 (3.3)	0	0	0
Skin ulcer	1 (3.3)	0	0	1 (3.3)	0
Vancomycin infusion reaction	1 (3.3)	0	0	1 (3.3)	0
Surgical and medical procedures					
-Total	1 (3.3)	0	0	1 (3.3)	0
Thrombolysis	1 (3.3)	0	0	1 (3.3)	0
Vascular disorders					
-Total	14 (46.7)	0	3 (10.0)	6 (20.0)	5 (16.7)
Hypotension	12 (40.0)	0	2 (6.7)	5 (16.7)	5 (16.7)
Hypertension	7 (23.3)	1 (3.3)	4 (13.3)	2 (6.7)	0
Peripheral ischaemia	2 (6.7)	0	2 (6.7)	0	0
Capillary leak syndrome	1 (3.3)	0	1 (3.3)	0	0
Flushing	1 (3.3)	1 (3.3)	0	0	0
Venoocclusive disease	1 (3.3)	0	0	1 (3.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	2 (11.1)	15 (83.3)
Blood and lymphatic system disorders					
-Total	12 (66.7)	0	1 (5.6)	8 (44.4)	3 (16.7)
Febrile neutropenia	10 (55.6)	0	0	10 (55.6)	0
Anaemia	6 (33.3)	0	3 (16.7)	2 (11.1)	1 (5.6)
Neutropenia	4 (22.2)	1 (5.6)	1 (5.6)	0	2 (11.1)
Splenomegaly	2 (11.1)	2 (11.1)	0	0	0
Thrombocytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Disseminated intravascular coagulation	1 (5.6)	0	0	1 (5.6)	0
Hypofibrinogenaemia	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (5.6)	0	1 (5.6)	0	0
Leukopenia	1 (5.6)	0	0	0	1 (5.6)
Lymphopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	8 (44.4)	4 (22.2)	2 (11.1)	0	2 (11.1)
Tachycardia	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Cardiac arrest	2 (11.1)	0	0	0	2 (11.1)
Bradycardia	1 (5.6)	0	1 (5.6)	0	0
Cardiac dysfunction	1 (5.6)	1 (5.6)	0	0	0
Cardiac failure	1 (5.6)	0	0	1 (5.6)	0
Sinus tachycardia	1 (5.6)	1 (5.6)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Ear pruritus	1 (5.6)	1 (5.6)	0	0	0
Endocrine disorders					
-Total	2 (11.1)	0	2 (11.1)	0	0
Hypothyroidism	2 (11.1)	0	2 (11.1)	0	0
Delayed puberty	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	5 (27.8)	4 (22.2)	1 (5.6)	0	0
Conjunctival haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Dry eye	1 (5.6)	1 (5.6)	0	0	0
Mydriasis	1 (5.6)	0	1 (5.6)	0	0
Periorbital oedema	1 (5.6)	1 (5.6)	0	0	0
Vision blurred	1 (5.6)	1 (5.6)	0	0	0
Visual impairment	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	14 (77.8)	4 (22.2)	6 (33.3)	4 (22.2)	0
Diarrhoea	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Nausea	7 (38.9)	4 (22.2)	3 (16.7)	0	0
Vomiting	6 (33.3)	4 (22.2)	1 (5.6)	1 (5.6)	0
Constipation	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Stomatitis	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	2 (11.1)	0	0
Haematemesis	2 (11.1)	2 (11.1)	0	0	0
Oral pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Anal inflammation	1 (5.6)	0	0	1 (5.6)	0
Dysphagia	1 (5.6)	0	0	1 (5.6)	0
Gastrointestinal inflammation	1 (5.6)	0	1 (5.6)	0	0
Gingival erythema	1 (5.6)	1 (5.6)	0	0	0
Lip oedema	1 (5.6)	1 (5.6)	0	0	0
Neutropenic colitis	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					
-Total	15 (83.3)	7 (38.9)	5 (27.8)	3 (16.7)	0
Pyrexia	10 (55.6)	4 (22.2)	3 (16.7)	3 (16.7)	0
Fatigue	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Generalised oedema	2 (11.1)	2 (11.1)	0	0	0
Oedema peripheral	2 (11.1)	2 (11.1)	0	0	0
Catheter site haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Catheter site pain	1 (5.6)	0	1 (5.6)	0	0
Complication associated with device	1 (5.6)	1 (5.6)	0	0	0
Face oedema	1 (5.6)	1 (5.6)	0	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised oedema	1 (5.6)	1 (5.6)	0	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Vascular device occlusion	1 (5.6)	1 (5.6)	0	0	0
Hepatobiliary disorders					
-Total	4 (22.2)	1 (5.6)	2 (11.1)	0	1 (5.6)
Hypertransaminasaemia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Hepatic function abnormal	1 (5.6)	0	1 (5.6)	0	0
Hepatomegaly	1 (5.6)	0	0	0	1 (5.6)
Hyperbilirubinaemia	1 (5.6)	0	1 (5.6)	0	0
Immune system disorders					
-Total	14 (77.8)	0	5 (27.8)	5 (27.8)	4 (22.2)
Cytokine release syndrome	12 (66.7)	0	4 (22.2)	4 (22.2)	4 (22.2)
Hypogammaglobulinaemia	6 (33.3)	1 (5.6)	4 (22.2)	1 (5.6)	0
Seasonal allergy	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Haemophagocytic lymphohistiocytosis	1 (5.6)	0	1 (5.6)	0	0
Immunodeficiency	1 (5.6)	0	0	1 (5.6)	0
Selective igg subclass deficiency	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	14 (77.8)	1 (5.6)	3 (16.7)	9 (50.0)	1 (5.6)
Sinusitis	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Staphylococcal infection	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Upper respiratory tract infection	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Bronchitis	2 (11.1)	0	2 (11.1)	0	0
Bronchopulmonary aspergillosis	2 (11.1)	0	0	2 (11.1)	0
Nail infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Otitis media	2 (11.1)	0	2 (11.1)	0	0
Pneumonia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Adenovirus infection	1 (5.6)	0	0	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	0	0	1 (5.6)
Bacteraemia	1 (5.6)	0	1 (5.6)	0	0
Bk virus infection	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	1 (5.6)	0	0
Conjunctivitis	1 (5.6)	1 (5.6)	0	0	0
Covid-19	1 (5.6)	1 (5.6)	0	0	0
Cytomegalovirus infection reactivation	1 (5.6)	0	0	1 (5.6)	0
Device related sepsis	1 (5.6)	0	0	1 (5.6)	0
Ear infection	1 (5.6)	0	1 (5.6)	0	0
Escherichia bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Folliculitis	1 (5.6)	0	1 (5.6)	0	0
Fungal skin infection	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis clostridial	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	0	1 (5.6)	0	0
Herpes simplex	1 (5.6)	0	1 (5.6)	0	0
Human herpesvirus 6 infection	1 (5.6)	0	0	1 (5.6)	0
Metapneumovirus infection	1 (5.6)	0	0	1 (5.6)	0
Nasopharyngitis	1 (5.6)	1 (5.6)	0	0	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Pharyngitis	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	1 (5.6)	0	0	1 (5.6)	0
Pneumonia respiratory syncytial viral	1 (5.6)	0	0	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0
Sinusitis fungal	1 (5.6)	0	0	1 (5.6)	0
Syphilis	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection viral	1 (5.6)	1 (5.6)	0	0	0
Varicella zoster virus infection	1 (5.6)	0	1 (5.6)	0	0
Viral infection	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Contusion	1 (5.6)	1 (5.6)	0	0	0
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0
Transfusion reaction	1 (5.6)	0	1 (5.6)	0	0
Wound	1 (5.6)	0	1 (5.6)	0	0
Investigations					

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (77.8)	0	2 (11.1)	3 (16.7)	9 (50.0)
Alanine aminotransferase increased	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Platelet count decreased	6 (33.3)	0	1 (5.6)	2 (11.1)	3 (16.7)
White blood cell count decreased	6 (33.3)	0	0	0	6 (33.3)
Aspartate aminotransferase increased	5 (27.8)	1 (5.6)	2 (11.1)	1 (5.6)	1 (5.6)
Neutrophil count decreased	4 (22.2)	0	0	0	4 (22.2)
Activated partial thromboplastin time prolonged	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0
Blood bilirubin increased	3 (16.7)	0	0	3 (16.7)	0
International normalised ratio increased	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Lymphocyte count decreased	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Blood creatinine increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Blood fibrinogen decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gamma-glutamyltransferase increased	2 (11.1)	0	0	2 (11.1)	0
Serum ferritin increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (5.6)	0	1 (5.6)	0	0
Blood glucose increased	1 (5.6)	1 (5.6)	0	0	0
Blood immunoglobulin a decreased	1 (5.6)	1 (5.6)	0	0	0
Blood immunoglobulin m decreased	1 (5.6)	1 (5.6)	0	0	0
Blood lactate dehydrogenase increased	1 (5.6)	0	0	1 (5.6)	0
Blood thyroid stimulating hormone increased	1 (5.6)	1 (5.6)	0	0	0
Blood uric acid increased	1 (5.6)	0	0	1 (5.6)	0
Cardiac murmur	1 (5.6)	1 (5.6)	0	0	0
Ejection fraction decreased	1 (5.6)	0	1 (5.6)	0	0
Electrocardiogram qt prolonged	1 (5.6)	1 (5.6)	0	0	0
Eosinophil count decreased	1 (5.6)	1 (5.6)	0	0	0
Fibrin d dimer increased	1 (5.6)	1 (5.6)	0	0	0
Haematocrit decreased	1 (5.6)	1 (5.6)	0	0	0
Haptoglobin decreased	1 (5.6)	1 (5.6)	0	0	0
Red blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Urine output decreased	1 (5.6)	0	0	0	1 (5.6)
Weight decreased	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (5.6)	0	0	1 (5.6)	0
Metabolism and nutrition disorders					
-Total	12 (66.7)	1 (5.6)	3 (16.7)	5 (27.8)	3 (16.7)
Decreased appetite	7 (38.9)	2 (11.1)	3 (16.7)	2 (11.1)	0
Hypokalaemia	6 (33.3)	0	0	5 (27.8)	1 (5.6)
Hypophosphataemia	5 (27.8)	0	1 (5.6)	3 (16.7)	1 (5.6)
Hypocalcaemia	4 (22.2)	0	3 (16.7)	1 (5.6)	0
Hypoalbuminaemia	3 (16.7)	0	3 (16.7)	0	0
Hyperkalaemia	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Hyperphosphataemia	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Hypercalcaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperchloraemia	1 (5.6)	1 (5.6)	0	0	0
Hypercholesterolaemia	1 (5.6)	0	1 (5.6)	0	0
Hyperlipidaemia	1 (5.6)	0	1 (5.6)	0	0
Hypertriglyceridaemia	1 (5.6)	0	1 (5.6)	0	0
Hyperuricaemia	1 (5.6)	1 (5.6)	0	0	0
Hypervolaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (5.6)	1 (5.6)	0	0	0
Iron overload	1 (5.6)	0	1 (5.6)	0	0
Malnutrition	1 (5.6)	0	0	1 (5.6)	0
Metabolic acidosis	1 (5.6)	0	0	0	1 (5.6)
Metabolic syndrome	1 (5.6)	0	1 (5.6)	0	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0
Vitamin d deficiency	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (61.1)	4 (22.2)	4 (22.2)	3 (16.7)	0
Arthralgia	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Pain in extremity	5 (27.8)	2 (11.1)	2 (11.1)	1 (5.6)	0
Back pain	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Myalgia	2 (11.1)	0	2 (11.1)	0	0
Growth retardation	1 (5.6)	0	1 (5.6)	0	0
Joint effusion	1 (5.6)	0	1 (5.6)	0	0
Muscle rigidity	1 (5.6)	1 (5.6)	0	0	0
Muscular weakness	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (5.6)	1 (5.6)	0	0	0
Osteopenia	1 (5.6)	1 (5.6)	0	0	0
Synovitis	1 (5.6)	0	1 (5.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.6)	0	1 (5.6)	0	0
Cancer pain	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	10 (55.6)	2 (11.1)	7 (38.9)	1 (5.6)	0
Headache	8 (44.4)	2 (11.1)	6 (33.3)	0	0
Cognitive disorder	1 (5.6)	0	1 (5.6)	0	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Generalised tonic-clonic seizure	1 (5.6)	0	1 (5.6)	0	0
Neuralgia	1 (5.6)	0	1 (5.6)	0	0
Posterior reversible encephalopathy syndrome	1 (5.6)	0	1 (5.6)	0	0
Seizure	1 (5.6)	0	1 (5.6)	0	0
Somnolence	1 (5.6)	0	0	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	1 (5.6)	0	1 (5.6)	0	0
Psychiatric disorders					
-Total	10 (55.6)	3 (16.7)	4 (22.2)	3 (16.7)	0
Anxiety	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Confusional state	3 (16.7)	3 (16.7)	0	0	0
Delirium	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Agitation	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Automatism	1 (5.6)	1 (5.6)	0	0	0
Insomnia	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Acute kidney injury	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Anuria	1 (5.6)	1 (5.6)	0	0	0
Azotaemia	1 (5.6)	0	1 (5.6)	0	0
Dysuria	1 (5.6)	0	1 (5.6)	0	0
Haematuria	1 (5.6)	0	0	1 (5.6)	0
Kidney enlargement	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal mass	1 (5.6)	0	1 (5.6)	0	0
Reproductive system and breast disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Dysmenorrhoea	1 (5.6)	0	1 (5.6)	0	0
Endometriosis	1 (5.6)	0	0	1 (5.6)	0
Perineal rash	1 (5.6)	0	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (50.0)	3 (16.7)	2 (11.1)	2 (11.1)	2 (11.1)
Cough	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Hypoxia	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Nasal congestion	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Rhinorrhoea	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Dyspnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Oropharyngeal pain	2 (11.1)	2 (11.1)	0	0	0
Pleural effusion	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Tachypnoea	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Wheezing	2 (11.1)	0	2 (11.1)	0	0

Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (5.6)	0	1 (5.6)	0	0
Haemoptysis	1 (5.6)	0	1 (5.6)	0	0
Nasal discomfort	1 (5.6)	0	1 (5.6)	0	0
Nasal dryness	1 (5.6)	1 (5.6)	0	0	0
Pharyngeal haemorrhage	1 (5.6)	0	1 (5.6)	0	0
Pulmonary oedema	1 (5.6)	0	1 (5.6)	0	0
Respiratory distress	1 (5.6)	0	1 (5.6)	0	0
Respiratory failure	1 (5.6)	0	0	0	1 (5.6)
Upper respiratory tract inflammation	1 (5.6)	0	1 (5.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (27.8)	2 (11.1)	3 (16.7)	0	0
Dry skin	2 (11.1)	2 (11.1)	0	0	0
Pruritus	2 (11.1)	2 (11.1)	0	0	0
Blister	1 (5.6)	1 (5.6)	0	0	0
Dermatitis diaper	1 (5.6)	0	1 (5.6)	0	0
Drug eruption	1 (5.6)	0	1 (5.6)	0	0
Eczema	1 (5.6)	1 (5.6)	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema	1 (5.6)	1 (5.6)	0	0	0
Ingrowing nail	1 (5.6)	0	1 (5.6)	0	0
Petechiae	1 (5.6)	0	1 (5.6)	0	0
Photosensitivity reaction	1 (5.6)	0	1 (5.6)	0	0
Rash	1 (5.6)	0	1 (5.6)	0	0
Rash erythematous	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					
-Total	12 (66.7)	0	4 (22.2)	5 (27.8)	3 (16.7)
Hypotension	6 (33.3)	0	2 (11.1)	2 (11.1)	2 (11.1)
Hypertension	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Capillary leak syndrome	1 (5.6)	0	0	1 (5.6)	0
Thrombosis	1 (5.6)	0	1 (5.6)	0	0
Venoocclusive disease	1 (5.6)	0	0	0	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 208r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (100)	0	1 (2.4)	9 (21.4)	32 (76.2)
Blood and lymphatic system disorders					
-Total	31 (73.8)	0	3 (7.1)	19 (45.2)	9 (21.4)
Anaemia	19 (45.2)	2 (4.8)	4 (9.5)	13 (31.0)	0
Febrile neutropenia	17 (40.5)	0	0	16 (38.1)	1 (2.4)
Neutropenia	8 (19.0)	0	1 (2.4)	2 (4.8)	5 (11.9)
Thrombocytopenia	6 (14.3)	0	1 (2.4)	2 (4.8)	3 (7.1)
Disseminated intravascular coagulation	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Leukopenia	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Pancytopenia	3 (7.1)	0	0	2 (4.8)	1 (2.4)

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Coagulopathy	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Agranulocytosis	1 (2.4)	0	0	1 (2.4)	0
B-cell aplasia	1 (2.4)	0	1 (2.4)	0	0
Eosinophilia	1 (2.4)	0	1 (2.4)	0	0
Lymphopenia	1 (2.4)	0	0	0	1 (2.4)
Splenomegaly	1 (2.4)	0	1 (2.4)	0	0
Cardiac disorders					
-Total	12 (28.6)	4 (9.5)	3 (7.1)	4 (9.5)	1 (2.4)
Tachycardia	5 (11.9)	2 (4.8)	2 (4.8)	1 (2.4)	0
Left ventricular dysfunction	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Pericardial effusion	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Cardiac arrest	1 (2.4)	0	0	0	1 (2.4)
Cardiac dysfunction	1 (2.4)	1 (2.4)	0	0	0
Cardiac failure	1 (2.4)	0	0	1 (2.4)	0
Cardiac failure congestive	1 (2.4)	0	1 (2.4)	0	0
Mitral valve incompetence	1 (2.4)	1 (2.4)	0	0	0
Right ventricular dysfunction	1 (2.4)	1 (2.4)	0	0	0
Sinus tachycardia	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tricuspid valve incompetence	1 (2.4)	1 (2.4)	0	0	0
Congenital, familial and genetic disorders					
-Total	1 (2.4)	1 (2.4)	0	0	0
Cerebral cavernous malformation	1 (2.4)	1 (2.4)	0	0	0
Ear and labyrinth disorders					
-Total	2 (4.8)	0	2 (4.8)	0	0
Deafness unilateral	1 (2.4)	0	1 (2.4)	0	0
Vertigo	1 (2.4)	0	1 (2.4)	0	0
Endocrine disorders					
-Total	3 (7.1)	0	3 (7.1)	0	0
Adrenal insufficiency	3 (7.1)	0	3 (7.1)	0	0
Eye disorders					
-Total	9 (21.4)	5 (11.9)	3 (7.1)	1 (2.4)	0
Eye pain	3 (7.1)	2 (4.8)	0	1 (2.4)	0
Cataract	2 (4.8)	2 (4.8)	0	0	0
Eyelid oedema	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Eye oedema	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypermetropia	1 (2.4)	1 (2.4)	0	0	0
Ocular hyperaemia	1 (2.4)	1 (2.4)	0	0	0
Periorbital swelling	1 (2.4)	0	1 (2.4)	0	0
Retinal haemorrhage	1 (2.4)	0	1 (2.4)	0	0
Visual field defect	1 (2.4)	0	1 (2.4)	0	0
Visual impairment	1 (2.4)	1 (2.4)	0	0	0
Gastrointestinal disorders					
-Total	31 (73.8)	8 (19.0)	14 (33.3)	9 (21.4)	0
Diarrhoea	13 (31.0)	6 (14.3)	5 (11.9)	2 (4.8)	0
Nausea	13 (31.0)	5 (11.9)	7 (16.7)	1 (2.4)	0
Vomiting	12 (28.6)	7 (16.7)	5 (11.9)	0	0
Abdominal pain	9 (21.4)	2 (4.8)	6 (14.3)	1 (2.4)	0
Constipation	7 (16.7)	4 (9.5)	3 (7.1)	0	0
Stomatitis	5 (11.9)	0	3 (7.1)	2 (4.8)	0
Mouth haemorrhage	4 (9.5)	2 (4.8)	1 (2.4)	1 (2.4)	0
Abdominal pain upper	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Abdominal distension	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Ascites	2 (4.8)	1 (2.4)	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal sounds abnormal	2 (4.8)	2 (4.8)	0	0	0
Gingival bleeding	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Pancreatitis	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Trichoglossia	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Abdominal rigidity	1 (2.4)	0	1 (2.4)	0	0
Anal erythema	1 (2.4)	1 (2.4)	0	0	0
Anal fistula	1 (2.4)	0	0	1 (2.4)	0
Duodenal perforation	1 (2.4)	0	0	1 (2.4)	0
Dyspepsia	1 (2.4)	1 (2.4)	0	0	0
Enteritis	1 (2.4)	0	1 (2.4)	0	0
Enterocolitis	1 (2.4)	0	1 (2.4)	0	0
Gastritis	1 (2.4)	0	1 (2.4)	0	0
Gastrooesophageal reflux disease	1 (2.4)	0	1 (2.4)	0	0
Gingivitis ulcerative	1 (2.4)	0	0	1 (2.4)	0
Haemorrhoids	1 (2.4)	0	1 (2.4)	0	0
Lip dry	1 (2.4)	0	1 (2.4)	0	0
Mouth swelling	1 (2.4)	1 (2.4)	0	0	0
Odynophagia	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oral disorder	1 (2.4)	1 (2.4)	0	0	0
Peritoneal haematoma	1 (2.4)	1 (2.4)	0	0	0
Proctalgia	1 (2.4)	0	0	1 (2.4)	0
Upper gastrointestinal haemorrhage	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					
-Total	25 (59.5)	15 (35.7)	5 (11.9)	4 (9.5)	1 (2.4)
Pyrexia	16 (38.1)	9 (21.4)	3 (7.1)	3 (7.1)	1 (2.4)
Fatigue	6 (14.3)	6 (14.3)	0	0	0
Chills	5 (11.9)	3 (7.1)	2 (4.8)	0	0
Asthenia	4 (9.5)	3 (7.1)	1 (2.4)	0	0
Pain	4 (9.5)	1 (2.4)	1 (2.4)	2 (4.8)	0
Face oedema	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Catheter site pain	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Generalised oedema	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Influenza like illness	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Localised oedema	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Non-cardiac chest pain	2 (4.8)	2 (4.8)	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site erythema	1 (2.4)	1 (2.4)	0	0	0
Chest discomfort	1 (2.4)	0	0	1 (2.4)	0
Crying	1 (2.4)	0	1 (2.4)	0	0
Facial pain	1 (2.4)	0	1 (2.4)	0	0
Malaise	1 (2.4)	0	1 (2.4)	0	0
Sluggishness	1 (2.4)	0	1 (2.4)	0	0
Swelling face	1 (2.4)	1 (2.4)	0	0	0
Thirst	1 (2.4)	1 (2.4)	0	0	0
Vascular device occlusion	1 (2.4)	1 (2.4)	0	0	0
Xerosis	1 (2.4)	1 (2.4)	0	0	0
Hepatobiliary disorders					
-Total	12 (28.6)	3 (7.1)	4 (9.5)	4 (9.5)	1 (2.4)
Hyperbilirubinaemia	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Hepatic cytolysis	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Hepatic function abnormal	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Cholelithiasis	1 (2.4)	0	1 (2.4)	0	0
Drug-induced liver injury	1 (2.4)	0	0	1 (2.4)	0
Hepatomegaly	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatosplenomegaly	1 (2.4)	0	1 (2.4)	0	0
Liver disorder	1 (2.4)	0	1 (2.4)	0	0
Immune system disorders					
-Total	33 (78.6)	1 (2.4)	8 (19.0)	15 (35.7)	9 (21.4)
Cytokine release syndrome	29 (69.0)	3 (7.1)	8 (19.0)	9 (21.4)	9 (21.4)
Hypogammaglobulinaemia	17 (40.5)	0	12 (28.6)	5 (11.9)	0
Drug hypersensitivity	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Graft versus host disease	2 (4.8)	0	0	2 (4.8)	0
Immunodeficiency	2 (4.8)	0	0	2 (4.8)	0
Allergy to immunoglobulin therapy	1 (2.4)	1 (2.4)	0	0	0
Chronic graft versus host disease	1 (2.4)	0	1 (2.4)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.4)	1 (2.4)	0	0	0
Hypersensitivity	1 (2.4)	1 (2.4)	0	0	0
Infections and infestations					
-Total	36 (85.7)	3 (7.1)	5 (11.9)	16 (38.1)	12 (28.6)
Upper respiratory tract infection	6 (14.3)	3 (7.1)	1 (2.4)	2 (4.8)	0
Gastroenteritis	5 (11.9)	2 (4.8)	1 (2.4)	2 (4.8)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	5 (11.9)	3 (7.1)	2 (4.8)	0	0
Pneumonia	5 (11.9)	1 (2.4)	1 (2.4)	2 (4.8)	1 (2.4)
Sinusitis	5 (11.9)	0	3 (7.1)	2 (4.8)	0
Conjunctivitis	4 (9.5)	1 (2.4)	3 (7.1)	0	0
Oral herpes	4 (9.5)	1 (2.4)	2 (4.8)	1 (2.4)	0
Parainfluenzae virus infection	4 (9.5)	0	0	3 (7.1)	1 (2.4)
Paronychia	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Rhinovirus infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Bacteraemia	3 (7.1)	0	0	2 (4.8)	1 (2.4)
Candida infection	3 (7.1)	0	2 (4.8)	0	1 (2.4)
Device related infection	3 (7.1)	0	1 (2.4)	2 (4.8)	0
Gingivitis	3 (7.1)	3 (7.1)	0	0	0
Herpes zoster	3 (7.1)	0	2 (4.8)	1 (2.4)	0
Oral candidiasis	3 (7.1)	0	3 (7.1)	0	0
Rhinitis	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Sepsis	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Septic shock	3 (7.1)	0	0	0	3 (7.1)
Urinary tract infection	3 (7.1)	0	2 (4.8)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	2 (4.8)	0	0	2 (4.8)	0
Fungal infection	2 (4.8)	0	2 (4.8)	0	0
Nail infection	2 (4.8)	2 (4.8)	0	0	0
Oral infection	2 (4.8)	0	2 (4.8)	0	0
Otitis externa	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Otitis media	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Skin infection	2 (4.8)	0	2 (4.8)	0	0
Staphylococcal infection	2 (4.8)	0	0	2 (4.8)	0
Staphylococcal skin infection	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Acute sinusitis	1 (2.4)	0	1 (2.4)	0	0
Adenovirus infection	1 (2.4)	0	0	1 (2.4)	0
Anal abscess	1 (2.4)	0	0	1 (2.4)	0
Bk virus infection	1 (2.4)	1 (2.4)	0	0	0
Bronchiolitis	1 (2.4)	0	0	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	0	1 (2.4)
Clostridium difficile infection	1 (2.4)	0	0	1 (2.4)	0
Covid-19	1 (2.4)	0	0	1 (2.4)	0
Cytomegalovirus infection reactivation	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related bacteraemia	1 (2.4)	0	1 (2.4)	0	0
Ear infection	1 (2.4)	0	0	1 (2.4)	0
Ear, nose and throat infection	1 (2.4)	0	1 (2.4)	0	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Encephalitis viral	1 (2.4)	0	0	1 (2.4)	0
Enterobacter infection	1 (2.4)	0	0	1 (2.4)	0
Epstein-barr virus infection	1 (2.4)	0	1 (2.4)	0	0
Escherichia bacteraemia	1 (2.4)	0	0	0	1 (2.4)
Fungaemia	1 (2.4)	0	0	0	1 (2.4)
Fungal pharyngitis	1 (2.4)	0	0	1 (2.4)	0
Gastroenteritis norovirus	1 (2.4)	1 (2.4)	0	0	0
Granulicatella infection	1 (2.4)	0	0	1 (2.4)	0
Herpes simplex	1 (2.4)	0	0	1 (2.4)	0
Herpes virus infection	1 (2.4)	0	1 (2.4)	0	0
Human herpesvirus 6 infection	1 (2.4)	0	0	1 (2.4)	0
Influenza	1 (2.4)	0	1 (2.4)	0	0
Klebsiella infection	1 (2.4)	0	0	1 (2.4)	0
Mastoiditis	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (2.4)	0	0	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	0	0	1 (2.4)	0
Myringitis	1 (2.4)	1 (2.4)	0	0	0
Neutropenic infection	1 (2.4)	0	0	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	1 (2.4)	0	0
Peritonitis	1 (2.4)	0	0	1 (2.4)	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	0	0	1 (2.4)
Pneumonia fungal	1 (2.4)	0	0	1 (2.4)	0
Pneumonia viral	1 (2.4)	0	0	1 (2.4)	0
Respiratory syncytial virus infection	1 (2.4)	0	0	1 (2.4)	0
Respiratory tract infection	1 (2.4)	0	1 (2.4)	0	0
Respiratory tract infection viral	1 (2.4)	0	1 (2.4)	0	0
Salmonellosis	1 (2.4)	0	1 (2.4)	0	0
Soft tissue infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal abscess	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal sepsis	1 (2.4)	0	0	0	1 (2.4)
Stomatococcal infection	1 (2.4)	0	0	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal sepsis	1 (2.4)	0	1 (2.4)	0	0
Systemic candida	1 (2.4)	0	0	1 (2.4)	0
Tinea pedis	1 (2.4)	1 (2.4)	0	0	0
Urinary tract infection pseudomonal	1 (2.4)	0	1 (2.4)	0	0
Varicella zoster virus infection	1 (2.4)	0	0	1 (2.4)	0
Vascular device infection	1 (2.4)	0	0	1 (2.4)	0
Viral haemorrhagic cystitis	1 (2.4)	0	0	1 (2.4)	0
Viral infection	1 (2.4)	0	1 (2.4)	0	0
Viral skin infection	1 (2.4)	1 (2.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	12 (28.6)	3 (7.1)	6 (14.3)	1 (2.4)	2 (4.8)
Fall	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Infusion related reaction	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Ligament sprain	2 (4.8)	2 (4.8)	0	0	0
Extradural haematoma	1 (2.4)	0	1 (2.4)	0	0
Limb injury	1 (2.4)	0	1 (2.4)	0	0
Procedural pain	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal obstruction	1 (2.4)	0	0	0	1 (2.4)
Transplant failure	1 (2.4)	0	0	0	1 (2.4)
Traumatic haematoma	1 (2.4)	0	1 (2.4)	0	0
Wound	1 (2.4)	1 (2.4)	0	0	0
Investigations					
-Total	29 (69.0)	0	3 (7.1)	10 (23.8)	16 (38.1)
Neutrophil count decreased	16 (38.1)	1 (2.4)	2 (4.8)	1 (2.4)	12 (28.6)
Platelet count decreased	13 (31.0)	3 (7.1)	0	3 (7.1)	7 (16.7)
White blood cell count decreased	13 (31.0)	1 (2.4)	1 (2.4)	0	11 (26.2)
Lymphocyte count decreased	11 (26.2)	0	1 (2.4)	3 (7.1)	7 (16.7)
Alanine aminotransferase increased	9 (21.4)	2 (4.8)	3 (7.1)	4 (9.5)	0
Aspartate aminotransferase increased	6 (14.3)	1 (2.4)	1 (2.4)	3 (7.1)	1 (2.4)
C-reactive protein increased	5 (11.9)	1 (2.4)	1 (2.4)	3 (7.1)	0
Serum ferritin increased	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Blood bilirubin increased	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Blood immunoglobulin a decreased	3 (7.1)	2 (4.8)	0	1 (2.4)	0
Blood lactate dehydrogenase increased	3 (7.1)	2 (4.8)	1 (2.4)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
International normalised ratio increased	3 (7.1)	3 (7.1)	0	0	0
Blood fibrinogen decreased	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Blood fibrinogen increased	2 (4.8)	2 (4.8)	0	0	0
Blood immunoglobulin m decreased	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Immunoglobulins decreased	2 (4.8)	0	2 (4.8)	0	0
Weight decreased	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Weight increased	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Blood creatine phosphokinase increased	1 (2.4)	0	0	1 (2.4)	0
Blood creatinine increased	1 (2.4)	0	0	1 (2.4)	0
Blood glucose increased	1 (2.4)	0	0	0	1 (2.4)
Blood phosphorus decreased	1 (2.4)	0	0	1 (2.4)	0
Blood potassium decreased	1 (2.4)	0	0	0	1 (2.4)
Blood testosterone decreased	1 (2.4)	1 (2.4)	0	0	0
Blood uric acid increased	1 (2.4)	0	0	0	1 (2.4)
Bone density decreased	1 (2.4)	1 (2.4)	0	0	0
Breath sounds abnormal	1 (2.4)	0	1 (2.4)	0	0
Enterovirus test positive	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoglobin decreased	1 (2.4)	0	0	1 (2.4)	0
Hepatitis b virus test positive	1 (2.4)	0	1 (2.4)	0	0
Prothrombin time prolonged	1 (2.4)	0	1 (2.4)	0	0
Metabolism and nutrition disorders					
-Total	24 (57.1)	4 (9.5)	5 (11.9)	10 (23.8)	5 (11.9)
Decreased appetite	14 (33.3)	6 (14.3)	3 (7.1)	3 (7.1)	2 (4.8)
Hypokalaemia	12 (28.6)	3 (7.1)	2 (4.8)	6 (14.3)	1 (2.4)
Hypophosphataemia	8 (19.0)	2 (4.8)	4 (9.5)	2 (4.8)	0
Hypocalcaemia	4 (9.5)	1 (2.4)	1 (2.4)	2 (4.8)	0
Hypomagnesaemia	4 (9.5)	3 (7.1)	1 (2.4)	0	0
Hyperglycaemia	3 (7.1)	0	1 (2.4)	2 (4.8)	0
Hyperuricaemia	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Hypervolaemia	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Hypoalbuminaemia	3 (7.1)	0	3 (7.1)	0	0
Tumour lysis syndrome	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Hypernatraemia	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Eating disorder symptom	1 (2.4)	0	1 (2.4)	0	0
Haemochromatosis	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperchloraemia	1 (2.4)	1 (2.4)	0	0	0
Hypermagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Hyperphosphataemia	1 (2.4)	1 (2.4)	0	0	0
Hyponatraemia	1 (2.4)	1 (2.4)	0	0	0
Hypophagia	1 (2.4)	0	1 (2.4)	0	0
Iron overload	1 (2.4)	0	1 (2.4)	0	0
Malnutrition	1 (2.4)	0	0	1 (2.4)	0
Polydipsia	1 (2.4)	0	0	1 (2.4)	0
Musculoskeletal and connective tissue disorders					
-Total	23 (54.8)	8 (19.0)	11 (26.2)	4 (9.5)	0
Pain in extremity	10 (23.8)	2 (4.8)	7 (16.7)	1 (2.4)	0
Back pain	8 (19.0)	2 (4.8)	4 (9.5)	2 (4.8)	0
Arthralgia	6 (14.3)	3 (7.1)	3 (7.1)	0	0
Myalgia	6 (14.3)	4 (9.5)	2 (4.8)	0	0
Bone pain	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Pain in jaw	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Groin pain	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Growth retardation	1 (2.4)	0	1 (2.4)	0	0
Joint effusion	1 (2.4)	0	0	1 (2.4)	0
Musculoskeletal chest pain	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal pain	1 (2.4)	0	1 (2.4)	0	0
Myopathy	1 (2.4)	0	0	1 (2.4)	0
Neck pain	1 (2.4)	0	1 (2.4)	0	0
Osteonecrosis	1 (2.4)	1 (2.4)	0	0	0
Spinal pain	1 (2.4)	0	0	1 (2.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	4 (9.5)	1 (2.4)	1 (2.4)	2 (4.8)	0
Skin papilloma	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Bone giant cell tumour benign	1 (2.4)	0	0	1 (2.4)	0
Myelodysplastic syndrome	1 (2.4)	0	0	1 (2.4)	0
Nervous system disorders					
-Total	27 (64.3)	9 (21.4)	7 (16.7)	8 (19.0)	3 (7.1)
Headache	16 (38.1)	8 (19.0)	5 (11.9)	3 (7.1)	0
Encephalopathy	4 (9.5)	0	2 (4.8)	2 (4.8)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	4 (9.5)	0	1 (2.4)	3 (7.1)	0
Tremor	4 (9.5)	4 (9.5)	0	0	0
Dizziness	3 (7.1)	3 (7.1)	0	0	0
Dysgeusia	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Lethargy	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Neuropathy peripheral	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Somnolence	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Amnesia	1 (2.4)	0	1 (2.4)	0	0
Aphasia	1 (2.4)	1 (2.4)	0	0	0
Autonomic neuropathy	1 (2.4)	0	0	1 (2.4)	0
Cerebral haemorrhage	1 (2.4)	0	0	0	1 (2.4)
Depressed level of consciousness	1 (2.4)	0	0	1 (2.4)	0
Disturbance in attention	1 (2.4)	1 (2.4)	0	0	0
Dysarthria	1 (2.4)	0	1 (2.4)	0	0
Haemorrhage intracranial	1 (2.4)	0	0	0	1 (2.4)
Hydrocephalus	1 (2.4)	0	0	0	1 (2.4)
Hyperaesthesia	1 (2.4)	1 (2.4)	0	0	0
Hypoaesthesia	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Memory impairment	1 (2.4)	0	1 (2.4)	0	0
Nervous system disorder	1 (2.4)	0	0	1 (2.4)	0
Paraesthesia	1 (2.4)	0	1 (2.4)	0	0
Psychiatric disorders					
-Total	17 (40.5)	4 (9.5)	11 (26.2)	2 (4.8)	0
Anxiety	8 (19.0)	4 (9.5)	3 (7.1)	1 (2.4)	0
Agitation	3 (7.1)	3 (7.1)	0	0	0
Hallucination	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Insomnia	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Mental status changes	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Sleep disorder	2 (4.8)	0	2 (4.8)	0	0
Affect lability	1 (2.4)	0	1 (2.4)	0	0
Confusional state	1 (2.4)	1 (2.4)	0	0	0
Delirium	1 (2.4)	0	1 (2.4)	0	0
Hallucination, visual	1 (2.4)	0	1 (2.4)	0	0
Irritability	1 (2.4)	1 (2.4)	0	0	0
Mood altered	1 (2.4)	1 (2.4)	0	0	0
Nightmare	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Restlessness	1 (2.4)	0	1 (2.4)	0	0
Social avoidant behaviour	1 (2.4)	0	1 (2.4)	0	0
Tearfulness	1 (2.4)	1 (2.4)	0	0	0
Tic	1 (2.4)	0	1 (2.4)	0	0
Renal and urinary disorders					
-Total	15 (35.7)	4 (9.5)	6 (14.3)	2 (4.8)	3 (7.1)
Acute kidney injury	5 (11.9)	2 (4.8)	1 (2.4)	0	2 (4.8)
Dysuria	2 (4.8)	2 (4.8)	0	0	0
Haematuria	2 (4.8)	2 (4.8)	0	0	0
Pollakiuria	2 (4.8)	0	2 (4.8)	0	0
Anuria	1 (2.4)	0	0	0	1 (2.4)
Cystitis haemorrhagic	1 (2.4)	0	1 (2.4)	0	0
Incontinence	1 (2.4)	0	1 (2.4)	0	0
Micturition urgency	1 (2.4)	0	1 (2.4)	0	0
Proteinuria	1 (2.4)	1 (2.4)	0	0	0
Renal failure	1 (2.4)	0	1 (2.4)	0	0
Renal tubular disorder	1 (2.4)	0	0	1 (2.4)	0
Renal tubular necrosis	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (2.4)	0	1 (2.4)	0	0
Urinary tract disorder	1 (2.4)	0	1 (2.4)	0	0
Reproductive system and breast disorders					
-Total	4 (9.5)	1 (2.4)	2 (4.8)	1 (2.4)	0
Female genital tract fistula	1 (2.4)	1 (2.4)	0	0	0
Heavy menstrual bleeding	1 (2.4)	0	1 (2.4)	0	0
Prostatitis	1 (2.4)	0	0	1 (2.4)	0
Vaginal haemorrhage	1 (2.4)	0	1 (2.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	30 (71.4)	10 (23.8)	5 (11.9)	7 (16.7)	8 (19.0)
Cough	13 (31.0)	10 (23.8)	3 (7.1)	0	0
Hypoxia	10 (23.8)	0	4 (9.5)	4 (9.5)	2 (4.8)
Epistaxis	8 (19.0)	7 (16.7)	0	1 (2.4)	0
Nasal congestion	5 (11.9)	5 (11.9)	0	0	0
Pulmonary oedema	5 (11.9)	1 (2.4)	0	4 (9.5)	0
Dyspnoea	4 (9.5)	1 (2.4)	1 (2.4)	2 (4.8)	0
Oropharyngeal pain	4 (9.5)	4 (9.5)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	4 (9.5)	2 (4.8)	2 (4.8)	0	0
Respiratory failure	3 (7.1)	0	0	0	3 (7.1)
Tachypnoea	3 (7.1)	0	2 (4.8)	1 (2.4)	0
Acute respiratory distress syndrome	2 (4.8)	0	0	0	2 (4.8)
Pharyngeal erythema	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Rhinorrhoea	2 (4.8)	2 (4.8)	0	0	0
Atelectasis	1 (2.4)	0	1 (2.4)	0	0
Bronchial oedema	1 (2.4)	1 (2.4)	0	0	0
Dyspnoea exertional	1 (2.4)	1 (2.4)	0	0	0
Laryngeal oedema	1 (2.4)	0	0	0	1 (2.4)
Lung disorder	1 (2.4)	1 (2.4)	0	0	0
Lung infiltration	1 (2.4)	0	0	1 (2.4)	0
Oropharyngeal plaque	1 (2.4)	0	1 (2.4)	0	0
Painful respiration	1 (2.4)	1 (2.4)	0	0	0
Paranasal sinus discomfort	1 (2.4)	0	1 (2.4)	0	0
Paranasal sinus inflammation	1 (2.4)	1 (2.4)	0	0	0
Pharyngeal exudate	1 (2.4)	0	1 (2.4)	0	0
Pharyngeal oedema	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Productive cough	1 (2.4)	1 (2.4)	0	0	0
Pulmonary haemorrhage	1 (2.4)	0	0	0	1 (2.4)
Pulmonary mass	1 (2.4)	0	1 (2.4)	0	0
Respiratory disorder	1 (2.4)	0	1 (2.4)	0	0
Sleep apnoea syndrome	1 (2.4)	1 (2.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	23 (54.8)	9 (21.4)	9 (21.4)	5 (11.9)	0
Rash	6 (14.3)	3 (7.1)	3 (7.1)	0	0
Pruritus	4 (9.5)	1 (2.4)	3 (7.1)	0	0
Dry skin	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Rash maculo-papular	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Dermatitis atopic	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Eczema	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Erythema	2 (4.8)	2 (4.8)	0	0	0
Rash papular	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Skin ulcer	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Acne	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decubitus ulcer	1 (2.4)	0	0	1 (2.4)	0
Erythema nodosum	1 (2.4)	1 (2.4)	0	0	0
Hangnail	1 (2.4)	1 (2.4)	0	0	0
Hyperhidrosis	1 (2.4)	0	1 (2.4)	0	0
Ingrowing nail	1 (2.4)	0	1 (2.4)	0	0
Night sweats	1 (2.4)	1 (2.4)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (2.4)	1 (2.4)	0	0	0
Papule	1 (2.4)	1 (2.4)	0	0	0
Pruritus allergic	1 (2.4)	0	1 (2.4)	0	0
Purpura	1 (2.4)	1 (2.4)	0	0	0
Rash macular	1 (2.4)	0	0	1 (2.4)	0
Skin lesion	1 (2.4)	0	1 (2.4)	0	0
Skin swelling	1 (2.4)	1 (2.4)	0	0	0
Urticaria	1 (2.4)	0	1 (2.4)	0	0
Social circumstances					
-Total	1 (2.4)	0	1 (2.4)	0	0
Patient uncooperative	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	13 (31.0)	5 (11.9)	4 (9.5)	2 (4.8)	2 (4.8)
Hypotension	8 (19.0)	2 (4.8)	2 (4.8)	2 (4.8)	2 (4.8)
Hypertension	6 (14.3)	3 (7.1)	3 (7.1)	0	0
Flushing	1 (2.4)	1 (2.4)	0	0	0
Haematoma	1 (2.4)	1 (2.4)	0	0	0
Hot flush	1 (2.4)	1 (2.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	19 (57.6)	8 (24.2)	9 (27.3)
Blood and lymphatic system disorders			
-Total	6 (18.2)	6 (18.2)	0
Febrile neutropenia	6 (18.2)	6 (18.2)	0
Disseminated intravascular coagulation	1 (3.0)	0	0
Cardiac disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Left ventricular dysfunction	1 (3.0)	1 (3.0)	0
Tachycardia	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Abdominal compartment syndrome	1 (3.0)	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (3.0)	1 (3.0)	0
Neutropenic colitis	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	3 (9.1)	0	1 (3.0)
Pyrexia	2 (6.1)	0	0
Multiple organ dysfunction syndrome	1 (3.0)	0	1 (3.0)
Systemic inflammatory response syndrome	1 (3.0)	1 (3.0)	0
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Cholestasis	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	18 (54.5)	3 (9.1)	8 (24.2)
Cytokine release syndrome	18 (54.5)	3 (9.1)	8 (24.2)
Haemophagocytic lymphohistiocytosis	1 (3.0)	0	1 (3.0)
Infections and infestations			
-Total	5 (15.2)	4 (12.1)	1 (3.0)
Encephalitis	1 (3.0)	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (3.0)	1 (3.0)	0
Pneumonia viral	1 (3.0)	1 (3.0)	0
Soft tissue infection	1 (3.0)	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	1 (3.0)	0
Injury, poisoning and procedural complications			
-Total	1 (3.0)	0	1 (3.0)
Vasoplegia syndrome	1 (3.0)	0	1 (3.0)
Metabolism and nutrition disorders			
-Total	2 (6.1)	0	1 (3.0)
Dehydration	1 (3.0)	0	0
Hypernatraemia	1 (3.0)	0	1 (3.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.0)	0	1 (3.0)
Rhabdomyolysis	1 (3.0)	0	1 (3.0)
Nervous system disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Cerebral haemorrhage	1 (3.0)	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	2 (6.1)	0	2 (6.1)
Acute kidney injury	2 (6.1)	0	2 (6.1)
Renal tubular necrosis	1 (3.0)	0	1 (3.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.1)	0	2 (6.1)
Acute respiratory distress syndrome	1 (3.0)	0	1 (3.0)
Dyspnoea	1 (3.0)	0	1 (3.0)
Hypoxia	1 (3.0)	0	1 (3.0)
Respiratory distress	1 (3.0)	0	0
Vascular disorders			
-Total	3 (9.1)	0	3 (9.1)
Hypotension	3 (9.1)	0	3 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	26 (78.8)	11 (33.3)	13 (39.4)
Blood and lymphatic system disorders			
-Total	9 (27.3)	7 (21.2)	2 (6.1)
Febrile neutropenia	6 (18.2)	5 (15.2)	1 (3.0)
Coagulopathy	1 (3.0)	1 (3.0)	0
Disseminated intravascular coagulation	1 (3.0)	1 (3.0)	0
Pancytopenia	1 (3.0)	1 (3.0)	0
Thrombocytopenia	1 (3.0)	0	1 (3.0)
Cardiac disorders			
-Total	2 (6.1)	0	1 (3.0)
Atrioventricular block first degree	1 (3.0)	0	0
Cardiac arrest	1 (3.0)	0	1 (3.0)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Pancreatitis	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	0
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Hepatomegaly	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	23 (69.7)	10 (30.3)	9 (27.3)
Cytokine release syndrome	23 (69.7)	10 (30.3)	9 (27.3)
Infections and infestations			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Encephalitis viral	1 (3.0)	0	1 (3.0)
Meningitis bacterial	1 (3.0)	1 (3.0)	0
Pneumonia fungal	1 (3.0)	1 (3.0)	0
Investigations			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
Electrocardiogram qt prolonged	1 (3.0)	0	1 (3.0)
Metabolism and nutrition disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Hypercalcaemia	1 (3.0)	1 (3.0)	0
Hyperkalaemia	1 (3.0)	0	1 (3.0)
Hyperphosphataemia	1 (3.0)	0	1 (3.0)
Metabolic acidosis	1 (3.0)	0	1 (3.0)
Tumour lysis syndrome	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.0)	1 (3.0)	0
Haemarthrosis	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	2 (6.1)	2 (6.1)	0
Dysarthria	1 (3.0)	1 (3.0)	0
Headache	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	1 (3.0)	1 (3.0)	0
Delirium	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	2 (6.1)	2 (6.1)	0
Acute kidney injury	2 (6.1)	2 (6.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.2)	3 (9.1)	3 (9.1)
Hypoxia	2 (6.1)	1 (3.0)	1 (3.0)
Pleural effusion	2 (6.1)	1 (3.0)	1 (3.0)
Respiratory failure	2 (6.1)	0	2 (6.1)
Acute respiratory failure	1 (3.0)	1 (3.0)	0
Pulmonary oedema	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	4 (12.1)	2 (6.1)	2 (6.1)
Hypotension	4 (12.1)	2 (6.1)	2 (6.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (64.3)	3 (21.4)	5 (35.7)
Blood and lymphatic system disorders			
-Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiac failure	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			
-Total	1 (7.1)	0	0
Constipation	1 (7.1)	0	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Age: >=18

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	1 (7.1)
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Immune system disorders			
-Total	9 (64.3)	3 (21.4)	4 (28.6)
Cytokine release syndrome	9 (64.3)	3 (21.4)	4 (28.6)
Infections and infestations			
-Total	4 (28.6)	2 (14.3)	1 (7.1)
Candida infection	1 (7.1)	0	1 (7.1)
Encephalitis viral	1 (7.1)	1 (7.1)	0
Rhinovirus infection	1 (7.1)	0	0
Varicella zoster virus infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	1 (7.1)	0	0
Cognitive disorder	1 (7.1)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	1 (7.1)	0	1 (7.1)
Renal failure	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.1)	0	1 (7.1)
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (36.7)	6 (20.0)	5 (16.7)
Blood and lymphatic system disorders			
-Total	3 (10.0)	3 (10.0)	0
Febrile neutropenia	3 (10.0)	3 (10.0)	0
Cardiac disorders			
-Total	1 (3.3)	0	1 (3.3)
Cardiac arrest	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	2 (6.7)	1 (3.3)	0
Diarrhoea	1 (3.3)	0	0
Pancreatitis	1 (3.3)	1 (3.3)	0
Vomiting	1 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (10.0)	0	0
Pyrexia	3 (10.0)	0	0
Infections and infestations			
-Total	8 (26.7)	4 (13.3)	4 (13.3)
Bronchopulmonary aspergillosis	1 (3.3)	0	1 (3.3)
Cytomegalovirus infection reactivation	1 (3.3)	1 (3.3)	0
Device related infection	1 (3.3)	1 (3.3)	0
Enterobacter infection	1 (3.3)	1 (3.3)	0
Gastroenteritis	1 (3.3)	1 (3.3)	0
Herpes zoster	1 (3.3)	1 (3.3)	0
Human herpesvirus 6 infection	1 (3.3)	1 (3.3)	0
Klebsiella infection	1 (3.3)	1 (3.3)	0
Mastoiditis	1 (3.3)	1 (3.3)	0
Metapneumovirus infection	1 (3.3)	1 (3.3)	0
Otitis externa	1 (3.3)	1 (3.3)	0
Otitis media	1 (3.3)	1 (3.3)	0
Pneumocystis jirovecii pneumonia	1 (3.3)	0	1 (3.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.3)	0	1 (3.3)
Staphylococcal sepsis	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	1 (3.3)	1 (3.3)	0
Hypokalaemia	1 (3.3)	1 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.3)	1 (3.3)	0
Back pain	1 (3.3)	1 (3.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.3)	1 (3.3)	0
Myelodysplastic syndrome	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	1 (3.3)	0	1 (3.3)
Hydrocephalus	1 (3.3)	0	1 (3.3)
Psychiatric disorders			
-Total	1 (3.3)	1 (3.3)	0
Mental status changes	1 (3.3)	1 (3.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Hypoxia	1 (3.3)	1 (3.3)	0
Respiratory failure	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (22.6)	3 (9.7)	4 (12.9)
Blood and lymphatic system disorders			
-Total	1 (3.2)	1 (3.2)	0
Disseminated intravascular coagulation	1 (3.2)	1 (3.2)	0
Cardiac disorders			
-Total	1 (3.2)	0	1 (3.2)
Cardiac arrest	1 (3.2)	0	1 (3.2)
Cardiac failure	1 (3.2)	1 (3.2)	0
General disorders and administration site conditions			
-Total	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (3.2)	1 (3.2)	0
Infections and infestations			
-Total	4 (12.9)	2 (6.5)	2 (6.5)
Encephalitis	1 (3.2)	0	1 (3.2)
Respiratory syncytial virus infection	1 (3.2)	1 (3.2)	0
Septic shock	1 (3.2)	0	1 (3.2)
Sinusitis	1 (3.2)	1 (3.2)	0
Upper respiratory tract infection	1 (3.2)	1 (3.2)	0
Viral haemorrhagic cystitis	1 (3.2)	1 (3.2)	0
Investigations			
-Total	1 (3.2)	0	1 (3.2)
Blood uric acid increased	1 (3.2)	0	1 (3.2)
Metabolism and nutrition disorders			
-Total	1 (3.2)	0	1 (3.2)
Tumour lysis syndrome	1 (3.2)	0	1 (3.2)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.2)	1 (3.2)	0
Back pain	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	1 (3.2)	0	0
Mental status changes	1 (3.2)	0	0
Renal and urinary disorders			
-Total	1 (3.2)	0	1 (3.2)
Acute kidney injury	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.7)	1 (3.2)	2 (6.5)
Acute respiratory distress syndrome	1 (3.2)	0	1 (3.2)
Epistaxis	1 (3.2)	0	0
Hypoxia	1 (3.2)	1 (3.2)	0
Respiratory distress	1 (3.2)	0	1 (3.2)
Vascular disorders			
-Total	1 (3.2)	0	1 (3.2)
Hypotension	1 (3.2)	0	1 (3.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (35.7)	3 (21.4)	2 (14.3)
Gastrointestinal disorders			
-Total	1 (7.1)	0	0
Nausea	1 (7.1)	0	0
General disorders and administration site conditions			
-Total	1 (7.1)	0	0
Non-cardiac chest pain	1 (7.1)	0	0
Immune system disorders			
-Total	1 (7.1)	1 (7.1)	0
Allergy to immunoglobulin therapy	1 (7.1)	1 (7.1)	0
Infections and infestations			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Bacteraemia	1 (7.1)	0	1 (7.1)
Gastroenteritis	1 (7.1)	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Rhinovirus infection	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	1 (7.1)	1 (7.1)	0
Malnutrition	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	0	0
Back pain	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	0
Bronchial oedema	1 (7.1)	0	0
Vascular disorders			
-Total	1 (7.1)	0	1 (7.1)
Venoocclusive disease	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (15.0)	1 (5.0)	2 (10.0)
General disorders and administration site conditions			
-Total	1 (5.0)	0	1 (5.0)
Multiple organ dysfunction syndrome	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	2 (10.0)	0	2 (10.0)
Candida infection	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (5.0)	0	1 (5.0)
Ophthalmic herpes zoster	1 (5.0)	0	0
Sepsis	1 (5.0)	0	1 (5.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	1 (5.0)	0
Bone giant cell tumour benign	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	1 (5.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	0	0
Dyspnoea exertional	1 (5.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (40.9)	6 (27.3)	3 (13.6)
Gastrointestinal disorders			
-Total	1 (4.5)	0	0
Irritable bowel syndrome	1 (4.5)	0	0
General disorders and administration site conditions			
-Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Immune system disorders			
-Total	1 (4.5)	1 (4.5)	0
Drug hypersensitivity	1 (4.5)	1 (4.5)	0
Infections and infestations			

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (40.9)	7 (31.8)	2 (9.1)
Sepsis	2 (9.1)	1 (4.5)	1 (4.5)
Clostridium difficile colitis	1 (4.5)	1 (4.5)	0
Covid-19	1 (4.5)	1 (4.5)	0
Device related sepsis	1 (4.5)	1 (4.5)	0
Gastroenteritis escherichia coli	1 (4.5)	1 (4.5)	0
Gastroenteritis salmonella	1 (4.5)	1 (4.5)	0
Herpes zoster	1 (4.5)	1 (4.5)	0
Meningitis pneumococcal	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	1 (4.5)	0
Pneumonia respiratory syncytial viral	1 (4.5)	1 (4.5)	0
Septic shock	1 (4.5)	0	1 (4.5)
Staphylococcal bacteraemia	1 (4.5)	1 (4.5)	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0
Injury, poisoning and procedural complications			
-Total	1 (4.5)	1 (4.5)	0
Infusion related reaction	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	0	1 (4.5)
Decreased appetite	1 (4.5)	0	1 (4.5)
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Nervous system disorder	1 (4.5)	1 (4.5)	0
Seizure	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.5)	0	1 (4.5)
Respiratory failure	1 (4.5)	0	1 (4.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (37.5)	1 (12.5)	1 (12.5)
General disorders and administration site conditions			
-Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0
Infections and infestations			
-Total	2 (25.0)	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	0
Staphylococcal abscess	1 (12.5)	1 (12.5)	0
Reproductive system and breast disorders			
-Total	1 (12.5)	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endometriosis	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Laryngeal oedema	1 (12.5)	0	1 (12.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (69.7)	9 (27.3)	13 (39.4)
Blood and lymphatic system disorders			
-Total	8 (24.2)	8 (24.2)	0
Febrile neutropenia	8 (24.2)	8 (24.2)	0
Disseminated intravascular coagulation	1 (3.0)	0	0
Cardiac disorders			
-Total	3 (9.1)	1 (3.0)	2 (6.1)
Cardiac arrest	1 (3.0)	0	1 (3.0)
Left ventricular dysfunction	1 (3.0)	1 (3.0)	0
Tachycardia	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (15.2)	3 (9.1)	1 (3.0)
Diarrhoea	2 (6.1)	1 (3.0)	0
Abdominal compartment syndrome	1 (3.0)	0	1 (3.0)
Neutropenic colitis	1 (3.0)	1 (3.0)	0
Pancreatitis	1 (3.0)	1 (3.0)	0
Vomiting	1 (3.0)	0	0
General disorders and administration site conditions			
-Total	6 (18.2)	0	2 (6.1)
Pyrexia	4 (12.1)	0	0
Multiple organ dysfunction syndrome	2 (6.1)	0	2 (6.1)
Systemic inflammatory response syndrome	1 (3.0)	1 (3.0)	0
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Cholestasis	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	19 (57.6)	3 (9.1)	9 (27.3)
Cytokine release syndrome	18 (54.5)	3 (9.1)	8 (24.2)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	2 (6.1)
Infections and infestations			
-Total	12 (36.4)	6 (18.2)	6 (18.2)
Bronchopulmonary aspergillosis	1 (3.0)	0	1 (3.0)
Candida infection	1 (3.0)	0	0
Covid-19 pneumonia	1 (3.0)	0	1 (3.0)
Cytomegalovirus infection reactivation	1 (3.0)	1 (3.0)	0
Device related infection	1 (3.0)	1 (3.0)	0
Encephalitis	1 (3.0)	0	1 (3.0)
Enterobacter infection	1 (3.0)	1 (3.0)	0
Gastroenteritis	1 (3.0)	1 (3.0)	0
Herpes zoster	1 (3.0)	1 (3.0)	0
Human herpesvirus 6 infection	1 (3.0)	1 (3.0)	0
Klebsiella infection	1 (3.0)	1 (3.0)	0
Mastoiditis	1 (3.0)	1 (3.0)	0
Metapneumovirus infection	1 (3.0)	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	0
Otitis externa	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (3.0)	1 (3.0)	0
Pneumocystis jirovecii pneumonia	1 (3.0)	0	1 (3.0)
Pneumonia	1 (3.0)	0	1 (3.0)
Pneumonia viral	1 (3.0)	1 (3.0)	0
Sepsis	1 (3.0)	0	1 (3.0)
Soft tissue infection	1 (3.0)	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	1 (3.0)	0
Staphylococcal sepsis	1 (3.0)	0	1 (3.0)
Injury, poisoning and procedural complications			
-Total	1 (3.0)	0	1 (3.0)
Vasoplegia syndrome	1 (3.0)	0	1 (3.0)
Metabolism and nutrition disorders			
-Total	3 (9.1)	1 (3.0)	1 (3.0)
Dehydration	1 (3.0)	0	0
Hypernatraemia	1 (3.0)	0	1 (3.0)
Hypokalaemia	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Back pain	1 (3.0)	1 (3.0)	0
Rhabdomyolysis	1 (3.0)	0	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (6.1)	2 (6.1)	0
Bone giant cell tumour benign	1 (3.0)	1 (3.0)	0
Myelodysplastic syndrome	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	4 (12.1)	2 (6.1)	2 (6.1)
Cerebral haemorrhage	1 (3.0)	0	1 (3.0)
Encephalopathy	1 (3.0)	1 (3.0)	0
Headache	1 (3.0)	1 (3.0)	0
Hydrocephalus	1 (3.0)	0	1 (3.0)
Psychiatric disorders			
-Total	1 (3.0)	1 (3.0)	0
Mental status changes	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	2 (6.1)	0	2 (6.1)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (6.1)	0	2 (6.1)
Renal tubular necrosis	1 (3.0)	0	1 (3.0)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.2)	1 (3.0)	3 (9.1)
Hypoxia	2 (6.1)	1 (3.0)	1 (3.0)
Acute respiratory distress syndrome	1 (3.0)	0	1 (3.0)
Dyspnoea	1 (3.0)	0	1 (3.0)
Dyspnoea exertional	1 (3.0)	0	0
Respiratory distress	1 (3.0)	0	0
Respiratory failure	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	3 (9.1)	0	3 (9.1)
Hypotension	3 (9.1)	0	3 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	28 (84.8)	10 (30.3)	17 (51.5)
Blood and lymphatic system disorders			
-Total	9 (27.3)	7 (21.2)	2 (6.1)
Febrile neutropenia	6 (18.2)	5 (15.2)	1 (3.0)
Disseminated intravascular coagulation	2 (6.1)	2 (6.1)	0
Coagulopathy	1 (3.0)	1 (3.0)	0
Pancytopenia	1 (3.0)	1 (3.0)	0
Thrombocytopenia	1 (3.0)	0	1 (3.0)
Cardiac disorders			
-Total	3 (9.1)	0	2 (6.1)
Cardiac arrest	2 (6.1)	0	2 (6.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (3.0)	0	0
Cardiac failure	1 (3.0)	1 (3.0)	0
Gastrointestinal disorders			
-Total	2 (6.1)	1 (3.0)	0
Irritable bowel syndrome	1 (3.0)	0	0
Pancreatitis	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	2 (6.1)	1 (3.0)	0
Pyrexia	2 (6.1)	1 (3.0)	0
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Hepatomegaly	1 (3.0)	0	1 (3.0)
Immune system disorders			
-Total	23 (69.7)	10 (30.3)	9 (27.3)
Cytokine release syndrome	23 (69.7)	10 (30.3)	9 (27.3)
Drug hypersensitivity	1 (3.0)	1 (3.0)	0
Infections and infestations			
-Total	13 (39.4)	8 (24.2)	5 (15.2)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (6.1)	1 (3.0)	1 (3.0)
Septic shock	2 (6.1)	0	2 (6.1)
Upper respiratory tract infection	2 (6.1)	2 (6.1)	0
Clostridium difficile colitis	1 (3.0)	1 (3.0)	0
Covid-19	1 (3.0)	1 (3.0)	0
Device related sepsis	1 (3.0)	1 (3.0)	0
Encephalitis	1 (3.0)	0	1 (3.0)
Encephalitis viral	1 (3.0)	0	1 (3.0)
Gastroenteritis escherichia coli	1 (3.0)	1 (3.0)	0
Gastroenteritis salmonella	1 (3.0)	1 (3.0)	0
Herpes zoster	1 (3.0)	1 (3.0)	0
Meningitis bacterial	1 (3.0)	1 (3.0)	0
Meningitis pneumococcal	1 (3.0)	1 (3.0)	0
Pneumonia	1 (3.0)	1 (3.0)	0
Pneumonia fungal	1 (3.0)	1 (3.0)	0
Pneumonia respiratory syncytial viral	1 (3.0)	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	1 (3.0)	0
Sinusitis	1 (3.0)	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (3.0)	1 (3.0)	0
Injury, poisoning and procedural complications			
-Total	1 (3.0)	1 (3.0)	0
Infusion related reaction	1 (3.0)	1 (3.0)	0
Investigations			
-Total	3 (9.1)	1 (3.0)	2 (6.1)
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
Blood uric acid increased	1 (3.0)	0	1 (3.0)
Electrocardiogram qt prolonged	1 (3.0)	0	1 (3.0)
Metabolism and nutrition disorders			
-Total	4 (12.1)	1 (3.0)	3 (9.1)
Tumour lysis syndrome	2 (6.1)	1 (3.0)	1 (3.0)
Decreased appetite	1 (3.0)	0	1 (3.0)
Hypercalcaemia	1 (3.0)	1 (3.0)	0
Hyperkalaemia	1 (3.0)	0	1 (3.0)
Hyperphosphataemia	1 (3.0)	0	1 (3.0)
Metabolic acidosis	1 (3.0)	0	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (6.1)	2 (6.1)	0
Back pain	1 (3.0)	1 (3.0)	0
Haemarthrosis	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	3 (9.1)	3 (9.1)	0
Dysarthria	1 (3.0)	1 (3.0)	0
Headache	1 (3.0)	1 (3.0)	0
Nervous system disorder	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0
Psychiatric disorders			
-Total	2 (6.1)	1 (3.0)	0
Delirium	1 (3.0)	1 (3.0)	0
Mental status changes	1 (3.0)	0	0
Renal and urinary disorders			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Acute kidney injury	3 (9.1)	2 (6.1)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	9 (27.3)	3 (9.1)	6 (18.2)
Hypoxia	3 (9.1)	2 (6.1)	1 (3.0)
Respiratory failure	3 (9.1)	0	3 (9.1)
Pleural effusion	2 (6.1)	1 (3.0)	1 (3.0)
Acute respiratory distress syndrome	1 (3.0)	0	1 (3.0)
Acute respiratory failure	1 (3.0)	1 (3.0)	0
Epistaxis	1 (3.0)	0	0
Pulmonary oedema	1 (3.0)	1 (3.0)	0
Respiratory distress	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	4 (12.1)	1 (3.0)	3 (9.1)
Hypotension	4 (12.1)	1 (3.0)	3 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	12 (85.7)	4 (28.6)	7 (50.0)
Blood and lymphatic system disorders			
-Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiac failure	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			
-Total	1 (7.1)	0	0
Constipation	1 (7.1)	0	0
Nausea	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (21.4)	0	1 (7.1)
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Non-cardiac chest pain	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	0
Immune system disorders			
-Total	9 (64.3)	3 (21.4)	4 (28.6)
Cytokine release syndrome	9 (64.3)	3 (21.4)	4 (28.6)
Allergy to immunoglobulin therapy	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Rhinovirus infection	2 (14.3)	1 (7.1)	0
Bacteraemia	1 (7.1)	0	1 (7.1)
Candida infection	1 (7.1)	0	1 (7.1)
Encephalitis viral	1 (7.1)	1 (7.1)	0
Gastroenteritis	1 (7.1)	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Staphylococcal abscess	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Varicella zoster virus infection	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	1 (7.1)	1 (7.1)	0
Malnutrition	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	0	0
Back pain	1 (7.1)	0	0
Nervous system disorders			

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	0
Cognitive disorder	1 (7.1)	0	0
Renal and urinary disorders			
-Total	1 (7.1)	0	1 (7.1)
Renal failure	1 (7.1)	0	1 (7.1)
Reproductive system and breast disorders			
-Total	1 (7.1)	1 (7.1)	0
Endometriosis	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	0	2 (14.3)
Bronchial oedema	1 (7.1)	0	0
Laryngeal oedema	1 (7.1)	0	1 (7.1)
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypotension	1 (7.1)	0	1 (7.1)
Venoocclusive disease	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	26 (56.5)	10 (21.7)	13 (28.3)
Blood and lymphatic system disorders			
-Total	7 (15.2)	6 (13.0)	1 (2.2)
Febrile neutropenia	6 (13.0)	6 (13.0)	0
Disseminated intravascular coagulation	1 (2.2)	0	0
Pancytopenia	1 (2.2)	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	2 (4.3)	1 (2.2)	0
Atrioventricular block first degree	1 (2.2)	0	0
Left ventricular dysfunction	1 (2.2)	1 (2.2)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.7)	3 (6.5)	1 (2.2)
Abdominal compartment syndrome	1 (2.2)	0	1 (2.2)
Diarrhoea	1 (2.2)	1 (2.2)	0
Neutropenic colitis	1 (2.2)	1 (2.2)	0
Pancreatitis	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	2 (4.3)	0	0
Pyrexia	2 (4.3)	0	0
Immune system disorders			
-Total	23 (50.0)	7 (15.2)	11 (23.9)
Cytokine release syndrome	23 (50.0)	7 (15.2)	11 (23.9)
Infections and infestations			
-Total	4 (8.7)	4 (8.7)	0
Pneumonia fungal	1 (2.2)	1 (2.2)	0
Soft tissue infection	1 (2.2)	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	1 (2.2)	0
Investigations			

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.3)	2 (4.3)	0
Aspartate aminotransferase increased	2 (4.3)	2 (4.3)	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	2 (4.3)	1 (2.2)	0
Dehydration	1 (2.2)	0	0
Tumour lysis syndrome	1 (2.2)	1 (2.2)	0
Nervous system disorders			
-Total	3 (6.5)	2 (4.3)	1 (2.2)
Cerebral haemorrhage	1 (2.2)	0	1 (2.2)
Dysarthria	1 (2.2)	1 (2.2)	0
Headache	1 (2.2)	1 (2.2)	0
Psychiatric disorders			
-Total	1 (2.2)	1 (2.2)	0
Delirium	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	2 (4.3)	0	2 (4.3)
Acute kidney injury	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (2.2)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (13.0)	1 (2.2)	4 (8.7)
Pleural effusion	2 (4.3)	1 (2.2)	1 (2.2)
Respiratory failure	2 (4.3)	0	2 (4.3)
Hypoxia	1 (2.2)	0	1 (2.2)
Pulmonary oedema	1 (2.2)	1 (2.2)	0
Respiratory distress	1 (2.2)	0	0
Vascular disorders			
-Total	2 (4.3)	0	2 (4.3)
Hypotension	2 (4.3)	0	2 (4.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	28 (82.4)	12 (35.3)	14 (41.2)
Blood and lymphatic system disorders			
-Total	9 (26.5)	8 (23.5)	1 (2.9)
Febrile neutropenia	7 (20.6)	6 (17.6)	1 (2.9)
Coagulopathy	1 (2.9)	1 (2.9)	0
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	3 (8.8)	0	3 (8.8)
Cardiac arrest	1 (2.9)	0	1 (2.9)
Cardiac failure	1 (2.9)	0	1 (2.9)
Tachycardia	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	0
Constipation	1 (2.9)	0	0
General disorders and administration site conditions			
-Total	3 (8.8)	0	2 (5.9)
Multiple organ dysfunction syndrome	2 (5.9)	0	2 (5.9)
Pyrexia	1 (2.9)	0	0
Systemic inflammatory response syndrome	1 (2.9)	1 (2.9)	0
Hepatobiliary disorders			
-Total	2 (5.9)	0	2 (5.9)
Cholestasis	1 (2.9)	0	1 (2.9)
Hepatomegaly	1 (2.9)	0	1 (2.9)
Immune system disorders			
-Total	27 (79.4)	9 (26.5)	10 (29.4)
Cytokine release syndrome	27 (79.4)	9 (26.5)	10 (29.4)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)
Infections and infestations			
-Total	7 (20.6)	3 (8.8)	3 (8.8)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (5.9)	1 (2.9)	1 (2.9)
Candida infection	1 (2.9)	0	1 (2.9)
Encephalitis	1 (2.9)	0	1 (2.9)
Klebsiella infection	1 (2.9)	1 (2.9)	0
Meningitis bacterial	1 (2.9)	1 (2.9)	0
Pneumonia viral	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0
Injury, poisoning and procedural complications			
-Total	1 (2.9)	0	1 (2.9)
Vasoplegia syndrome	1 (2.9)	0	1 (2.9)
Investigations			
-Total	1 (2.9)	0	1 (2.9)
Electrocardiogram qt prolonged	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	2 (5.9)	0	2 (5.9)
Hypercalcaemia	1 (2.9)	1 (2.9)	0
Hyperkalaemia	1 (2.9)	0	1 (2.9)
Hypernatraemia	1 (2.9)	0	1 (2.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (2.9)	0	1 (2.9)
Metabolic acidosis	1 (2.9)	0	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Haemarthrosis	1 (2.9)	1 (2.9)	0
Rhabdomyolysis	1 (2.9)	0	1 (2.9)
Nervous system disorders			
-Total	2 (5.9)	1 (2.9)	0
Cognitive disorder	1 (2.9)	0	0
Encephalopathy	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	3 (8.8)	2 (5.9)	1 (2.9)
Acute kidney injury	3 (8.8)	2 (5.9)	1 (2.9)
Renal tubular necrosis	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (11.8)	2 (5.9)	2 (5.9)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Acute respiratory failure	1 (2.9)	1 (2.9)	0
Dyspnoea	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	6 (17.6)	2 (5.9)	4 (11.8)
Hypotension	6 (17.6)	2 (5.9)	4 (11.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (32.6)	7 (16.3)	7 (16.3)
Blood and lymphatic system disorders			
-Total	4 (9.3)	4 (9.3)	0
Febrile neutropenia	3 (7.0)	3 (7.0)	0
Disseminated intravascular coagulation	1 (2.3)	1 (2.3)	0
Cardiac disorders			
-Total	1 (2.3)	0	1 (2.3)
Cardiac arrest	1 (2.3)	0	1 (2.3)
Cardiac failure	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	2 (4.7)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (2.3)	0	0
Pancreatitis	1 (2.3)	1 (2.3)	0
Vomiting	1 (2.3)	0	0
General disorders and administration site conditions			
-Total	3 (7.0)	1 (2.3)	0
Pyrexia	3 (7.0)	1 (2.3)	0
Infections and infestations			
-Total	8 (18.6)	4 (9.3)	4 (9.3)
Cytomegalovirus infection reactivation	1 (2.3)	1 (2.3)	0
Device related infection	1 (2.3)	1 (2.3)	0
Encephalitis	1 (2.3)	0	1 (2.3)
Herpes zoster	1 (2.3)	1 (2.3)	0
Human herpesvirus 6 infection	1 (2.3)	1 (2.3)	0
Metapneumovirus infection	1 (2.3)	1 (2.3)	0
Pneumocystis jirovecii pneumonia	1 (2.3)	0	1 (2.3)
Pneumonia	1 (2.3)	0	1 (2.3)
Respiratory syncytial virus infection	1 (2.3)	1 (2.3)	0
Staphylococcal sepsis	1 (2.3)	0	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Viral haemorrhagic cystitis	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (4.7)	2 (4.7)	0
Back pain	2 (4.7)	2 (4.7)	0
Nervous system disorders			
-Total	1 (2.3)	0	1 (2.3)
Hydrocephalus	1 (2.3)	0	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.0)	1 (2.3)	2 (4.7)
Epistaxis	1 (2.3)	0	0
Hypoxia	1 (2.3)	1 (2.3)	0
Respiratory distress	1 (2.3)	0	1 (2.3)
Respiratory failure	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	1 (2.3)	0	1 (2.3)
Venoocclusive disease	1 (2.3)	0	1 (2.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (28.1)	5 (15.6)	4 (12.5)
Cardiac disorders			
-Total	1 (3.1)	0	1 (3.1)
Cardiac arrest	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	1 (3.1)	0	0
Nausea	1 (3.1)	0	0
General disorders and administration site conditions			
-Total	2 (6.3)	0	0
Non-cardiac chest pain	1 (3.1)	0	0
Pyrexia	1 (3.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (3.1)	1 (3.1)	0
Allergy to immunoglobulin therapy	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	8 (25.0)	5 (15.6)	3 (9.4)
Gastroenteritis	2 (6.3)	2 (6.3)	0
Bacteraemia	1 (3.1)	0	1 (3.1)
Bronchopulmonary aspergillosis	1 (3.1)	0	1 (3.1)
Enterobacter infection	1 (3.1)	1 (3.1)	0
Klebsiella infection	1 (3.1)	1 (3.1)	0
Mastoiditis	1 (3.1)	1 (3.1)	0
Otitis externa	1 (3.1)	1 (3.1)	0
Otitis media	1 (3.1)	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	1 (3.1)	0
Pharyngitis streptococcal	1 (3.1)	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0
Septic shock	1 (3.1)	0	1 (3.1)
Sinusitis	1 (3.1)	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Urinary tract infection	1 (3.1)	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	1 (3.1)	0	1 (3.1)
Blood uric acid increased	1 (3.1)	0	1 (3.1)
Metabolism and nutrition disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Hypokalaemia	1 (3.1)	1 (3.1)	0
Malnutrition	1 (3.1)	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	0	0
Back pain	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.1)	1 (3.1)	0
Myelodysplastic syndrome	1 (3.1)	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (6.3)	1 (3.1)	0
Mental status changes	2 (6.3)	1 (3.1)	0
Renal and urinary disorders			
-Total	1 (3.1)	0	1 (3.1)
Acute kidney injury	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.4)	1 (3.1)	1 (3.1)
Acute respiratory distress syndrome	1 (3.1)	0	1 (3.1)
Bronchial oedema	1 (3.1)	0	0
Hypoxia	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	1 (3.1)	0	1 (3.1)
Hypotension	1 (3.1)	0	1 (3.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (27.6)	4 (13.8)	4 (13.8)
Gastrointestinal disorders			
-Total	1 (3.4)	0	0
Irritable bowel syndrome	1 (3.4)	0	0
General disorders and administration site conditions			
-Total	2 (6.9)	0	1 (3.4)
Multiple organ dysfunction syndrome	1 (3.4)	0	1 (3.4)
Pyrexia	1 (3.4)	0	0
Immune system disorders			
-Total	1 (3.4)	0	1 (3.4)

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (3.4)	0	1 (3.4)
Infections and infestations			
-Total	8 (27.6)	6 (20.7)	2 (6.9)
Sepsis	2 (6.9)	1 (3.4)	1 (3.4)
Candida infection	1 (3.4)	0	0
Clostridium difficile colitis	1 (3.4)	1 (3.4)	0
Covid-19	1 (3.4)	1 (3.4)	0
Covid-19 pneumonia	1 (3.4)	0	1 (3.4)
Gastroenteritis escherichia coli	1 (3.4)	1 (3.4)	0
Gastroenteritis salmonella	1 (3.4)	1 (3.4)	0
Ophthalmic herpes zoster	1 (3.4)	0	0
Pneumonia	1 (3.4)	1 (3.4)	0
Staphylococcal abscess	1 (3.4)	1 (3.4)	0
Staphylococcal bacteraemia	1 (3.4)	1 (3.4)	0
Upper respiratory tract infection	1 (3.4)	1 (3.4)	0
Injury, poisoning and procedural complications			
-Total	1 (3.4)	1 (3.4)	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	1 (3.4)	0	1 (3.4)
Decreased appetite	1 (3.4)	0	1 (3.4)
Nervous system disorders			
-Total	1 (3.4)	1 (3.4)	0
Headache	1 (3.4)	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	0	1 (3.4)
Laryngeal oedema	1 (3.4)	0	1 (3.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (33.3)	4 (19.0)	2 (9.5)
General disorders and administration site conditions			
-Total	1 (4.8)	0	0
Pyrexia	1 (4.8)	0	0
Immune system disorders			
-Total	1 (4.8)	1 (4.8)	0
Drug hypersensitivity	1 (4.8)	1 (4.8)	0
Infections and infestations			
-Total	5 (23.8)	2 (9.5)	2 (9.5)
Device related sepsis	1 (4.8)	1 (4.8)	0
Herpes zoster	1 (4.8)	1 (4.8)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis pneumococcal	1 (4.8)	1 (4.8)	0
Pneumonia respiratory syncytial viral	1 (4.8)	1 (4.8)	0
Rhinovirus infection	1 (4.8)	0	0
Sepsis	1 (4.8)	0	1 (4.8)
Septic shock	1 (4.8)	0	1 (4.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.8)	1 (4.8)	0
Bone giant cell tumour benign	1 (4.8)	1 (4.8)	0
Nervous system disorders			
-Total	1 (4.8)	1 (4.8)	0
Nervous system disorder	1 (4.8)	1 (4.8)	0
Seizure	1 (4.8)	1 (4.8)	0
Reproductive system and breast disorders			
-Total	1 (4.8)	1 (4.8)	0
Endometriosis	1 (4.8)	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.5)	0	1 (4.8)

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (4.8)	0	0
Respiratory failure	1 (4.8)	0	1 (4.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	33 (71.7)	12 (26.1)	20 (43.5)
Blood and lymphatic system disorders			
-Total	9 (19.6)	8 (17.4)	1 (2.2)
Febrile neutropenia	8 (17.4)	8 (17.4)	0
Disseminated intravascular coagulation	2 (4.3)	1 (2.2)	0
Pancytopenia	1 (2.2)	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	3 (6.5)	1 (2.2)	1 (2.2)
Atrioventricular block first degree	1 (2.2)	0	0
Cardiac arrest	1 (2.2)	0	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (2.2)	1 (2.2)	0
Left ventricular dysfunction	1 (2.2)	1 (2.2)	0
Gastrointestinal disorders			
-Total	7 (15.2)	4 (8.7)	1 (2.2)
Diarrhoea	2 (4.3)	1 (2.2)	0
Pancreatitis	2 (4.3)	2 (4.3)	0
Abdominal compartment syndrome	1 (2.2)	0	1 (2.2)
Irritable bowel syndrome	1 (2.2)	0	0
Neutropenic colitis	1 (2.2)	1 (2.2)	0
Vomiting	1 (2.2)	0	0
General disorders and administration site conditions			
-Total	6 (13.0)	1 (2.2)	1 (2.2)
Pyrexia	5 (10.9)	1 (2.2)	0
Multiple organ dysfunction syndrome	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	24 (52.2)	7 (15.2)	12 (26.1)
Cytokine release syndrome	23 (50.0)	7 (15.2)	11 (23.9)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)
Infections and infestations			
-Total	16 (34.8)	11 (23.9)	5 (10.9)
Pneumonia	2 (4.3)	1 (2.2)	1 (2.2)
Sepsis	2 (4.3)	1 (2.2)	1 (2.2)
Staphylococcal bacteraemia	2 (4.3)	2 (4.3)	0
Upper respiratory tract infection	2 (4.3)	2 (4.3)	0
Candida infection	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	1 (2.2)	0
Covid-19	1 (2.2)	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	1 (2.2)
Cytomegalovirus infection reactivation	1 (2.2)	1 (2.2)	0
Device related infection	1 (2.2)	1 (2.2)	0
Encephalitis	1 (2.2)	0	1 (2.2)
Gastroenteritis escherichia coli	1 (2.2)	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	1 (2.2)	0
Herpes zoster	1 (2.2)	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (2.2)	1 (2.2)	0
Ophthalmic herpes zoster	1 (2.2)	0	0
Pneumocystis jirovecii pneumonia	1 (2.2)	0	1 (2.2)
Pneumonia fungal	1 (2.2)	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	1 (2.2)	0
Soft tissue infection	1 (2.2)	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	1 (2.2)	0
Staphylococcal sepsis	1 (2.2)	0	1 (2.2)
Varicella zoster virus infection	1 (2.2)	1 (2.2)	0
Viral haemorrhagic cystitis	1 (2.2)	1 (2.2)	0
Injury, poisoning and procedural complications			
-Total	1 (2.2)	1 (2.2)	0
Infusion related reaction	1 (2.2)	1 (2.2)	0
Investigations			
-Total	2 (4.3)	2 (4.3)	0
Aspartate aminotransferase increased	2 (4.3)	2 (4.3)	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	3 (6.5)	1 (2.2)	1 (2.2)
Decreased appetite	1 (2.2)	0	1 (2.2)
Dehydration	1 (2.2)	0	0
Tumour lysis syndrome	1 (2.2)	1 (2.2)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (4.3)	2 (4.3)	0
Back pain	2 (4.3)	2 (4.3)	0
Nervous system disorders			
-Total	5 (10.9)	3 (6.5)	2 (4.3)
Headache	2 (4.3)	2 (4.3)	0
Cerebral haemorrhage	1 (2.2)	0	1 (2.2)
Dysarthria	1 (2.2)	1 (2.2)	0
Hydrocephalus	1 (2.2)	0	1 (2.2)
Psychiatric disorders			
-Total	1 (2.2)	1 (2.2)	0
Delirium	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.3)	0	2 (4.3)
Acute kidney injury	1 (2.2)	0	1 (2.2)
Renal failure	1 (2.2)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (19.6)	1 (2.2)	7 (15.2)
Respiratory failure	3 (6.5)	0	3 (6.5)
Hypoxia	2 (4.3)	1 (2.2)	1 (2.2)
Pleural effusion	2 (4.3)	1 (2.2)	1 (2.2)
Respiratory distress	2 (4.3)	0	1 (2.2)
Epistaxis	1 (2.2)	0	0
Laryngeal oedema	1 (2.2)	0	1 (2.2)
Pulmonary oedema	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	3 (6.5)	0	3 (6.5)
Hypotension	2 (4.3)	0	2 (4.3)
Venoocclusive disease	1 (2.2)	0	1 (2.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	30 (88.2)	11 (32.4)	17 (50.0)
Blood and lymphatic system disorders			
-Total	9 (26.5)	8 (23.5)	1 (2.9)
Febrile neutropenia	7 (20.6)	6 (17.6)	1 (2.9)
Coagulopathy	1 (2.9)	1 (2.9)	0
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	4 (11.8)	0	4 (11.8)
Cardiac arrest	2 (5.9)	0	2 (5.9)
Cardiac failure	1 (2.9)	0	1 (2.9)
Tachycardia	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (2.9)	0	0
Constipation	1 (2.9)	0	0
Nausea	1 (2.9)	0	0
General disorders and administration site conditions			
-Total	5 (14.7)	0	2 (5.9)
Multiple organ dysfunction syndrome	2 (5.9)	0	2 (5.9)
Pyrexia	2 (5.9)	0	0
Non-cardiac chest pain	1 (2.9)	0	0
Systemic inflammatory response syndrome	1 (2.9)	1 (2.9)	0
Hepatobiliary disorders			
-Total	2 (5.9)	0	2 (5.9)
Cholestasis	1 (2.9)	0	1 (2.9)
Hepatomegaly	1 (2.9)	0	1 (2.9)
Immune system disorders			
-Total	27 (79.4)	9 (26.5)	10 (29.4)
Cytokine release syndrome	27 (79.4)	9 (26.5)	10 (29.4)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Allergy to immunoglobulin therapy	1 (2.9)	1 (2.9)	0
Drug hypersensitivity	1 (2.9)	1 (2.9)	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)
Infections and infestations			
-Total	15 (44.1)	7 (20.6)	8 (23.5)
Encephalitis viral	2 (5.9)	1 (2.9)	1 (2.9)
Gastroenteritis	2 (5.9)	2 (5.9)	0
Rhinovirus infection	2 (5.9)	1 (2.9)	0
Septic shock	2 (5.9)	0	2 (5.9)
Bacteraemia	1 (2.9)	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	1 (2.9)
Candida infection	1 (2.9)	0	1 (2.9)
Device related sepsis	1 (2.9)	1 (2.9)	0
Encephalitis	1 (2.9)	0	1 (2.9)
Enterobacter infection	1 (2.9)	1 (2.9)	0
Herpes zoster	1 (2.9)	1 (2.9)	0
Klebsiella infection	1 (2.9)	1 (2.9)	0
Mastoiditis	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (2.9)	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	1 (2.9)	0
Otitis externa	1 (2.9)	1 (2.9)	0
Otitis media	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0
Pharyngitis streptococcal	1 (2.9)	1 (2.9)	0
Pneumonia respiratory syncytial viral	1 (2.9)	1 (2.9)	0
Pneumonia viral	1 (2.9)	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	1 (2.9)	0
Sepsis	1 (2.9)	0	1 (2.9)
Sinusitis	1 (2.9)	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Urinary tract infection	1 (2.9)	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Injury, poisoning and procedural complications			
-Total	1 (2.9)	0	1 (2.9)
Vasoplegia syndrome	1 (2.9)	0	1 (2.9)
Investigations			

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.9)	0	2 (5.9)
Blood uric acid increased	1 (2.9)	0	1 (2.9)
Electrocardiogram qt prolonged	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	5 (14.7)	2 (5.9)	3 (8.8)
Hypercalcaemia	1 (2.9)	1 (2.9)	0
Hyperkalaemia	1 (2.9)	0	1 (2.9)
Hypernatraemia	1 (2.9)	0	1 (2.9)
Hyperphosphataemia	1 (2.9)	0	1 (2.9)
Hypokalaemia	1 (2.9)	1 (2.9)	0
Malnutrition	1 (2.9)	1 (2.9)	0
Metabolic acidosis	1 (2.9)	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	3 (8.8)	1 (2.9)	1 (2.9)
Back pain	1 (2.9)	0	0
Haemarthrosis	1 (2.9)	1 (2.9)	0
Rhabdomyolysis	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (5.9)	2 (5.9)	0
Bone giant cell tumour benign	1 (2.9)	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	3 (8.8)	2 (5.9)	0
Cognitive disorder	1 (2.9)	0	0
Encephalopathy	1 (2.9)	1 (2.9)	0
Nervous system disorder	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	2 (5.9)	1 (2.9)	0
Mental status changes	2 (5.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	4 (11.8)	2 (5.9)	2 (5.9)
Acute kidney injury	4 (11.8)	2 (5.9)	2 (5.9)
Renal tubular necrosis	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.9)	1 (2.9)	0
Endometriosis	1 (2.9)	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (26.5)	3 (8.8)	4 (11.8)
Hypoxia	3 (8.8)	2 (5.9)	1 (2.9)
Acute respiratory distress syndrome	2 (5.9)	0	2 (5.9)
Respiratory failure	2 (5.9)	0	2 (5.9)
Acute respiratory failure	1 (2.9)	1 (2.9)	0
Bronchial oedema	1 (2.9)	0	0
Dyspnoea	1 (2.9)	0	1 (2.9)
Dyspnoea exertional	1 (2.9)	0	0
Vascular disorders			
-Total	6 (17.6)	1 (2.9)	5 (14.7)
Hypotension	6 (17.6)	1 (2.9)	5 (14.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	40 (67.8)	19 (32.2)	16 (27.1)
Blood and lymphatic system disorders			
-Total	12 (20.3)	10 (16.9)	2 (3.4)
Febrile neutropenia	10 (16.9)	9 (15.3)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0
Disseminated intravascular coagulation	1 (1.7)	0	0
Pancytopenia	1 (1.7)	1 (1.7)	0
Thrombocytopenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	4 (6.8)	1 (1.7)	2 (3.4)
Atrioventricular block first degree	1 (1.7)	0	0
Cardiac failure	1 (1.7)	0	1 (1.7)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.7)	1 (1.7)	0
Tachycardia	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	4 (6.8)	3 (5.1)	1 (1.7)
Abdominal compartment syndrome	1 (1.7)	0	1 (1.7)
Diarrhoea	1 (1.7)	1 (1.7)	0
Neutropenic colitis	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	3 (5.1)	0	1 (1.7)
Pyrexia	2 (3.4)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Systemic inflammatory response syndrome	1 (1.7)	1 (1.7)	0
Hepatobiliary disorders			
-Total	1 (1.7)	0	1 (1.7)
Cholestasis	1 (1.7)	0	1 (1.7)
Immune system disorders			

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	37 (62.7)	14 (23.7)	12 (20.3)
Cytokine release syndrome	37 (62.7)	14 (23.7)	12 (20.3)
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	7 (11.9)	5 (8.5)	2 (3.4)
Candida infection	1 (1.7)	0	1 (1.7)
Encephalitis	1 (1.7)	0	1 (1.7)
Pneumonia fungal	1 (1.7)	1 (1.7)	0
Pneumonia viral	1 (1.7)	1 (1.7)	0
Soft tissue infection	1 (1.7)	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Vasoplegia syndrome	1 (1.7)	0	1 (1.7)
Investigations			
-Total	2 (3.4)	2 (3.4)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (3.4)	2 (3.4)	0
Blood bilirubin increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	2 (3.4)	0	1 (1.7)
Dehydration	1 (1.7)	0	0
Hypernatraemia	1 (1.7)	0	1 (1.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.7)	0	1 (1.7)
Rhabdomyolysis	1 (1.7)	0	1 (1.7)
Nervous system disorders			
-Total	4 (6.8)	3 (5.1)	1 (1.7)
Cerebral haemorrhage	1 (1.7)	0	1 (1.7)
Dysarthria	1 (1.7)	1 (1.7)	0
Encephalopathy	1 (1.7)	1 (1.7)	0
Headache	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (1.7)	1 (1.7)	0
Renal and urinary disorders			
-Total	5 (8.5)	2 (3.4)	3 (5.1)
Acute kidney injury	4 (6.8)	2 (3.4)	2 (3.4)
Renal failure	1 (1.7)	0	1 (1.7)
Renal tubular necrosis	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (13.6)	3 (5.1)	4 (6.8)
Hypoxia	2 (3.4)	1 (1.7)	1 (1.7)
Respiratory failure	2 (3.4)	0	2 (3.4)
Acute respiratory distress syndrome	1 (1.7)	0	1 (1.7)
Acute respiratory failure	1 (1.7)	1 (1.7)	0
Dyspnoea	1 (1.7)	0	1 (1.7)
Pleural effusion	1 (1.7)	1 (1.7)	0
Pulmonary oedema	1 (1.7)	1 (1.7)	0
Respiratory distress	1 (1.7)	0	0
Vascular disorders			
-Total	6 (10.2)	2 (3.4)	4 (6.8)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	6 (10.2)	2 (3.4)	4 (6.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (50.0)	1 (10.0)	4 (40.0)
Blood and lymphatic system disorders			
-Total	1 (10.0)	1 (10.0)	0
Disseminated intravascular coagulation	1 (10.0)	1 (10.0)	0
Cardiac disorders			
-Total	1 (10.0)	0	1 (10.0)
Cardiac arrest	1 (10.0)	0	1 (10.0)
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatomegaly	1 (10.0)	0	1 (10.0)
Immune system disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	4 (40.0)	1 (10.0)	3 (30.0)
Infections and infestations			
-Total	1 (10.0)	0	1 (10.0)
Encephalitis viral	1 (10.0)	0	1 (10.0)
Meningitis bacterial	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypercalcaemia	1 (10.0)	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	1 (10.0)
Metabolic acidosis	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (81.8)	2 (18.2)	7 (63.6)
Blood and lymphatic system disorders			
-Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	3 (27.3)	3 (27.3)	0
Gastrointestinal disorders			
-Total	1 (9.1)	0	0
Constipation	1 (9.1)	0	0
General disorders and administration site conditions			
-Total	2 (18.2)	0	1 (9.1)
Multiple organ dysfunction syndrome	1 (9.1)	0	1 (9.1)
Pyrexia	1 (9.1)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	9 (81.8)	1 (9.1)	6 (54.5)
Cytokine release syndrome	9 (81.8)	1 (9.1)	6 (54.5)
Infections and infestations			
-Total	3 (27.3)	2 (18.2)	0
Encephalitis viral	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	0
Investigations			
-Total	1 (9.1)	0	1 (9.1)
Electrocardiogram qt prolonged	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Haemarthrosis	1 (9.1)	1 (9.1)	0
Nervous system disorders			

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	0
Cognitive disorder	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	0	1 (9.1)
Pleural effusion	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	2 (18.2)	0	2 (18.2)
Hypotension	2 (18.2)	0	2 (18.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (27.3)	7 (12.7)	8 (14.5)
Blood and lymphatic system disorders			
-Total	3 (5.5)	3 (5.5)	0
Febrile neutropenia	2 (3.6)	2 (3.6)	0
Disseminated intravascular coagulation	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	1 (1.8)	0	1 (1.8)
Cardiac arrest	1 (1.8)	0	1 (1.8)
Cardiac failure	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.8)	0	0
Pyrexia	1 (1.8)	0	0
Infections and infestations			
-Total	10 (18.2)	4 (7.3)	6 (10.9)
Gastroenteritis	2 (3.6)	2 (3.6)	0
Bronchopulmonary aspergillosis	1 (1.8)	0	1 (1.8)
Device related infection	1 (1.8)	1 (1.8)	0
Encephalitis	1 (1.8)	0	1 (1.8)
Metapneumovirus infection	1 (1.8)	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0
Pneumocystis jirovecii pneumonia	1 (1.8)	0	1 (1.8)
Pneumonia	1 (1.8)	0	1 (1.8)
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Rhinovirus infection	1 (1.8)	1 (1.8)	0
Septic shock	1 (1.8)	0	1 (1.8)
Sinusitis	1 (1.8)	1 (1.8)	0
Staphylococcal sepsis	1 (1.8)	0	1 (1.8)
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Viral haemorrhagic cystitis	1 (1.8)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (1.8)	0	1 (1.8)
Blood uric acid increased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	1 (1.8)	0	1 (1.8)
Tumour lysis syndrome	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.8)	1 (1.8)	0
Back pain	1 (1.8)	1 (1.8)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.8)	1 (1.8)	0
Myelodysplastic syndrome	1 (1.8)	1 (1.8)	0
Nervous system disorders			
-Total	1 (1.8)	0	1 (1.8)
Hydrocephalus	1 (1.8)	0	1 (1.8)
Psychiatric disorders			
-Total	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (1.8)	0	0
Renal and urinary disorders			
-Total	1 (1.8)	0	1 (1.8)
Acute kidney injury	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (7.3)	1 (1.8)	3 (5.5)
Acute respiratory distress syndrome	1 (1.8)	0	1 (1.8)
Epistaxis	1 (1.8)	0	0
Hypoxia	1 (1.8)	1 (1.8)	0
Respiratory distress	1 (1.8)	0	1 (1.8)
Respiratory failure	1 (1.8)	0	1 (1.8)
Vascular disorders			
-Total	1 (1.8)	0	1 (1.8)
Hypotension	1 (1.8)	0	1 (1.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (11.1)	1 (11.1)	0
Blood and lymphatic system disorders			
-Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	1 (11.1)	0	0
Diarrhoea	1 (11.1)	0	0
Vomiting	1 (11.1)	0	0
General disorders and administration site conditions			
-Total	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (11.1)	1 (11.1)	0
Cytomegalovirus infection reactivation	1 (11.1)	1 (11.1)	0
Human herpesvirus 6 infection	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (11.1)	1 (11.1)	0
Back pain	1 (11.1)	1 (11.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (63.6)	4 (36.4)	3 (27.3)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiac arrest	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	2 (18.2)	1 (9.1)	0
Nausea	1 (9.1)	0	0
Pancreatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	3 (27.3)	1 (9.1)	0
Pyrexia	2 (18.2)	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (9.1)	0	0
Immune system disorders			
-Total	1 (9.1)	1 (9.1)	0
Allergy to immunoglobulin therapy	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	5 (45.5)	4 (36.4)	1 (9.1)
Bacteraemia	1 (9.1)	0	1 (9.1)
Enterobacter infection	1 (9.1)	1 (9.1)	0
Herpes zoster	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Mastoiditis	1 (9.1)	1 (9.1)	0
Otitis externa	1 (9.1)	1 (9.1)	0
Otitis media	1 (9.1)	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	2 (18.2)	0
Hypokalaemia	1 (9.1)	1 (9.1)	0
Malnutrition	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	0	0
Back pain	1 (9.1)	0	0
Psychiatric disorders			
-Total	1 (9.1)	1 (9.1)	0
Mental status changes	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (18.2)	1 (9.1)	0
Bronchial oedema	1 (9.1)	0	0
Hypoxia	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	1 (9.1)	0	1 (9.1)
Venoocclusive disease	1 (9.1)	0	1 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	12 (30.8)	6 (15.4)	5 (12.8)
Gastrointestinal disorders			
-Total	1 (2.6)	0	0
Irritable bowel syndrome	1 (2.6)	0	0
General disorders and administration site conditions			
-Total	2 (5.1)	0	0
Pyrexia	2 (5.1)	0	0
Immune system disorders			
-Total	1 (2.6)	1 (2.6)	0
Drug hypersensitivity	1 (2.6)	1 (2.6)	0
Infections and infestations			

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (28.2)	7 (17.9)	3 (7.7)
Sepsis	3 (7.7)	1 (2.6)	2 (5.1)
Candida infection	1 (2.6)	0	0
Clostridium difficile colitis	1 (2.6)	1 (2.6)	0
Covid-19	1 (2.6)	1 (2.6)	0
Device related sepsis	1 (2.6)	1 (2.6)	0
Gastroenteritis escherichia coli	1 (2.6)	1 (2.6)	0
Gastroenteritis salmonella	1 (2.6)	1 (2.6)	0
Herpes zoster	1 (2.6)	1 (2.6)	0
Meningitis pneumococcal	1 (2.6)	1 (2.6)	0
Ophthalmic herpes zoster	1 (2.6)	0	0
Pneumonia	1 (2.6)	1 (2.6)	0
Pneumonia respiratory syncytial viral	1 (2.6)	1 (2.6)	0
Rhinovirus infection	1 (2.6)	0	0
Septic shock	1 (2.6)	0	1 (2.6)
Staphylococcal abscess	1 (2.6)	1 (2.6)	0
Staphylococcal bacteraemia	1 (2.6)	1 (2.6)	0
Injury, poisoning and procedural complications			

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.6)	1 (2.6)	0
Infusion related reaction	1 (2.6)	1 (2.6)	0
Metabolism and nutrition disorders			
-Total	1 (2.6)	0	1 (2.6)
Decreased appetite	1 (2.6)	0	1 (2.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.6)	1 (2.6)	0
Bone giant cell tumour benign	1 (2.6)	1 (2.6)	0
Nervous system disorders			
-Total	2 (5.1)	2 (5.1)	0
Headache	1 (2.6)	1 (2.6)	0
Nervous system disorder	1 (2.6)	1 (2.6)	0
Seizure	1 (2.6)	1 (2.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.7)	0	2 (5.1)
Dyspnoea exertional	1 (2.6)	0	0
Laryngeal oedema	1 (2.6)	0	1 (2.6)

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.6)	0	1 (2.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (33.3)	2 (33.3)	0
Infections and infestations			
-Total	1 (16.7)	1 (16.7)	0
Upper respiratory tract infection	1 (16.7)	1 (16.7)	0
Reproductive system and breast disorders			
-Total	1 (16.7)	1 (16.7)	0
Endometriosis	1 (16.7)	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (20.0)	0	1 (20.0)
General disorders and administration site conditions			
-Total	1 (20.0)	0	1 (20.0)
Multiple organ dysfunction syndrome	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Haemophagocytic lymphohistiocytosis	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	0	1 (20.0)
Covid-19 pneumonia	1 (20.0)	0	1 (20.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	45 (76.3)	19 (32.2)	23 (39.0)
Blood and lymphatic system disorders			
-Total	13 (22.0)	11 (18.6)	2 (3.4)
Febrile neutropenia	11 (18.6)	10 (16.9)	1 (1.7)
Disseminated intravascular coagulation	2 (3.4)	1 (1.7)	0
Coagulopathy	1 (1.7)	1 (1.7)	0
Pancytopenia	1 (1.7)	1 (1.7)	0
Thrombocytopenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	5 (8.5)	1 (1.7)	3 (5.1)
Cardiac failure	2 (3.4)	1 (1.7)	1 (1.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.7)	0	0
Cardiac arrest	1 (1.7)	0	1 (1.7)
Left ventricular dysfunction	1 (1.7)	1 (1.7)	0
Tachycardia	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	5 (8.5)	3 (5.1)	1 (1.7)
Abdominal compartment syndrome	1 (1.7)	0	1 (1.7)
Diarrhoea	1 (1.7)	1 (1.7)	0
Irritable bowel syndrome	1 (1.7)	0	0
Neutropenic colitis	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	5 (8.5)	0	1 (1.7)
Pyrexia	4 (6.8)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Systemic inflammatory response syndrome	1 (1.7)	1 (1.7)	0
Hepatobiliary disorders			

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.7)	0	1 (1.7)
Cholestasis	1 (1.7)	0	1 (1.7)
Immune system disorders			
-Total	37 (62.7)	14 (23.7)	12 (20.3)
Cytokine release syndrome	37 (62.7)	14 (23.7)	12 (20.3)
Drug hypersensitivity	1 (1.7)	1 (1.7)	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	23 (39.0)	13 (22.0)	10 (16.9)
Sepsis	3 (5.1)	1 (1.7)	2 (3.4)
Candida infection	2 (3.4)	0	1 (1.7)
Encephalitis	2 (3.4)	0	2 (3.4)
Gastroenteritis	2 (3.4)	2 (3.4)	0
Pneumonia	2 (3.4)	1 (1.7)	1 (1.7)
Septic shock	2 (3.4)	0	2 (3.4)
Staphylococcal bacteraemia	2 (3.4)	2 (3.4)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	1 (1.7)
Clostridium difficile colitis	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (1.7)	1 (1.7)	0
Device related infection	1 (1.7)	1 (1.7)	0
Device related sepsis	1 (1.7)	1 (1.7)	0
Gastroenteritis escherichia coli	1 (1.7)	1 (1.7)	0
Gastroenteritis salmonella	1 (1.7)	1 (1.7)	0
Herpes zoster	1 (1.7)	1 (1.7)	0
Meningitis pneumococcal	1 (1.7)	1 (1.7)	0
Metapneumovirus infection	1 (1.7)	1 (1.7)	0
Ophthalmic herpes zoster	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0
Pneumocystis jirovecii pneumonia	1 (1.7)	0	1 (1.7)
Pneumonia fungal	1 (1.7)	1 (1.7)	0
Pneumonia respiratory syncytial viral	1 (1.7)	1 (1.7)	0
Pneumonia viral	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0
Sinusitis	1 (1.7)	1 (1.7)	0
Soft tissue infection	1 (1.7)	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.7)	0	1 (1.7)
Upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	2 (3.4)	1 (1.7)	1 (1.7)
Infusion related reaction	1 (1.7)	1 (1.7)	0
Vasoplegia syndrome	1 (1.7)	0	1 (1.7)
Investigations			
-Total	3 (5.1)	2 (3.4)	1 (1.7)
Aspartate aminotransferase increased	2 (3.4)	2 (3.4)	0
Blood bilirubin increased	1 (1.7)	1 (1.7)	0
Blood uric acid increased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	4 (6.8)	0	3 (5.1)
Decreased appetite	1 (1.7)	0	1 (1.7)
Dehydration	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (1.7)	0	1 (1.7)
Tumour lysis syndrome	1 (1.7)	0	1 (1.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (3.4)	1 (1.7)	1 (1.7)
Back pain	1 (1.7)	1 (1.7)	0
Rhabdomyolysis	1 (1.7)	0	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.4)	2 (3.4)	0
Bone giant cell tumour benign	1 (1.7)	1 (1.7)	0
Myelodysplastic syndrome	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	7 (11.9)	5 (8.5)	2 (3.4)
Headache	2 (3.4)	2 (3.4)	0
Cerebral haemorrhage	1 (1.7)	0	1 (1.7)
Dysarthria	1 (1.7)	1 (1.7)	0
Encephalopathy	1 (1.7)	1 (1.7)	0
Hydrocephalus	1 (1.7)	0	1 (1.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorder	1 (1.7)	1 (1.7)	0
Seizure	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	2 (3.4)	1 (1.7)	0
Delirium	1 (1.7)	1 (1.7)	0
Mental status changes	1 (1.7)	0	0
Renal and urinary disorders			
-Total	6 (10.2)	2 (3.4)	4 (6.8)
Acute kidney injury	5 (8.5)	2 (3.4)	3 (5.1)
Renal failure	1 (1.7)	0	1 (1.7)
Renal tubular necrosis	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (23.7)	3 (5.1)	9 (15.3)
Respiratory failure	4 (6.8)	0	4 (6.8)
Hypoxia	3 (5.1)	2 (3.4)	1 (1.7)
Acute respiratory distress syndrome	2 (3.4)	0	2 (3.4)
Respiratory distress	2 (3.4)	0	1 (1.7)
Acute respiratory failure	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (1.7)	0	1 (1.7)
Dyspnoea exertional	1 (1.7)	0	0
Epistaxis	1 (1.7)	0	0
Laryngeal oedema	1 (1.7)	0	1 (1.7)
Pleural effusion	1 (1.7)	1 (1.7)	0
Pulmonary oedema	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	6 (10.2)	1 (1.7)	5 (8.5)
Hypotension	6 (10.2)	1 (1.7)	5 (8.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (70.0)	3 (30.0)	4 (40.0)
Blood and lymphatic system disorders			
-Total	2 (20.0)	2 (20.0)	0
Disseminated intravascular coagulation	1 (10.0)	1 (10.0)	0
Febrile neutropenia	1 (10.0)	1 (10.0)	0
Cardiac disorders			
-Total	1 (10.0)	0	1 (10.0)
Cardiac arrest	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	1 (10.0)	0	0
Diarrhoea	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (10.0)	0	0
General disorders and administration site conditions			
-Total	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatomegaly	1 (10.0)	0	1 (10.0)
Immune system disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Cytokine release syndrome	4 (40.0)	1 (10.0)	3 (30.0)
Infections and infestations			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Cytomegalovirus infection reactivation	1 (10.0)	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	1 (10.0)
Human herpesvirus 6 infection	1 (10.0)	1 (10.0)	0
Meningitis bacterial	1 (10.0)	1 (10.0)	0
Upper respiratory tract infection	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	0	1 (10.0)
Hypercalcaemia	1 (10.0)	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	1 (10.0)
Metabolic acidosis	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (10.0)	1 (10.0)	0
Back pain	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders			
-Total	1 (10.0)	1 (10.0)	0
Endometriosis	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (100)	1 (9.1)	10 (90.9)
Blood and lymphatic system disorders			
-Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	3 (27.3)	3 (27.3)	0
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiac arrest	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	2 (18.2)	1 (9.1)	0
Constipation	1 (9.1)	0	0
Nausea	1 (9.1)	0	0
Pancreatitis	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	2 (18.2)
Multiple organ dysfunction syndrome	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	1 (9.1)	0
Non-cardiac chest pain	1 (9.1)	0	0
Immune system disorders			
-Total	10 (90.9)	1 (9.1)	7 (63.6)
Cytokine release syndrome	9 (81.8)	1 (9.1)	6 (54.5)
Allergy to immunoglobulin therapy	1 (9.1)	1 (9.1)	0
Haemophagocytic lymphohistiocytosis	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Bacteraemia	1 (9.1)	0	1 (9.1)
Covid-19 pneumonia	1 (9.1)	0	1 (9.1)
Encephalitis viral	1 (9.1)	1 (9.1)	0
Enterobacter infection	1 (9.1)	1 (9.1)	0
Herpes zoster	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (9.1)	1 (9.1)	0
Mastoiditis	1 (9.1)	1 (9.1)	0
Otitis externa	1 (9.1)	1 (9.1)	0
Otitis media	1 (9.1)	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	1 (9.1)	0	1 (9.1)
Electrocardiogram qt prolonged	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	3 (27.3)	3 (27.3)	0
Hypokalaemia	1 (9.1)	1 (9.1)	0
Malnutrition	1 (9.1)	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	1 (9.1)	0
Back pain	1 (9.1)	0	0
Haemarthrosis	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	1 (9.1)	0	0
Cognitive disorder	1 (9.1)	0	0
Psychiatric disorders			
-Total	1 (9.1)	1 (9.1)	0
Mental status changes	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	1 (9.1)	1 (9.1)
Bronchial oedema	1 (9.1)	0	0
Hypoxia	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	3 (27.3)	0	3 (27.3)

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	2 (18.2)	0	2 (18.2)
Venoocclusive disease	1 (9.1)	0	1 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (86.7)	3 (20.0)	9 (60.0)
Blood and lymphatic system disorders			
-Total	6 (40.0)	5 (33.3)	1 (6.7)
Febrile neutropenia	5 (33.3)	4 (26.7)	1 (6.7)
Coagulopathy	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	0	0
Gastrointestinal disorders			
-Total	2 (13.3)	0	1 (6.7)
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)
Constipation	1 (6.7)	0	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	0	1 (6.7)
Multiple organ dysfunction syndrome	1 (6.7)	0	1 (6.7)
Immune system disorders			
-Total	13 (86.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	1 (6.7)	8 (53.3)
Infections and infestations			
-Total	3 (20.0)	2 (13.3)	0
Encephalitis viral	1 (6.7)	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	0
Staphylococcal bacteraemia	1 (6.7)	1 (6.7)	0
Investigations			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Aspartate aminotransferase increased	1 (6.7)	1 (6.7)	0
Blood bilirubin increased	1 (6.7)	1 (6.7)	0
Electrocardiogram qt prolonged	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	1 (6.7)	1 (6.7)	0
Tumour lysis syndrome	1 (6.7)	1 (6.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (6.7)	1 (6.7)	0
Haemarthrosis	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	2 (13.3)	0	1 (6.7)
Cerebral haemorrhage	1 (6.7)	0	1 (6.7)
Cognitive disorder	1 (6.7)	0	0
Renal and urinary disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Acute kidney injury	2 (13.3)	1 (6.7)	1 (6.7)
Renal failure	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Acute respiratory failure	1 (6.7)	1 (6.7)	0
Hypoxia	1 (6.7)	0	1 (6.7)
Pleural effusion	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Hypotension	3 (20.0)	1 (6.7)	2 (13.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	41 (63.1)	19 (29.2)	18 (27.7)
Blood and lymphatic system disorders			
-Total	10 (15.4)	9 (13.8)	1 (1.5)
Febrile neutropenia	8 (12.3)	8 (12.3)	0
Disseminated intravascular coagulation	1 (1.5)	1 (1.5)	0
Pancytopenia	1 (1.5)	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	1 (1.5)
Cardiac disorders			
-Total	5 (7.7)	1 (1.5)	3 (4.6)
Atrioventricular block first degree	1 (1.5)	0	0
Cardiac arrest	1 (1.5)	0	1 (1.5)
Cardiac failure	1 (1.5)	0	1 (1.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.5)	1 (1.5)	0
Tachycardia	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	3 (4.6)	3 (4.6)	0
Diarrhoea	1 (1.5)	1 (1.5)	0
Neutropenic colitis	1 (1.5)	1 (1.5)	0
Pancreatitis	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	4 (6.2)	0	1 (1.5)
Pyrexia	3 (4.6)	0	0
Multiple organ dysfunction syndrome	1 (1.5)	0	1 (1.5)
Systemic inflammatory response syndrome	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	2 (3.1)	0	2 (3.1)
Cholestasis	1 (1.5)	0	1 (1.5)
Hepatomegaly	1 (1.5)	0	1 (1.5)
Immune system disorders			

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	37 (56.9)	15 (23.1)	13 (20.0)
Cytokine release syndrome	37 (56.9)	15 (23.1)	13 (20.0)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)
Infections and infestations			
-Total	8 (12.3)	5 (7.7)	3 (4.6)
Candida infection	1 (1.5)	0	1 (1.5)
Encephalitis	1 (1.5)	0	1 (1.5)
Encephalitis viral	1 (1.5)	0	1 (1.5)
Klebsiella infection	1 (1.5)	1 (1.5)	0
Meningitis bacterial	1 (1.5)	1 (1.5)	0
Pneumonia fungal	1 (1.5)	1 (1.5)	0
Pneumonia viral	1 (1.5)	1 (1.5)	0
Soft tissue infection	1 (1.5)	1 (1.5)	0
Varicella zoster virus infection	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	1 (1.5)	0	1 (1.5)
Vasoplegia syndrome	1 (1.5)	0	1 (1.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (1.5)	1 (1.5)	0
Aspartate aminotransferase increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	3 (4.6)	0	2 (3.1)
Dehydration	1 (1.5)	0	0
Hypercalcaemia	1 (1.5)	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	1 (1.5)
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hyperphosphataemia	1 (1.5)	0	1 (1.5)
Metabolic acidosis	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.5)	0	1 (1.5)
Rhabdomyolysis	1 (1.5)	0	1 (1.5)
Nervous system disorders			
-Total	3 (4.6)	3 (4.6)	0
Dysarthria	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (1.5)	1 (1.5)	0
Headache	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	1 (1.5)	1 (1.5)	0
Delirium	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	2 (3.1)	1 (1.5)	1 (1.5)
Acute kidney injury	2 (3.1)	1 (1.5)	1 (1.5)
Renal tubular necrosis	1 (1.5)	0	1 (1.5)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (9.2)	2 (3.1)	3 (4.6)
Hypoxia	2 (3.1)	1 (1.5)	1 (1.5)
Respiratory failure	2 (3.1)	0	2 (3.1)
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Dyspnoea	1 (1.5)	0	1 (1.5)
Pleural effusion	1 (1.5)	1 (1.5)	0
Pulmonary oedema	1 (1.5)	1 (1.5)	0
Respiratory distress	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	5 (7.7)	1 (1.5)	4 (6.2)
Hypotension	5 (7.7)	1 (1.5)	4 (6.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (42.9)	3 (21.4)	3 (21.4)
Blood and lymphatic system disorders			
-Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiac arrest	1 (7.1)	0	1 (7.1)
Cardiac failure	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
-Total	1 (7.1)	0	0
Nausea	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (14.3)	1 (7.1)	0
Non-cardiac chest pain	1 (7.1)	0	0
Pyrexia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	1 (7.1)	1 (7.1)	0
Allergy to immunoglobulin therapy	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Bacteraemia	1 (7.1)	0	1 (7.1)
Pharyngitis streptococcal	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Septic shock	1 (7.1)	0	1 (7.1)
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Malnutrition	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	1 (7.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (14.3)	1 (7.1)	0
Back pain	2 (14.3)	1 (7.1)	0
Psychiatric disorders			
-Total	1 (7.1)	0	0
Mental status changes	1 (7.1)	0	0
Renal and urinary disorders			
-Total	1 (7.1)	0	1 (7.1)
Acute kidney injury	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	0	1 (7.1)
Acute respiratory distress syndrome	1 (7.1)	0	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchial oedema	1 (7.1)	0	0
Vascular disorders			
-Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	17 (27.9)	9 (14.8)	8 (13.1)
Blood and lymphatic system disorders			
-Total	3 (4.9)	3 (4.9)	0
Febrile neutropenia	2 (3.3)	2 (3.3)	0
Disseminated intravascular coagulation	1 (1.6)	1 (1.6)	0
Cardiac disorders			
-Total	1 (1.6)	0	1 (1.6)
Cardiac arrest	1 (1.6)	0	1 (1.6)
Gastrointestinal disorders			
-Total	2 (3.3)	1 (1.6)	0
Diarrhoea	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (1.6)	1 (1.6)	0
Vomiting	1 (1.6)	0	0
General disorders and administration site conditions			
-Total	3 (4.9)	0	0
Pyrexia	3 (4.9)	0	0
Infections and infestations			
-Total	12 (19.7)	7 (11.5)	5 (8.2)
Gastroenteritis	2 (3.3)	2 (3.3)	0
Bronchopulmonary aspergillosis	1 (1.6)	0	1 (1.6)
Cytomegalovirus infection reactivation	1 (1.6)	1 (1.6)	0
Device related infection	1 (1.6)	1 (1.6)	0
Encephalitis	1 (1.6)	0	1 (1.6)
Enterobacter infection	1 (1.6)	1 (1.6)	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	1 (1.6)	0
Klebsiella infection	1 (1.6)	1 (1.6)	0
Mastoiditis	1 (1.6)	1 (1.6)	0
Metapneumovirus infection	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.6)	1 (1.6)	0
Otitis media	1 (1.6)	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	1 (1.6)
Pneumonia	1 (1.6)	0	1 (1.6)
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	1 (1.6)	0
Sinusitis	1 (1.6)	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Viral haemorrhagic cystitis	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	1 (1.6)	1 (1.6)	0
Hypokalaemia	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Back pain	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.6)	1 (1.6)	0
Myelodysplastic syndrome	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	1 (1.6)	0	1 (1.6)
Hydrocephalus	1 (1.6)	0	1 (1.6)
Psychiatric disorders			
-Total	1 (1.6)	1 (1.6)	0
Mental status changes	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (6.6)	2 (3.3)	2 (3.3)
Hypoxia	2 (3.3)	2 (3.3)	0
Epistaxis	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	1 (1.6)
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
-Total	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	1 (1.6)	0	1 (1.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (34.9)	8 (18.6)	6 (14.0)
Gastrointestinal disorders			
-Total	1 (2.3)	0	0
Irritable bowel syndrome	1 (2.3)	0	0
General disorders and administration site conditions			
-Total	3 (7.0)	0	1 (2.3)
Pyrexia	2 (4.7)	0	0
Multiple organ dysfunction syndrome	1 (2.3)	0	1 (2.3)
Immune system disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Drug hypersensitivity	1 (2.3)	1 (2.3)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)
Infections and infestations			
-Total	13 (30.2)	8 (18.6)	4 (9.3)
Sepsis	3 (7.0)	1 (2.3)	2 (4.7)
Candida infection	1 (2.3)	0	0
Clostridium difficile colitis	1 (2.3)	1 (2.3)	0
Covid-19	1 (2.3)	1 (2.3)	0
Covid-19 pneumonia	1 (2.3)	0	1 (2.3)
Device related sepsis	1 (2.3)	1 (2.3)	0
Gastroenteritis escherichia coli	1 (2.3)	1 (2.3)	0
Gastroenteritis salmonella	1 (2.3)	1 (2.3)	0
Herpes zoster	1 (2.3)	1 (2.3)	0
Meningitis pneumococcal	1 (2.3)	1 (2.3)	0
Ophthalmic herpes zoster	1 (2.3)	0	0
Pneumonia	1 (2.3)	1 (2.3)	0
Pneumonia respiratory syncytial viral	1 (2.3)	1 (2.3)	0
Rhinovirus infection	1 (2.3)	0	0
Septic shock	1 (2.3)	0	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (2.3)	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Injury, poisoning and procedural complications			
-Total	1 (2.3)	1 (2.3)	0
Infusion related reaction	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	1 (2.3)	0	1 (2.3)
Decreased appetite	1 (2.3)	0	1 (2.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.3)	1 (2.3)	0
Bone giant cell tumour benign	1 (2.3)	1 (2.3)	0
Nervous system disorders			
-Total	2 (4.7)	2 (4.7)	0
Headache	1 (2.3)	1 (2.3)	0
Nervous system disorder	1 (2.3)	1 (2.3)	0
Seizure	1 (2.3)	1 (2.3)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.3)	1 (2.3)	0
Endometriosis	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.0)	0	2 (4.7)
Dyspnoea exertional	1 (2.3)	0	0
Laryngeal oedema	1 (2.3)	0	1 (2.3)
Respiratory failure	1 (2.3)	0	1 (2.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (93.3)	2 (13.3)	11 (73.3)
Blood and lymphatic system disorders			
-Total	6 (40.0)	5 (33.3)	1 (6.7)
Febrile neutropenia	5 (33.3)	4 (26.7)	1 (6.7)
Coagulopathy	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	0	0
Cardiac disorders			
-Total	1 (6.7)	0	1 (6.7)
Cardiac arrest	1 (6.7)	0	1 (6.7)
Cardiac failure	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (13.3)	0	1 (6.7)
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)
Constipation	1 (6.7)	0	0
Nausea	1 (6.7)	0	0
General disorders and administration site conditions			
-Total	3 (20.0)	1 (6.7)	1 (6.7)
Multiple organ dysfunction syndrome	1 (6.7)	0	1 (6.7)
Non-cardiac chest pain	1 (6.7)	0	0
Pyrexia	1 (6.7)	1 (6.7)	0
Immune system disorders			
-Total	13 (86.7)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	1 (6.7)	8 (53.3)
Allergy to immunoglobulin therapy	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	5 (33.3)	3 (20.0)	2 (13.3)
Bacteraemia	1 (6.7)	0	1 (6.7)
Encephalitis viral	1 (6.7)	1 (6.7)	0
Pharyngitis streptococcal	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (6.7)	1 (6.7)	0
Rhinovirus infection	1 (6.7)	0	0
Septic shock	1 (6.7)	0	1 (6.7)
Staphylococcal bacteraemia	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Urinary tract infection	1 (6.7)	1 (6.7)	0
Viral upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Investigations			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Aspartate aminotransferase increased	1 (6.7)	1 (6.7)	0
Blood bilirubin increased	1 (6.7)	1 (6.7)	0
Blood uric acid increased	1 (6.7)	0	1 (6.7)
Electrocardiogram qt prolonged	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Tumour lysis syndrome	2 (13.3)	1 (6.7)	1 (6.7)
Malnutrition	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	3 (20.0)	2 (13.3)	0
Back pain	2 (13.3)	1 (6.7)	0
Haemarthrosis	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	2 (13.3)	0	1 (6.7)
Cerebral haemorrhage	1 (6.7)	0	1 (6.7)
Cognitive disorder	1 (6.7)	0	0
Psychiatric disorders			
-Total	1 (6.7)	0	0
Mental status changes	1 (6.7)	0	0
Renal and urinary disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Acute kidney injury	3 (20.0)	1 (6.7)	2 (13.3)
Renal failure	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (40.0)	1 (6.7)	4 (26.7)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Acute respiratory failure	1 (6.7)	1 (6.7)	0
Bronchial oedema	1 (6.7)	0	0
Hypoxia	1 (6.7)	0	1 (6.7)
Pleural effusion	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Vascular disorders			
-Total	3 (20.0)	0	3 (20.0)
Hypotension	3 (20.0)	0	3 (20.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	49 (75.4)	21 (32.3)	26 (40.0)
Blood and lymphatic system disorders			
-Total	12 (18.5)	11 (16.9)	1 (1.5)
Febrile neutropenia	10 (15.4)	10 (15.4)	0
Disseminated intravascular coagulation	2 (3.1)	2 (3.1)	0
Pancytopenia	1 (1.5)	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	1 (1.5)
Cardiac disorders			
-Total	6 (9.2)	1 (1.5)	4 (6.2)
Cardiac arrest	2 (3.1)	0	2 (3.1)
Atrioventricular block first degree	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.5)	0	1 (1.5)
Left ventricular dysfunction	1 (1.5)	1 (1.5)	0
Tachycardia	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	6 (9.2)	4 (6.2)	0
Diarrhoea	2 (3.1)	1 (1.5)	0
Pancreatitis	2 (3.1)	2 (3.1)	0
Irritable bowel syndrome	1 (1.5)	0	0
Neutropenic colitis	1 (1.5)	1 (1.5)	0
Vomiting	1 (1.5)	0	0
General disorders and administration site conditions			
-Total	8 (12.3)	0	2 (3.1)
Pyrexia	6 (9.2)	0	0
Multiple organ dysfunction syndrome	2 (3.1)	0	2 (3.1)
Systemic inflammatory response syndrome	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	2 (3.1)	0	2 (3.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (1.5)	0	1 (1.5)
Hepatomegaly	1 (1.5)	0	1 (1.5)
Immune system disorders			
-Total	38 (58.5)	15 (23.1)	14 (21.5)
Cytokine release syndrome	37 (56.9)	15 (23.1)	13 (20.0)
Haemophagocytic lymphohistiocytosis	2 (3.1)	0	2 (3.1)
Drug hypersensitivity	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	26 (40.0)	15 (23.1)	11 (16.9)
Sepsis	3 (4.6)	1 (1.5)	2 (3.1)
Candida infection	2 (3.1)	0	1 (1.5)
Encephalitis	2 (3.1)	0	2 (3.1)
Gastroenteritis	2 (3.1)	2 (3.1)	0
Herpes zoster	2 (3.1)	2 (3.1)	0
Pneumonia	2 (3.1)	1 (1.5)	1 (1.5)
Upper respiratory tract infection	2 (3.1)	2 (3.1)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	1 (1.5)
Clostridium difficile colitis	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (1.5)	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	1 (1.5)
Cytomegalovirus infection reactivation	1 (1.5)	1 (1.5)	0
Device related infection	1 (1.5)	1 (1.5)	0
Device related sepsis	1 (1.5)	1 (1.5)	0
Encephalitis viral	1 (1.5)	0	1 (1.5)
Enterobacter infection	1 (1.5)	1 (1.5)	0
Gastroenteritis escherichia coli	1 (1.5)	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	1 (1.5)	0
Klebsiella infection	1 (1.5)	1 (1.5)	0
Mastoiditis	1 (1.5)	1 (1.5)	0
Meningitis bacterial	1 (1.5)	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	0
Otitis externa	1 (1.5)	1 (1.5)	0
Otitis media	1 (1.5)	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	1 (1.5)	0	1 (1.5)
Pneumonia fungal	1 (1.5)	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	1 (1.5)	0
Pneumonia viral	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	1 (1.5)	0
Rhinovirus infection	1 (1.5)	1 (1.5)	0
Septic shock	1 (1.5)	0	1 (1.5)
Sinusitis	1 (1.5)	1 (1.5)	0
Soft tissue infection	1 (1.5)	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	1 (1.5)
Varicella zoster virus infection	1 (1.5)	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	2 (3.1)	1 (1.5)	1 (1.5)
Infusion related reaction	1 (1.5)	1 (1.5)	0
Vasoplegia syndrome	1 (1.5)	0	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (1.5)	1 (1.5)	0
Aspartate aminotransferase increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	5 (7.7)	1 (1.5)	3 (4.6)
Decreased appetite	1 (1.5)	0	1 (1.5)
Dehydration	1 (1.5)	0	0
Hypercalcaemia	1 (1.5)	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	1 (1.5)
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hyperphosphataemia	1 (1.5)	0	1 (1.5)
Hypokalaemia	1 (1.5)	1 (1.5)	0
Metabolic acidosis	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (3.1)	1 (1.5)	1 (1.5)
Back pain	1 (1.5)	1 (1.5)	0
Rhabdomyolysis	1 (1.5)	0	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.1)	2 (3.1)	0
Bone giant cell tumour benign	1 (1.5)	1 (1.5)	0
Myelodysplastic syndrome	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	6 (9.2)	5 (7.7)	1 (1.5)
Headache	2 (3.1)	2 (3.1)	0
Dysarthria	1 (1.5)	1 (1.5)	0
Encephalopathy	1 (1.5)	1 (1.5)	0
Hydrocephalus	1 (1.5)	0	1 (1.5)
Nervous system disorder	1 (1.5)	1 (1.5)	0
Seizure	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	2 (3.1)	2 (3.1)	0
Delirium	1 (1.5)	1 (1.5)	0
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	2 (3.1)	1 (1.5)	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (3.1)	1 (1.5)	1 (1.5)
Renal tubular necrosis	1 (1.5)	0	1 (1.5)
Reproductive system and breast disorders			
-Total	1 (1.5)	1 (1.5)	0
Endometriosis	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	12 (18.5)	3 (4.6)	7 (10.8)
Hypoxia	4 (6.2)	3 (4.6)	1 (1.5)
Respiratory failure	4 (6.2)	0	4 (6.2)
Respiratory distress	2 (3.1)	0	1 (1.5)
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Dyspnoea	1 (1.5)	0	1 (1.5)
Dyspnoea exertional	1 (1.5)	0	0
Epistaxis	1 (1.5)	0	0
Laryngeal oedema	1 (1.5)	0	1 (1.5)
Pleural effusion	1 (1.5)	1 (1.5)	0
Pulmonary oedema	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	6 (9.2)	1 (1.5)	5 (7.7)
Hypotension	5 (7.7)	1 (1.5)	4 (6.2)
Venoocclusive disease	1 (1.5)	0	1 (1.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)
General disorders and administration site conditions			
-Total	2 (33.3)	0	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)
Encephalitis	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypernatraemia	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Renal tubular necrosis	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	49 (66.2)	21 (28.4)	24 (32.4)
Blood and lymphatic system disorders			
-Total	13 (17.6)	12 (16.2)	1 (1.4)
Febrile neutropenia	11 (14.9)	11 (14.9)	0
Disseminated intravascular coagulation	2 (2.7)	1 (1.4)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	4 (5.4)	1 (1.4)	2 (2.7)
Atrioventricular block first degree	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	1 (1.4)
Cardiac failure	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	5 (6.8)	3 (4.1)	1 (1.4)
Abdominal compartment syndrome	1 (1.4)	0	1 (1.4)
Constipation	1 (1.4)	0	0
Diarrhoea	1 (1.4)	1 (1.4)	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	3 (4.1)	0	1 (1.4)
Pyrexia	2 (2.7)	0	0
Multiple organ dysfunction syndrome	1 (1.4)	0	1 (1.4)
Hepatobiliary disorders			
-Total	1 (1.4)	0	1 (1.4)
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	46 (62.2)	16 (21.6)	19 (25.7)
Cytokine release syndrome	46 (62.2)	16 (21.6)	19 (25.7)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	10 (13.5)	7 (9.5)	2 (2.7)
Encephalitis viral	2 (2.7)	1 (1.4)	1 (1.4)
Candida infection	1 (1.4)	0	1 (1.4)
Klebsiella infection	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Aspartate aminotransferase increased	2 (2.7)	2 (2.7)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.1)	1 (1.4)	1 (1.4)
Dehydration	1 (1.4)	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	1 (1.4)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Haemarthrosis	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	4 (5.4)	2 (2.7)	1 (1.4)
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Headache	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Acute kidney injury	2 (2.7)	1 (1.4)	1 (1.4)
Renal failure	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (10.8)	2 (2.7)	5 (6.8)
Hypoxia	3 (4.1)	1 (1.4)	2 (2.7)
Respiratory failure	3 (4.1)	0	3 (4.1)
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0
Respiratory distress	1 (1.4)	0	0
Vascular disorders			
-Total	7 (9.5)	2 (2.7)	5 (6.8)
Hypotension	7 (9.5)	2 (2.7)	5 (6.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (32.9)	12 (17.1)	11 (15.7)
Blood and lymphatic system disorders			
-Total	4 (5.7)	4 (5.7)	0
Febrile neutropenia	3 (4.3)	3 (4.3)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.9)	0	2 (2.9)
Cardiac arrest	2 (2.9)	0	2 (2.9)
Cardiac failure	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	3 (4.3)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (1.4)	0	0
Nausea	1 (1.4)	0	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	5 (7.1)	1 (1.4)	0
Pyrexia	4 (5.7)	1 (1.4)	0
Non-cardiac chest pain	1 (1.4)	0	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	16 (22.9)	9 (12.9)	7 (10.0)
Gastroenteritis	2 (2.9)	2 (2.9)	0
Respiratory syncytial virus infection	2 (2.9)	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	2 (2.9)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related infection	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Septic shock	1 (1.4)	0	1 (1.4)
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.4)	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.3)	2 (2.9)	0
Back pain	3 (4.3)	2 (2.9)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (1.4)	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	1 (1.4)
Psychiatric disorders			
-Total	2 (2.9)	1 (1.4)	0
Mental status changes	2 (2.9)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.6)	2 (2.9)	3 (4.3)
Hypoxia	2 (2.9)	2 (2.9)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.9)	0	2 (2.9)
Hypotension	1 (1.4)	0	1 (1.4)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	0
Irritable bowel syndrome	1 (33.3)	0	0
General disorders and administration site conditions			
-Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (33.3)	1 (33.3)	0
Pneumonia	1 (33.3)	1 (33.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (29.8)	7 (14.9)	6 (12.8)
General disorders and administration site conditions			
-Total	2 (4.3)	0	1 (2.1)
Multiple organ dysfunction syndrome	1 (2.1)	0	1 (2.1)
Pyrexia	1 (2.1)	0	0
Immune system disorders			
-Total	2 (4.3)	1 (2.1)	1 (2.1)
Drug hypersensitivity	1 (2.1)	1 (2.1)	0
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	1 (2.1)
Infections and infestations			

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (25.5)	7 (14.9)	4 (8.5)
Sepsis	3 (6.4)	1 (2.1)	2 (4.3)
Candida infection	1 (2.1)	0	0
Covid-19	1 (2.1)	1 (2.1)	0
Covid-19 pneumonia	1 (2.1)	0	1 (2.1)
Device related sepsis	1 (2.1)	1 (2.1)	0
Herpes zoster	1 (2.1)	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	0
Pneumonia respiratory syncytial viral	1 (2.1)	1 (2.1)	0
Rhinovirus infection	1 (2.1)	0	0
Septic shock	1 (2.1)	0	1 (2.1)
Staphylococcal abscess	1 (2.1)	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Upper respiratory tract infection	1 (2.1)	1 (2.1)	0
Injury, poisoning and procedural complications			
-Total	1 (2.1)	1 (2.1)	0
Infusion related reaction	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (2.1)	0	1 (2.1)
Decreased appetite	1 (2.1)	0	1 (2.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.1)	1 (2.1)	0
Bone giant cell tumour benign	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	2 (4.3)	2 (4.3)	0
Headache	1 (2.1)	1 (2.1)	0
Nervous system disorder	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	1 (2.1)	0
Reproductive system and breast disorders			
-Total	1 (2.1)	1 (2.1)	0
Endometriosis	1 (2.1)	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.4)	0	2 (4.3)
Dyspnoea exertional	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (2.1)	0	1 (2.1)
Respiratory failure	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			
-Total	1 (16.7)	0	0
Irritable bowel syndrome	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (33.3)	0	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	1 (16.7)	0
Encephalitis	1 (16.7)	0	1 (16.7)
Gastroenteritis escherichia coli	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (16.7)	1 (16.7)	0
Pneumonia	1 (16.7)	1 (16.7)	0
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypernatraemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	58 (78.4)	21 (28.4)	34 (45.9)
Blood and lymphatic system disorders			
-Total	15 (20.3)	14 (18.9)	1 (1.4)
Febrile neutropenia	13 (17.6)	13 (17.6)	0
Disseminated intravascular coagulation	3 (4.1)	2 (2.7)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	6 (8.1)	1 (1.4)	4 (5.4)
Cardiac arrest	3 (4.1)	0	3 (4.1)
Cardiac failure	2 (2.7)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.4)	0	0
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	7 (9.5)	4 (5.4)	1 (1.4)
Diarrhoea	2 (2.7)	1 (1.4)	0
Pancreatitis	2 (2.7)	2 (2.7)	0
Abdominal compartment syndrome	1 (1.4)	0	1 (1.4)
Constipation	1 (1.4)	0	0
Nausea	1 (1.4)	0	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	9 (12.2)	1 (1.4)	2 (2.7)
Pyrexia	6 (8.1)	1 (1.4)	0
Multiple organ dysfunction syndrome	2 (2.7)	0	2 (2.7)
Non-cardiac chest pain	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	1 (1.4)	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	47 (63.5)	16 (21.6)	20 (27.0)
Cytokine release syndrome	46 (62.2)	16 (21.6)	19 (25.7)
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	1 (1.4)	1 (1.4)	0
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)
Infections and infestations			
-Total	29 (39.2)	17 (23.0)	12 (16.2)
Sepsis	3 (4.1)	1 (1.4)	2 (2.7)
Upper respiratory tract infection	3 (4.1)	3 (4.1)	0
Candida infection	2 (2.7)	0	1 (1.4)
Encephalitis viral	2 (2.7)	1 (1.4)	1 (1.4)
Gastroenteritis	2 (2.7)	2 (2.7)	0
Herpes zoster	2 (2.7)	2 (2.7)	0
Respiratory syncytial virus infection	2 (2.7)	2 (2.7)	0
Rhinovirus infection	2 (2.7)	1 (1.4)	0
Septic shock	2 (2.7)	0	2 (2.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Covid-19	1 (1.4)	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related infection	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	1 (1.4)	1 (1.4)	0
Infusion related reaction	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	4 (5.4)	2 (2.7)	2 (2.7)
Aspartate aminotransferase increased	2 (2.7)	2 (2.7)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Electrocardiogram qt prolonged	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	7 (9.5)	3 (4.1)	3 (4.1)
Tumour lysis syndrome	2 (2.7)	1 (1.4)	1 (1.4)
Decreased appetite	1 (1.4)	0	1 (1.4)
Dehydration	1 (1.4)	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	4 (5.4)	3 (4.1)	0
Back pain	3 (4.1)	2 (2.7)	0
Haemarthrosis	1 (1.4)	1 (1.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.7)	2 (2.7)	0
Bone giant cell tumour benign	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	7 (9.5)	4 (5.4)	2 (2.7)
Headache	2 (2.7)	2 (2.7)	0
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Hydrocephalus	1 (1.4)	0	1 (1.4)
Nervous system disorder	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	3 (4.1)	2 (2.7)	0
Mental status changes	2 (2.7)	1 (1.4)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	4 (5.4)	1 (1.4)	3 (4.1)
Acute kidney injury	3 (4.1)	1 (1.4)	2 (2.7)
Renal failure	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	1 (1.4)	1 (1.4)	0
Endometriosis	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (21.6)	3 (4.1)	10 (13.5)
Hypoxia	5 (6.8)	3 (4.1)	2 (2.7)
Respiratory failure	5 (6.8)	0	5 (6.8)
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)
Respiratory distress	2 (2.7)	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Dyspnoea exertional	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	8 (10.8)	1 (1.4)	7 (9.5)
Hypotension	7 (9.5)	1 (1.4)	6 (8.1)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Pancytopenia	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (50.0)	0	1 (50.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	52 (66.7)	21 (26.9)	26 (33.3)
Blood and lymphatic system disorders			
-Total	15 (19.2)	13 (16.7)	2 (2.6)
Febrile neutropenia	13 (16.7)	12 (15.4)	1 (1.3)
Disseminated intravascular coagulation	2 (2.6)	1 (1.3)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	5 (6.4)	1 (1.3)	3 (3.8)
Atrioventricular block first degree	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	1 (1.3)
Cardiac failure	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	5 (6.4)	3 (3.8)	1 (1.3)
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Diarrhoea	1 (1.3)	1 (1.3)	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Pancreatitis	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			
-Total	5 (6.4)	0	2 (2.6)
Pyrexia	3 (3.8)	0	0
Multiple organ dysfunction syndrome	2 (2.6)	0	2 (2.6)
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.6)	0	2 (2.6)
Cholestasis	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	48 (61.5)	15 (19.2)	20 (25.6)
Cytokine release syndrome	48 (61.5)	15 (19.2)	20 (25.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	1 (1.3)
Infections and infestations			
-Total	11 (14.1)	7 (9.0)	3 (3.8)
Encephalitis viral	2 (2.6)	1 (1.3)	1 (1.3)
Candida infection	1 (1.3)	0	1 (1.3)
Encephalitis	1 (1.3)	0	1 (1.3)
Klebsiella infection	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (1.3)	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	3 (3.8)	2 (2.6)	1 (1.3)
Aspartate aminotransferase increased	2 (2.6)	2 (2.6)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	3 (3.8)	0	2 (2.6)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Metabolic acidosis	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.6)	1 (1.3)	1 (1.3)
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Nervous system disorders			
-Total	5 (6.4)	3 (3.8)	1 (1.3)
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Headache	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	5 (6.4)	2 (2.6)	3 (3.8)
Acute kidney injury	4 (5.1)	2 (2.6)	2 (2.6)
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	9 (11.5)	3 (3.8)	5 (6.4)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.6)
Respiratory failure	3 (3.8)	0	3 (3.8)
Acute respiratory distress syndrome	1 (1.3)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Pleural effusion	1 (1.3)	1 (1.3)	0
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Respiratory distress	1 (1.3)	0	0
Vascular disorders			
-Total	8 (10.3)	2 (2.6)	6 (7.7)
Hypotension	8 (10.3)	2 (2.6)	6 (7.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	1 (50.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	1 (50.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	21 (28.8)	11 (15.1)	10 (13.7)
Blood and lymphatic system disorders			
-Total	3 (4.1)	3 (4.1)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Cardiac disorders			
-Total	2 (2.7)	0	2 (2.7)
Cardiac arrest	2 (2.7)	0	2 (2.7)
Cardiac failure	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	3 (4.1)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0
Nausea	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	4 (5.5)	0	0
Pyrexia	3 (4.1)	0	0
Non-cardiac chest pain	1 (1.4)	0	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	14 (19.2)	8 (11.0)	6 (8.2)
Gastroenteritis	2 (2.7)	2 (2.7)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related infection	1 (1.4)	1 (1.4)	0
Enterobacter infection	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Septic shock	1 (1.4)	0	1 (1.4)
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Urinary tract infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.1)	2 (2.7)	0
Back pain	3 (4.1)	2 (2.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	1 (1.4)	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	1 (1.4)
Psychiatric disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.7)	1 (1.4)	0
Mental status changes	2 (2.7)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.2)	2 (2.7)	3 (4.1)
Hypoxia	2 (2.7)	2 (2.7)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	2 (2.7)	0	2 (2.7)
Hypotension	1 (1.4)	0	1 (1.4)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Sepsis	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=48	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (29.2)	8 (16.7)	5 (10.4)
Gastrointestinal disorders			
-Total	1 (2.1)	0	0
Irritable bowel syndrome	1 (2.1)	0	0
General disorders and administration site conditions			
-Total	3 (6.3)	0	1 (2.1)
Pyrexia	2 (4.2)	0	0
Multiple organ dysfunction syndrome	1 (2.1)	0	1 (2.1)
Immune system disorders			
-Total	2 (4.2)	1 (2.1)	1 (2.1)
Drug hypersensitivity	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	1 (2.1)
Infections and infestations			
-Total	12 (25.0)	7 (14.6)	4 (8.3)
Sepsis	2 (4.2)	0	2 (4.2)
Candida infection	1 (2.1)	0	0
Clostridium difficile colitis	1 (2.1)	1 (2.1)	0
Covid-19	1 (2.1)	1 (2.1)	0
Covid-19 pneumonia	1 (2.1)	0	1 (2.1)
Device related sepsis	1 (2.1)	1 (2.1)	0
Gastroenteritis escherichia coli	1 (2.1)	1 (2.1)	0
Gastroenteritis salmonella	1 (2.1)	1 (2.1)	0
Herpes zoster	1 (2.1)	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	0
Pneumonia	1 (2.1)	1 (2.1)	0
Pneumonia respiratory syncytial viral	1 (2.1)	1 (2.1)	0
Rhinovirus infection	1 (2.1)	0	0
Septic shock	1 (2.1)	0	1 (2.1)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (2.1)	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Upper respiratory tract infection	1 (2.1)	1 (2.1)	0
Injury, poisoning and procedural complications			
-Total	1 (2.1)	1 (2.1)	0
Infusion related reaction	1 (2.1)	1 (2.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.1)	1 (2.1)	0
Bone giant cell tumour benign	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	2 (4.2)	2 (4.2)	0
Headache	1 (2.1)	1 (2.1)	0
Nervous system disorder	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	1 (2.1)	0
Reproductive system and breast disorders			
-Total	1 (2.1)	1 (2.1)	0
Endometriosis	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.3)	0	2 (4.2)
Dyspnoea exertional	1 (2.1)	0	0
Laryngeal oedema	1 (2.1)	0	1 (2.1)
Respiratory failure	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
Pancytopenia	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	1 (50.0)	0
Sepsis	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)
Tumour lysis syndrome	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pleural effusion	1 (50.0)	0	1 (50.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	61 (78.2)	23 (29.5)	35 (44.9)
Blood and lymphatic system disorders			
-Total	17 (21.8)	15 (19.2)	2 (2.6)
Febrile neutropenia	15 (19.2)	14 (17.9)	1 (1.3)
Disseminated intravascular coagulation	2 (2.6)	1 (1.3)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	7 (9.0)	1 (1.3)	5 (6.4)
Cardiac arrest	3 (3.8)	0	3 (3.8)
Cardiac failure	2 (2.6)	1 (1.3)	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.3)	0	0
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	8 (10.3)	4 (5.1)	1 (1.3)
Diarrhoea	2 (2.6)	1 (1.3)	0
Pancreatitis	2 (2.6)	2 (2.6)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	0
Nausea	1 (1.3)	0	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	0	0
General disorders and administration site conditions			
-Total	10 (12.8)	0	3 (3.8)
Pyrexia	6 (7.7)	0	0
Multiple organ dysfunction syndrome	3 (3.8)	0	3 (3.8)
Non-cardiac chest pain	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.6)	0	2 (2.6)
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	49 (62.8)	15 (19.2)	21 (26.9)
Cytokine release syndrome	48 (61.5)	15 (19.2)	20 (25.6)
Haemophagocytic lymphohistiocytosis	2 (2.6)	0	2 (2.6)
Allergy to immunoglobulin therapy	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	29 (37.2)	17 (21.8)	12 (15.4)
Candida infection	2 (2.6)	0	1 (1.3)
Encephalitis viral	2 (2.6)	1 (1.3)	1 (1.3)
Gastroenteritis	2 (2.6)	2 (2.6)	0
Herpes zoster	2 (2.6)	2 (2.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (2.6)	1 (1.3)	1 (1.3)
Rhinovirus infection	2 (2.6)	1 (1.3)	0
Sepsis	2 (2.6)	0	2 (2.6)
Septic shock	2 (2.6)	0	2 (2.6)
Staphylococcal bacteraemia	2 (2.6)	2 (2.6)	0
Upper respiratory tract infection	2 (2.6)	2 (2.6)	0
Bacteraemia	1 (1.3)	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	1 (1.3)	0
Covid-19	1 (1.3)	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	1 (1.3)	0
Device related infection	1 (1.3)	1 (1.3)	0
Device related sepsis	1 (1.3)	1 (1.3)	0
Encephalitis	1 (1.3)	0	1 (1.3)
Enterobacter infection	1 (1.3)	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.3)	1 (1.3)	0
Mastoiditis	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	0
Otitis externa	1 (1.3)	1 (1.3)	0
Otitis media	1 (1.3)	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	1 (1.3)
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	1 (1.3)	0
Sinusitis	1 (1.3)	1 (1.3)	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.3)	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	2 (2.6)	1 (1.3)	1 (1.3)
Infusion related reaction	1 (1.3)	1 (1.3)	0
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	4 (5.1)	2 (2.6)	2 (2.6)
Aspartate aminotransferase increased	2 (2.6)	2 (2.6)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Blood uric acid increased	1 (1.3)	0	1 (1.3)
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	6 (7.7)	2 (2.6)	3 (3.8)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Hypokalaemia	1 (1.3)	1 (1.3)	0
Malnutrition	1 (1.3)	1 (1.3)	0
Metabolic acidosis	1 (1.3)	0	1 (1.3)
Tumour lysis syndrome	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.4)	3 (3.8)	1 (1.3)
Back pain	3 (3.8)	2 (2.6)	0
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.6)	2 (2.6)	0
Bone giant cell tumour benign	1 (1.3)	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	1 (1.3)	0
Nervous system disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (10.3)	5 (6.4)	2 (2.6)
Headache	2 (2.6)	2 (2.6)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Hydrocephalus	1 (1.3)	0	1 (1.3)
Nervous system disorder	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	3 (3.8)	2 (2.6)	0
Mental status changes	2 (2.6)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	6 (7.7)	2 (2.6)	4 (5.1)
Acute kidney injury	5 (6.4)	2 (2.6)	3 (3.8)
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (1.3)	1 (1.3)	0
Endometriosis	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (21.8)	4 (5.1)	10 (12.8)
Hypoxia	5 (6.4)	3 (3.8)	2 (2.6)
Respiratory failure	5 (6.4)	0	5 (6.4)
Acute respiratory distress syndrome	2 (2.6)	0	2 (2.6)
Respiratory distress	2 (2.6)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Bronchial oedema	1 (1.3)	0	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Dyspnoea exertional	1 (1.3)	0	0
Epistaxis	1 (1.3)	0	0
Laryngeal oedema	1 (1.3)	0	1 (1.3)
Pleural effusion	1 (1.3)	1 (1.3)	0
Pulmonary oedema	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	9 (11.5)	1 (1.3)	8 (10.3)
Hypotension	8 (10.3)	1 (1.3)	7 (9.0)
Venoocclusive disease	1 (1.3)	0	1 (1.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	54 (68.4)	22 (27.8)	27 (34.2)
Blood and lymphatic system disorders			
-Total	16 (20.3)	14 (17.7)	2 (2.5)
Febrile neutropenia	13 (16.5)	12 (15.2)	1 (1.3)
Disseminated intravascular coagulation	2 (2.5)	1 (1.3)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	5 (6.3)	1 (1.3)	3 (3.8)
Atrioventricular block first degree	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.3)	0	1 (1.3)
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Diarrhoea	1 (1.3)	1 (1.3)	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Pancreatitis	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			
-Total	5 (6.3)	0	2 (2.5)
Pyrexia	3 (3.8)	0	0
Multiple organ dysfunction syndrome	2 (2.5)	0	2 (2.5)
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	0	2 (2.5)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	1 (1.3)
Infections and infestations			
-Total	11 (13.9)	7 (8.9)	3 (3.8)
Encephalitis viral	2 (2.5)	1 (1.3)	1 (1.3)
Candida infection	1 (1.3)	0	1 (1.3)
Encephalitis	1 (1.3)	0	1 (1.3)
Klebsiella infection	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	1 (1.3)	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	3 (3.8)	2 (2.5)	1 (1.3)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	4 (5.1)	1 (1.3)	2 (2.5)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Metabolic acidosis	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Nervous system disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Headache	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	5 (6.3)	2 (2.5)	3 (3.8)
Acute kidney injury	4 (5.1)	2 (2.5)	2 (2.5)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (12.7)	3 (3.8)	6 (7.6)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.5)
Respiratory failure	3 (3.8)	0	3 (3.8)
Pleural effusion	2 (2.5)	1 (1.3)	1 (1.3)
Acute respiratory distress syndrome	1 (1.3)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Respiratory distress	1 (1.3)	0	0
Vascular disorders			
-Total	8 (10.1)	2 (2.5)	6 (7.6)
Hypotension	8 (10.1)	2 (2.5)	6 (7.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (31.1)	12 (16.2)	11 (14.9)
Blood and lymphatic system disorders			
-Total	4 (5.4)	4 (5.4)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.7)	0	2 (2.7)
Cardiac arrest	2 (2.7)	0	2 (2.7)
Cardiac failure	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	3 (4.1)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (1.4)	0	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	5 (6.8)	1 (1.4)	0
Pyrexia	4 (5.4)	1 (1.4)	0
Non-cardiac chest pain	1 (1.4)	0	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	16 (21.6)	9 (12.2)	7 (9.5)
Gastroenteritis	2 (2.7)	2 (2.7)	0
Respiratory syncytial virus infection	2 (2.7)	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	2 (2.7)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Septic shock	1 (1.4)	0	1 (1.4)
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.1)	2 (2.7)	0
Back pain	3 (4.1)	2 (2.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	1 (1.4)
Psychiatric disorders			
-Total	2 (2.7)	1 (1.4)	0
Mental status changes	2 (2.7)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.1)	2 (2.7)	3 (4.1)
Hypoxia	2 (2.7)	2 (2.7)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	2 (2.7)	0	2 (2.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (1.4)	0	1 (1.4)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (30.0)	8 (16.0)	6 (12.0)
Gastrointestinal disorders			
-Total	1 (2.0)	0	0
Irritable bowel syndrome	1 (2.0)	0	0
General disorders and administration site conditions			
-Total	3 (6.0)	0	1 (2.0)
Pyrexia	2 (4.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	1 (2.0)
Immune system disorders			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Drug hypersensitivity	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)
Infections and infestations			
-Total	13 (26.0)	8 (16.0)	4 (8.0)
Sepsis	3 (6.0)	1 (2.0)	2 (4.0)
Candida infection	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	1 (2.0)	0
Covid-19	1 (2.0)	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	1 (2.0)
Device related sepsis	1 (2.0)	1 (2.0)	0
Gastroenteritis escherichia coli	1 (2.0)	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	1 (2.0)	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Meningitis pneumococcal	1 (2.0)	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	0
Pneumonia	1 (2.0)	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	0
Septic shock	1 (2.0)	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (2.0)	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Injury, poisoning and procedural complications			
-Total	1 (2.0)	1 (2.0)	0
Infusion related reaction	1 (2.0)	1 (2.0)	0
Metabolism and nutrition disorders			
-Total	1 (2.0)	0	1 (2.0)
Decreased appetite	1 (2.0)	0	1 (2.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	1 (2.0)	0
Bone giant cell tumour benign	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	2 (4.0)	2 (4.0)	0
Headache	1 (2.0)	1 (2.0)	0
Nervous system disorder	1 (2.0)	1 (2.0)	0
Seizure	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.0)	1 (2.0)	0
Endometriosis	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.0)	0	2 (4.0)
Dyspnoea exertional	1 (2.0)	0	0
Laryngeal oedema	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	63 (79.7)	23 (29.1)	37 (46.8)
Blood and lymphatic system disorders			
-Total	18 (22.8)	16 (20.3)	2 (2.5)
Febrile neutropenia	15 (19.0)	14 (17.7)	1 (1.3)
Disseminated intravascular coagulation	3 (3.8)	2 (2.5)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	7 (8.9)	1 (1.3)	5 (6.3)
Cardiac arrest	3 (3.8)	0	3 (3.8)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (2.5)	1 (1.3)	1 (1.3)
Atrioventricular block first degree	1 (1.3)	0	0
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	8 (10.1)	4 (5.1)	1 (1.3)
Diarrhoea	2 (2.5)	1 (1.3)	0
Pancreatitis	2 (2.5)	2 (2.5)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	0
Nausea	1 (1.3)	0	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	0	0
General disorders and administration site conditions			
-Total	11 (13.9)	1 (1.3)	3 (3.8)
Pyrexia	7 (8.9)	1 (1.3)	0
Multiple organ dysfunction syndrome	3 (3.8)	0	3 (3.8)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (1.3)	0	0
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	0	2 (2.5)
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	51 (64.6)	16 (20.3)	22 (27.8)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	2 (2.5)
Allergy to immunoglobulin therapy	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	31 (39.2)	18 (22.8)	13 (16.5)
Sepsis	3 (3.8)	1 (1.3)	2 (2.5)
Upper respiratory tract infection	3 (3.8)	3 (3.8)	0
Candida infection	2 (2.5)	0	1 (1.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	2 (2.5)	0	2 (2.5)
Encephalitis viral	2 (2.5)	1 (1.3)	1 (1.3)
Gastroenteritis	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Pneumonia	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory syncytial virus infection	2 (2.5)	2 (2.5)	0
Rhinovirus infection	2 (2.5)	1 (1.3)	0
Septic shock	2 (2.5)	0	2 (2.5)
Staphylococcal bacteraemia	2 (2.5)	2 (2.5)	0
Bacteraemia	1 (1.3)	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	1 (1.3)	0
Covid-19	1 (1.3)	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	1 (1.3)	0
Device related infection	1 (1.3)	1 (1.3)	0
Device related sepsis	1 (1.3)	1 (1.3)	0
Enterobacter infection	1 (1.3)	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	1 (1.3)	0
Klebsiella infection	1 (1.3)	1 (1.3)	0
Mastoiditis	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	0
Otitis externa	1 (1.3)	1 (1.3)	0
Otitis media	1 (1.3)	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	1 (1.3)
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Sinusitis	1 (1.3)	1 (1.3)	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)
Urinary tract infection	1 (1.3)	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Infusion related reaction	1 (1.3)	1 (1.3)	0
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	4 (5.1)	2 (2.5)	2 (2.5)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Blood uric acid increased	1 (1.3)	0	1 (1.3)
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	8 (10.1)	3 (3.8)	4 (5.1)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (2.5)	1 (1.3)	1 (1.3)
Decreased appetite	1 (1.3)	0	1 (1.3)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Hypokalaemia	1 (1.3)	1 (1.3)	0
Malnutrition	1 (1.3)	1 (1.3)	0
Metabolic acidosis	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Back pain	3 (3.8)	2 (2.5)	0
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.5)	2 (2.5)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone giant cell tumour benign	1 (1.3)	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	8 (10.1)	5 (6.3)	2 (2.5)
Headache	2 (2.5)	2 (2.5)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Hydrocephalus	1 (1.3)	0	1 (1.3)
Nervous system disorder	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	3 (3.8)	2 (2.5)	0
Mental status changes	2 (2.5)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	6 (7.6)	2 (2.5)	4 (5.1)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)
Reproductive system and breast disorders			
-Total	1 (1.3)	1 (1.3)	0
Endometriosis	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	18 (22.8)	4 (5.1)	11 (13.9)
Hypoxia	5 (6.3)	3 (3.8)	2 (2.5)
Respiratory failure	5 (6.3)	0	5 (6.3)
Acute respiratory distress syndrome	2 (2.5)	0	2 (2.5)
Pleural effusion	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory distress	2 (2.5)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Bronchial oedema	1 (1.3)	0	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Dyspnoea exertional	1 (1.3)	0	0
Epistaxis	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	9 (11.4)	1 (1.3)	8 (10.1)
Hypotension	8 (10.1)	1 (1.3)	7 (8.9)
Venoocclusive disease	1 (1.3)	0	1 (1.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	54 (68.4)	22 (27.8)	27 (34.2)
Blood and lymphatic system disorders			
-Total	16 (20.3)	14 (17.7)	2 (2.5)
Febrile neutropenia	13 (16.5)	12 (15.2)	1 (1.3)
Disseminated intravascular coagulation	2 (2.5)	1 (1.3)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	5 (6.3)	1 (1.3)	3 (3.8)
Atrioventricular block first degree	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.3)	0	1 (1.3)
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Diarrhoea	1 (1.3)	1 (1.3)	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Pancreatitis	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			
-Total	5 (6.3)	0	2 (2.5)
Pyrexia	3 (3.8)	0	0
Multiple organ dysfunction syndrome	2 (2.5)	0	2 (2.5)
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	0	2 (2.5)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	1 (1.3)
Infections and infestations			
-Total	11 (13.9)	7 (8.9)	3 (3.8)
Encephalitis viral	2 (2.5)	1 (1.3)	1 (1.3)
Candida infection	1 (1.3)	0	1 (1.3)
Encephalitis	1 (1.3)	0	1 (1.3)
Klebsiella infection	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	1 (1.3)	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	3 (3.8)	2 (2.5)	1 (1.3)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	4 (5.1)	1 (1.3)	2 (2.5)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Metabolic acidosis	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Nervous system disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Headache	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	5 (6.3)	2 (2.5)	3 (3.8)
Acute kidney injury	4 (5.1)	2 (2.5)	2 (2.5)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (12.7)	3 (3.8)	6 (7.6)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.5)
Respiratory failure	3 (3.8)	0	3 (3.8)
Pleural effusion	2 (2.5)	1 (1.3)	1 (1.3)
Acute respiratory distress syndrome	1 (1.3)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Respiratory distress	1 (1.3)	0	0
Vascular disorders			
-Total	8 (10.1)	2 (2.5)	6 (7.6)
Hypotension	8 (10.1)	2 (2.5)	6 (7.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (31.1)	12 (16.2)	11 (14.9)
Blood and lymphatic system disorders			
-Total	4 (5.4)	4 (5.4)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.7)	0	2 (2.7)
Cardiac arrest	2 (2.7)	0	2 (2.7)
Cardiac failure	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	3 (4.1)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (1.4)	0	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	5 (6.8)	1 (1.4)	0
Pyrexia	4 (5.4)	1 (1.4)	0
Non-cardiac chest pain	1 (1.4)	0	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	16 (21.6)	9 (12.2)	7 (9.5)
Gastroenteritis	2 (2.7)	2 (2.7)	0
Respiratory syncytial virus infection	2 (2.7)	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	2 (2.7)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Septic shock	1 (1.4)	0	1 (1.4)
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.1)	2 (2.7)	0
Back pain	3 (4.1)	2 (2.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	1 (1.4)
Psychiatric disorders			
-Total	2 (2.7)	1 (1.4)	0
Mental status changes	2 (2.7)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.1)	2 (2.7)	3 (4.1)
Hypoxia	2 (2.7)	2 (2.7)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	2 (2.7)	0	2 (2.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (1.4)	0	1 (1.4)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (30.6)	8 (16.3)	6 (12.2)
Gastrointestinal disorders			
-Total	1 (2.0)	0	0
Irritable bowel syndrome	1 (2.0)	0	0
General disorders and administration site conditions			
-Total	3 (6.1)	0	1 (2.0)
Pyrexia	2 (4.1)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	1 (2.0)
Immune system disorders			
-Total	2 (4.1)	1 (2.0)	1 (2.0)
Drug hypersensitivity	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)
Infections and infestations			
-Total	13 (26.5)	8 (16.3)	4 (8.2)
Sepsis	3 (6.1)	1 (2.0)	2 (4.1)
Candida infection	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	1 (2.0)	0
Covid-19	1 (2.0)	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	1 (2.0)
Device related sepsis	1 (2.0)	1 (2.0)	0
Gastroenteritis escherichia coli	1 (2.0)	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	1 (2.0)	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Meningitis pneumococcal	1 (2.0)	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	0
Pneumonia	1 (2.0)	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	0
Septic shock	1 (2.0)	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (2.0)	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Injury, poisoning and procedural complications			
-Total	1 (2.0)	1 (2.0)	0
Infusion related reaction	1 (2.0)	1 (2.0)	0
Metabolism and nutrition disorders			
-Total	1 (2.0)	0	1 (2.0)
Decreased appetite	1 (2.0)	0	1 (2.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	1 (2.0)	0
Bone giant cell tumour benign	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	2 (4.1)	2 (4.1)	0
Headache	1 (2.0)	1 (2.0)	0
Nervous system disorder	1 (2.0)	1 (2.0)	0
Seizure	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.0)	1 (2.0)	0
Endometriosis	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.1)	0	2 (4.1)
Dyspnoea exertional	1 (2.0)	0	0
Laryngeal oedema	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	63 (79.7)	23 (29.1)	37 (46.8)
Blood and lymphatic system disorders			
-Total	18 (22.8)	16 (20.3)	2 (2.5)
Febrile neutropenia	15 (19.0)	14 (17.7)	1 (1.3)
Disseminated intravascular coagulation	3 (3.8)	2 (2.5)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	7 (8.9)	1 (1.3)	5 (6.3)
Cardiac arrest	3 (3.8)	0	3 (3.8)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (2.5)	1 (1.3)	1 (1.3)
Atrioventricular block first degree	1 (1.3)	0	0
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	8 (10.1)	4 (5.1)	1 (1.3)
Diarrhoea	2 (2.5)	1 (1.3)	0
Pancreatitis	2 (2.5)	2 (2.5)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	0
Nausea	1 (1.3)	0	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	0	0
General disorders and administration site conditions			
-Total	11 (13.9)	1 (1.3)	3 (3.8)
Pyrexia	7 (8.9)	1 (1.3)	0
Multiple organ dysfunction syndrome	3 (3.8)	0	3 (3.8)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (1.3)	0	0
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	0	2 (2.5)
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	51 (64.6)	16 (20.3)	22 (27.8)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	2 (2.5)
Allergy to immunoglobulin therapy	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	31 (39.2)	18 (22.8)	13 (16.5)
Sepsis	3 (3.8)	1 (1.3)	2 (2.5)
Upper respiratory tract infection	3 (3.8)	3 (3.8)	0
Candida infection	2 (2.5)	0	1 (1.3)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	2 (2.5)	0	2 (2.5)
Encephalitis viral	2 (2.5)	1 (1.3)	1 (1.3)
Gastroenteritis	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Pneumonia	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory syncytial virus infection	2 (2.5)	2 (2.5)	0
Rhinovirus infection	2 (2.5)	1 (1.3)	0
Septic shock	2 (2.5)	0	2 (2.5)
Staphylococcal bacteraemia	2 (2.5)	2 (2.5)	0
Bacteraemia	1 (1.3)	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	1 (1.3)	0
Covid-19	1 (1.3)	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	1 (1.3)	0
Device related infection	1 (1.3)	1 (1.3)	0
Device related sepsis	1 (1.3)	1 (1.3)	0
Enterobacter infection	1 (1.3)	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	1 (1.3)	0
Klebsiella infection	1 (1.3)	1 (1.3)	0
Mastoiditis	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	0
Otitis externa	1 (1.3)	1 (1.3)	0
Otitis media	1 (1.3)	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	1 (1.3)
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Sinusitis	1 (1.3)	1 (1.3)	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)
Urinary tract infection	1 (1.3)	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Infusion related reaction	1 (1.3)	1 (1.3)	0
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	4 (5.1)	2 (2.5)	2 (2.5)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Blood uric acid increased	1 (1.3)	0	1 (1.3)
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	8 (10.1)	3 (3.8)	4 (5.1)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (2.5)	1 (1.3)	1 (1.3)
Decreased appetite	1 (1.3)	0	1 (1.3)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Hypokalaemia	1 (1.3)	1 (1.3)	0
Malnutrition	1 (1.3)	1 (1.3)	0
Metabolic acidosis	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Back pain	3 (3.8)	2 (2.5)	0
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.5)	2 (2.5)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone giant cell tumour benign	1 (1.3)	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	8 (10.1)	5 (6.3)	2 (2.5)
Headache	2 (2.5)	2 (2.5)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Hydrocephalus	1 (1.3)	0	1 (1.3)
Nervous system disorder	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	3 (3.8)	2 (2.5)	0
Mental status changes	2 (2.5)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	6 (7.6)	2 (2.5)	4 (5.1)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)
Reproductive system and breast disorders			
-Total	1 (1.3)	1 (1.3)	0
Endometriosis	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	18 (22.8)	4 (5.1)	11 (13.9)
Hypoxia	5 (6.3)	3 (3.8)	2 (2.5)
Respiratory failure	5 (6.3)	0	5 (6.3)
Acute respiratory distress syndrome	2 (2.5)	0	2 (2.5)
Pleural effusion	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory distress	2 (2.5)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Bronchial oedema	1 (1.3)	0	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Dyspnoea exertional	1 (1.3)	0	0
Epistaxis	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=79 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Laryngeal oedema	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	9 (11.4)	1 (1.3)	8 (10.1)
Hypotension	8 (10.1)	1 (1.3)	7 (8.9)
Venoocclusive disease	1 (1.3)	0	1 (1.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	54 (68.4)	22 (27.8)	27 (34.2)
Blood and lymphatic system disorders			
-Total	16 (20.3)	14 (17.7)	2 (2.5)
Febrile neutropenia	13 (16.5)	12 (15.2)	1 (1.3)
Disseminated intravascular coagulation	2 (2.5)	1 (1.3)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	5 (6.3)	1 (1.3)	3 (3.8)
Atrioventricular block first degree	1 (1.3)	0	0
Cardiac arrest	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.3)	0	1 (1.3)
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Diarrhoea	1 (1.3)	1 (1.3)	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Pancreatitis	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			
-Total	5 (6.3)	0	2 (2.5)
Pyrexia	3 (3.8)	0	0
Multiple organ dysfunction syndrome	2 (2.5)	0	2 (2.5)
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	0	2 (2.5)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	50 (63.3)	16 (20.3)	21 (26.6)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	1 (1.3)
Infections and infestations			
-Total	11 (13.9)	7 (8.9)	3 (3.8)
Encephalitis viral	2 (2.5)	1 (1.3)	1 (1.3)
Candida infection	1 (1.3)	0	1 (1.3)
Encephalitis	1 (1.3)	0	1 (1.3)
Klebsiella infection	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Rhinovirus infection	1 (1.3)	0	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	1 (1.3)	1 (1.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	1 (1.3)	0	1 (1.3)
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	3 (3.8)	2 (2.5)	1 (1.3)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	4 (5.1)	1 (1.3)	2 (2.5)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Metabolic acidosis	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Nervous system disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Headache	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	5 (6.3)	2 (2.5)	3 (3.8)
Acute kidney injury	4 (5.1)	2 (2.5)	2 (2.5)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (12.7)	3 (3.8)	6 (7.6)
Hypoxia	3 (3.8)	1 (1.3)	2 (2.5)
Respiratory failure	3 (3.8)	0	3 (3.8)
Pleural effusion	2 (2.5)	1 (1.3)	1 (1.3)
Acute respiratory distress syndrome	1 (1.3)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Respiratory distress	1 (1.3)	0	0
Vascular disorders			
-Total	8 (10.1)	2 (2.5)	6 (7.6)
Hypotension	8 (10.1)	2 (2.5)	6 (7.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (31.1)	12 (16.2)	11 (14.9)
Blood and lymphatic system disorders			
-Total	4 (5.4)	4 (5.4)	0
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.7)	0	2 (2.7)
Cardiac arrest	2 (2.7)	0	2 (2.7)
Cardiac failure	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	3 (4.1)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (1.4)	0	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	5 (6.8)	1 (1.4)	0
Pyrexia	4 (5.4)	1 (1.4)	0
Non-cardiac chest pain	1 (1.4)	0	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	16 (21.6)	9 (12.2)	7 (9.5)
Gastroenteritis	2 (2.7)	2 (2.7)	0
Respiratory syncytial virus infection	2 (2.7)	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	2 (2.7)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Septic shock	1 (1.4)	0	1 (1.4)
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.1)	2 (2.7)	0
Back pain	3 (4.1)	2 (2.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	1 (1.4)
Psychiatric disorders			
-Total	2 (2.7)	1 (1.4)	0
Mental status changes	2 (2.7)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.1)	2 (2.7)	3 (4.1)
Hypoxia	2 (2.7)	2 (2.7)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	2 (2.7)	0	2 (2.7)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (1.4)	0	1 (1.4)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (30.6)	8 (16.3)	6 (12.2)
Gastrointestinal disorders			
-Total	1 (2.0)	0	0
Irritable bowel syndrome	1 (2.0)	0	0
General disorders and administration site conditions			
-Total	3 (6.1)	0	1 (2.0)
Pyrexia	2 (4.1)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	1 (2.0)
Immune system disorders			
-Total	2 (4.1)	1 (2.0)	1 (2.0)
Drug hypersensitivity	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)
Infections and infestations			
-Total	13 (26.5)	8 (16.3)	4 (8.2)
Sepsis	3 (6.1)	1 (2.0)	2 (4.1)
Candida infection	1 (2.0)	0	0
Clostridium difficile colitis	1 (2.0)	1 (2.0)	0
Covid-19	1 (2.0)	1 (2.0)	0
Covid-19 pneumonia	1 (2.0)	0	1 (2.0)
Device related sepsis	1 (2.0)	1 (2.0)	0
Gastroenteritis escherichia coli	1 (2.0)	1 (2.0)	0
Gastroenteritis salmonella	1 (2.0)	1 (2.0)	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Meningitis pneumococcal	1 (2.0)	1 (2.0)	0
Ophthalmic herpes zoster	1 (2.0)	0	0
Pneumonia	1 (2.0)	1 (2.0)	0
Pneumonia respiratory syncytial viral	1 (2.0)	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	0
Septic shock	1 (2.0)	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (2.0)	1 (2.0)	0
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Injury, poisoning and procedural complications			
-Total	1 (2.0)	1 (2.0)	0
Infusion related reaction	1 (2.0)	1 (2.0)	0
Metabolism and nutrition disorders			
-Total	1 (2.0)	0	1 (2.0)
Decreased appetite	1 (2.0)	0	1 (2.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	1 (2.0)	0
Bone giant cell tumour benign	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	2 (4.1)	2 (4.1)	0
Headache	1 (2.0)	1 (2.0)	0
Nervous system disorder	1 (2.0)	1 (2.0)	0
Seizure	1 (2.0)	1 (2.0)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.0)	1 (2.0)	0
Endometriosis	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.1)	0	2 (4.1)
Dyspnoea exertional	1 (2.0)	0	0
Laryngeal oedema	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	63 (79.7)	23 (29.1)	37 (46.8)
Blood and lymphatic system disorders			
-Total	18 (22.8)	16 (20.3)	2 (2.5)
Febrile neutropenia	15 (19.0)	14 (17.7)	1 (1.3)
Disseminated intravascular coagulation	3 (3.8)	2 (2.5)	0
Coagulopathy	1 (1.3)	1 (1.3)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	7 (8.9)	1 (1.3)	5 (6.3)
Cardiac arrest	3 (3.8)	0	3 (3.8)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (2.5)	1 (1.3)	1 (1.3)
Atrioventricular block first degree	1 (1.3)	0	0
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	8 (10.1)	4 (5.1)	1 (1.3)
Diarrhoea	2 (2.5)	1 (1.3)	0
Pancreatitis	2 (2.5)	2 (2.5)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Constipation	1 (1.3)	0	0
Irritable bowel syndrome	1 (1.3)	0	0
Nausea	1 (1.3)	0	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	0	0
General disorders and administration site conditions			
-Total	11 (13.9)	1 (1.3)	3 (3.8)
Pyrexia	7 (8.9)	1 (1.3)	0
Multiple organ dysfunction syndrome	3 (3.8)	0	3 (3.8)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (1.3)	0	0
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	0	2 (2.5)
Cholestasis	1 (1.3)	0	1 (1.3)
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	51 (64.6)	16 (20.3)	22 (27.8)
Cytokine release syndrome	50 (63.3)	16 (20.3)	21 (26.6)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	2 (2.5)
Allergy to immunoglobulin therapy	1 (1.3)	1 (1.3)	0
Drug hypersensitivity	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	31 (39.2)	18 (22.8)	13 (16.5)
Sepsis	3 (3.8)	1 (1.3)	2 (2.5)
Upper respiratory tract infection	3 (3.8)	3 (3.8)	0
Candida infection	2 (2.5)	0	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	2 (2.5)	0	2 (2.5)
Encephalitis viral	2 (2.5)	1 (1.3)	1 (1.3)
Gastroenteritis	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Pneumonia	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory syncytial virus infection	2 (2.5)	2 (2.5)	0
Rhinovirus infection	2 (2.5)	1 (1.3)	0
Septic shock	2 (2.5)	0	2 (2.5)
Staphylococcal bacteraemia	2 (2.5)	2 (2.5)	0
Bacteraemia	1 (1.3)	0	1 (1.3)
Bronchopulmonary aspergillosis	1 (1.3)	0	1 (1.3)
Clostridium difficile colitis	1 (1.3)	1 (1.3)	0
Covid-19	1 (1.3)	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	1 (1.3)	0
Device related infection	1 (1.3)	1 (1.3)	0
Device related sepsis	1 (1.3)	1 (1.3)	0
Enterobacter infection	1 (1.3)	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	1 (1.3)	0
Klebsiella infection	1 (1.3)	1 (1.3)	0
Mastoiditis	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	0
Otitis externa	1 (1.3)	1 (1.3)	0
Otitis media	1 (1.3)	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	1 (1.3)	0
Pharyngitis streptococcal	1 (1.3)	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	1 (1.3)
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Sinusitis	1 (1.3)	1 (1.3)	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	1 (1.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)
Urinary tract infection	1 (1.3)	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Infusion related reaction	1 (1.3)	1 (1.3)	0
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	4 (5.1)	2 (2.5)	2 (2.5)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Blood bilirubin increased	1 (1.3)	1 (1.3)	0
Blood uric acid increased	1 (1.3)	0	1 (1.3)
Electrocardiogram qt prolonged	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	8 (10.1)	3 (3.8)	4 (5.1)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (2.5)	1 (1.3)	1 (1.3)
Decreased appetite	1 (1.3)	0	1 (1.3)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Hypokalaemia	1 (1.3)	1 (1.3)	0
Malnutrition	1 (1.3)	1 (1.3)	0
Metabolic acidosis	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.3)	3 (3.8)	1 (1.3)
Back pain	3 (3.8)	2 (2.5)	0
Haemarthrosis	1 (1.3)	1 (1.3)	0
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.5)	2 (2.5)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone giant cell tumour benign	1 (1.3)	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	8 (10.1)	5 (6.3)	2 (2.5)
Headache	2 (2.5)	2 (2.5)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Cognitive disorder	1 (1.3)	0	0
Dysarthria	1 (1.3)	1 (1.3)	0
Encephalopathy	1 (1.3)	1 (1.3)	0
Hydrocephalus	1 (1.3)	0	1 (1.3)
Nervous system disorder	1 (1.3)	1 (1.3)	0
Seizure	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	3 (3.8)	2 (2.5)	0
Mental status changes	2 (2.5)	1 (1.3)	0
Delirium	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	6 (7.6)	2 (2.5)	4 (5.1)
Acute kidney injury	5 (6.3)	2 (2.5)	3 (3.8)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.3)	0	1 (1.3)
Renal tubular necrosis	1 (1.3)	0	1 (1.3)
Reproductive system and breast disorders			
-Total	1 (1.3)	1 (1.3)	0
Endometriosis	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	18 (22.8)	4 (5.1)	11 (13.9)
Hypoxia	5 (6.3)	3 (3.8)	2 (2.5)
Respiratory failure	5 (6.3)	0	5 (6.3)
Acute respiratory distress syndrome	2 (2.5)	0	2 (2.5)
Pleural effusion	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory distress	2 (2.5)	0	1 (1.3)
Acute respiratory failure	1 (1.3)	1 (1.3)	0
Bronchial oedema	1 (1.3)	0	0
Dyspnoea	1 (1.3)	0	1 (1.3)
Dyspnoea exertional	1 (1.3)	0	0
Epistaxis	1 (1.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Laryngeal oedema	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	9 (11.4)	1 (1.3)	8 (10.1)
Hypotension	8 (10.1)	1 (1.3)	7 (8.9)
Venoocclusive disease	1 (1.3)	0	1 (1.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	20 (74.1)	8 (29.6)	10 (37.0)
Blood and lymphatic system disorders			
-Total	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Cardiac disorders			
-Total	1 (3.7)	0	1 (3.7)
Tachycardia	1 (3.7)	0	1 (3.7)
Gastrointestinal disorders			
-Total	2 (7.4)	2 (7.4)	0
Diarrhoea	1 (3.7)	1 (3.7)	0
Pancreatitis	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.7)	0	1 (3.7)
Multiple organ dysfunction syndrome	1 (3.7)	0	1 (3.7)
Systemic inflammatory response syndrome	1 (3.7)	1 (3.7)	0
Hepatobiliary disorders			
-Total	1 (3.7)	0	1 (3.7)
Cholestasis	1 (3.7)	0	1 (3.7)
Immune system disorders			
-Total	19 (70.4)	7 (25.9)	9 (33.3)
Cytokine release syndrome	19 (70.4)	7 (25.9)	9 (33.3)
Haemophagocytic lymphohistiocytosis	1 (3.7)	0	1 (3.7)
Infections and infestations			
-Total	2 (7.4)	0	2 (7.4)
Encephalitis	1 (3.7)	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	1 (3.7)
Meningitis bacterial	1 (3.7)	1 (3.7)	0
Injury, poisoning and procedural complications			
-Total	1 (3.7)	0	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (3.7)	0	1 (3.7)
Metabolism and nutrition disorders			
-Total	1 (3.7)	0	1 (3.7)
Hypernatraemia	1 (3.7)	0	1 (3.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.7)	0	1 (3.7)
Rhabdomyolysis	1 (3.7)	0	1 (3.7)
Nervous system disorders			
-Total	1 (3.7)	1 (3.7)	0
Encephalopathy	1 (3.7)	1 (3.7)	0
Renal and urinary disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Acute kidney injury	2 (7.4)	1 (3.7)	1 (3.7)
Renal tubular necrosis	1 (3.7)	0	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Acute respiratory distress syndrome	1 (3.7)	0	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (3.7)	0	1 (3.7)
Hypoxia	1 (3.7)	1 (3.7)	0
Pleural effusion	1 (3.7)	1 (3.7)	0
Pulmonary oedema	1 (3.7)	1 (3.7)	0
Vascular disorders			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
Hypotension	5 (18.5)	2 (7.4)	3 (11.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	34 (64.2)	14 (26.4)	17 (32.1)
Blood and lymphatic system disorders			
-Total	14 (26.4)	12 (22.6)	2 (3.8)
Febrile neutropenia	11 (20.8)	10 (18.9)	1 (1.9)
Disseminated intravascular coagulation	2 (3.8)	1 (1.9)	0
Coagulopathy	1 (1.9)	1 (1.9)	0
Pancytopenia	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	4 (7.5)	1 (1.9)	2 (3.8)
Atrioventricular block first degree	1 (1.9)	0	0
Cardiac arrest	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.9)	0	1 (1.9)
Left ventricular dysfunction	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	3 (5.7)	1 (1.9)	1 (1.9)
Abdominal compartment syndrome	1 (1.9)	0	1 (1.9)
Constipation	1 (1.9)	0	0
Neutropenic colitis	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	4 (7.5)	0	1 (1.9)
Pyrexia	3 (5.7)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	1 (1.9)
Hepatobiliary disorders			
-Total	1 (1.9)	0	1 (1.9)
Hepatomegaly	1 (1.9)	0	1 (1.9)
Immune system disorders			
-Total	31 (58.5)	9 (17.0)	12 (22.6)
Cytokine release syndrome	31 (58.5)	9 (17.0)	12 (22.6)
Infections and infestations			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (17.0)	7 (13.2)	1 (1.9)
Candida infection	1 (1.9)	0	1 (1.9)
Encephalitis viral	1 (1.9)	1 (1.9)	0
Klebsiella infection	1 (1.9)	1 (1.9)	0
Pneumonia fungal	1 (1.9)	1 (1.9)	0
Pneumonia viral	1 (1.9)	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	0
Soft tissue infection	1 (1.9)	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Aspartate aminotransferase increased	2 (3.8)	2 (3.8)	0
Blood bilirubin increased	1 (1.9)	1 (1.9)	0
Electrocardiogram qt prolonged	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	3 (5.7)	1 (1.9)	1 (1.9)
Dehydration	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (1.9)	1 (1.9)	0
Hyperkalaemia	1 (1.9)	0	1 (1.9)
Hyperphosphataemia	1 (1.9)	0	1 (1.9)
Metabolic acidosis	1 (1.9)	0	1 (1.9)
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.9)	1 (1.9)	0
Haemarthrosis	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	4 (7.5)	2 (3.8)	1 (1.9)
Cerebral haemorrhage	1 (1.9)	0	1 (1.9)
Cognitive disorder	1 (1.9)	0	0
Dysarthria	1 (1.9)	1 (1.9)	0
Headache	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	1 (1.9)	1 (1.9)	0
Delirium	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.7)	1 (1.9)	2 (3.8)
Acute kidney injury	2 (3.8)	1 (1.9)	1 (1.9)
Renal failure	1 (1.9)	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (13.2)	1 (1.9)	5 (9.4)
Respiratory failure	3 (5.7)	0	3 (5.7)
Hypoxia	2 (3.8)	0	2 (3.8)
Acute respiratory failure	1 (1.9)	1 (1.9)	0
Pleural effusion	1 (1.9)	0	1 (1.9)
Respiratory distress	1 (1.9)	0	0
Vascular disorders			
-Total	3 (5.7)	0	3 (5.7)
Hypotension	3 (5.7)	0	3 (5.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (36.0)	4 (16.0)	5 (20.0)
Blood and lymphatic system disorders			
-Total	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
Gastrointestinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Pancreatitis	1 (4.0)	1 (4.0)	0
Infections and infestations			
-Total	5 (20.0)	2 (8.0)	3 (12.0)
Device related infection	1 (4.0)	1 (4.0)	0
Gastroenteritis	1 (4.0)	1 (4.0)	0
Pneumocystis jirovecii pneumonia	1 (4.0)	0	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (4.0)	0	1 (4.0)
Sinusitis	1 (4.0)	1 (4.0)	0
Staphylococcal sepsis	1 (4.0)	0	1 (4.0)
Investigations			
-Total	1 (4.0)	0	1 (4.0)
Blood uric acid increased	1 (4.0)	0	1 (4.0)
Metabolism and nutrition disorders			
-Total	1 (4.0)	0	1 (4.0)
Tumour lysis syndrome	1 (4.0)	0	1 (4.0)
Nervous system disorders			
-Total	1 (4.0)	0	1 (4.0)
Hydrocephalus	1 (4.0)	0	1 (4.0)
Psychiatric disorders			
-Total	1 (4.0)	0	0
Mental status changes	1 (4.0)	0	0
Renal and urinary disorders			
-Total	1 (4.0)	0	1 (4.0)
Acute kidney injury	1 (4.0)	0	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (12.0)	1 (4.0)	2 (8.0)
Acute respiratory distress syndrome	1 (4.0)	0	1 (4.0)
Epistaxis	1 (4.0)	0	0
Hypoxia	1 (4.0)	1 (4.0)	0
Respiratory distress	1 (4.0)	0	1 (4.0)
Vascular disorders			
-Total	2 (8.0)	0	2 (8.0)
Hypotension	1 (4.0)	0	1 (4.0)
Venoocclusive disease	1 (4.0)	0	1 (4.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (28.0)	8 (16.0)	6 (12.0)
Blood and lymphatic system disorders			
-Total	3 (6.0)	3 (6.0)	0
Febrile neutropenia	2 (4.0)	2 (4.0)	0
Disseminated intravascular coagulation	1 (2.0)	1 (2.0)	0
Cardiac disorders			
-Total	2 (4.0)	0	2 (4.0)
Cardiac arrest	2 (4.0)	0	2 (4.0)
Cardiac failure	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	2 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (2.0)	0	0
Nausea	1 (2.0)	0	0
Vomiting	1 (2.0)	0	0
General disorders and administration site conditions			
-Total	5 (10.0)	1 (2.0)	0
Pyrexia	4 (8.0)	1 (2.0)	0
Non-cardiac chest pain	1 (2.0)	0	0
Immune system disorders			
-Total	1 (2.0)	1 (2.0)	0
Allergy to immunoglobulin therapy	1 (2.0)	1 (2.0)	0
Infections and infestations			
-Total	11 (22.0)	7 (14.0)	4 (8.0)
Respiratory syncytial virus infection	2 (4.0)	2 (4.0)	0
Upper respiratory tract infection	2 (4.0)	2 (4.0)	0
Bacteraemia	1 (2.0)	0	1 (2.0)
Bronchopulmonary aspergillosis	1 (2.0)	0	1 (2.0)
Cytomegalovirus infection reactivation	1 (2.0)	1 (2.0)	0
Encephalitis	1 (2.0)	0	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (2.0)	1 (2.0)	0
Gastroenteritis	1 (2.0)	1 (2.0)	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	1 (2.0)	0
Klebsiella infection	1 (2.0)	1 (2.0)	0
Mastoiditis	1 (2.0)	1 (2.0)	0
Metapneumovirus infection	1 (2.0)	1 (2.0)	0
Otitis externa	1 (2.0)	1 (2.0)	0
Otitis media	1 (2.0)	1 (2.0)	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0
Pharyngitis streptococcal	1 (2.0)	1 (2.0)	0
Pneumonia	1 (2.0)	0	1 (2.0)
Rhinovirus infection	1 (2.0)	1 (2.0)	0
Urinary tract infection	1 (2.0)	1 (2.0)	0
Viral haemorrhagic cystitis	1 (2.0)	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Metabolism and nutrition disorders			
-Total	2 (4.0)	2 (4.0)	0
Hypokalaemia	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (2.0)	1 (2.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (6.0)	2 (4.0)	0
Back pain	3 (6.0)	2 (4.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	1 (2.0)	0
Myelodysplastic syndrome	1 (2.0)	1 (2.0)	0
Psychiatric disorders			
-Total	1 (2.0)	1 (2.0)	0
Mental status changes	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.0)	1 (2.0)	1 (2.0)
Bronchial oedema	1 (2.0)	0	0
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (43.8)	5 (31.3)	2 (12.5)
Immune system disorders			
-Total	1 (6.3)	1 (6.3)	0
Drug hypersensitivity	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	7 (43.8)	5 (31.3)	2 (12.5)
Sepsis	2 (12.5)	0	2 (12.5)
Candida infection	1 (6.3)	0	0
Covid-19	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Herpes zoster	1 (6.3)	1 (6.3)	0
Ophthalmic herpes zoster	1 (6.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (6.3)	1 (6.3)	0
Staphylococcal bacteraemia	1 (6.3)	1 (6.3)	0
Upper respiratory tract infection	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
-Total	1 (6.3)	1 (6.3)	0
Infusion related reaction	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	1 (6.3)	1 (6.3)	0
Headache	1 (6.3)	1 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (23.5)	3 (8.8)	4 (11.8)
Gastrointestinal disorders			
-Total	1 (2.9)	0	0
Irritable bowel syndrome	1 (2.9)	0	0
General disorders and administration site conditions			
-Total	3 (8.8)	0	1 (2.9)
Pyrexia	2 (5.9)	0	0
Multiple organ dysfunction syndrome	1 (2.9)	0	1 (2.9)
Immune system disorders			
-Total	1 (2.9)	0	1 (2.9)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)
Infections and infestations			
-Total	6 (17.6)	3 (8.8)	2 (5.9)
Clostridium difficile colitis	1 (2.9)	1 (2.9)	0
Covid-19 pneumonia	1 (2.9)	0	1 (2.9)
Gastroenteritis escherichia coli	1 (2.9)	1 (2.9)	0
Gastroenteritis salmonella	1 (2.9)	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	1 (2.9)	0
Pneumonia	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0
Sepsis	1 (2.9)	1 (2.9)	0
Septic shock	1 (2.9)	0	1 (2.9)
Staphylococcal abscess	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	1 (2.9)	0	1 (2.9)
Decreased appetite	1 (2.9)	0	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	1 (2.9)	0
Bone giant cell tumour benign	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	1 (2.9)	1 (2.9)	0
Nervous system disorder	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0
Reproductive system and breast disorders			
-Total	1 (2.9)	1 (2.9)	0
Endometriosis	1 (2.9)	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (8.8)	0	2 (5.9)
Dyspnoea exertional	1 (2.9)	0	0
Laryngeal oedema	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term **Preferred term**	**All grades** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
Number of patients with at least one SAE	22 (81.5)	8 (29.6)	13 (48.1)
Blood and lymphatic system disorders			
-Total	3 (11.1)	3 (11.1)	0
Febrile neutropenia	3 (11.1)	3 (11.1)	0
Cardiac disorders			
-Total	1 (3.7)	0	1 (3.7)
Tachycardia	1 (3.7)	0	1 (3.7)
Gastrointestinal disorders			
-Total	3 (11.1)	3 (11.1)	0
Pancreatitis	2 (7.4)	2 (7.4)	0
Diarrhoea	1 (3.7)	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (3.7)	0	1 (3.7)
Multiple organ dysfunction syndrome	1 (3.7)	0	1 (3.7)
Systemic inflammatory response syndrome	1 (3.7)	1 (3.7)	0
Hepatobiliary disorders			
-Total	1 (3.7)	0	1 (3.7)
Cholestasis	1 (3.7)	0	1 (3.7)
Immune system disorders			
-Total	19 (70.4)	7 (25.9)	9 (33.3)
Cytokine release syndrome	19 (70.4)	7 (25.9)	9 (33.3)
Drug hypersensitivity	1 (3.7)	1 (3.7)	0
Haemophagocytic lymphohistiocytosis	1 (3.7)	0	1 (3.7)
Infections and infestations			
-Total	12 (44.4)	6 (22.2)	6 (22.2)
Sepsis	2 (7.4)	0	2 (7.4)
Candida infection	1 (3.7)	0	0
Covid-19	1 (3.7)	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (3.7)	1 (3.7)	0
Device related sepsis	1 (3.7)	1 (3.7)	0
Encephalitis	1 (3.7)	0	1 (3.7)
Encephalitis viral	1 (3.7)	0	1 (3.7)
Gastroenteritis	1 (3.7)	1 (3.7)	0
Herpes zoster	1 (3.7)	1 (3.7)	0
Meningitis bacterial	1 (3.7)	1 (3.7)	0
Ophthalmic herpes zoster	1 (3.7)	0	0
Pneumocystis jirovecii pneumonia	1 (3.7)	0	1 (3.7)
Pneumonia respiratory syncytial viral	1 (3.7)	1 (3.7)	0
Septic shock	1 (3.7)	0	1 (3.7)
Sinusitis	1 (3.7)	1 (3.7)	0
Staphylococcal bacteraemia	1 (3.7)	1 (3.7)	0
Staphylococcal sepsis	1 (3.7)	0	1 (3.7)
Upper respiratory tract infection	1 (3.7)	1 (3.7)	0
Injury, poisoning and procedural complications			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Infusion related reaction	1 (3.7)	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (3.7)	0	1 (3.7)
Investigations			
-Total	1 (3.7)	0	1 (3.7)
Blood uric acid increased	1 (3.7)	0	1 (3.7)
Metabolism and nutrition disorders			
-Total	2 (7.4)	0	2 (7.4)
Hypernatraemia	1 (3.7)	0	1 (3.7)
Tumour lysis syndrome	1 (3.7)	0	1 (3.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.7)	0	1 (3.7)
Rhabdomyolysis	1 (3.7)	0	1 (3.7)
Nervous system disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Encephalopathy	1 (3.7)	1 (3.7)	0
Headache	1 (3.7)	1 (3.7)	0
Hydrocephalus	1 (3.7)	0	1 (3.7)
Psychiatric disorders			
-Total	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (3.7)	0	0
Renal and urinary disorders			
-Total	3 (11.1)	1 (3.7)	2 (7.4)
Acute kidney injury	3 (11.1)	1 (3.7)	2 (7.4)
Renal tubular necrosis	1 (3.7)	0	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
Acute respiratory distress syndrome	2 (7.4)	0	2 (7.4)
Hypoxia	2 (7.4)	2 (7.4)	0
Dyspnoea	1 (3.7)	0	1 (3.7)
Epistaxis	1 (3.7)	0	0
Pleural effusion	1 (3.7)	1 (3.7)	0
Pulmonary oedema	1 (3.7)	1 (3.7)	0
Respiratory distress	1 (3.7)	0	1 (3.7)
Vascular disorders			
-Total	6 (22.2)	1 (3.7)	5 (18.5)
Hypotension	5 (18.5)	1 (3.7)	4 (14.8)
Venoocclusive disease	1 (3.7)	0	1 (3.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	41 (77.4)	15 (28.3)	24 (45.3)
Blood and lymphatic system disorders			
-Total	15 (28.3)	13 (24.5)	2 (3.8)
Febrile neutropenia	12 (22.6)	11 (20.8)	1 (1.9)
Disseminated intravascular coagulation	3 (5.7)	2 (3.8)	0
Coagulopathy	1 (1.9)	1 (1.9)	0
Pancytopenia	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	6 (11.3)	1 (1.9)	4 (7.5)
Cardiac arrest	3 (5.7)	0	3 (5.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (3.8)	1 (1.9)	1 (1.9)
Atrioventricular block first degree	1 (1.9)	0	0
Left ventricular dysfunction	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	5 (9.4)	1 (1.9)	1 (1.9)
Abdominal compartment syndrome	1 (1.9)	0	1 (1.9)
Constipation	1 (1.9)	0	0
Diarrhoea	1 (1.9)	0	0
Irritable bowel syndrome	1 (1.9)	0	0
Nausea	1 (1.9)	0	0
Neutropenic colitis	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	0	0
General disorders and administration site conditions			
-Total	10 (18.9)	1 (1.9)	2 (3.8)
Pyrexia	7 (13.2)	1 (1.9)	0
Multiple organ dysfunction syndrome	2 (3.8)	0	2 (3.8)
Non-cardiac chest pain	1 (1.9)	0	0
Hepatobiliary disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	1 (1.9)
Hepatomegaly	1 (1.9)	0	1 (1.9)
Immune system disorders			
-Total	32 (60.4)	9 (17.0)	13 (24.5)
Cytokine release syndrome	31 (58.5)	9 (17.0)	12 (22.6)
Allergy to immunoglobulin therapy	1 (1.9)	1 (1.9)	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)
Infections and infestations			
-Total	19 (35.8)	12 (22.6)	7 (13.2)
Pneumonia	2 (3.8)	1 (1.9)	1 (1.9)
Respiratory syncytial virus infection	2 (3.8)	2 (3.8)	0
Rhinovirus infection	2 (3.8)	1 (1.9)	0
Upper respiratory tract infection	2 (3.8)	2 (3.8)	0
Bacteraemia	1 (1.9)	0	1 (1.9)
Bronchopulmonary aspergillosis	1 (1.9)	0	1 (1.9)
Candida infection	1 (1.9)	0	1 (1.9)
Clostridium difficile colitis	1 (1.9)	1 (1.9)	0
Covid-19 pneumonia	1 (1.9)	0	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.9)	1 (1.9)	0
Encephalitis	1 (1.9)	0	1 (1.9)
Encephalitis viral	1 (1.9)	1 (1.9)	0
Enterobacter infection	1 (1.9)	1 (1.9)	0
Gastroenteritis	1 (1.9)	1 (1.9)	0
Gastroenteritis escherichia coli	1 (1.9)	1 (1.9)	0
Gastroenteritis salmonella	1 (1.9)	1 (1.9)	0
Herpes zoster	1 (1.9)	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	1 (1.9)	0
Klebsiella infection	1 (1.9)	1 (1.9)	0
Mastoiditis	1 (1.9)	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	1 (1.9)	0
Otitis externa	1 (1.9)	1 (1.9)	0
Otitis media	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Pharyngitis streptococcal	1 (1.9)	1 (1.9)	0
Pneumonia fungal	1 (1.9)	1 (1.9)	0
Pneumonia viral	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.9)	1 (1.9)	0
Septic shock	1 (1.9)	0	1 (1.9)
Soft tissue infection	1 (1.9)	1 (1.9)	0
Staphylococcal abscess	1 (1.9)	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	1 (1.9)	0
Urinary tract infection	1 (1.9)	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	1 (1.9)	0
Viral haemorrhagic cystitis	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Aspartate aminotransferase increased	2 (3.8)	2 (3.8)	0
Blood bilirubin increased	1 (1.9)	1 (1.9)	0
Electrocardiogram qt prolonged	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	6 (11.3)	3 (5.7)	2 (3.8)
Decreased appetite	1 (1.9)	0	1 (1.9)
Dehydration	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (1.9)	1 (1.9)	0
Hyperkalaemia	1 (1.9)	0	1 (1.9)
Hyperphosphataemia	1 (1.9)	0	1 (1.9)
Hypokalaemia	1 (1.9)	1 (1.9)	0
Malnutrition	1 (1.9)	1 (1.9)	0
Metabolic acidosis	1 (1.9)	0	1 (1.9)
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (7.5)	3 (5.7)	0
Back pain	3 (5.7)	2 (3.8)	0
Haemarthrosis	1 (1.9)	1 (1.9)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.8)	2 (3.8)	0
Bone giant cell tumour benign	1 (1.9)	1 (1.9)	0
Myelodysplastic syndrome	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	5 (9.4)	3 (5.7)	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (1.9)	0	1 (1.9)
Cognitive disorder	1 (1.9)	0	0
Dysarthria	1 (1.9)	1 (1.9)	0
Headache	1 (1.9)	1 (1.9)	0
Nervous system disorder	1 (1.9)	1 (1.9)	0
Seizure	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	2 (3.8)	2 (3.8)	0
Delirium	1 (1.9)	1 (1.9)	0
Mental status changes	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	3 (5.7)	1 (1.9)	2 (3.8)
Acute kidney injury	2 (3.8)	1 (1.9)	1 (1.9)
Renal failure	1 (1.9)	0	1 (1.9)
Reproductive system and breast disorders			
-Total	1 (1.9)	1 (1.9)	0
Endometriosis	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	13 (24.5)	2 (3.8)	8 (15.1)
Respiratory failure	5 (9.4)	0	5 (9.4)
Hypoxia	3 (5.7)	1 (1.9)	2 (3.8)
Acute respiratory failure	1 (1.9)	1 (1.9)	0
Bronchial oedema	1 (1.9)	0	0
Dyspnoea exertional	1 (1.9)	0	0
Laryngeal oedema	1 (1.9)	0	1 (1.9)
Pleural effusion	1 (1.9)	0	1 (1.9)
Respiratory distress	1 (1.9)	0	0
Vascular disorders			
-Total	3 (5.7)	0	3 (5.7)
Hypotension	3 (5.7)	0	3 (5.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (53.6)	5 (17.9)	8 (28.6)
Blood and lymphatic system disorders			
-Total	1 (3.6)	1 (3.6)	0
Pancytopenia	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	15 (53.6)	5 (17.9)	8 (28.6)
Cytokine release syndrome	15 (53.6)	5 (17.9)	8 (28.6)
Infections and infestations			
-Total	3 (10.7)	3 (10.7)	0
Encephalitis viral	1 (3.6)	1 (3.6)	0
Pneumonia fungal	1 (3.6)	1 (3.6)	0
Pneumonia viral	1 (3.6)	1 (3.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	35 (77.8)	16 (35.6)	16 (35.6)
Blood and lymphatic system disorders			
-Total	15 (33.3)	13 (28.9)	2 (4.4)
Febrile neutropenia	13 (28.9)	12 (26.7)	1 (2.2)
Disseminated intravascular coagulation	2 (4.4)	1 (2.2)	0
Coagulopathy	1 (2.2)	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	5 (11.1)	1 (2.2)	3 (6.7)
Atrioventricular block first degree	1 (2.2)	0	0
Cardiac arrest	1 (2.2)	0	1 (2.2)
Cardiac failure	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (2.2)	1 (2.2)	0
Tachycardia	1 (2.2)	0	1 (2.2)
Gastrointestinal disorders			
-Total	5 (11.1)	3 (6.7)	1 (2.2)
Abdominal compartment syndrome	1 (2.2)	0	1 (2.2)
Constipation	1 (2.2)	0	0
Diarrhoea	1 (2.2)	1 (2.2)	0
Neutropenic colitis	1 (2.2)	1 (2.2)	0
Pancreatitis	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	5 (11.1)	0	2 (4.4)
Pyrexia	3 (6.7)	0	0
Multiple organ dysfunction syndrome	2 (4.4)	0	2 (4.4)
Systemic inflammatory response syndrome	1 (2.2)	1 (2.2)	0
Hepatobiliary disorders			
-Total	2 (4.4)	0	2 (4.4)
Cholestasis	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	31 (68.9)	10 (22.2)	10 (22.2)
Cytokine release syndrome	31 (68.9)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)
Infections and infestations			
-Total	7 (15.6)	4 (8.9)	2 (4.4)
Candida infection	1 (2.2)	0	1 (2.2)
Encephalitis	1 (2.2)	0	1 (2.2)
Klebsiella infection	1 (2.2)	1 (2.2)	0
Rhinovirus infection	1 (2.2)	0	0
Soft tissue infection	1 (2.2)	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Varicella zoster virus infection	1 (2.2)	1 (2.2)	0
Injury, poisoning and procedural complications			
-Total	1 (2.2)	0	1 (2.2)
Vasoplegia syndrome	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	3 (6.7)	2 (4.4)	1 (2.2)
Aspartate aminotransferase increased	2 (4.4)	2 (4.4)	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0
Electrocardiogram qt prolonged	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	4 (8.9)	1 (2.2)	2 (4.4)
Dehydration	1 (2.2)	0	0
Hypercalcaemia	1 (2.2)	1 (2.2)	0
Hyperkalaemia	1 (2.2)	0	1 (2.2)
Hypernatraemia	1 (2.2)	0	1 (2.2)
Hyperphosphataemia	1 (2.2)	0	1 (2.2)
Metabolic acidosis	1 (2.2)	0	1 (2.2)
Tumour lysis syndrome	1 (2.2)	1 (2.2)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (4.4)	1 (2.2)	1 (2.2)
Haemarthrosis	1 (2.2)	1 (2.2)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (2.2)	0	1 (2.2)
Nervous system disorders			
-Total	5 (11.1)	3 (6.7)	1 (2.2)
Cerebral haemorrhage	1 (2.2)	0	1 (2.2)
Cognitive disorder	1 (2.2)	0	0
Dysarthria	1 (2.2)	1 (2.2)	0
Encephalopathy	1 (2.2)	1 (2.2)	0
Headache	1 (2.2)	1 (2.2)	0
Psychiatric disorders			
-Total	1 (2.2)	1 (2.2)	0
Delirium	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	5 (11.1)	2 (4.4)	3 (6.7)
Acute kidney injury	4 (8.9)	2 (4.4)	2 (4.4)
Renal failure	1 (2.2)	0	1 (2.2)
Renal tubular necrosis	1 (2.2)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (22.2)	3 (6.7)	6 (13.3)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (6.7)	1 (2.2)	2 (4.4)
Respiratory failure	3 (6.7)	0	3 (6.7)
Pleural effusion	2 (4.4)	1 (2.2)	1 (2.2)
Acute respiratory distress syndrome	1 (2.2)	0	1 (2.2)
Acute respiratory failure	1 (2.2)	1 (2.2)	0
Dyspnoea	1 (2.2)	0	1 (2.2)
Pulmonary oedema	1 (2.2)	1 (2.2)	0
Respiratory distress	1 (2.2)	0	0
Vascular disorders			
-Total	8 (17.8)	2 (4.4)	6 (13.3)
Hypotension	8 (17.8)	2 (4.4)	6 (13.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (57.1)	1 (14.3)	3 (42.9)
Immune system disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Cytokine release syndrome	4 (57.1)	1 (14.3)	3 (42.9)
Infections and infestations			
-Total	1 (14.3)	0	1 (14.3)
Encephalitis viral	1 (14.3)	0	1 (14.3)
Meningitis bacterial	1 (14.3)	1 (14.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	12 (42.9)	5 (17.9)	7 (25.0)
Blood and lymphatic system disorders			
-Total	2 (7.1)	2 (7.1)	0
Disseminated intravascular coagulation	1 (3.6)	1 (3.6)	0
Febrile neutropenia	1 (3.6)	1 (3.6)	0
Gastrointestinal disorders			
-Total	1 (3.6)	1 (3.6)	0
Pancreatitis	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	1 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (3.6)	0	0
Infections and infestations			
-Total	9 (32.1)	3 (10.7)	6 (21.4)
Gastroenteritis	2 (7.1)	2 (7.1)	0
Bacteraemia	1 (3.6)	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	1 (3.6)
Device related infection	1 (3.6)	1 (3.6)	0
Encephalitis	1 (3.6)	0	1 (3.6)
Herpes zoster	1 (3.6)	1 (3.6)	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	1 (3.6)
Pneumonia	1 (3.6)	0	1 (3.6)
Sinusitis	1 (3.6)	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	1 (3.6)
Urinary tract infection	1 (3.6)	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	1 (3.6)	1 (3.6)	0
Malnutrition	1 (3.6)	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.6)	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	1 (3.6)	0	1 (3.6)
Hydrocephalus	1 (3.6)	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (7.1)	0	1 (3.6)
Bronchial oedema	1 (3.6)	0	0
Respiratory failure	1 (3.6)	0	1 (3.6)
Vascular disorders			
-Total	1 (3.6)	0	1 (3.6)
Venoocclusive disease	1 (3.6)	0	1 (3.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	10 (25.0)	6 (15.0)	4 (10.0)
Blood and lymphatic system disorders			
-Total	2 (5.0)	2 (5.0)	0
Febrile neutropenia	2 (5.0)	2 (5.0)	0
Cardiac disorders			
-Total	2 (5.0)	0	2 (5.0)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	2 (5.0)	0	0
Diarrhoea	1 (2.5)	0	0
Nausea	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (2.5)	0	0
General disorders and administration site conditions			
-Total	4 (10.0)	1 (2.5)	0
Pyrexia	4 (10.0)	1 (2.5)	0
Immune system disorders			
-Total	1 (2.5)	1 (2.5)	0
Allergy to immunoglobulin therapy	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	6 (15.0)	5 (12.5)	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	1 (2.5)	0
Enterobacter infection	1 (2.5)	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	1 (2.5)	0
Klebsiella infection	1 (2.5)	1 (2.5)	0
Mastoiditis	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0
Otitis externa	1 (2.5)	1 (2.5)	0
Otitis media	1 (2.5)	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Septic shock	1 (2.5)	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	1 (2.5)	0	1 (2.5)
Blood uric acid increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Hypokalaemia	1 (2.5)	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	3 (7.5)	2 (5.0)	0
Back pain	3 (7.5)	2 (5.0)	0
Psychiatric disorders			
-Total	2 (5.0)	1 (2.5)	0
Mental status changes	2 (5.0)	1 (2.5)	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	0	1 (2.5)
Acute kidney injury	1 (2.5)	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Hypoxia	2 (5.0)	2 (5.0)	0
Acute respiratory distress syndrome	1 (2.5)	0	1 (2.5)
Epistaxis	1 (2.5)	0	0
Respiratory distress	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypotension	1 (2.5)	0	1 (2.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Parainfluenzae virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (31.8)	3 (13.6)	4 (18.2)
General disorders and administration site conditions			
-Total	1 (4.5)	0	1 (4.5)
Multiple organ dysfunction syndrome	1 (4.5)	0	1 (4.5)
Immune system disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Drug hypersensitivity	1 (4.5)	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)
Infections and infestations			
-Total	6 (27.3)	3 (13.6)	3 (13.6)

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	3 (13.6)	1 (4.5)	2 (9.1)
Candida infection	1 (4.5)	0	0
Covid-19	1 (4.5)	1 (4.5)	0
Covid-19 pneumonia	1 (4.5)	0	1 (4.5)
Device related sepsis	1 (4.5)	1 (4.5)	0
Herpes zoster	1 (4.5)	1 (4.5)	0
Ophthalmic herpes zoster	1 (4.5)	0	0
Metabolism and nutrition disorders			
-Total	1 (4.5)	0	1 (4.5)
Decreased appetite	1 (4.5)	0	1 (4.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.5)	1 (4.5)	0
Bone giant cell tumour benign	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Headache	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	0	0
Dyspnoea exertional	1 (4.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (26.1)	4 (17.4)	2 (8.7)
Gastrointestinal disorders			
-Total	1 (4.3)	0	0
Irritable bowel syndrome	1 (4.3)	0	0
General disorders and administration site conditions			
-Total	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	0
Infections and infestations			
-Total	5 (21.7)	4 (17.4)	1 (4.3)
Clostridium difficile colitis	1 (4.3)	1 (4.3)	0
Gastroenteritis escherichia coli	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (4.3)	1 (4.3)	0
Meningitis pneumococcal	1 (4.3)	1 (4.3)	0
Pneumonia	1 (4.3)	1 (4.3)	0
Pneumonia respiratory syncytial viral	1 (4.3)	1 (4.3)	0
Septic shock	1 (4.3)	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	1 (4.3)	0
Injury, poisoning and procedural complications			
-Total	1 (4.3)	1 (4.3)	0
Infusion related reaction	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	1 (4.3)	1 (4.3)	0
Nervous system disorder	1 (4.3)	1 (4.3)	0
Seizure	1 (4.3)	1 (4.3)	0
Reproductive system and breast disorders			
-Total	1 (4.3)	1 (4.3)	0
Endometriosis	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Region: US

Group term Preferred term	All patients N=23 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.7)	0	2 (8.7)
Laryngeal oedema	1 (4.3)	0	1 (4.3)
Respiratory failure	1 (4.3)	0	1 (4.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (40.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0
Infections and infestations			
-Total	2 (40.0)	1 (20.0)	0
Rhinovirus infection	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	19 (67.9)	5 (17.9)	13 (46.4)
Blood and lymphatic system disorders			
-Total	2 (7.1)	2 (7.1)	0
Disseminated intravascular coagulation	1 (3.6)	1 (3.6)	0
Febrile neutropenia	1 (3.6)	1 (3.6)	0
Pancytopenia	1 (3.6)	1 (3.6)	0
Gastrointestinal disorders			
-Total	1 (3.6)	1 (3.6)	0
Pancreatitis	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.1)	0	1 (3.6)
Multiple organ dysfunction syndrome	1 (3.6)	0	1 (3.6)
Non-cardiac chest pain	1 (3.6)	0	0
Immune system disorders			
-Total	16 (57.1)	5 (17.9)	9 (32.1)
Cytokine release syndrome	15 (53.6)	5 (17.9)	8 (28.6)
Drug hypersensitivity	1 (3.6)	1 (3.6)	0
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	1 (3.6)
Infections and infestations			
-Total	13 (46.4)	5 (17.9)	8 (28.6)
Sepsis	3 (10.7)	1 (3.6)	2 (7.1)
Gastroenteritis	2 (7.1)	2 (7.1)	0
Herpes zoster	2 (7.1)	2 (7.1)	0
Bacteraemia	1 (3.6)	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	1 (3.6)
Candida infection	1 (3.6)	0	0
Covid-19	1 (3.6)	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	1 (3.6)

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (3.6)	1 (3.6)	0
Device related sepsis	1 (3.6)	1 (3.6)	0
Encephalitis	1 (3.6)	0	1 (3.6)
Encephalitis viral	1 (3.6)	1 (3.6)	0
Ophthalmic herpes zoster	1 (3.6)	0	0
Pneumocystis jirovecii pneumonia	1 (3.6)	0	1 (3.6)
Pneumonia	1 (3.6)	0	1 (3.6)
Pneumonia fungal	1 (3.6)	1 (3.6)	0
Pneumonia viral	1 (3.6)	1 (3.6)	0
Sinusitis	1 (3.6)	1 (3.6)	0
Staphylococcal sepsis	1 (3.6)	0	1 (3.6)
Urinary tract infection	1 (3.6)	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Decreased appetite	1 (3.6)	0	1 (3.6)
Malnutrition	1 (3.6)	1 (3.6)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.1)	2 (7.1)	0
Bone giant cell tumour benign	1 (3.6)	1 (3.6)	0
Myelodysplastic syndrome	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Headache	1 (3.6)	1 (3.6)	0
Hydrocephalus	1 (3.6)	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.7)	0	1 (3.6)
Bronchial oedema	1 (3.6)	0	0
Dyspnoea exertional	1 (3.6)	0	0
Respiratory failure	1 (3.6)	0	1 (3.6)
Vascular disorders			
-Total	1 (3.6)	0	1 (3.6)
Venoocclusive disease	1 (3.6)	0	1 (3.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	39 (86.7)	16 (35.6)	21 (46.7)
Blood and lymphatic system disorders			
-Total	16 (35.6)	14 (31.1)	2 (4.4)
Febrile neutropenia	14 (31.1)	13 (28.9)	1 (2.2)
Disseminated intravascular coagulation	2 (4.4)	1 (2.2)	0
Coagulopathy	1 (2.2)	1 (2.2)	0
Thrombocytopenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	7 (15.6)	1 (2.2)	5 (11.1)
Cardiac arrest	3 (6.7)	0	3 (6.7)
Cardiac failure	2 (4.4)	1 (2.2)	1 (2.2)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (2.2)	0	0
Left ventricular dysfunction	1 (2.2)	1 (2.2)	0
Tachycardia	1 (2.2)	0	1 (2.2)
Gastrointestinal disorders			
-Total	7 (15.6)	3 (6.7)	1 (2.2)
Diarrhoea	2 (4.4)	1 (2.2)	0
Abdominal compartment syndrome	1 (2.2)	0	1 (2.2)
Constipation	1 (2.2)	0	0
Irritable bowel syndrome	1 (2.2)	0	0
Nausea	1 (2.2)	0	0
Neutropenic colitis	1 (2.2)	1 (2.2)	0
Pancreatitis	1 (2.2)	1 (2.2)	0
Vomiting	1 (2.2)	0	0
General disorders and administration site conditions			
-Total	8 (17.8)	1 (2.2)	2 (4.4)
Pyrexia	6 (13.3)	1 (2.2)	0
Multiple organ dysfunction syndrome	2 (4.4)	0	2 (4.4)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (2.2)	1 (2.2)	0
Hepatobiliary disorders			
-Total	2 (4.4)	0	2 (4.4)
Cholestasis	1 (2.2)	0	1 (2.2)
Hepatomegaly	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	31 (68.9)	10 (22.2)	10 (22.2)
Cytokine release syndrome	31 (68.9)	10 (22.2)	10 (22.2)
Allergy to immunoglobulin therapy	1 (2.2)	1 (2.2)	0
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)
Infections and infestations			
-Total	15 (33.3)	11 (24.4)	4 (8.9)
Septic shock	2 (4.4)	0	2 (4.4)
Staphylococcal bacteraemia	2 (4.4)	2 (4.4)	0
Candida infection	1 (2.2)	0	1 (2.2)
Clostridium difficile colitis	1 (2.2)	1 (2.2)	0
Cytomegalovirus infection reactivation	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.2)	0	1 (2.2)
Enterobacter infection	1 (2.2)	1 (2.2)	0
Gastroenteritis escherichia coli	1 (2.2)	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	1 (2.2)	0
Klebsiella infection	1 (2.2)	1 (2.2)	0
Mastoiditis	1 (2.2)	1 (2.2)	0
Meningitis pneumococcal	1 (2.2)	1 (2.2)	0
Metapneumovirus infection	1 (2.2)	1 (2.2)	0
Otitis externa	1 (2.2)	1 (2.2)	0
Otitis media	1 (2.2)	1 (2.2)	0
Pharyngitis streptococcal	1 (2.2)	1 (2.2)	0
Pneumonia	1 (2.2)	1 (2.2)	0
Pneumonia respiratory syncytial viral	1 (2.2)	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	1 (2.2)	0
Rhinovirus infection	1 (2.2)	0	0
Soft tissue infection	1 (2.2)	1 (2.2)	0
Staphylococcal abscess	1 (2.2)	1 (2.2)	0
Upper respiratory tract infection	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (2.2)	1 (2.2)	0
Viral upper respiratory tract infection	1 (2.2)	1 (2.2)	0
Injury, poisoning and procedural complications			
-Total	2 (4.4)	1 (2.2)	1 (2.2)
Infusion related reaction	1 (2.2)	1 (2.2)	0
Vasoplegia syndrome	1 (2.2)	0	1 (2.2)
Investigations			
-Total	4 (8.9)	2 (4.4)	2 (4.4)
Aspartate aminotransferase increased	2 (4.4)	2 (4.4)	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0
Blood uric acid increased	1 (2.2)	0	1 (2.2)
Electrocardiogram qt prolonged	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	6 (13.3)	2 (4.4)	3 (6.7)
Tumour lysis syndrome	2 (4.4)	1 (2.2)	1 (2.2)
Dehydration	1 (2.2)	0	0
Hypercalcaemia	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (2.2)	0	1 (2.2)
Hypernatraemia	1 (2.2)	0	1 (2.2)
Hyperphosphataemia	1 (2.2)	0	1 (2.2)
Hypokalaemia	1 (2.2)	1 (2.2)	0
Metabolic acidosis	1 (2.2)	0	1 (2.2)
Musculoskeletal and connective tissue disorders			
-Total	5 (11.1)	3 (6.7)	1 (2.2)
Back pain	3 (6.7)	2 (4.4)	0
Haemarthrosis	1 (2.2)	1 (2.2)	0
Rhabdomyolysis	1 (2.2)	0	1 (2.2)
Nervous system disorders			
-Total	6 (13.3)	4 (8.9)	1 (2.2)
Cerebral haemorrhage	1 (2.2)	0	1 (2.2)
Cognitive disorder	1 (2.2)	0	0
Dysarthria	1 (2.2)	1 (2.2)	0
Encephalopathy	1 (2.2)	1 (2.2)	0
Headache	1 (2.2)	1 (2.2)	0
Nervous system disorder	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (2.2)	1 (2.2)	0
Psychiatric disorders			
-Total	3 (6.7)	2 (4.4)	0
Mental status changes	2 (4.4)	1 (2.2)	0
Delirium	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	6 (13.3)	2 (4.4)	4 (8.9)
Acute kidney injury	5 (11.1)	2 (4.4)	3 (6.7)
Renal failure	1 (2.2)	0	1 (2.2)
Renal tubular necrosis	1 (2.2)	0	1 (2.2)
Reproductive system and breast disorders			
-Total	1 (2.2)	1 (2.2)	0
Endometriosis	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	15 (33.3)	4 (8.9)	10 (22.2)
Hypoxia	5 (11.1)	3 (6.7)	2 (4.4)
Respiratory failure	4 (8.9)	0	4 (8.9)

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Acute respiratory distress syndrome	2 (4.4)	0	2 (4.4)
Pleural effusion	2 (4.4)	1 (2.2)	1 (2.2)
Respiratory distress	2 (4.4)	0	1 (2.2)
Acute respiratory failure	1 (2.2)	1 (2.2)	0
Dyspnoea	1 (2.2)	0	1 (2.2)
Epistaxis	1 (2.2)	0	0
Laryngeal oedema	1 (2.2)	0	1 (2.2)
Pulmonary oedema	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	8 (17.8)	1 (2.2)	7 (15.6)
Hypotension	8 (17.8)	1 (2.2)	7 (15.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (71.4)	2 (28.6)	3 (42.9)
General disorders and administration site conditions			
-Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Cytokine release syndrome	4 (57.1)	1 (14.3)	3 (42.9)
Infections and infestations			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Upper respiratory tract infection	2 (28.6)	2 (28.6)	0
Encephalitis viral	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis bacterial	1 (14.3)	1 (14.3)	0
Parainfluenzae virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	31 (64.6)	15 (31.3)	14 (29.2)
Blood and lymphatic system disorders			
-Total	6 (12.5)	6 (12.5)	0
Febrile neutropenia	5 (10.4)	5 (10.4)	0
Pancytopenia	1 (2.1)	1 (2.1)	0
Cardiac disorders			
-Total	1 (2.1)	1 (2.1)	0
Left ventricular dysfunction	1 (2.1)	1 (2.1)	0
Gastrointestinal disorders			
-Total	2 (4.2)	2 (4.2)	0
Diarrhoea	1 (2.1)	1 (2.1)	0
Neutropenic colitis	1 (2.1)	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.1)	0	0
Pyrexia	1 (2.1)	0	0
Immune system disorders			
-Total	29 (60.4)	11 (22.9)	11 (22.9)
Cytokine release syndrome	29 (60.4)	11 (22.9)	11 (22.9)
Infections and infestations			
-Total	8 (16.7)	7 (14.6)	1 (2.1)
Candida infection	1 (2.1)	0	1 (2.1)
Encephalitis viral	1 (2.1)	1 (2.1)	0
Klebsiella infection	1 (2.1)	1 (2.1)	0
Pneumonia fungal	1 (2.1)	1 (2.1)	0
Pneumonia viral	1 (2.1)	1 (2.1)	0
Soft tissue infection	1 (2.1)	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Varicella zoster virus infection	1 (2.1)	1 (2.1)	0
Metabolism and nutrition disorders			
-Total	1 (2.1)	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	1 (2.1)	1 (2.1)	0
Headache	1 (2.1)	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.2)	0	1 (2.1)
Pleural effusion	1 (2.1)	0	1 (2.1)
Respiratory distress	1 (2.1)	0	0
Vascular disorders			
-Total	3 (6.3)	1 (2.1)	2 (4.2)
Hypotension	3 (6.3)	1 (2.1)	2 (4.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (71.9)	7 (21.9)	13 (40.6)
Blood and lymphatic system disorders			
-Total	10 (31.3)	8 (25.0)	2 (6.3)
Febrile neutropenia	8 (25.0)	7 (21.9)	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	1 (3.1)	0
Coagulopathy	1 (3.1)	1 (3.1)	0
Thrombocytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	4 (12.5)	0	3 (9.4)
Atrioventricular block first degree	1 (3.1)	0	0
Cardiac arrest	1 (3.1)	0	1 (3.1)
Cardiac failure	1 (3.1)	0	1 (3.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	3 (9.4)	1 (3.1)	1 (3.1)
Abdominal compartment syndrome	1 (3.1)	0	1 (3.1)
Constipation	1 (3.1)	0	0
Pancreatitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	4 (12.5)	0	2 (6.3)
Multiple organ dysfunction syndrome	2 (6.3)	0	2 (6.3)
Pyrexia	2 (6.3)	0	0
Systemic inflammatory response syndrome	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	0	2 (6.3)
Cholestasis	1 (3.1)	0	1 (3.1)
Hepatomegaly	1 (3.1)	0	1 (3.1)
Immune system disorders			
-Total	21 (65.6)	5 (15.6)	10 (31.3)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	21 (65.6)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)
Infections and infestations			
-Total	3 (9.4)	0	2 (6.3)
Encephalitis	1 (3.1)	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	1 (3.1)
Meningitis bacterial	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.1)	0	1 (3.1)
Vasoplegia syndrome	1 (3.1)	0	1 (3.1)
Investigations			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Aspartate aminotransferase increased	2 (6.3)	2 (6.3)	0
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Electrocardiogram qt prolonged	1 (3.1)	0	1 (3.1)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.4)	0	2 (6.3)
Dehydration	1 (3.1)	0	0
Hypercalcaemia	1 (3.1)	1 (3.1)	0
Hyperkalaemia	1 (3.1)	0	1 (3.1)
Hypernatraemia	1 (3.1)	0	1 (3.1)
Hyperphosphataemia	1 (3.1)	0	1 (3.1)
Metabolic acidosis	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Haemarthrosis	1 (3.1)	1 (3.1)	0
Rhabdomyolysis	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	4 (12.5)	2 (6.3)	1 (3.1)
Cerebral haemorrhage	1 (3.1)	0	1 (3.1)
Cognitive disorder	1 (3.1)	0	0
Dysarthria	1 (3.1)	1 (3.1)	0
Encephalopathy	1 (3.1)	1 (3.1)	0
Psychiatric disorders			

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	1 (3.1)	0
Delirium	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Acute kidney injury	4 (12.5)	2 (6.3)	2 (6.3)
Renal failure	1 (3.1)	0	1 (3.1)
Renal tubular necrosis	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (25.0)	3 (9.4)	5 (15.6)
Hypoxia	3 (9.4)	1 (3.1)	2 (6.3)
Respiratory failure	3 (9.4)	0	3 (9.4)
Acute respiratory distress syndrome	1 (3.1)	0	1 (3.1)
Acute respiratory failure	1 (3.1)	1 (3.1)	0
Dyspnoea	1 (3.1)	0	1 (3.1)
Pleural effusion	1 (3.1)	1 (3.1)	0
Pulmonary oedema	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	5 (15.6)	1 (3.1)	4 (12.5)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	5 (15.6)	1 (3.1)	4 (12.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=48	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	17 (35.4)	9 (18.8)	8 (16.7)
Blood and lymphatic system disorders			
-Total	4 (8.3)	4 (8.3)	0
Febrile neutropenia	3 (6.3)	3 (6.3)	0
Disseminated intravascular coagulation	1 (2.1)	1 (2.1)	0
Cardiac disorders			
-Total	1 (2.1)	0	1 (2.1)
Cardiac arrest	1 (2.1)	0	1 (2.1)
Gastrointestinal disorders			
-Total	2 (4.2)	1 (2.1)	0
Diarrhoea	1 (2.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (2.1)	1 (2.1)	0
Vomiting	1 (2.1)	0	0
General disorders and administration site conditions			
-Total	5 (10.4)	1 (2.1)	0
Pyrexia	4 (8.3)	1 (2.1)	0
Non-cardiac chest pain	1 (2.1)	0	0
Infections and infestations			
-Total	13 (27.1)	7 (14.6)	6 (12.5)
Gastroenteritis	2 (4.2)	2 (4.2)	0
Respiratory syncytial virus infection	2 (4.2)	2 (4.2)	0
Upper respiratory tract infection	2 (4.2)	2 (4.2)	0
Bacteraemia	1 (2.1)	0	1 (2.1)
Bronchopulmonary aspergillosis	1 (2.1)	0	1 (2.1)
Cytomegalovirus infection reactivation	1 (2.1)	1 (2.1)	0
Device related infection	1 (2.1)	1 (2.1)	0
Encephalitis	1 (2.1)	0	1 (2.1)
Enterobacter infection	1 (2.1)	1 (2.1)	0
Human herpesvirus 6 infection	1 (2.1)	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (2.1)	1 (2.1)	0
Mastoiditis	1 (2.1)	1 (2.1)	0
Metapneumovirus infection	1 (2.1)	1 (2.1)	0
Otitis externa	1 (2.1)	1 (2.1)	0
Otitis media	1 (2.1)	1 (2.1)	0
Parainfluenzae virus infection	1 (2.1)	1 (2.1)	0
Pneumocystis jirovecii pneumonia	1 (2.1)	0	1 (2.1)
Rhinovirus infection	1 (2.1)	1 (2.1)	0
Septic shock	1 (2.1)	0	1 (2.1)
Sinusitis	1 (2.1)	1 (2.1)	0
Staphylococcal sepsis	1 (2.1)	0	1 (2.1)
Urinary tract infection	1 (2.1)	1 (2.1)	0
Viral haemorrhagic cystitis	1 (2.1)	1 (2.1)	0
Investigations			
-Total	1 (2.1)	0	1 (2.1)
Blood uric acid increased	1 (2.1)	0	1 (2.1)
Metabolism and nutrition disorders			
-Total	3 (6.3)	2 (4.2)	1 (2.1)
Hypokalaemia	1 (2.1)	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (2.1)	1 (2.1)	0
Tumour lysis syndrome	1 (2.1)	0	1 (2.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (2.1)	1 (2.1)	0
Back pain	1 (2.1)	1 (2.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.1)	1 (2.1)	0
Myelodysplastic syndrome	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	1 (2.1)	0	1 (2.1)
Hydrocephalus	1 (2.1)	0	1 (2.1)
Psychiatric disorders			
-Total	2 (4.2)	1 (2.1)	0
Mental status changes	2 (4.2)	1 (2.1)	0
Renal and urinary disorders			
-Total	1 (2.1)	0	1 (2.1)
Acute kidney injury	1 (2.1)	0	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	4 (8.3)	1 (2.1)	2 (4.2)
Acute respiratory distress syndrome	1 (2.1)	0	1 (2.1)
Bronchial oedema	1 (2.1)	0	0
Hypoxia	1 (2.1)	1 (2.1)	0
Respiratory distress	1 (2.1)	0	1 (2.1)
Vascular disorders			
-Total	1 (2.1)	0	1 (2.1)
Hypotension	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (22.2)	3 (11.1)	3 (11.1)
Cardiac disorders			
-Total	1 (3.7)	0	1 (3.7)
Cardiac arrest	1 (3.7)	0	1 (3.7)
Cardiac failure	1 (3.7)	1 (3.7)	0
Gastrointestinal disorders			
-Total	1 (3.7)	0	0
Nausea	1 (3.7)	0	0
Immune system disorders			
-Total	1 (3.7)	1 (3.7)	0
Allergy to immunoglobulin therapy	1 (3.7)	1 (3.7)	0
Infections and infestations			

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Herpes zoster	1 (3.7)	1 (3.7)	0
Pharyngitis streptococcal	1 (3.7)	1 (3.7)	0
Pneumonia	1 (3.7)	0	1 (3.7)
Viral upper respiratory tract infection	1 (3.7)	1 (3.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (7.4)	1 (3.7)	0
Back pain	2 (7.4)	1 (3.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Epistaxis	1 (3.7)	0	0
Hypoxia	1 (3.7)	1 (3.7)	0
Respiratory failure	1 (3.7)	0	1 (3.7)
Vascular disorders			
-Total	1 (3.7)	0	1 (3.7)
Venoocclusive disease	1 (3.7)	0	1 (3.7)

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (33.3)	5 (15.2)	5 (15.2)
General disorders and administration site conditions			
-Total	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	0
Immune system disorders			
-Total	1 (3.0)	1 (3.0)	0
Drug hypersensitivity	1 (3.0)	1 (3.0)	0
Infections and infestations			
-Total	9 (27.3)	5 (15.2)	3 (9.1)
Sepsis	3 (9.1)	1 (3.0)	2 (6.1)
Candida infection	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (3.0)	1 (3.0)	0
Device related sepsis	1 (3.0)	1 (3.0)	0
Herpes zoster	1 (3.0)	1 (3.0)	0
Meningitis pneumococcal	1 (3.0)	1 (3.0)	0
Ophthalmic herpes zoster	1 (3.0)	0	0
Rhinovirus infection	1 (3.0)	0	0
Septic shock	1 (3.0)	0	1 (3.0)
Staphylococcal abscess	1 (3.0)	1 (3.0)	0
Upper respiratory tract infection	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	0	1 (3.0)
Decreased appetite	1 (3.0)	0	1 (3.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.0)	1 (3.0)	0
Bone giant cell tumour benign	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	2 (6.1)	2 (6.1)	0
Headache	1 (3.0)	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorder	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0
Reproductive system and breast disorders			
-Total	1 (3.0)	1 (3.0)	0
Endometriosis	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.1)	0	2 (6.1)
Dyspnoea exertional	1 (3.0)	0	0
Laryngeal oedema	1 (3.0)	0	1 (3.0)
Respiratory failure	1 (3.0)	0	1 (3.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (23.5)	3 (17.6)	1 (5.9)
Gastrointestinal disorders			
-Total	1 (5.9)	0	0
Irritable bowel syndrome	1 (5.9)	0	0
General disorders and administration site conditions			
-Total	2 (11.8)	0	1 (5.9)
Multiple organ dysfunction syndrome	1 (5.9)	0	1 (5.9)
Pyrexia	1 (5.9)	0	0
Immune system disorders			
-Total	1 (5.9)	0	1 (5.9)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)
Infections and infestations			
-Total	4 (23.5)	3 (17.6)	1 (5.9)
Clostridium difficile colitis	1 (5.9)	1 (5.9)	0
Covid-19 pneumonia	1 (5.9)	0	1 (5.9)
Gastroenteritis escherichia coli	1 (5.9)	1 (5.9)	0
Gastroenteritis salmonella	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Infusion related reaction	1 (5.9)	1 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	36 (75.0)	15 (31.3)	20 (41.7)
Blood and lymphatic system disorders			
-Total	8 (16.7)	8 (16.7)	0
Febrile neutropenia	7 (14.6)	7 (14.6)	0
Disseminated intravascular coagulation	1 (2.1)	1 (2.1)	0
Pancytopenia	1 (2.1)	1 (2.1)	0
Cardiac disorders			
-Total	2 (4.2)	1 (2.1)	1 (2.1)
Cardiac arrest	1 (2.1)	0	1 (2.1)
Left ventricular dysfunction	1 (2.1)	1 (2.1)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.3)	3 (6.3)	0
Diarrhoea	2 (4.2)	1 (2.1)	0
Neutropenic colitis	1 (2.1)	1 (2.1)	0
Pancreatitis	1 (2.1)	1 (2.1)	0
Vomiting	1 (2.1)	0	0
General disorders and administration site conditions			
-Total	6 (12.5)	1 (2.1)	0
Pyrexia	5 (10.4)	1 (2.1)	0
Non-cardiac chest pain	1 (2.1)	0	0
Immune system disorders			
-Total	29 (60.4)	11 (22.9)	11 (22.9)
Cytokine release syndrome	29 (60.4)	11 (22.9)	11 (22.9)
Drug hypersensitivity	1 (2.1)	1 (2.1)	0
Infections and infestations			
-Total	23 (47.9)	14 (29.2)	9 (18.8)
Sepsis	3 (6.3)	1 (2.1)	2 (4.2)
Upper respiratory tract infection	3 (6.3)	3 (6.3)	0
Candida infection	2 (4.2)	0	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (4.2)	2 (4.2)	0
Respiratory syncytial virus infection	2 (4.2)	2 (4.2)	0
Septic shock	2 (4.2)	0	2 (4.2)
Bacteraemia	1 (2.1)	0	1 (2.1)
Bronchopulmonary aspergillosis	1 (2.1)	0	1 (2.1)
Covid-19	1 (2.1)	1 (2.1)	0
Cytomegalovirus infection reactivation	1 (2.1)	1 (2.1)	0
Device related infection	1 (2.1)	1 (2.1)	0
Device related sepsis	1 (2.1)	1 (2.1)	0
Encephalitis	1 (2.1)	0	1 (2.1)
Encephalitis viral	1 (2.1)	1 (2.1)	0
Enterobacter infection	1 (2.1)	1 (2.1)	0
Herpes zoster	1 (2.1)	1 (2.1)	0
Human herpesvirus 6 infection	1 (2.1)	1 (2.1)	0
Klebsiella infection	1 (2.1)	1 (2.1)	0
Mastoiditis	1 (2.1)	1 (2.1)	0
Meningitis pneumococcal	1 (2.1)	1 (2.1)	0
Metapneumovirus infection	1 (2.1)	1 (2.1)	0
Ophthalmic herpes zoster	1 (2.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (2.1)	1 (2.1)	0
Otitis media	1 (2.1)	1 (2.1)	0
Parainfluenzae virus infection	1 (2.1)	1 (2.1)	0
Pneumocystis jirovecii pneumonia	1 (2.1)	0	1 (2.1)
Pneumonia fungal	1 (2.1)	1 (2.1)	0
Pneumonia viral	1 (2.1)	1 (2.1)	0
Rhinovirus infection	1 (2.1)	1 (2.1)	0
Sinusitis	1 (2.1)	1 (2.1)	0
Soft tissue infection	1 (2.1)	1 (2.1)	0
Staphylococcal abscess	1 (2.1)	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Staphylococcal sepsis	1 (2.1)	0	1 (2.1)
Urinary tract infection	1 (2.1)	1 (2.1)	0
Varicella zoster virus infection	1 (2.1)	1 (2.1)	0
Viral haemorrhagic cystitis	1 (2.1)	1 (2.1)	0
Investigations			
-Total	1 (2.1)	0	1 (2.1)
Blood uric acid increased	1 (2.1)	0	1 (2.1)
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.4)	3 (6.3)	2 (4.2)
Tumour lysis syndrome	2 (4.2)	1 (2.1)	1 (2.1)
Decreased appetite	1 (2.1)	0	1 (2.1)
Hypokalaemia	1 (2.1)	1 (2.1)	0
Malnutrition	1 (2.1)	1 (2.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.1)	1 (2.1)	0
Back pain	1 (2.1)	1 (2.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (4.2)	2 (4.2)	0
Bone giant cell tumour benign	1 (2.1)	1 (2.1)	0
Myelodysplastic syndrome	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	4 (8.3)	3 (6.3)	1 (2.1)
Headache	2 (4.2)	2 (4.2)	0
Hydrocephalus	1 (2.1)	0	1 (2.1)
Nervous system disorder	1 (2.1)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (2.1)	1 (2.1)	0
Psychiatric disorders			
-Total	2 (4.2)	1 (2.1)	0
Mental status changes	2 (4.2)	1 (2.1)	0
Renal and urinary disorders			
-Total	1 (2.1)	0	1 (2.1)
Acute kidney injury	1 (2.1)	0	1 (2.1)
Reproductive system and breast disorders			
-Total	1 (2.1)	1 (2.1)	0
Endometriosis	1 (2.1)	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (18.8)	1 (2.1)	5 (10.4)
Respiratory distress	2 (4.2)	0	1 (2.1)
Acute respiratory distress syndrome	1 (2.1)	0	1 (2.1)
Bronchial oedema	1 (2.1)	0	0
Dyspnoea exertional	1 (2.1)	0	0
Hypoxia	1 (2.1)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (2.1)	0	1 (2.1)
Pleural effusion	1 (2.1)	0	1 (2.1)
Respiratory failure	1 (2.1)	0	1 (2.1)
Vascular disorders			
-Total	3 (6.3)	0	3 (6.3)
Hypotension	3 (6.3)	0	3 (6.3)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 209l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	27 (84.4)	8 (25.0)	17 (53.1)
Blood and lymphatic system disorders			
-Total	10 (31.3)	8 (25.0)	2 (6.3)
Febrile neutropenia	8 (25.0)	7 (21.9)	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	1 (3.1)	0
Coagulopathy	1 (3.1)	1 (3.1)	0
Thrombocytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	5 (15.6)	0	4 (12.5)
Cardiac arrest	2 (6.3)	0	2 (6.3)
Cardiac failure	2 (6.3)	1 (3.1)	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (3.1)	0	0
Tachycardia	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	4 (12.5)	1 (3.1)	1 (3.1)
Abdominal compartment syndrome	1 (3.1)	0	1 (3.1)
Constipation	1 (3.1)	0	0
Irritable bowel syndrome	1 (3.1)	0	0
Nausea	1 (3.1)	0	0
Pancreatitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	5 (15.6)	0	3 (9.4)
Multiple organ dysfunction syndrome	3 (9.4)	0	3 (9.4)
Pyrexia	2 (6.3)	0	0
Systemic inflammatory response syndrome	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	0	2 (6.3)
Cholestasis	1 (3.1)	0	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (3.1)	0	1 (3.1)
Immune system disorders			
-Total	22 (68.8)	5 (15.6)	11 (34.4)
Cytokine release syndrome	21 (65.6)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	2 (6.3)	0	2 (6.3)
Allergy to immunoglobulin therapy	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	8 (25.0)	4 (12.5)	4 (12.5)
Pneumonia	2 (6.3)	1 (3.1)	1 (3.1)
Clostridium difficile colitis	1 (3.1)	1 (3.1)	0
Covid-19 pneumonia	1 (3.1)	0	1 (3.1)
Encephalitis	1 (3.1)	0	1 (3.1)
Encephalitis viral	1 (3.1)	0	1 (3.1)
Gastroenteritis escherichia coli	1 (3.1)	1 (3.1)	0
Gastroenteritis salmonella	1 (3.1)	1 (3.1)	0
Herpes zoster	1 (3.1)	1 (3.1)	0
Meningitis bacterial	1 (3.1)	1 (3.1)	0
Pharyngitis streptococcal	1 (3.1)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Infusion related reaction	1 (3.1)	1 (3.1)	0
Vasoplegia syndrome	1 (3.1)	0	1 (3.1)
Investigations			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Aspartate aminotransferase increased	2 (6.3)	2 (6.3)	0
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Electrocardiogram qt prolonged	1 (3.1)	0	1 (3.1)
Metabolism and nutrition disorders			
-Total	3 (9.4)	0	2 (6.3)
Dehydration	1 (3.1)	0	0
Hypercalcaemia	1 (3.1)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (3.1)	0	1 (3.1)
Hypernatraemia	1 (3.1)	0	1 (3.1)
Hyperphosphataemia	1 (3.1)	0	1 (3.1)
Metabolic acidosis	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	4 (12.5)	2 (6.3)	1 (3.1)
Back pain	2 (6.3)	1 (3.1)	0
Haemarthrosis	1 (3.1)	1 (3.1)	0
Rhabdomyolysis	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	4 (12.5)	2 (6.3)	1 (3.1)
Cerebral haemorrhage	1 (3.1)	0	1 (3.1)
Cognitive disorder	1 (3.1)	0	0
Dysarthria	1 (3.1)	1 (3.1)	0
Encephalopathy	1 (3.1)	1 (3.1)	0
Psychiatric disorders			
-Total	1 (3.1)	1 (3.1)	0
Delirium	1 (3.1)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Acute kidney injury	4 (12.5)	2 (6.3)	2 (6.3)
Renal failure	1 (3.1)	0	1 (3.1)
Renal tubular necrosis	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (28.1)	3 (9.4)	6 (18.8)
Hypoxia	4 (12.5)	2 (6.3)	2 (6.3)
Respiratory failure	4 (12.5)	0	4 (12.5)
Acute respiratory distress syndrome	1 (3.1)	0	1 (3.1)
Acute respiratory failure	1 (3.1)	1 (3.1)	0
Dyspnoea	1 (3.1)	0	1 (3.1)
Epistaxis	1 (3.1)	0	0
Pleural effusion	1 (3.1)	1 (3.1)	0
Pulmonary oedema	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	6 (18.8)	1 (3.1)	5 (15.6)
Hypotension	5 (15.6)	1 (3.1)	4 (12.5)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	1 (3.1)	0	1 (3.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	10 (76.9)	7 (53.8)	2 (15.4)
Blood and lymphatic system disorders			
-Total	6 (46.2)	6 (46.2)	0
Febrile neutropenia	6 (46.2)	6 (46.2)	0
Cardiac disorders			
-Total	1 (7.7)	1 (7.7)	0
Left ventricular dysfunction	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	1 (7.7)	1 (7.7)	0
Neutropenic colitis	1 (7.7)	1 (7.7)	0
General disorders and administration site conditions			
-Total	1 (7.7)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (7.7)	0	0
Immune system disorders			
-Total	10 (76.9)	4 (30.8)	1 (7.7)
Cytokine release syndrome	10 (76.9)	4 (30.8)	1 (7.7)
Infections and infestations			
-Total	1 (7.7)	1 (7.7)	0
Varicella zoster virus infection	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	1 (7.7)	0	0
Dehydration	1 (7.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (15.4)	1 (7.7)	0
Hypoxia	1 (7.7)	1 (7.7)	0
Respiratory distress	1 (7.7)	0	0
Vascular disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	44 (65.7)	15 (22.4)	25 (37.3)
Blood and lymphatic system disorders			
-Total	10 (14.9)	8 (11.9)	2 (3.0)
Febrile neutropenia	7 (10.4)	6 (9.0)	1 (1.5)
Disseminated intravascular coagulation	2 (3.0)	1 (1.5)	0
Coagulopathy	1 (1.5)	1 (1.5)	0
Pancytopenia	1 (1.5)	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	1 (1.5)
Cardiac disorders			
-Total	4 (6.0)	0	3 (4.5)
Atrioventricular block first degree	1 (1.5)	0	0
Cardiac arrest	1 (1.5)	0	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.5)	0	1 (1.5)
Tachycardia	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	4 (6.0)	2 (3.0)	1 (1.5)
Abdominal compartment syndrome	1 (1.5)	0	1 (1.5)
Constipation	1 (1.5)	0	0
Diarrhoea	1 (1.5)	1 (1.5)	0
Pancreatitis	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	4 (6.0)	0	2 (3.0)
Multiple organ dysfunction syndrome	2 (3.0)	0	2 (3.0)
Pyrexia	2 (3.0)	0	0
Systemic inflammatory response syndrome	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	2 (3.0)	0	2 (3.0)
Cholestasis	1 (1.5)	0	1 (1.5)
Hepatomegaly	1 (1.5)	0	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	40 (59.7)	12 (17.9)	20 (29.9)
Cytokine release syndrome	40 (59.7)	12 (17.9)	20 (29.9)
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)
Infections and infestations			
-Total	10 (14.9)	6 (9.0)	3 (4.5)
Encephalitis viral	2 (3.0)	1 (1.5)	1 (1.5)
Candida infection	1 (1.5)	0	1 (1.5)
Encephalitis	1 (1.5)	0	1 (1.5)
Klebsiella infection	1 (1.5)	1 (1.5)	0
Meningitis bacterial	1 (1.5)	1 (1.5)	0
Pneumonia fungal	1 (1.5)	1 (1.5)	0
Pneumonia viral	1 (1.5)	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	0
Soft tissue infection	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.5)	0	1 (1.5)
Vasoplegia syndrome	1 (1.5)	0	1 (1.5)
Investigations			
-Total	3 (4.5)	2 (3.0)	1 (1.5)
Aspartate aminotransferase increased	2 (3.0)	2 (3.0)	0
Blood bilirubin increased	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	3 (4.5)	1 (1.5)	2 (3.0)
Hypercalcaemia	1 (1.5)	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	1 (1.5)
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hyperphosphataemia	1 (1.5)	0	1 (1.5)
Metabolic acidosis	1 (1.5)	0	1 (1.5)
Tumour lysis syndrome	1 (1.5)	1 (1.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.0)	1 (1.5)	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (1.5)	1 (1.5)	0
Rhabdomyolysis	1 (1.5)	0	1 (1.5)
Nervous system disorders			
-Total	5 (7.5)	3 (4.5)	1 (1.5)
Cerebral haemorrhage	1 (1.5)	0	1 (1.5)
Cognitive disorder	1 (1.5)	0	0
Dysarthria	1 (1.5)	1 (1.5)	0
Encephalopathy	1 (1.5)	1 (1.5)	0
Headache	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	1 (1.5)	1 (1.5)	0
Delirium	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	5 (7.5)	2 (3.0)	3 (4.5)
Acute kidney injury	4 (6.0)	2 (3.0)	2 (3.0)
Renal failure	1 (1.5)	0	1 (1.5)
Renal tubular necrosis	1 (1.5)	0	1 (1.5)
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (11.9)	2 (3.0)	6 (9.0)
Respiratory failure	3 (4.5)	0	3 (4.5)
Hypoxia	2 (3.0)	0	2 (3.0)
Pleural effusion	2 (3.0)	1 (1.5)	1 (1.5)
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Acute respiratory failure	1 (1.5)	1 (1.5)	0
Dyspnoea	1 (1.5)	0	1 (1.5)
Pulmonary oedema	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	6 (9.0)	1 (1.5)	5 (7.5)
Hypotension	6 (9.0)	1 (1.5)	5 (7.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (37.1)	12 (19.4)	11 (17.7)
Blood and lymphatic system disorders			
-Total	4 (6.5)	4 (6.5)	0
Febrile neutropenia	3 (4.8)	3 (4.8)	0
Disseminated intravascular coagulation	1 (1.6)	1 (1.6)	0
Cardiac disorders			
-Total	2 (3.2)	0	2 (3.2)
Cardiac arrest	2 (3.2)	0	2 (3.2)
Cardiac failure	1 (1.6)	1 (1.6)	0
Gastrointestinal disorders			
-Total	3 (4.8)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (1.6)	0	0
Nausea	1 (1.6)	0	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Vomiting	1 (1.6)	0	0
General disorders and administration site conditions			
-Total	5 (8.1)	1 (1.6)	0
Pyrexia	4 (6.5)	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	0	0
Immune system disorders			
-Total	1 (1.6)	1 (1.6)	0
Allergy to immunoglobulin therapy	1 (1.6)	1 (1.6)	0
Infections and infestations			
-Total	16 (25.8)	9 (14.5)	7 (11.3)
Gastroenteritis	2 (3.2)	2 (3.2)	0
Respiratory syncytial virus infection	2 (3.2)	2 (3.2)	0
Upper respiratory tract infection	2 (3.2)	2 (3.2)	0
Bacteraemia	1 (1.6)	0	1 (1.6)
Bronchopulmonary aspergillosis	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.6)	1 (1.6)	0
Device related infection	1 (1.6)	1 (1.6)	0
Encephalitis	1 (1.6)	0	1 (1.6)
Enterobacter infection	1 (1.6)	1 (1.6)	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	1 (1.6)	0
Klebsiella infection	1 (1.6)	1 (1.6)	0
Mastoiditis	1 (1.6)	1 (1.6)	0
Metapneumovirus infection	1 (1.6)	1 (1.6)	0
Otitis externa	1 (1.6)	1 (1.6)	0
Otitis media	1 (1.6)	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0
Pharyngitis streptococcal	1 (1.6)	1 (1.6)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	1 (1.6)
Pneumonia	1 (1.6)	0	1 (1.6)
Rhinovirus infection	1 (1.6)	1 (1.6)	0
Septic shock	1 (1.6)	0	1 (1.6)
Sinusitis	1 (1.6)	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (1.6)	1 (1.6)	0
Viral haemorrhagic cystitis	1 (1.6)	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Investigations			
-Total	1 (1.6)	0	1 (1.6)
Blood uric acid increased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	3 (4.8)	2 (3.2)	1 (1.6)
Hypokalaemia	1 (1.6)	1 (1.6)	0
Malnutrition	1 (1.6)	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	1 (1.6)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.8)	2 (3.2)	0
Back pain	3 (4.8)	2 (3.2)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.6)	1 (1.6)	0
Myelodysplastic syndrome	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (1.6)	0	1 (1.6)
Hydrocephalus	1 (1.6)	0	1 (1.6)
Psychiatric disorders			
-Total	2 (3.2)	1 (1.6)	0
Mental status changes	2 (3.2)	1 (1.6)	0
Renal and urinary disorders			
-Total	1 (1.6)	0	1 (1.6)
Acute kidney injury	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (9.7)	2 (3.2)	3 (4.8)
Hypoxia	2 (3.2)	2 (3.2)	0
Acute respiratory distress syndrome	1 (1.6)	0	1 (1.6)
Bronchial oedema	1 (1.6)	0	0
Epistaxis	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	1 (1.6)
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.2)	0	2 (3.2)
Hypotension	1 (1.6)	0	1 (1.6)
Venoocclusive disease	1 (1.6)	0	1 (1.6)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (25.0)	1 (12.5)	1 (12.5)
Infections and infestations			
-Total	2 (25.0)	2 (25.0)	0
Staphylococcal abscess	1 (12.5)	1 (12.5)	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Laryngeal oedema	1 (12.5)	0	1 (12.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (31.0)	7 (16.7)	5 (11.9)
Gastrointestinal disorders			
-Total	1 (2.4)	0	0
Irritable bowel syndrome	1 (2.4)	0	0
General disorders and administration site conditions			
-Total	3 (7.1)	0	1 (2.4)
Pyrexia	2 (4.8)	0	0
Multiple organ dysfunction syndrome	1 (2.4)	0	1 (2.4)
Immune system disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Drug hypersensitivity	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	1 (2.4)
Infections and infestations			
-Total	11 (26.2)	6 (14.3)	4 (9.5)
Sepsis	3 (7.1)	1 (2.4)	2 (4.8)
Candida infection	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	1 (2.4)	0
Covid-19	1 (2.4)	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	1 (2.4)
Device related sepsis	1 (2.4)	1 (2.4)	0
Gastroenteritis escherichia coli	1 (2.4)	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	1 (2.4)	0
Herpes zoster	1 (2.4)	1 (2.4)	0
Meningitis pneumococcal	1 (2.4)	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	0
Pneumonia	1 (2.4)	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	1 (2.4)	0
Rhinovirus infection	1 (2.4)	0	0
Septic shock	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Injury, poisoning and procedural complications			
-Total	1 (2.4)	1 (2.4)	0
Infusion related reaction	1 (2.4)	1 (2.4)	0
Metabolism and nutrition disorders			
-Total	1 (2.4)	0	1 (2.4)
Decreased appetite	1 (2.4)	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.4)	1 (2.4)	0
Bone giant cell tumour benign	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	2 (4.8)	2 (4.8)	0
Headache	1 (2.4)	1 (2.4)	0
Nervous system disorder	1 (2.4)	1 (2.4)	0
Seizure	1 (2.4)	1 (2.4)	0
Reproductive system and breast disorders			
-Total	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endometriosis	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.8)	0	1 (2.4)
Dyspnoea exertional	1 (2.4)	0	0
Respiratory failure	1 (2.4)	0	1 (2.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	10 (76.9)	6 (46.2)	3 (23.1)
Blood and lymphatic system disorders			
-Total	6 (46.2)	6 (46.2)	0
Febrile neutropenia	6 (46.2)	6 (46.2)	0
Cardiac disorders			
-Total	1 (7.7)	1 (7.7)	0
Left ventricular dysfunction	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	1 (7.7)	1 (7.7)	0
Neutropenic colitis	1 (7.7)	1 (7.7)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.7)	0	0
Pyrexia	1 (7.7)	0	0
Immune system disorders			
-Total	10 (76.9)	4 (30.8)	1 (7.7)
Cytokine release syndrome	10 (76.9)	4 (30.8)	1 (7.7)
Infections and infestations			
-Total	2 (15.4)	2 (15.4)	0
Staphylococcal abscess	1 (7.7)	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	1 (7.7)	0
Varicella zoster virus infection	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	1 (7.7)	0	0
Dehydration	1 (7.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (23.1)	1 (7.7)	1 (7.7)
Hypoxia	1 (7.7)	1 (7.7)	0
Laryngeal oedema	1 (7.7)	0	1 (7.7)
Respiratory distress	1 (7.7)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	53 (79.1)	17 (25.4)	34 (50.7)
Blood and lymphatic system disorders			
-Total	12 (17.9)	10 (14.9)	2 (3.0)
Febrile neutropenia	9 (13.4)	8 (11.9)	1 (1.5)
Disseminated intravascular coagulation	3 (4.5)	2 (3.0)	0
Coagulopathy	1 (1.5)	1 (1.5)	0
Pancytopenia	1 (1.5)	1 (1.5)	0
Thrombocytopenia	1 (1.5)	0	1 (1.5)
Cardiac disorders			
-Total	6 (9.0)	0	5 (7.5)
Cardiac arrest	3 (4.5)	0	3 (4.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (3.0)	1 (1.5)	1 (1.5)
Atrioventricular block first degree	1 (1.5)	0	0
Tachycardia	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	7 (10.4)	3 (4.5)	1 (1.5)
Diarrhoea	2 (3.0)	1 (1.5)	0
Pancreatitis	2 (3.0)	2 (3.0)	0
Abdominal compartment syndrome	1 (1.5)	0	1 (1.5)
Constipation	1 (1.5)	0	0
Irritable bowel syndrome	1 (1.5)	0	0
Nausea	1 (1.5)	0	0
Vomiting	1 (1.5)	0	0
General disorders and administration site conditions			
-Total	10 (14.9)	1 (1.5)	3 (4.5)
Pyrexia	6 (9.0)	1 (1.5)	0
Multiple organ dysfunction syndrome	3 (4.5)	0	3 (4.5)
Non-cardiac chest pain	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	2 (3.0)	0	2 (3.0)
Cholestasis	1 (1.5)	0	1 (1.5)
Hepatomegaly	1 (1.5)	0	1 (1.5)
Immune system disorders			
-Total	41 (61.2)	12 (17.9)	21 (31.3)
Cytokine release syndrome	40 (59.7)	12 (17.9)	20 (29.9)
Haemophagocytic lymphohistiocytosis	2 (3.0)	0	2 (3.0)
Allergy to immunoglobulin therapy	1 (1.5)	1 (1.5)	0
Drug hypersensitivity	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	29 (43.3)	16 (23.9)	13 (19.4)
Sepsis	3 (4.5)	1 (1.5)	2 (3.0)
Candida infection	2 (3.0)	0	1 (1.5)
Encephalitis	2 (3.0)	0	2 (3.0)
Encephalitis viral	2 (3.0)	1 (1.5)	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (3.0)	2 (3.0)	0
Herpes zoster	2 (3.0)	2 (3.0)	0
Pneumonia	2 (3.0)	1 (1.5)	1 (1.5)
Respiratory syncytial virus infection	2 (3.0)	2 (3.0)	0
Rhinovirus infection	2 (3.0)	1 (1.5)	0
Septic shock	2 (3.0)	0	2 (3.0)
Staphylococcal bacteraemia	2 (3.0)	2 (3.0)	0
Upper respiratory tract infection	2 (3.0)	2 (3.0)	0
Bacteraemia	1 (1.5)	0	1 (1.5)
Bronchopulmonary aspergillosis	1 (1.5)	0	1 (1.5)
Clostridium difficile colitis	1 (1.5)	1 (1.5)	0
Covid-19	1 (1.5)	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	1 (1.5)
Cytomegalovirus infection reactivation	1 (1.5)	1 (1.5)	0
Device related infection	1 (1.5)	1 (1.5)	0
Device related sepsis	1 (1.5)	1 (1.5)	0
Enterobacter infection	1 (1.5)	1 (1.5)	0
Gastroenteritis escherichia coli	1 (1.5)	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.5)	1 (1.5)	0
Klebsiella infection	1 (1.5)	1 (1.5)	0
Mastoiditis	1 (1.5)	1 (1.5)	0
Meningitis bacterial	1 (1.5)	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	1 (1.5)	0
Ophthalmic herpes zoster	1 (1.5)	0	0
Otitis externa	1 (1.5)	1 (1.5)	0
Otitis media	1 (1.5)	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	1 (1.5)	0
Pharyngitis streptococcal	1 (1.5)	1 (1.5)	0
Pneumocystis jirovecii pneumonia	1 (1.5)	0	1 (1.5)
Pneumonia fungal	1 (1.5)	1 (1.5)	0
Pneumonia respiratory syncytial viral	1 (1.5)	1 (1.5)	0
Pneumonia viral	1 (1.5)	1 (1.5)	0
Sinusitis	1 (1.5)	1 (1.5)	0
Soft tissue infection	1 (1.5)	1 (1.5)	0
Staphylococcal sepsis	1 (1.5)	0	1 (1.5)
Urinary tract infection	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.5)	1 (1.5)	0
Viral upper respiratory tract infection	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	2 (3.0)	1 (1.5)	1 (1.5)
Infusion related reaction	1 (1.5)	1 (1.5)	0
Vasoplegia syndrome	1 (1.5)	0	1 (1.5)
Investigations			
-Total	4 (6.0)	2 (3.0)	2 (3.0)
Aspartate aminotransferase increased	2 (3.0)	2 (3.0)	0
Blood bilirubin increased	1 (1.5)	1 (1.5)	0
Blood uric acid increased	1 (1.5)	0	1 (1.5)
Electrocardiogram qt prolonged	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	7 (10.4)	3 (4.5)	4 (6.0)
Tumour lysis syndrome	2 (3.0)	1 (1.5)	1 (1.5)
Decreased appetite	1 (1.5)	0	1 (1.5)
Hypercalcaemia	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (1.5)	0	1 (1.5)
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hyperphosphataemia	1 (1.5)	0	1 (1.5)
Hypokalaemia	1 (1.5)	1 (1.5)	0
Malnutrition	1 (1.5)	1 (1.5)	0
Metabolic acidosis	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	5 (7.5)	3 (4.5)	1 (1.5)
Back pain	3 (4.5)	2 (3.0)	0
Haemarthrosis	1 (1.5)	1 (1.5)	0
Rhabdomyolysis	1 (1.5)	0	1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.0)	2 (3.0)	0
Bone giant cell tumour benign	1 (1.5)	1 (1.5)	0
Myelodysplastic syndrome	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	8 (11.9)	5 (7.5)	2 (3.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (3.0)	2 (3.0)	0
Cerebral haemorrhage	1 (1.5)	0	1 (1.5)
Cognitive disorder	1 (1.5)	0	0
Dysarthria	1 (1.5)	1 (1.5)	0
Encephalopathy	1 (1.5)	1 (1.5)	0
Hydrocephalus	1 (1.5)	0	1 (1.5)
Nervous system disorder	1 (1.5)	1 (1.5)	0
Seizure	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	3 (4.5)	2 (3.0)	0
Mental status changes	2 (3.0)	1 (1.5)	0
Delirium	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	6 (9.0)	2 (3.0)	4 (6.0)
Acute kidney injury	5 (7.5)	2 (3.0)	3 (4.5)
Renal failure	1 (1.5)	0	1 (1.5)
Renal tubular necrosis	1 (1.5)	0	1 (1.5)
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.5)	1 (1.5)	0
Endometriosis	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	15 (22.4)	3 (4.5)	10 (14.9)
Respiratory failure	5 (7.5)	0	5 (7.5)
Hypoxia	4 (6.0)	2 (3.0)	2 (3.0)
Acute respiratory distress syndrome	2 (3.0)	0	2 (3.0)
Pleural effusion	2 (3.0)	1 (1.5)	1 (1.5)
Acute respiratory failure	1 (1.5)	1 (1.5)	0
Bronchial oedema	1 (1.5)	0	0
Dyspnoea	1 (1.5)	0	1 (1.5)
Dyspnoea exertional	1 (1.5)	0	0
Epistaxis	1 (1.5)	0	0
Pulmonary oedema	1 (1.5)	1 (1.5)	0
Respiratory distress	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	7 (10.4)	0	7 (10.4)
Hypotension	6 (9.0)	0	6 (9.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	1 (1.5)	0	1 (1.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (53.8)	8 (30.8)	4 (15.4)
Blood and lymphatic system disorders			
-Total	5 (19.2)	5 (19.2)	0
Febrile neutropenia	4 (15.4)	4 (15.4)	0
Pancytopenia	1 (3.8)	1 (3.8)	0
Cardiac disorders			
-Total	1 (3.8)	0	1 (3.8)
Tachycardia	1 (3.8)	0	1 (3.8)
Gastrointestinal disorders			
-Total	1 (3.8)	1 (3.8)	0
Pancreatitis	1 (3.8)	1 (3.8)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (11.5)	0	1 (3.8)
Pyrexia	2 (7.7)	0	0
Multiple organ dysfunction syndrome	1 (3.8)	0	1 (3.8)
Systemic inflammatory response syndrome	1 (3.8)	1 (3.8)	0
Hepatobiliary disorders			
-Total	1 (3.8)	0	1 (3.8)
Cholestasis	1 (3.8)	0	1 (3.8)
Immune system disorders			
-Total	12 (46.2)	3 (11.5)	4 (15.4)
Cytokine release syndrome	12 (46.2)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	1 (3.8)	0	1 (3.8)
Infections and infestations			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Encephalitis	1 (3.8)	0	1 (3.8)
Staphylococcal bacteraemia	1 (3.8)	1 (3.8)	0
Injury, poisoning and procedural complications			
-Total	1 (3.8)	0	1 (3.8)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (3.8)	0	1 (3.8)
Investigations			
-Total	1 (3.8)	0	1 (3.8)
Electrocardiogram qt prolonged	1 (3.8)	0	1 (3.8)
Metabolism and nutrition disorders			
-Total	3 (11.5)	1 (3.8)	1 (3.8)
Dehydration	1 (3.8)	0	0
Hypernatraemia	1 (3.8)	0	1 (3.8)
Tumour lysis syndrome	1 (3.8)	1 (3.8)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Haemarthrosis	1 (3.8)	1 (3.8)	0
Rhabdomyolysis	1 (3.8)	0	1 (3.8)
Nervous system disorders			
-Total	2 (7.7)	2 (7.7)	0
Encephalopathy	1 (3.8)	1 (3.8)	0
Headache	1 (3.8)	1 (3.8)	0
Renal and urinary disorders			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.8)	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	1 (3.8)
Renal tubular necrosis	1 (3.8)	0	1 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (11.5)	1 (3.8)	2 (7.7)
Pleural effusion	2 (7.7)	1 (3.8)	1 (3.8)
Acute respiratory distress syndrome	1 (3.8)	0	1 (3.8)
Dyspnoea	1 (3.8)	0	1 (3.8)
Pulmonary oedema	1 (3.8)	1 (3.8)	0
Vascular disorders			
-Total	1 (3.8)	0	1 (3.8)
Hypotension	1 (3.8)	0	1 (3.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	40 (74.1)	14 (25.9)	23 (42.6)
Blood and lymphatic system disorders			
-Total	11 (20.4)	9 (16.7)	2 (3.7)
Febrile neutropenia	9 (16.7)	8 (14.8)	1 (1.9)
Disseminated intravascular coagulation	2 (3.7)	1 (1.9)	0
Coagulopathy	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	4 (7.4)	1 (1.9)	2 (3.7)
Atrioventricular block first degree	1 (1.9)	0	0
Cardiac arrest	1 (1.9)	0	1 (1.9)
Cardiac failure	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	4 (7.4)	2 (3.7)	1 (1.9)
Abdominal compartment syndrome	1 (1.9)	0	1 (1.9)
Constipation	1 (1.9)	0	0
Diarrhoea	1 (1.9)	1 (1.9)	0
Neutropenic colitis	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	2 (3.7)	0	1 (1.9)
Multiple organ dysfunction syndrome	1 (1.9)	0	1 (1.9)
Pyrexia	1 (1.9)	0	0
Hepatobiliary disorders			
-Total	1 (1.9)	0	1 (1.9)
Hepatomegaly	1 (1.9)	0	1 (1.9)
Immune system disorders			
-Total	38 (70.4)	13 (24.1)	17 (31.5)
Cytokine release syndrome	38 (70.4)	13 (24.1)	17 (31.5)
Infections and infestations			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (16.7)	6 (11.1)	2 (3.7)
Encephalitis viral	2 (3.7)	1 (1.9)	1 (1.9)
Candida infection	1 (1.9)	0	1 (1.9)
Klebsiella infection	1 (1.9)	1 (1.9)	0
Meningitis bacterial	1 (1.9)	1 (1.9)	0
Pneumonia fungal	1 (1.9)	1 (1.9)	0
Pneumonia viral	1 (1.9)	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	0
Soft tissue infection	1 (1.9)	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	2 (3.7)	2 (3.7)	0
Aspartate aminotransferase increased	2 (3.7)	2 (3.7)	0
Blood bilirubin increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	1 (1.9)	0	1 (1.9)
Hypercalcaemia	1 (1.9)	1 (1.9)	0
Hyperkalaemia	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (1.9)	0	1 (1.9)
Metabolic acidosis	1 (1.9)	0	1 (1.9)
Nervous system disorders			
-Total	3 (5.6)	1 (1.9)	1 (1.9)
Cerebral haemorrhage	1 (1.9)	0	1 (1.9)
Cognitive disorder	1 (1.9)	0	0
Dysarthria	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	1 (1.9)	1 (1.9)	0
Delirium	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	4 (7.4)	2 (3.7)	2 (3.7)
Acute kidney injury	3 (5.6)	2 (3.7)	1 (1.9)
Renal failure	1 (1.9)	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (13.0)	2 (3.7)	4 (7.4)
Hypoxia	3 (5.6)	1 (1.9)	2 (3.7)
Respiratory failure	3 (5.6)	0	3 (5.6)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory failure	1 (1.9)	1 (1.9)	0
Respiratory distress	1 (1.9)	0	0
Vascular disorders			
-Total	7 (13.0)	2 (3.7)	5 (9.3)
Hypotension	7 (13.0)	2 (3.7)	5 (9.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (28.0)	5 (20.0)	2 (8.0)
Blood and lymphatic system disorders			
-Total	2 (8.0)	2 (8.0)	0
Disseminated intravascular coagulation	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	1 (4.0)	1 (4.0)	0
Pyrexia	1 (4.0)	1 (4.0)	0
Infections and infestations			
-Total	5 (20.0)	3 (12.0)	2 (8.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (8.0)	2 (8.0)	0
Upper respiratory tract infection	2 (8.0)	2 (8.0)	0
Bronchopulmonary aspergillosis	1 (4.0)	0	1 (4.0)
Encephalitis	1 (4.0)	0	1 (4.0)
Gastroenteritis	1 (4.0)	1 (4.0)	0
Herpes zoster	1 (4.0)	1 (4.0)	0
Parainfluenzae virus infection	1 (4.0)	1 (4.0)	0
Rhinovirus infection	1 (4.0)	1 (4.0)	0
Viral haemorrhagic cystitis	1 (4.0)	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Epistaxis	1 (4.0)	0	0
Hypoxia	1 (4.0)	1 (4.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (32.0)	7 (14.0)	9 (18.0)
Blood and lymphatic system disorders			
-Total	2 (4.0)	2 (4.0)	0
Febrile neutropenia	2 (4.0)	2 (4.0)	0
Cardiac disorders			
-Total	2 (4.0)	0	2 (4.0)
Cardiac arrest	2 (4.0)	0	2 (4.0)
Cardiac failure	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	3 (6.0)	1 (2.0)	0
Diarrhoea	1 (2.0)	0	0
Nausea	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (2.0)	1 (2.0)	0
Vomiting	1 (2.0)	0	0
General disorders and administration site conditions			
-Total	4 (8.0)	0	0
Pyrexia	3 (6.0)	0	0
Non-cardiac chest pain	1 (2.0)	0	0
Immune system disorders			
-Total	1 (2.0)	1 (2.0)	0
Allergy to immunoglobulin therapy	1 (2.0)	1 (2.0)	0
Infections and infestations			
-Total	11 (22.0)	6 (12.0)	5 (10.0)
Bacteraemia	1 (2.0)	0	1 (2.0)
Cytomegalovirus infection reactivation	1 (2.0)	1 (2.0)	0
Device related infection	1 (2.0)	1 (2.0)	0
Enterobacter infection	1 (2.0)	1 (2.0)	0
Gastroenteritis	1 (2.0)	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	1 (2.0)	0
Klebsiella infection	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (2.0)	1 (2.0)	0
Metapneumovirus infection	1 (2.0)	1 (2.0)	0
Otitis externa	1 (2.0)	1 (2.0)	0
Otitis media	1 (2.0)	1 (2.0)	0
Pharyngitis streptococcal	1 (2.0)	1 (2.0)	0
Pneumocystis jirovecii pneumonia	1 (2.0)	0	1 (2.0)
Pneumonia	1 (2.0)	0	1 (2.0)
Septic shock	1 (2.0)	0	1 (2.0)
Sinusitis	1 (2.0)	1 (2.0)	0
Staphylococcal sepsis	1 (2.0)	0	1 (2.0)
Urinary tract infection	1 (2.0)	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Investigations			
-Total	1 (2.0)	0	1 (2.0)
Blood uric acid increased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	3 (6.0)	2 (4.0)	1 (2.0)
Hypokalaemia	1 (2.0)	1 (2.0)	0
Malnutrition	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (2.0)	0	1 (2.0)
Musculoskeletal and connective tissue disorders			
-Total	3 (6.0)	2 (4.0)	0
Back pain	3 (6.0)	2 (4.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	1 (2.0)	0
Myelodysplastic syndrome	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	1 (2.0)	0	1 (2.0)
Hydrocephalus	1 (2.0)	0	1 (2.0)
Psychiatric disorders			
-Total	2 (4.0)	1 (2.0)	0
Mental status changes	2 (4.0)	1 (2.0)	0
Renal and urinary disorders			
-Total	1 (2.0)	0	1 (2.0)
Acute kidney injury	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.0)	1 (2.0)	3 (6.0)
Acute respiratory distress syndrome	1 (2.0)	0	1 (2.0)
Bronchial oedema	1 (2.0)	0	0
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory distress	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)
Vascular disorders			
-Total	2 (4.0)	0	2 (4.0)
Hypotension	1 (2.0)	0	1 (2.0)
Venoocclusive disease	1 (2.0)	0	1 (2.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (35.0)	4 (20.0)	2 (10.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	0
Irritable bowel syndrome	1 (5.0)	0	0
General disorders and administration site conditions			
-Total	3 (15.0)	0	1 (5.0)
Pyrexia	2 (10.0)	0	0
Multiple organ dysfunction syndrome	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	5 (25.0)	3 (15.0)	1 (5.0)
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0
Covid-19 pneumonia	1 (5.0)	0	1 (5.0)
Gastroenteritis escherichia coli	1 (5.0)	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Rhinovirus infection	1 (5.0)	0	0
Sepsis	1 (5.0)	1 (5.0)	0
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Infusion related reaction	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	0	1 (5.0)
Decreased appetite	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	1 (5.0)	0
Bone giant cell tumour benign	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders			
-Total	1 (5.0)	1 (5.0)	0
Endometriosis	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	0	0
Dyspnoea exertional	1 (5.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (26.7)	4 (13.3)	4 (13.3)
Immune system disorders			
-Total	1 (3.3)	1 (3.3)	0
Drug hypersensitivity	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	8 (26.7)	5 (16.7)	3 (10.0)
Sepsis	2 (6.7)	0	2 (6.7)
Candida infection	1 (3.3)	0	0
Covid-19	1 (3.3)	1 (3.3)	0
Device related sepsis	1 (3.3)	1 (3.3)	0
Herpes zoster	1 (3.3)	1 (3.3)	0
Meningitis pneumococcal	1 (3.3)	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (3.3)	0	0
Pneumonia respiratory syncytial viral	1 (3.3)	1 (3.3)	0
Septic shock	1 (3.3)	0	1 (3.3)
Staphylococcal abscess	1 (3.3)	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	2 (6.7)	2 (6.7)	0
Headache	1 (3.3)	1 (3.3)	0
Nervous system disorder	1 (3.3)	1 (3.3)	0
Seizure	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	0	2 (6.7)
Laryngeal oedema	1 (3.3)	0	1 (3.3)
Respiratory failure	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=26	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	17 (65.4)	10 (38.5)	6 (23.1)
Blood and lymphatic system disorders			
-Total	5 (19.2)	5 (19.2)	0
Febrile neutropenia	4 (15.4)	4 (15.4)	0
Disseminated intravascular coagulation	1 (3.8)	1 (3.8)	0
Pancytopenia	1 (3.8)	1 (3.8)	0
Cardiac disorders			
-Total	1 (3.8)	0	1 (3.8)
Tachycardia	1 (3.8)	0	1 (3.8)
Gastrointestinal disorders			
-Total	2 (7.7)	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (3.8)	0	0
Pancreatitis	1 (3.8)	1 (3.8)	0
General disorders and administration site conditions			
-Total	6 (23.1)	1 (3.8)	2 (7.7)
Pyrexia	4 (15.4)	1 (3.8)	0
Multiple organ dysfunction syndrome	2 (7.7)	0	2 (7.7)
Systemic inflammatory response syndrome	1 (3.8)	1 (3.8)	0
Hepatobiliary disorders			
-Total	1 (3.8)	0	1 (3.8)
Cholestasis	1 (3.8)	0	1 (3.8)
Immune system disorders			
-Total	13 (50.0)	3 (11.5)	5 (19.2)
Cytokine release syndrome	12 (46.2)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	2 (7.7)	0	2 (7.7)
Infections and infestations			
-Total	9 (34.6)	5 (19.2)	4 (15.4)
Encephalitis	2 (7.7)	0	2 (7.7)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (7.7)	2 (7.7)	0
Staphylococcal bacteraemia	2 (7.7)	2 (7.7)	0
Upper respiratory tract infection	2 (7.7)	2 (7.7)	0
Bronchopulmonary aspergillosis	1 (3.8)	0	1 (3.8)
Clostridium difficile colitis	1 (3.8)	1 (3.8)	0
Covid-19 pneumonia	1 (3.8)	0	1 (3.8)
Gastroenteritis	1 (3.8)	1 (3.8)	0
Gastroenteritis escherichia coli	1 (3.8)	1 (3.8)	0
Gastroenteritis salmonella	1 (3.8)	1 (3.8)	0
Herpes zoster	1 (3.8)	1 (3.8)	0
Parainfluenzae virus infection	1 (3.8)	1 (3.8)	0
Pneumonia	1 (3.8)	1 (3.8)	0
Rhinovirus infection	1 (3.8)	1 (3.8)	0
Sepsis	1 (3.8)	1 (3.8)	0
Viral haemorrhagic cystitis	1 (3.8)	1 (3.8)	0
Injury, poisoning and procedural complications			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Infusion related reaction	1 (3.8)	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vasoplegia syndrome	1 (3.8)	0	1 (3.8)
Investigations			
-Total	1 (3.8)	0	1 (3.8)
Electrocardiogram qt prolonged	1 (3.8)	0	1 (3.8)
Metabolism and nutrition disorders			
-Total	4 (15.4)	1 (3.8)	2 (7.7)
Decreased appetite	1 (3.8)	0	1 (3.8)
Dehydration	1 (3.8)	0	0
Hypernatraemia	1 (3.8)	0	1 (3.8)
Tumour lysis syndrome	1 (3.8)	1 (3.8)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Haemarthrosis	1 (3.8)	1 (3.8)	0
Rhabdomyolysis	1 (3.8)	0	1 (3.8)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.8)	1 (3.8)	0
Bone giant cell tumour benign	1 (3.8)	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	2 (7.7)	2 (7.7)	0
Encephalopathy	1 (3.8)	1 (3.8)	0
Headache	1 (3.8)	1 (3.8)	0
Renal and urinary disorders			
-Total	1 (3.8)	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	1 (3.8)
Renal tubular necrosis	1 (3.8)	0	1 (3.8)
Reproductive system and breast disorders			
-Total	1 (3.8)	1 (3.8)	0
Endometriosis	1 (3.8)	1 (3.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (15.4)	1 (3.8)	2 (7.7)
Pleural effusion	2 (7.7)	1 (3.8)	1 (3.8)
Acute respiratory distress syndrome	1 (3.8)	0	1 (3.8)
Dyspnoea	1 (3.8)	0	1 (3.8)
Dyspnoea exertional	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (3.8)	0	0
Hypoxia	1 (3.8)	1 (3.8)	0
Pulmonary oedema	1 (3.8)	1 (3.8)	0
Vascular disorders			
-Total	1 (3.8)	0	1 (3.8)
Hypotension	1 (3.8)	0	1 (3.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	46 (85.2)	13 (24.1)	31 (57.4)
Blood and lymphatic system disorders			
-Total	13 (24.1)	11 (20.4)	2 (3.7)
Febrile neutropenia	11 (20.4)	10 (18.5)	1 (1.9)
Disseminated intravascular coagulation	2 (3.7)	1 (1.9)	0
Coagulopathy	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	6 (11.1)	1 (1.9)	4 (7.4)
Cardiac arrest	3 (5.6)	0	3 (5.6)
Cardiac failure	2 (3.7)	1 (1.9)	1 (1.9)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.9)	0	0
Left ventricular dysfunction	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	6 (11.1)	3 (5.6)	1 (1.9)
Diarrhoea	2 (3.7)	1 (1.9)	0
Abdominal compartment syndrome	1 (1.9)	0	1 (1.9)
Constipation	1 (1.9)	0	0
Nausea	1 (1.9)	0	0
Neutropenic colitis	1 (1.9)	1 (1.9)	0
Pancreatitis	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	0	0
General disorders and administration site conditions			
-Total	5 (9.3)	0	1 (1.9)
Pyrexia	3 (5.6)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	1 (1.9)
Non-cardiac chest pain	1 (1.9)	0	0
Hepatobiliary disorders			
-Total	1 (1.9)	0	1 (1.9)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.9)	0	1 (1.9)
Immune system disorders			
-Total	38 (70.4)	13 (24.1)	17 (31.5)
Cytokine release syndrome	38 (70.4)	13 (24.1)	17 (31.5)
Allergy to immunoglobulin therapy	1 (1.9)	1 (1.9)	0
Drug hypersensitivity	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	22 (40.7)	13 (24.1)	9 (16.7)
Candida infection	2 (3.7)	0	1 (1.9)
Encephalitis viral	2 (3.7)	1 (1.9)	1 (1.9)
Sepsis	2 (3.7)	0	2 (3.7)
Septic shock	2 (3.7)	0	2 (3.7)
Bacteraemia	1 (1.9)	0	1 (1.9)
Covid-19	1 (1.9)	1 (1.9)	0
Cytomegalovirus infection reactivation	1 (1.9)	1 (1.9)	0
Device related infection	1 (1.9)	1 (1.9)	0
Device related sepsis	1 (1.9)	1 (1.9)	0
Enterobacter infection	1 (1.9)	1 (1.9)	0
Gastroenteritis	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (1.9)	1 (1.9)	0
Human herpesvirus 6 infection	1 (1.9)	1 (1.9)	0
Klebsiella infection	1 (1.9)	1 (1.9)	0
Mastoiditis	1 (1.9)	1 (1.9)	0
Meningitis bacterial	1 (1.9)	1 (1.9)	0
Meningitis pneumococcal	1 (1.9)	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	1 (1.9)	0
Ophthalmic herpes zoster	1 (1.9)	0	0
Otitis externa	1 (1.9)	1 (1.9)	0
Otitis media	1 (1.9)	1 (1.9)	0
Pharyngitis streptococcal	1 (1.9)	1 (1.9)	0
Pneumocystis jirovecii pneumonia	1 (1.9)	0	1 (1.9)
Pneumonia	1 (1.9)	0	1 (1.9)
Pneumonia fungal	1 (1.9)	1 (1.9)	0
Pneumonia respiratory syncytial viral	1 (1.9)	1 (1.9)	0
Pneumonia viral	1 (1.9)	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	0
Sinusitis	1 (1.9)	1 (1.9)	0
Soft tissue infection	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal abscess	1 (1.9)	1 (1.9)	0
Staphylococcal sepsis	1 (1.9)	0	1 (1.9)
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Urinary tract infection	1 (1.9)	1 (1.9)	0
Varicella zoster virus infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	3 (5.6)	2 (3.7)	1 (1.9)
Aspartate aminotransferase increased	2 (3.7)	2 (3.7)	0
Blood bilirubin increased	1 (1.9)	1 (1.9)	0
Blood uric acid increased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	4 (7.4)	2 (3.7)	2 (3.7)
Hypercalcaemia	1 (1.9)	1 (1.9)	0
Hyperkalaemia	1 (1.9)	0	1 (1.9)
Hyperphosphataemia	1 (1.9)	0	1 (1.9)
Hypokalaemia	1 (1.9)	1 (1.9)	0
Malnutrition	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (1.9)	0	1 (1.9)
Tumour lysis syndrome	1 (1.9)	0	1 (1.9)
Musculoskeletal and connective tissue disorders			
-Total	3 (5.6)	2 (3.7)	0
Back pain	3 (5.6)	2 (3.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.9)	1 (1.9)	0
Myelodysplastic syndrome	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	6 (11.1)	3 (5.6)	2 (3.7)
Cerebral haemorrhage	1 (1.9)	0	1 (1.9)
Cognitive disorder	1 (1.9)	0	0
Dysarthria	1 (1.9)	1 (1.9)	0
Headache	1 (1.9)	1 (1.9)	0
Hydrocephalus	1 (1.9)	0	1 (1.9)
Nervous system disorder	1 (1.9)	1 (1.9)	0
Seizure	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	3 (5.6)	2 (3.7)	0
Mental status changes	2 (3.7)	1 (1.9)	0
Delirium	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	5 (9.3)	2 (3.7)	3 (5.6)
Acute kidney injury	4 (7.4)	2 (3.7)	2 (3.7)
Renal failure	1 (1.9)	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (25.9)	3 (5.6)	9 (16.7)
Respiratory failure	5 (9.3)	0	5 (9.3)
Hypoxia	4 (7.4)	2 (3.7)	2 (3.7)
Respiratory distress	2 (3.7)	0	1 (1.9)
Acute respiratory distress syndrome	1 (1.9)	0	1 (1.9)
Acute respiratory failure	1 (1.9)	1 (1.9)	0
Bronchial oedema	1 (1.9)	0	0
Laryngeal oedema	1 (1.9)	0	1 (1.9)
Vascular disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (14.8)	1 (1.9)	7 (13.0)
Hypotension	7 (13.0)	1 (1.9)	6 (11.1)
Venoocclusive disease	1 (1.9)	0	1 (1.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (45.5)	2 (18.2)	1 (9.1)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancytopenia	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	4 (36.4)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	1 (9.1)	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	49 (71.0)	20 (29.0)	26 (37.7)
Blood and lymphatic system disorders			
-Total	15 (21.7)	13 (18.8)	2 (2.9)
Febrile neutropenia	13 (18.8)	12 (17.4)	1 (1.4)
Disseminated intravascular coagulation	2 (2.9)	1 (1.4)	0
Coagulopathy	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	5 (7.2)	1 (1.4)	3 (4.3)
Atrioventricular block first degree	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	1 (1.4)
Cardiac failure	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	5 (7.2)	3 (4.3)	1 (1.4)
Abdominal compartment syndrome	1 (1.4)	0	1 (1.4)
Constipation	1 (1.4)	0	0
Diarrhoea	1 (1.4)	1 (1.4)	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	5 (7.2)	0	2 (2.9)
Pyrexia	3 (4.3)	0	0
Multiple organ dysfunction syndrome	2 (2.9)	0	2 (2.9)
Systemic inflammatory response syndrome	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.9)	0	2 (2.9)
Cholestasis	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	46 (66.7)	15 (21.7)	20 (29.0)
Cytokine release syndrome	46 (66.7)	15 (21.7)	20 (29.0)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)
Infections and infestations			
-Total	11 (15.9)	7 (10.1)	3 (4.3)
Encephalitis viral	2 (2.9)	1 (1.4)	1 (1.4)
Candida infection	1 (1.4)	0	1 (1.4)
Encephalitis	1 (1.4)	0	1 (1.4)
Klebsiella infection	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (1.4)	0	1 (1.4)
Vasoplegia syndrome	1 (1.4)	0	1 (1.4)
Investigations			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Aspartate aminotransferase increased	2 (2.9)	2 (2.9)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	4 (5.8)	1 (1.4)	2 (2.9)
Dehydration	1 (1.4)	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
Haemarthrosis	1 (1.4)	1 (1.4)	0
Rhabdomyolysis	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	4 (5.8)	2 (2.9)	1 (1.4)
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Encephalopathy	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	5 (7.2)	2 (2.9)	3 (4.3)
Acute kidney injury	4 (5.8)	2 (2.9)	2 (2.9)
Renal failure	1 (1.4)	0	1 (1.4)
Renal tubular necrosis	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	10 (14.5)	3 (4.3)	6 (8.7)
Hypoxia	3 (4.3)	1 (1.4)	2 (2.9)
Respiratory failure	3 (4.3)	0	3 (4.3)
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Acute respiratory failure	1 (1.4)	1 (1.4)	0
Dyspnoea	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0
Respiratory distress	1 (1.4)	0	0
Vascular disorders			
-Total	8 (11.6)	2 (2.9)	6 (8.7)
Hypotension	8 (11.6)	2 (2.9)	6 (8.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term **Preferred term**	**All grades** **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
Number of patients with at least one SAE	3 (27.3)	2 (18.2)	1 (9.1)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Disseminated intravascular coagulation	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	20 (31.3)	10 (15.6)	10 (15.6)
Blood and lymphatic system disorders			
-Total	3 (4.7)	3 (4.7)	0
Febrile neutropenia	3 (4.7)	3 (4.7)	0
Cardiac disorders			
-Total	2 (3.1)	0	2 (3.1)
Cardiac arrest	2 (3.1)	0	2 (3.1)
Cardiac failure	1 (1.6)	1 (1.6)	0
Gastrointestinal disorders			
-Total	2 (3.1)	0	0
Diarrhoea	1 (1.6)	0	0
Nausea	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (1.6)	0	0
General disorders and administration site conditions			
-Total	5 (7.8)	1 (1.6)	0
Pyrexia	4 (6.3)	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	0	0
Immune system disorders			
-Total	1 (1.6)	1 (1.6)	0
Allergy to immunoglobulin therapy	1 (1.6)	1 (1.6)	0
Infections and infestations			
-Total	14 (21.9)	8 (12.5)	6 (9.4)
Gastroenteritis	2 (3.1)	2 (3.1)	0
Bacteraemia	1 (1.6)	0	1 (1.6)
Bronchopulmonary aspergillosis	1 (1.6)	0	1 (1.6)
Cytomegalovirus infection reactivation	1 (1.6)	1 (1.6)	0
Device related infection	1 (1.6)	1 (1.6)	0
Enterobacter infection	1 (1.6)	1 (1.6)	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (1.6)	1 (1.6)	0
Mastoiditis	1 (1.6)	1 (1.6)	0
Metapneumovirus infection	1 (1.6)	1 (1.6)	0
Otitis externa	1 (1.6)	1 (1.6)	0
Otitis media	1 (1.6)	1 (1.6)	0
Pharyngitis streptococcal	1 (1.6)	1 (1.6)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	1 (1.6)
Pneumonia	1 (1.6)	0	1 (1.6)
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Septic shock	1 (1.6)	0	1 (1.6)
Sinusitis	1 (1.6)	1 (1.6)	0
Staphylococcal sepsis	1 (1.6)	0	1 (1.6)
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Urinary tract infection	1 (1.6)	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Investigations			
-Total	1 (1.6)	0	1 (1.6)
Blood uric acid increased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.7)	2 (3.1)	1 (1.6)
Hypokalaemia	1 (1.6)	1 (1.6)	0
Malnutrition	1 (1.6)	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	1 (1.6)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.7)	2 (3.1)	0
Back pain	3 (4.7)	2 (3.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.6)	1 (1.6)	0
Myelodysplastic syndrome	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	1 (1.6)	0	1 (1.6)
Hydrocephalus	1 (1.6)	0	1 (1.6)
Psychiatric disorders			
-Total	2 (3.1)	1 (1.6)	0
Mental status changes	2 (3.1)	1 (1.6)	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.6)	0	1 (1.6)
Acute kidney injury	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (9.4)	2 (3.1)	3 (4.7)
Hypoxia	2 (3.1)	2 (3.1)	0
Acute respiratory distress syndrome	1 (1.6)	0	1 (1.6)
Bronchial oedema	1 (1.6)	0	0
Epistaxis	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	1 (1.6)
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
-Total	2 (3.1)	0	2 (3.1)
Hypotension	1 (1.6)	0	1 (1.6)
Venoocclusive disease	1 (1.6)	0	1 (1.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (33.3)	1 (11.1)	1 (11.1)
General disorders and administration site conditions			
-Total	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	0
Infections and infestations			
-Total	2 (22.2)	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	0
Sepsis	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Decreased appetite	1 (11.1)	0	1 (11.1)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (11.1)	1 (11.1)	0
Endometriosis	1 (11.1)	1 (11.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	12 (29.3)	7 (17.1)	5 (12.2)
Gastrointestinal disorders			
-Total	1 (2.4)	0	0
Irritable bowel syndrome	1 (2.4)	0	0
General disorders and administration site conditions			
-Total	2 (4.9)	0	1 (2.4)
Multiple organ dysfunction syndrome	1 (2.4)	0	1 (2.4)
Pyrexia	1 (2.4)	0	0
Immune system disorders			
-Total	2 (4.9)	1 (2.4)	1 (2.4)
Drug hypersensitivity	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	1 (2.4)
Infections and infestations			
-Total	11 (26.8)	7 (17.1)	4 (9.8)
Sepsis	2 (4.9)	0	2 (4.9)
Candida infection	1 (2.4)	0	0
Clostridium difficile colitis	1 (2.4)	1 (2.4)	0
Covid-19	1 (2.4)	1 (2.4)	0
Covid-19 pneumonia	1 (2.4)	0	1 (2.4)
Device related sepsis	1 (2.4)	1 (2.4)	0
Gastroenteritis escherichia coli	1 (2.4)	1 (2.4)	0
Gastroenteritis salmonella	1 (2.4)	1 (2.4)	0
Herpes zoster	1 (2.4)	1 (2.4)	0
Meningitis pneumococcal	1 (2.4)	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	0
Pneumonia	1 (2.4)	1 (2.4)	0
Pneumonia respiratory syncytial viral	1 (2.4)	1 (2.4)	0
Septic shock	1 (2.4)	0	1 (2.4)
Staphylococcal abscess	1 (2.4)	1 (2.4)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Upper respiratory tract infection	1 (2.4)	1 (2.4)	0
Injury, poisoning and procedural complications			
-Total	1 (2.4)	1 (2.4)	0
Infusion related reaction	1 (2.4)	1 (2.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.4)	1 (2.4)	0
Bone giant cell tumour benign	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	2 (4.9)	2 (4.9)	0
Headache	1 (2.4)	1 (2.4)	0
Nervous system disorder	1 (2.4)	1 (2.4)	0
Seizure	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.3)	0	2 (4.9)
Dyspnoea exertional	1 (2.4)	0	0
Laryngeal oedema	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.4)	0	1 (2.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (63.6)	3 (27.3)	2 (18.2)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Disseminated intravascular coagulation	1 (9.1)	1 (9.1)	0
Pancytopenia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (9.1)	0	0
Immune system disorders			
-Total	4 (36.4)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	1 (9.1)	1 (9.1)
Infections and infestations			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Endometriosis	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	56 (81.2)	20 (29.0)	35 (50.7)
Blood and lymphatic system disorders			
-Total	17 (24.6)	15 (21.7)	2 (2.9)
Febrile neutropenia	15 (21.7)	14 (20.3)	1 (1.4)
Disseminated intravascular coagulation	2 (2.9)	1 (1.4)	0
Coagulopathy	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	7 (10.1)	1 (1.4)	5 (7.2)
Cardiac arrest	3 (4.3)	0	3 (4.3)
Cardiac failure	2 (2.9)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (1.4)	0	0
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	7 (10.1)	3 (4.3)	1 (1.4)
Diarrhoea	2 (2.9)	1 (1.4)	0
Abdominal compartment syndrome	1 (1.4)	0	1 (1.4)
Constipation	1 (1.4)	0	0
Irritable bowel syndrome	1 (1.4)	0	0
Nausea	1 (1.4)	0	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	10 (14.5)	1 (1.4)	3 (4.3)
Pyrexia	6 (8.7)	1 (1.4)	0
Multiple organ dysfunction syndrome	3 (4.3)	0	3 (4.3)
Non-cardiac chest pain	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.9)	0	2 (2.9)
Cholestasis	1 (1.4)	0	1 (1.4)
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	47 (68.1)	15 (21.7)	21 (30.4)
Cytokine release syndrome	46 (66.7)	15 (21.7)	20 (29.0)
Haemophagocytic lymphohistiocytosis	2 (2.9)	0	2 (2.9)
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	29 (42.0)	17 (24.6)	12 (17.4)
Candida infection	2 (2.9)	0	1 (1.4)
Encephalitis viral	2 (2.9)	1 (1.4)	1 (1.4)
Gastroenteritis	2 (2.9)	2 (2.9)	0
Herpes zoster	2 (2.9)	2 (2.9)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (2.9)	1 (1.4)	1 (1.4)
Sepsis	2 (2.9)	0	2 (2.9)
Septic shock	2 (2.9)	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	2 (2.9)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Clostridium difficile colitis	1 (1.4)	1 (1.4)	0
Covid-19	1 (1.4)	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related infection	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Gastroenteritis escherichia coli	1 (1.4)	1 (1.4)	0
Gastroenteritis salmonella	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mastoiditis	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Sinusitis	1 (1.4)	1 (1.4)	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
Infusion related reaction	1 (1.4)	1 (1.4)	0
Vasoplegia syndrome	1 (1.4)	0	1 (1.4)
Investigations			
-Total	4 (5.8)	2 (2.9)	2 (2.9)
Aspartate aminotransferase increased	2 (2.9)	2 (2.9)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Electrocardiogram qt prolonged	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	7 (10.1)	3 (4.3)	3 (4.3)
Tumour lysis syndrome	2 (2.9)	1 (1.4)	1 (1.4)
Dehydration	1 (1.4)	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	5 (7.2)	3 (4.3)	1 (1.4)
Back pain	3 (4.3)	2 (2.9)	0
Haemarthrosis	1 (1.4)	1 (1.4)	0
Rhabdomyolysis	1 (1.4)	0	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.9)	2 (2.9)	0
Bone giant cell tumour benign	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	7 (10.1)	4 (5.8)	2 (2.9)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Encephalopathy	1 (1.4)	1 (1.4)	0
Headache	1 (1.4)	1 (1.4)	0
Hydrocephalus	1 (1.4)	0	1 (1.4)
Nervous system disorder	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	3 (4.3)	2 (2.9)	0
Mental status changes	2 (2.9)	1 (1.4)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	6 (8.7)	2 (2.9)	4 (5.8)
Acute kidney injury	5 (7.2)	2 (2.9)	3 (4.3)
Renal failure	1 (1.4)	0	1 (1.4)
Renal tubular necrosis	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (26.1)	4 (5.8)	11 (15.9)
Hypoxia	5 (7.2)	3 (4.3)	2 (2.9)
Respiratory failure	5 (7.2)	0	5 (7.2)
Acute respiratory distress syndrome	2 (2.9)	0	2 (2.9)
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)
Respiratory distress	2 (2.9)	0	1 (1.4)
Acute respiratory failure	1 (1.4)	1 (1.4)	0
Bronchial oedema	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)
Dyspnoea exertional	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	9 (13.0)	1 (1.4)	8 (11.6)
Hypotension	8 (11.6)	1 (1.4)	7 (10.1)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (66.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
-Total	2 (33.3)	2 (33.3)	0
Febrile neutropenia	2 (33.3)	2 (33.3)	0
Disseminated intravascular coagulation	1 (16.7)	0	0
Gastrointestinal disorders			
-Total	1 (16.7)	0	1 (16.7)
Abdominal compartment syndrome	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	0	3 (50.0)
Cytokine release syndrome	4 (66.7)	0	3 (50.0)
Nervous system disorders			

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	2 (33.3)	0	2 (33.3)
Hypotension	2 (33.3)	0	2 (33.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	50 (67.6)	21 (28.4)	24 (32.4)
Blood and lymphatic system disorders			
-Total	14 (18.9)	12 (16.2)	2 (2.7)
Febrile neutropenia	11 (14.9)	10 (13.5)	1 (1.4)
Coagulopathy	1 (1.4)	1 (1.4)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	5 (6.8)	1 (1.4)	3 (4.1)
Atrioventricular block first degree	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.4)	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	4 (5.4)	3 (4.1)	0
Constipation	1 (1.4)	0	0
Diarrhoea	1 (1.4)	1 (1.4)	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	5 (6.8)	0	2 (2.7)
Pyrexia	3 (4.1)	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	2 (2.7)
Systemic inflammatory response syndrome	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.7)	0	2 (2.7)
Cholestasis	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	46 (62.2)	16 (21.6)	18 (24.3)
Cytokine release syndrome	46 (62.2)	16 (21.6)	18 (24.3)
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)
Infections and infestations			
-Total	11 (14.9)	7 (9.5)	3 (4.1)
Encephalitis viral	2 (2.7)	1 (1.4)	1 (1.4)
Candida infection	1 (1.4)	0	1 (1.4)
Encephalitis	1 (1.4)	0	1 (1.4)
Klebsiella infection	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (1.4)	0	1 (1.4)
Vasoplegia syndrome	1 (1.4)	0	1 (1.4)
Investigations			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Aspartate aminotransferase increased	2 (2.7)	2 (2.7)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	4 (5.4)	1 (1.4)	2 (2.7)
Dehydration	1 (1.4)	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Haemarthrosis	1 (1.4)	1 (1.4)	0
Rhabdomyolysis	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	4 (5.4)	3 (4.1)	0
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Encephalopathy	1 (1.4)	1 (1.4)	0
Headache	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Acute kidney injury	2 (2.7)	1 (1.4)	1 (1.4)
Renal failure	1 (1.4)	0	1 (1.4)
Renal tubular necrosis	1 (1.4)	0	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	9 (12.2)	3 (4.1)	5 (6.8)
Respiratory failure	3 (4.1)	0	3 (4.1)
Hypoxia	2 (2.7)	1 (1.4)	1 (1.4)
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Acute respiratory failure	1 (1.4)	1 (1.4)	0
Dyspnoea	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0
Respiratory distress	1 (1.4)	0	0
Vascular disorders			
-Total	6 (8.1)	2 (2.7)	4 (5.4)
Hypotension	6 (8.1)	2 (2.7)	4 (5.4)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Metapneumovirus infection	1 (20.0)	1 (20.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	22 (31.4)	11 (15.7)	11 (15.7)
Blood and lymphatic system disorders			
-Total	4 (5.7)	4 (5.7)	0
Febrile neutropenia	3 (4.3)	3 (4.3)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.9)	0	2 (2.9)
Cardiac arrest	2 (2.9)	0	2 (2.9)
Cardiac failure	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	3 (4.3)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (1.4)	0	0
Nausea	1 (1.4)	0	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	4 (5.7)	1 (1.4)	0
Pyrexia	3 (4.3)	1 (1.4)	0
Non-cardiac chest pain	1 (1.4)	0	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	15 (21.4)	8 (11.4)	7 (10.0)
Gastroenteritis	2 (2.9)	2 (2.9)	0
Respiratory syncytial virus infection	2 (2.9)	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	2 (2.9)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related infection	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Septic shock	1 (1.4)	0	1 (1.4)
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	3 (4.3)	2 (2.9)	0
Back pain	3 (4.3)	2 (2.9)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	0	1 (1.4)
Hydrocephalus	1 (1.4)	0	1 (1.4)
Psychiatric disorders			
-Total	2 (2.9)	1 (1.4)	0
Mental status changes	2 (2.9)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.6)	2 (2.9)	3 (4.3)
Hypoxia	2 (2.9)	2 (2.9)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	2 (2.9)	0	2 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (1.4)	0	1 (1.4)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (50.0)	2 (50.0)	0
Infections and infestations			
-Total	2 (50.0)	2 (50.0)	0
Pneumonia respiratory syncytial viral	1 (25.0)	1 (25.0)	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (28.3)	6 (13.0)	6 (13.0)
Gastrointestinal disorders			
-Total	1 (2.2)	0	0
Irritable bowel syndrome	1 (2.2)	0	0
General disorders and administration site conditions			
-Total	3 (6.5)	0	1 (2.2)
Pyrexia	2 (4.3)	0	0
Multiple organ dysfunction syndrome	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	2 (4.3)	1 (2.2)	1 (2.2)
Drug hypersensitivity	1 (2.2)	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)
Infections and infestations			
-Total	11 (23.9)	6 (13.0)	4 (8.7)
Sepsis	3 (6.5)	1 (2.2)	2 (4.3)
Candida infection	1 (2.2)	0	0
Clostridium difficile colitis	1 (2.2)	1 (2.2)	0
Covid-19	1 (2.2)	1 (2.2)	0
Covid-19 pneumonia	1 (2.2)	0	1 (2.2)
Device related sepsis	1 (2.2)	1 (2.2)	0
Gastroenteritis escherichia coli	1 (2.2)	1 (2.2)	0
Gastroenteritis salmonella	1 (2.2)	1 (2.2)	0
Herpes zoster	1 (2.2)	1 (2.2)	0
Meningitis pneumococcal	1 (2.2)	1 (2.2)	0
Ophthalmic herpes zoster	1 (2.2)	0	0
Pneumonia	1 (2.2)	1 (2.2)	0
Rhinovirus infection	1 (2.2)	0	0
Septic shock	1 (2.2)	0	1 (2.2)
Staphylococcal abscess	1 (2.2)	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Injury, poisoning and procedural complications			
-Total	1 (2.2)	1 (2.2)	0
Infusion related reaction	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	1 (2.2)	0	1 (2.2)
Decreased appetite	1 (2.2)	0	1 (2.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.2)	1 (2.2)	0
Bone giant cell tumour benign	1 (2.2)	1 (2.2)	0
Nervous system disorders			
-Total	2 (4.3)	2 (4.3)	0
Headache	1 (2.2)	1 (2.2)	0
Nervous system disorder	1 (2.2)	1 (2.2)	0
Seizure	1 (2.2)	1 (2.2)	0
Reproductive system and breast disorders			
-Total	1 (2.2)	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endometriosis	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.5)	0	2 (4.3)
Dyspnoea exertional	1 (2.2)	0	0
Laryngeal oedema	1 (2.2)	0	1 (2.2)
Respiratory failure	1 (2.2)	0	1 (2.2)

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Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	2 (33.3)	2 (33.3)	0
Febrile neutropenia	2 (33.3)	2 (33.3)	0
Disseminated intravascular coagulation	1 (16.7)	0	0
Gastrointestinal disorders			
-Total	1 (16.7)	0	1 (16.7)
Abdominal compartment syndrome	1 (16.7)	0	1 (16.7)
General disorders and administration site conditions			
-Total	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (16.7)	0	0
Immune system disorders			
-Total	4 (66.7)	0	3 (50.0)
Cytokine release syndrome	4 (66.7)	0	3 (50.0)
Infections and infestations			
-Total	3 (50.0)	3 (50.0)	0
Metapneumovirus infection	1 (16.7)	1 (16.7)	0
Pneumonia respiratory syncytial viral	1 (16.7)	1 (16.7)	0
Upper respiratory tract infection	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	1 (16.7)	0	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	1 (16.7)
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	2 (33.3)	0	2 (33.3)
Hypotension	2 (33.3)	0	2 (33.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	58 (78.4)	21 (28.4)	34 (45.9)
Blood and lymphatic system disorders			
-Total	16 (21.6)	14 (18.9)	2 (2.7)
Febrile neutropenia	13 (17.6)	12 (16.2)	1 (1.4)
Disseminated intravascular coagulation	2 (2.7)	2 (2.7)	0
Coagulopathy	1 (1.4)	1 (1.4)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	7 (9.5)	1 (1.4)	5 (6.8)
Cardiac arrest	3 (4.1)	0	3 (4.1)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (2.7)	1 (1.4)	1 (1.4)
Atrioventricular block first degree	1 (1.4)	0	0
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	7 (9.5)	4 (5.4)	0
Diarrhoea	2 (2.7)	1 (1.4)	0
Pancreatitis	2 (2.7)	2 (2.7)	0
Constipation	1 (1.4)	0	0
Irritable bowel syndrome	1 (1.4)	0	0
Nausea	1 (1.4)	0	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0
General disorders and administration site conditions			
-Total	10 (13.5)	1 (1.4)	3 (4.1)
Pyrexia	6 (8.1)	1 (1.4)	0
Multiple organ dysfunction syndrome	3 (4.1)	0	3 (4.1)
Non-cardiac chest pain	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.7)	0	2 (2.7)
Cholestasis	1 (1.4)	0	1 (1.4)
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	47 (63.5)	16 (21.6)	19 (25.7)
Cytokine release syndrome	46 (62.2)	16 (21.6)	18 (24.3)
Haemophagocytic lymphohistiocytosis	2 (2.7)	0	2 (2.7)
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	28 (37.8)	15 (20.3)	13 (17.6)
Sepsis	3 (4.1)	1 (1.4)	2 (2.7)
Candida infection	2 (2.7)	0	1 (1.4)
Encephalitis	2 (2.7)	0	2 (2.7)
Encephalitis viral	2 (2.7)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (2.7)	2 (2.7)	0
Herpes zoster	2 (2.7)	2 (2.7)	0
Pneumonia	2 (2.7)	1 (1.4)	1 (1.4)
Respiratory syncytial virus infection	2 (2.7)	2 (2.7)	0
Rhinovirus infection	2 (2.7)	1 (1.4)	0
Septic shock	2 (2.7)	0	2 (2.7)
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	2 (2.7)	0
Bacteraemia	1 (1.4)	0	1 (1.4)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Clostridium difficile colitis	1 (1.4)	1 (1.4)	0
Covid-19	1 (1.4)	1 (1.4)	0
Covid-19 pneumonia	1 (1.4)	0	1 (1.4)
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related infection	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Enterobacter infection	1 (1.4)	1 (1.4)	0
Gastroenteritis escherichia coli	1 (1.4)	1 (1.4)	0
Gastroenteritis salmonella	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Urinary tract infection	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Infusion related reaction	1 (1.4)	1 (1.4)	0
Vasoplegia syndrome	1 (1.4)	0	1 (1.4)
Investigations			
-Total	4 (5.4)	2 (2.7)	2 (2.7)
Aspartate aminotransferase increased	2 (2.7)	2 (2.7)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Electrocardiogram qt prolonged	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	8 (10.8)	3 (4.1)	4 (5.4)
Tumour lysis syndrome	2 (2.7)	1 (1.4)	1 (1.4)
Decreased appetite	1 (1.4)	0	1 (1.4)
Dehydration	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Hypokalaemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.8)	3 (4.1)	1 (1.4)
Back pain	3 (4.1)	2 (2.7)	0
Haemarthrosis	1 (1.4)	1 (1.4)	0
Rhabdomyolysis	1 (1.4)	0	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.7)	2 (2.7)	0
Bone giant cell tumour benign	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (9.5)	5 (6.8)	1 (1.4)
Headache	2 (2.7)	2 (2.7)	0
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Encephalopathy	1 (1.4)	1 (1.4)	0
Hydrocephalus	1 (1.4)	0	1 (1.4)
Nervous system disorder	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	3 (4.1)	2 (2.7)	0
Mental status changes	2 (2.7)	1 (1.4)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	4 (5.4)	1 (1.4)	3 (4.1)
Acute kidney injury	3 (4.1)	1 (1.4)	2 (2.7)
Renal failure	1 (1.4)	0	1 (1.4)
Renal tubular necrosis	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Endometriosis	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (23.0)	4 (5.4)	10 (13.5)
Respiratory failure	5 (6.8)	0	5 (6.8)
Hypoxia	4 (5.4)	3 (4.1)	1 (1.4)
Acute respiratory distress syndrome	2 (2.7)	0	2 (2.7)
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)
Respiratory distress	2 (2.7)	0	1 (1.4)
Acute respiratory failure	1 (1.4)	1 (1.4)	0
Bronchial oedema	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)
Dyspnoea exertional	1 (1.4)	0	0
Epistaxis	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	7 (9.5)	1 (1.4)	6 (8.1)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	6 (8.1)	1 (1.4)	5 (6.8)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (57.5)	10 (25.0)	12 (30.0)
Blood and lymphatic system disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Febrile neutropenia	2 (5.0)	1 (2.5)	1 (2.5)
Coagulopathy	1 (2.5)	1 (2.5)	0
Pancytopenia	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	1 (2.5)	0	0
Pyrexia	1 (2.5)	0	0
Immune system disorders			
-Total	23 (57.5)	9 (22.5)	10 (25.0)
Cytokine release syndrome	23 (57.5)	9 (22.5)	10 (25.0)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	8 (20.0)	6 (15.0)	2 (5.0)
Encephalitis viral	2 (5.0)	1 (2.5)	1 (2.5)
Candida infection	1 (2.5)	0	1 (2.5)
Klebsiella infection	1 (2.5)	1 (2.5)	0
Meningitis bacterial	1 (2.5)	1 (2.5)	0
Pneumonia fungal	1 (2.5)	1 (2.5)	0
Pneumonia viral	1 (2.5)	1 (2.5)	0
Soft tissue infection	1 (2.5)	1 (2.5)	0
Varicella zoster virus infection	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	1 (2.5)	1 (2.5)	0
Acute kidney injury	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.5)	1 (2.5)	0
Acute respiratory failure	1 (2.5)	1 (2.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	31 (77.5)	12 (30.0)	15 (37.5)
Blood and lymphatic system disorders			
-Total	12 (30.0)	11 (27.5)	1 (2.5)
Febrile neutropenia	11 (27.5)	11 (27.5)	0
Disseminated intravascular coagulation	2 (5.0)	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	5 (12.5)	1 (2.5)	3 (7.5)
Atrioventricular block first degree	1 (2.5)	0	0
Cardiac arrest	1 (2.5)	0	1 (2.5)
Cardiac failure	1 (2.5)	0	1 (2.5)
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	5 (12.5)	3 (7.5)	1 (2.5)
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Constipation	1 (2.5)	0	0
Diarrhoea	1 (2.5)	1 (2.5)	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
Pancreatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	4 (10.0)	0	2 (5.0)
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Pyrexia	2 (5.0)	0	0
Systemic inflammatory response syndrome	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			
-Total	2 (5.0)	0	2 (5.0)
Cholestasis	1 (2.5)	0	1 (2.5)
Hepatomegaly	1 (2.5)	0	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	27 (67.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	3 (7.5)	1 (2.5)	1 (2.5)
Encephalitis	1 (2.5)	0	1 (2.5)
Rhinovirus infection	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	1 (2.5)	0	1 (2.5)
Vasoplegia syndrome	1 (2.5)	0	1 (2.5)
Investigations			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Aspartate aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	1 (2.5)	1 (2.5)	0
Electrocardiogram qt prolonged	1 (2.5)	0	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (10.0)	1 (2.5)	2 (5.0)
Dehydration	1 (2.5)	0	0
Hypercalcaemia	1 (2.5)	1 (2.5)	0
Hyperkalaemia	1 (2.5)	0	1 (2.5)
Hypernatraemia	1 (2.5)	0	1 (2.5)
Hyperphosphataemia	1 (2.5)	0	1 (2.5)
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Tumour lysis syndrome	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Haemarthrosis	1 (2.5)	1 (2.5)	0
Rhabdomyolysis	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	5 (12.5)	3 (7.5)	1 (2.5)
Cerebral haemorrhage	1 (2.5)	0	1 (2.5)
Cognitive disorder	1 (2.5)	0	0
Dysarthria	1 (2.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (2.5)	1 (2.5)	0
Headache	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Delirium	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)
Renal failure	1 (2.5)	0	1 (2.5)
Renal tubular necrosis	1 (2.5)	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (22.5)	2 (5.0)	6 (15.0)
Hypoxia	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory failure	3 (7.5)	0	3 (7.5)
Pleural effusion	2 (5.0)	1 (2.5)	1 (2.5)
Acute respiratory distress syndrome	1 (2.5)	0	1 (2.5)
Dyspnoea	1 (2.5)	0	1 (2.5)
Pulmonary oedema	1 (2.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (2.5)	0	0
Vascular disorders			
-Total	8 (20.0)	2 (5.0)	6 (15.0)
Hypotension	8 (20.0)	2 (5.0)	6 (15.0)

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (32.5)	7 (17.5)	6 (15.0)
Blood and lymphatic system disorders			
-Total	2 (5.0)	2 (5.0)	0
Disseminated intravascular coagulation	1 (2.5)	1 (2.5)	0
Febrile neutropenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	1 (2.5)	0	1 (2.5)
Cardiac arrest	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	1 (2.5)	0	0
Diarrhoea	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (2.5)	0	0
General disorders and administration site conditions			
-Total	4 (10.0)	0	0
Pyrexia	3 (7.5)	0	0
Non-cardiac chest pain	1 (2.5)	0	0
Infections and infestations			
-Total	11 (27.5)	7 (17.5)	4 (10.0)
Gastroenteritis	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	0	1 (2.5)
Bronchopulmonary aspergillosis	1 (2.5)	0	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	1 (2.5)	0
Encephalitis	1 (2.5)	0	1 (2.5)
Enterobacter infection	1 (2.5)	1 (2.5)	0
Herpes zoster	1 (2.5)	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	1 (2.5)	0
Klebsiella infection	1 (2.5)	1 (2.5)	0
Mastoiditis	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (2.5)	1 (2.5)	0
Otitis media	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	0	1 (2.5)
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Rhinovirus infection	1 (2.5)	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Urinary tract infection	1 (2.5)	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	2 (5.0)	2 (5.0)	0
Hypokalaemia	1 (2.5)	1 (2.5)	0
Malnutrition	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	1 (2.5)	0
Back pain	1 (2.5)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.5)	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.5)	1 (2.5)	1 (2.5)
Bronchial oedema	1 (2.5)	0	0
Hypoxia	1 (2.5)	1 (2.5)	0
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Venoocclusive disease	1 (2.5)	0	1 (2.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	10 (28.6)	5 (14.3)	5 (14.3)
Blood and lymphatic system disorders			
-Total	2 (5.7)	2 (5.7)	0
Febrile neutropenia	2 (5.7)	2 (5.7)	0
Cardiac disorders			
-Total	1 (2.9)	0	1 (2.9)
Cardiac arrest	1 (2.9)	0	1 (2.9)
Cardiac failure	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			
-Total	2 (5.7)	1 (2.9)	0
Nausea	1 (2.9)	0	0
Pancreatitis	1 (2.9)	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.9)	1 (2.9)	0
Pyrexia	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	1 (2.9)	1 (2.9)	0
Allergy to immunoglobulin therapy	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	5 (14.3)	2 (5.7)	3 (8.6)
Device related infection	1 (2.9)	1 (2.9)	0
Pharyngitis streptococcal	1 (2.9)	1 (2.9)	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	1 (2.9)
Respiratory syncytial virus infection	1 (2.9)	1 (2.9)	0
Septic shock	1 (2.9)	0	1 (2.9)
Staphylococcal sepsis	1 (2.9)	0	1 (2.9)
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Investigations			
-Total	1 (2.9)	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	1 (2.9)	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	2 (5.7)	1 (2.9)	0
Back pain	2 (5.7)	1 (2.9)	0
Nervous system disorders			
-Total	1 (2.9)	0	1 (2.9)
Hydrocephalus	1 (2.9)	0	1 (2.9)
Psychiatric disorders			
-Total	1 (2.9)	0	0
Mental status changes	1 (2.9)	0	0
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (8.6)	1 (2.9)	2 (5.7)
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Epistaxis	1 (2.9)	0	0
Hypoxia	1 (2.9)	1 (2.9)	0
Respiratory distress	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (26.7)	3 (10.0)	4 (13.3)
General disorders and administration site conditions			
-Total	2 (6.7)	0	1 (3.3)
Multiple organ dysfunction syndrome	1 (3.3)	0	1 (3.3)
Pyrexia	1 (3.3)	0	0
Immune system disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Drug hypersensitivity	1 (3.3)	1 (3.3)	0
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	1 (3.3)
Infections and infestations			

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (23.3)	4 (13.3)	2 (6.7)
Sepsis	2 (6.7)	1 (3.3)	1 (3.3)
Covid-19 pneumonia	1 (3.3)	0	1 (3.3)
Device related sepsis	1 (3.3)	1 (3.3)	0
Herpes zoster	1 (3.3)	1 (3.3)	0
Rhinovirus infection	1 (3.3)	0	0
Staphylococcal abscess	1 (3.3)	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	1 (3.3)	0	1 (3.3)
Decreased appetite	1 (3.3)	0	1 (3.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.3)	1 (3.3)	0
Bone giant cell tumour benign	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	0	1 (3.3)
Dyspnoea exertional	1 (3.3)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (35.0)	5 (25.0)	2 (10.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	0
Irritable bowel syndrome	1 (5.0)	0	0
General disorders and administration site conditions			
-Total	1 (5.0)	0	0
Pyrexia	1 (5.0)	0	0
Infections and infestations			
-Total	6 (30.0)	4 (20.0)	2 (10.0)
Candida infection	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (5.0)	1 (5.0)	0
Gastroenteritis escherichia coli	1 (5.0)	1 (5.0)	0
Gastroenteritis salmonella	1 (5.0)	1 (5.0)	0
Meningitis pneumococcal	1 (5.0)	1 (5.0)	0
Ophthalmic herpes zoster	1 (5.0)	0	0
Pneumonia	1 (5.0)	1 (5.0)	0
Pneumonia respiratory syncytial viral	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Septic shock	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Infusion related reaction	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Headache	1 (5.0)	1 (5.0)	0
Nervous system disorder	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (5.0)	1 (5.0)	0
Endometriosis	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	29 (72.5)	10 (25.0)	18 (45.0)
Blood and lymphatic system disorders			
-Total	5 (12.5)	4 (10.0)	1 (2.5)
Febrile neutropenia	3 (7.5)	2 (5.0)	1 (2.5)
Coagulopathy	1 (2.5)	1 (2.5)	0
Disseminated intravascular coagulation	1 (2.5)	1 (2.5)	0
Pancytopenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	1 (2.5)	0	1 (2.5)
Cardiac arrest	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	0	0
Diarrhoea	1 (2.5)	0	0
Vomiting	1 (2.5)	0	0
General disorders and administration site conditions			
-Total	6 (15.0)	0	1 (2.5)
Pyrexia	4 (10.0)	0	0
Multiple organ dysfunction syndrome	1 (2.5)	0	1 (2.5)
Non-cardiac chest pain	1 (2.5)	0	0
Immune system disorders			
-Total	24 (60.0)	9 (22.5)	11 (27.5)
Cytokine release syndrome	23 (57.5)	9 (22.5)	10 (25.0)
Drug hypersensitivity	1 (2.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	19 (47.5)	11 (27.5)	8 (20.0)
Encephalitis viral	2 (5.0)	1 (2.5)	1 (2.5)
Gastroenteritis	2 (5.0)	2 (5.0)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (5.0)	2 (5.0)	0
Sepsis	2 (5.0)	1 (2.5)	1 (2.5)
Upper respiratory tract infection	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	0	1 (2.5)
Bronchopulmonary aspergillosis	1 (2.5)	0	1 (2.5)
Candida infection	1 (2.5)	0	1 (2.5)
Covid-19 pneumonia	1 (2.5)	0	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	1 (2.5)	0
Device related sepsis	1 (2.5)	1 (2.5)	0
Encephalitis	1 (2.5)	0	1 (2.5)
Enterobacter infection	1 (2.5)	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	1 (2.5)	0
Klebsiella infection	1 (2.5)	1 (2.5)	0
Mastoiditis	1 (2.5)	1 (2.5)	0
Meningitis bacterial	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0
Otitis externa	1 (2.5)	1 (2.5)	0
Otitis media	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.5)	0	1 (2.5)
Pneumonia fungal	1 (2.5)	1 (2.5)	0
Pneumonia viral	1 (2.5)	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Rhinovirus infection	1 (2.5)	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0
Soft tissue infection	1 (2.5)	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	1 (2.5)	0
Urinary tract infection	1 (2.5)	1 (2.5)	0
Varicella zoster virus infection	1 (2.5)	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Decreased appetite	1 (2.5)	0	1 (2.5)
Hypokalaemia	1 (2.5)	1 (2.5)	0
Malnutrition	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (2.5)	1 (2.5)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (5.0)	2 (5.0)	0
Bone giant cell tumour benign	1 (2.5)	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	1 (2.5)	1 (2.5)	0
Acute kidney injury	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (15.0)	2 (5.0)	2 (5.0)
Acute respiratory failure	1 (2.5)	1 (2.5)	0
Bronchial oedema	1 (2.5)	0	0
Dyspnoea exertional	1 (2.5)	0	0
Hypoxia	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Laryngeal oedema	1 (2.5)	0	1 (2.5)
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Venoocclusive disease	1 (2.5)	0	1 (2.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	34 (85.0)	13 (32.5)	19 (47.5)
Blood and lymphatic system disorders			
-Total	13 (32.5)	12 (30.0)	1 (2.5)
Febrile neutropenia	12 (30.0)	12 (30.0)	0
Disseminated intravascular coagulation	2 (5.0)	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	6 (15.0)	1 (2.5)	4 (10.0)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	2 (5.0)	1 (2.5)	1 (2.5)
Atrioventricular block first degree	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Tachycardia	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	7 (17.5)	4 (10.0)	1 (2.5)
Pancreatitis	2 (5.0)	2 (5.0)	0
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Constipation	1 (2.5)	0	0
Diarrhoea	1 (2.5)	1 (2.5)	0
Irritable bowel syndrome	1 (2.5)	0	0
Nausea	1 (2.5)	0	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	5 (12.5)	1 (2.5)	2 (5.0)
Pyrexia	3 (7.5)	1 (2.5)	0
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Systemic inflammatory response syndrome	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.0)	0	2 (5.0)
Cholestasis	1 (2.5)	0	1 (2.5)
Hepatomegaly	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	27 (67.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	7 (17.5)	11 (27.5)
Allergy to immunoglobulin therapy	1 (2.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	12 (30.0)	7 (17.5)	5 (12.5)
Septic shock	2 (5.0)	0	2 (5.0)
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Candida infection	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	1 (2.5)	0
Covid-19	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Encephalitis	1 (2.5)	0	1 (2.5)
Gastroenteritis escherichia coli	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (2.5)	1 (2.5)	0
Meningitis pneumococcal	1 (2.5)	1 (2.5)	0
Ophthalmic herpes zoster	1 (2.5)	0	0
Pharyngitis streptococcal	1 (2.5)	1 (2.5)	0
Pneumocystis jirovecii pneumonia	1 (2.5)	0	1 (2.5)
Pneumonia	1 (2.5)	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	0
Sepsis	1 (2.5)	0	1 (2.5)
Staphylococcal sepsis	1 (2.5)	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Infusion related reaction	1 (2.5)	1 (2.5)	0
Vasoplegia syndrome	1 (2.5)	0	1 (2.5)
Investigations			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Aspartate aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	1 (2.5)	1 (2.5)	0
Blood uric acid increased	1 (2.5)	0	1 (2.5)
Electrocardiogram qt prolonged	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	5 (12.5)	1 (2.5)	3 (7.5)
Tumour lysis syndrome	2 (5.0)	1 (2.5)	1 (2.5)
Dehydration	1 (2.5)	0	0
Hypercalcaemia	1 (2.5)	1 (2.5)	0
Hyperkalaemia	1 (2.5)	0	1 (2.5)
Hypernatraemia	1 (2.5)	0	1 (2.5)
Hyperphosphataemia	1 (2.5)	0	1 (2.5)
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	4 (10.0)	2 (5.0)	1 (2.5)
Back pain	2 (5.0)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (2.5)	1 (2.5)	0
Rhabdomyolysis	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	8 (20.0)	5 (12.5)	2 (5.0)
Headache	2 (5.0)	2 (5.0)	0
Cerebral haemorrhage	1 (2.5)	0	1 (2.5)
Cognitive disorder	1 (2.5)	0	0
Dysarthria	1 (2.5)	1 (2.5)	0
Encephalopathy	1 (2.5)	1 (2.5)	0
Hydrocephalus	1 (2.5)	0	1 (2.5)
Nervous system disorder	1 (2.5)	1 (2.5)	0
Seizure	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	2 (5.0)	1 (2.5)	0
Delirium	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	0	0
Renal and urinary disorders			
-Total	5 (12.5)	1 (2.5)	4 (10.0)
Acute kidney injury	4 (10.0)	1 (2.5)	3 (7.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (2.5)	0	1 (2.5)
Renal tubular necrosis	1 (2.5)	0	1 (2.5)
Reproductive system and breast disorders			
-Total	1 (2.5)	1 (2.5)	0
Endometriosis	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	12 (30.0)	2 (5.0)	9 (22.5)
Hypoxia	4 (10.0)	2 (5.0)	2 (5.0)
Respiratory failure	4 (10.0)	0	4 (10.0)
Acute respiratory distress syndrome	2 (5.0)	0	2 (5.0)
Pleural effusion	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory distress	2 (5.0)	0	1 (2.5)
Dyspnoea	1 (2.5)	0	1 (2.5)
Epistaxis	1 (2.5)	0	0
Pulmonary oedema	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	8 (20.0)	1 (2.5)	7 (17.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	8 (20.0)	1 (2.5)	7 (17.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (83.3)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)
General disorders and administration site conditions			
-Total	2 (33.3)	0	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)
Encephalitis	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypernatraemia	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Renal tubular necrosis	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (59.1)	4 (18.2)	8 (36.4)
Blood and lymphatic system disorders			
-Total	4 (18.2)	3 (13.6)	1 (4.5)
Febrile neutropenia	4 (18.2)	4 (18.2)	0
Disseminated intravascular coagulation	1 (4.5)	0	0
Thrombocytopenia	1 (4.5)	0	1 (4.5)
Cardiac disorders			
-Total	3 (13.6)	1 (4.5)	1 (4.5)
Atrioventricular block first degree	1 (4.5)	0	0
Cardiac failure	1 (4.5)	0	1 (4.5)
Left ventricular dysfunction	1 (4.5)	1 (4.5)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (18.2)	2 (9.1)	1 (4.5)
Abdominal compartment syndrome	1 (4.5)	0	1 (4.5)
Constipation	1 (4.5)	0	0
Neutropenic colitis	1 (4.5)	1 (4.5)	0
Pancreatitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	2 (9.1)	0	1 (4.5)
Multiple organ dysfunction syndrome	1 (4.5)	0	1 (4.5)
Pyrexia	1 (4.5)	0	0
Immune system disorders			
-Total	13 (59.1)	4 (18.2)	6 (27.3)
Cytokine release syndrome	13 (59.1)	4 (18.2)	6 (27.3)
Infections and infestations			
-Total	2 (9.1)	0	1 (4.5)
Encephalitis viral	1 (4.5)	0	1 (4.5)
Meningitis bacterial	1 (4.5)	1 (4.5)	0
Rhinovirus infection	1 (4.5)	0	0
Investigations			

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Aspartate aminotransferase increased	2 (9.1)	2 (9.1)	0
Blood bilirubin increased	1 (4.5)	1 (4.5)	0
Electrocardiogram qt prolonged	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	1 (4.5)	0	0
Dehydration	1 (4.5)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (4.5)	1 (4.5)	0
Haemarthrosis	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	3 (13.6)	1 (4.5)	1 (4.5)
Cerebral haemorrhage	1 (4.5)	0	1 (4.5)
Cognitive disorder	1 (4.5)	0	0
Dysarthria	1 (4.5)	1 (4.5)	0
Psychiatric disorders			
-Total	1 (4.5)	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	2 (9.1)	0	2 (9.1)
Acute kidney injury	1 (4.5)	0	1 (4.5)
Renal failure	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (22.7)	1 (4.5)	3 (13.6)
Respiratory failure	2 (9.1)	0	2 (9.1)
Hypoxia	1 (4.5)	0	1 (4.5)
Pleural effusion	1 (4.5)	1 (4.5)	0
Pulmonary oedema	1 (4.5)	1 (4.5)	0
Respiratory distress	1 (4.5)	0	0
Vascular disorders			
-Total	3 (13.6)	0	3 (13.6)
Hypotension	3 (13.6)	0	3 (13.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (64.7)	4 (23.5)	6 (35.3)
Blood and lymphatic system disorders			
-Total	5 (29.4)	5 (29.4)	0
Febrile neutropenia	4 (23.5)	4 (23.5)	0
Disseminated intravascular coagulation	1 (5.9)	1 (5.9)	0
Cardiac disorders			
-Total	1 (5.9)	0	1 (5.9)
Cardiac arrest	1 (5.9)	0	1 (5.9)
Hepatobiliary disorders			
-Total	1 (5.9)	0	1 (5.9)
Hepatomegaly	1 (5.9)	0	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	10 (58.8)	4 (23.5)	4 (23.5)
Cytokine release syndrome	10 (58.8)	4 (23.5)	4 (23.5)
Infections and infestations			
-Total	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Hypercalcaemia	1 (5.9)	1 (5.9)	0
Hyperkalaemia	1 (5.9)	0	1 (5.9)
Hyperphosphataemia	1 (5.9)	0	1 (5.9)
Metabolic acidosis	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Acute kidney injury	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (17.6)	1 (5.9)	2 (11.8)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (11.8)	1 (5.9)	1 (5.9)
Pleural effusion	1 (5.9)	0	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Vascular disorders			
-Total	3 (17.6)	1 (5.9)	2 (11.8)
Hypotension	3 (17.6)	1 (5.9)	2 (11.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	25 (71.4)	13 (37.1)	10 (28.6)
Blood and lymphatic system disorders			
-Total	4 (11.4)	4 (11.4)	0
Febrile neutropenia	3 (8.6)	3 (8.6)	0
Pancytopenia	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			
-Total	1 (2.9)	1 (2.9)	0
Diarrhoea	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	1 (2.9)	0	0
Pyrexia	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	23 (65.7)	8 (22.9)	9 (25.7)
Cytokine release syndrome	23 (65.7)	8 (22.9)	9 (25.7)
Infections and infestations			
-Total	7 (20.0)	6 (17.1)	1 (2.9)
Candida infection	1 (2.9)	0	1 (2.9)
Encephalitis viral	1 (2.9)	1 (2.9)	0
Klebsiella infection	1 (2.9)	1 (2.9)	0
Pneumonia fungal	1 (2.9)	1 (2.9)	0
Pneumonia viral	1 (2.9)	1 (2.9)	0
Soft tissue infection	1 (2.9)	1 (2.9)	0
Varicella zoster virus infection	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	1 (2.9)	1 (2.9)	0
Headache	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	1 (2.9)	1 (2.9)	0
Hypotension	1 (2.9)	1 (2.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (25.0)	3 (15.0)	2 (10.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	0
Nausea	1 (5.0)	0	0
Immune system disorders			
-Total	1 (5.0)	1 (5.0)	0
Allergy to immunoglobulin therapy	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Herpes zoster	1 (5.0)	1 (5.0)	0
Pharyngitis streptococcal	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	0	1 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	0	0
Back pain	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Epistaxis	1 (5.0)	0	0
Hypoxia	1 (5.0)	1 (5.0)	0
Respiratory distress	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (40.0)	4 (26.7)	2 (13.3)
Blood and lymphatic system disorders			
-Total	2 (13.3)	2 (13.3)	0
Febrile neutropenia	2 (13.3)	2 (13.3)	0
Cardiac disorders			
-Total	1 (6.7)	0	1 (6.7)
Cardiac arrest	1 (6.7)	0	1 (6.7)
Cardiac failure	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	2 (13.3)	1 (6.7)	0
Diarrhoea	1 (6.7)	0	0
Pancreatitis	1 (6.7)	1 (6.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (6.7)	0	0
General disorders and administration site conditions			
-Total	2 (13.3)	1 (6.7)	0
Pyrexia	2 (13.3)	1 (6.7)	0
Infections and infestations			
-Total	2 (13.3)	2 (13.3)	0
Cytomegalovirus infection reactivation	1 (6.7)	1 (6.7)	0
Human herpesvirus 6 infection	1 (6.7)	1 (6.7)	0
Respiratory syncytial virus infection	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (13.3)	2 (13.3)	0
Back pain	2 (13.3)	2 (13.3)	0
Vascular disorders			
-Total	1 (6.7)	0	1 (6.7)
Venoocclusive disease	1 (6.7)	0	1 (6.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	12 (34.3)	5 (14.3)	7 (20.0)
Blood and lymphatic system disorders			
-Total	2 (5.7)	2 (5.7)	0
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Febrile neutropenia	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	1 (2.9)	0	1 (2.9)
Cardiac arrest	1 (2.9)	0	1 (2.9)
General disorders and administration site conditions			
-Total	3 (8.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (5.7)	0	0
Non-cardiac chest pain	1 (2.9)	0	0
Infections and infestations			
-Total	11 (31.4)	5 (14.3)	6 (17.1)
Gastroenteritis	2 (5.7)	2 (5.7)	0
Bacteraemia	1 (2.9)	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	1 (2.9)
Device related infection	1 (2.9)	1 (2.9)	0
Encephalitis	1 (2.9)	0	1 (2.9)
Enterobacter infection	1 (2.9)	1 (2.9)	0
Klebsiella infection	1 (2.9)	1 (2.9)	0
Mastoiditis	1 (2.9)	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	1 (2.9)	0
Otitis externa	1 (2.9)	1 (2.9)	0
Otitis media	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	1 (2.9)
Respiratory syncytial virus infection	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	1 (2.9)	0	1 (2.9)
Sinusitis	1 (2.9)	1 (2.9)	0
Staphylococcal sepsis	1 (2.9)	0	1 (2.9)
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Urinary tract infection	1 (2.9)	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	1 (2.9)	0
Investigations			
-Total	1 (2.9)	0	1 (2.9)
Blood uric acid increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	3 (8.6)	2 (5.7)	1 (2.9)
Hypokalaemia	1 (2.9)	1 (2.9)	0
Malnutrition	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.9)	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	1 (2.9)
Hydrocephalus	1 (2.9)	0	1 (2.9)
Psychiatric disorders			
-Total	2 (5.7)	1 (2.9)	0
Mental status changes	2 (5.7)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (8.6)	1 (2.9)	1 (2.9)
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Bronchial oedema	1 (2.9)	0	0
Hypoxia	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	0
Irritable bowel syndrome	1 (33.3)	0	0
General disorders and administration site conditions			
-Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (33.3)	1 (33.3)	0
Pneumonia	1 (33.3)	1 (33.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (15.4)	1 (7.7)	1 (7.7)
General disorders and administration site conditions			
-Total	1 (7.7)	0	1 (7.7)
Multiple organ dysfunction syndrome	1 (7.7)	0	1 (7.7)
Immune system disorders			
-Total	1 (7.7)	0	1 (7.7)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	1 (7.7)
Infections and infestations			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Covid-19 pneumonia	1 (7.7)	0	1 (7.7)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (7.7)	1 (7.7)	0
Injury, poisoning and procedural complications			
-Total	1 (7.7)	1 (7.7)	0
Infusion related reaction	1 (7.7)	1 (7.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (27.3)	3 (27.3)	0
Infections and infestations			
-Total	2 (18.2)	2 (18.2)	0
Device related sepsis	1 (9.1)	1 (9.1)	0
Pneumonia respiratory syncytial viral	1 (9.1)	1 (9.1)	0
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Endometriosis	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (39.1)	3 (13.0)	5 (21.7)
General disorders and administration site conditions			
-Total	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	0
Immune system disorders			
-Total	1 (4.3)	1 (4.3)	0
Drug hypersensitivity	1 (4.3)	1 (4.3)	0
Infections and infestations			
-Total	8 (34.8)	4 (17.4)	3 (13.0)
Sepsis	3 (13.0)	1 (4.3)	2 (8.7)
Candida infection	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (4.3)	1 (4.3)	0
Herpes zoster	1 (4.3)	1 (4.3)	0
Meningitis pneumococcal	1 (4.3)	1 (4.3)	0
Ophthalmic herpes zoster	1 (4.3)	0	0
Rhinovirus infection	1 (4.3)	0	0
Septic shock	1 (4.3)	0	1 (4.3)
Staphylococcal abscess	1 (4.3)	1 (4.3)	0
Upper respiratory tract infection	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	1 (4.3)	0	1 (4.3)
Decreased appetite	1 (4.3)	0	1 (4.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.3)	1 (4.3)	0
Bone giant cell tumour benign	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	2 (8.7)	2 (8.7)	0
Headache	1 (4.3)	1 (4.3)	0
Nervous system disorder	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (13.0)	0	2 (8.7)
Dyspnoea exertional	1 (4.3)	0	0
Laryngeal oedema	1 (4.3)	0	1 (4.3)
Respiratory failure	1 (4.3)	0	1 (4.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Febrile neutropenia	2 (33.3)	1 (16.7)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			
-Total	1 (16.7)	0	0
Irritable bowel syndrome	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (33.3)	0	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	0	2 (33.3)
Cytokine release syndrome	4 (66.7)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	1 (16.7)	0
Encephalitis	1 (16.7)	0	1 (16.7)
Gastroenteritis escherichia coli	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (16.7)	1 (16.7)	0
Pneumonia	1 (16.7)	1 (16.7)	0
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypernatraemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (16.7)	0	1 (16.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	0	1 (16.7)
Hypotension	1 (16.7)	0	1 (16.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (68.2)	4 (18.2)	10 (45.5)
Blood and lymphatic system disorders			
-Total	4 (18.2)	3 (13.6)	1 (4.5)
Febrile neutropenia	4 (18.2)	4 (18.2)	0
Disseminated intravascular coagulation	1 (4.5)	0	0
Thrombocytopenia	1 (4.5)	0	1 (4.5)
Cardiac disorders			
-Total	3 (13.6)	1 (4.5)	1 (4.5)
Atrioventricular block first degree	1 (4.5)	0	0
Cardiac failure	1 (4.5)	0	1 (4.5)
Left ventricular dysfunction	1 (4.5)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	4 (18.2)	2 (9.1)	1 (4.5)
Abdominal compartment syndrome	1 (4.5)	0	1 (4.5)
Constipation	1 (4.5)	0	0
Nausea	1 (4.5)	0	0
Neutropenic colitis	1 (4.5)	1 (4.5)	0
Pancreatitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	3 (13.6)	0	2 (9.1)
Multiple organ dysfunction syndrome	2 (9.1)	0	2 (9.1)
Pyrexia	1 (4.5)	0	0
Immune system disorders			
-Total	14 (63.6)	4 (18.2)	7 (31.8)
Cytokine release syndrome	13 (59.1)	4 (18.2)	6 (27.3)
Allergy to immunoglobulin therapy	1 (4.5)	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)
Infections and infestations			

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Covid-19 pneumonia	1 (4.5)	0	1 (4.5)
Encephalitis viral	1 (4.5)	0	1 (4.5)
Herpes zoster	1 (4.5)	1 (4.5)	0
Meningitis bacterial	1 (4.5)	1 (4.5)	0
Pharyngitis streptococcal	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	0	1 (4.5)
Rhinovirus infection	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	1 (4.5)	0
Viral upper respiratory tract infection	1 (4.5)	1 (4.5)	0
Injury, poisoning and procedural complications			
-Total	1 (4.5)	1 (4.5)	0
Infusion related reaction	1 (4.5)	1 (4.5)	0
Investigations			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Aspartate aminotransferase increased	2 (9.1)	2 (9.1)	0
Blood bilirubin increased	1 (4.5)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	1 (4.5)	0	0
Dehydration	1 (4.5)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (9.1)	1 (4.5)	0
Back pain	1 (4.5)	0	0
Haemarthrosis	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	3 (13.6)	1 (4.5)	1 (4.5)
Cerebral haemorrhage	1 (4.5)	0	1 (4.5)
Cognitive disorder	1 (4.5)	0	0
Dysarthria	1 (4.5)	1 (4.5)	0
Psychiatric disorders			
-Total	1 (4.5)	1 (4.5)	0
Delirium	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	2 (9.1)	0	2 (9.1)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (4.5)	0	1 (4.5)
Renal failure	1 (4.5)	0	1 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (31.8)	1 (4.5)	5 (22.7)
Respiratory failure	3 (13.6)	0	3 (13.6)
Hypoxia	2 (9.1)	1 (4.5)	1 (4.5)
Respiratory distress	2 (9.1)	0	1 (4.5)
Epistaxis	1 (4.5)	0	0
Pleural effusion	1 (4.5)	1 (4.5)	0
Pulmonary oedema	1 (4.5)	1 (4.5)	0
Vascular disorders			
-Total	3 (13.6)	0	3 (13.6)
Hypotension	3 (13.6)	0	3 (13.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (88.2)	6 (35.3)	8 (47.1)
Blood and lymphatic system disorders			
-Total	6 (35.3)	6 (35.3)	0
Febrile neutropenia	5 (29.4)	5 (29.4)	0
Disseminated intravascular coagulation	1 (5.9)	1 (5.9)	0
Cardiac disorders			
-Total	2 (11.8)	0	2 (11.8)
Cardiac arrest	2 (11.8)	0	2 (11.8)
Cardiac failure	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	2 (11.8)	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (5.9)	0	0
Pancreatitis	1 (5.9)	1 (5.9)	0
Vomiting	1 (5.9)	0	0
General disorders and administration site conditions			
-Total	2 (11.8)	1 (5.9)	0
Pyrexia	2 (11.8)	1 (5.9)	0
Hepatobiliary disorders			
-Total	1 (5.9)	0	1 (5.9)
Hepatomegaly	1 (5.9)	0	1 (5.9)
Immune system disorders			
-Total	10 (58.8)	4 (23.5)	4 (23.5)
Cytokine release syndrome	10 (58.8)	4 (23.5)	4 (23.5)
Infections and infestations			
-Total	5 (29.4)	5 (29.4)	0
Cytomegalovirus infection reactivation	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Human herpesvirus 6 infection	1 (5.9)	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Hypercalcaemia	1 (5.9)	1 (5.9)	0
Hyperkalaemia	1 (5.9)	0	1 (5.9)
Hyperphosphataemia	1 (5.9)	0	1 (5.9)
Metabolic acidosis	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (11.8)	2 (11.8)	0
Back pain	2 (11.8)	2 (11.8)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Acute kidney injury	1 (5.9)	1 (5.9)	0
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	1 (5.9)	0
Endometriosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (17.6)	1 (5.9)	2 (11.8)
Hypoxia	2 (11.8)	1 (5.9)	1 (5.9)
Pleural effusion	1 (5.9)	0	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Vascular disorders			
-Total	4 (23.5)	1 (5.9)	3 (17.6)
Hypotension	3 (17.6)	1 (5.9)	2 (11.8)
Venoocclusive disease	1 (5.9)	0	1 (5.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 209r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	28 (80.0)	11 (31.4)	16 (45.7)
Blood and lymphatic system disorders			
-Total	5 (14.3)	5 (14.3)	0
Febrile neutropenia	4 (11.4)	4 (11.4)	0
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Pancytopenia	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	1 (2.9)	0	1 (2.9)
Cardiac arrest	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			
-Total	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	4 (11.4)	0	0
Pyrexia	3 (8.6)	0	0
Non-cardiac chest pain	1 (2.9)	0	0
Immune system disorders			
-Total	23 (65.7)	8 (22.9)	9 (25.7)
Cytokine release syndrome	23 (65.7)	8 (22.9)	9 (25.7)
Drug hypersensitivity	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	19 (54.3)	10 (28.6)	9 (25.7)
Sepsis	3 (8.6)	1 (2.9)	2 (5.7)
Candida infection	2 (5.7)	0	1 (2.9)
Gastroenteritis	2 (5.7)	2 (5.7)	0
Septic shock	2 (5.7)	0	2 (5.7)
Upper respiratory tract infection	2 (5.7)	2 (5.7)	0
Bacteraemia	1 (2.9)	0	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19	1 (2.9)	1 (2.9)	0
Device related infection	1 (2.9)	1 (2.9)	0
Encephalitis	1 (2.9)	0	1 (2.9)
Encephalitis viral	1 (2.9)	1 (2.9)	0
Enterobacter infection	1 (2.9)	1 (2.9)	0
Herpes zoster	1 (2.9)	1 (2.9)	0
Klebsiella infection	1 (2.9)	1 (2.9)	0
Mastoiditis	1 (2.9)	1 (2.9)	0
Meningitis pneumococcal	1 (2.9)	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	1 (2.9)	0
Ophthalmic herpes zoster	1 (2.9)	0	0
Otitis externa	1 (2.9)	1 (2.9)	0
Otitis media	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	1 (2.9)
Pneumonia fungal	1 (2.9)	1 (2.9)	0
Pneumonia viral	1 (2.9)	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (2.9)	1 (2.9)	0
Soft tissue infection	1 (2.9)	1 (2.9)	0
Staphylococcal abscess	1 (2.9)	1 (2.9)	0
Staphylococcal sepsis	1 (2.9)	0	1 (2.9)
Urinary tract infection	1 (2.9)	1 (2.9)	0
Varicella zoster virus infection	1 (2.9)	1 (2.9)	0
Viral haemorrhagic cystitis	1 (2.9)	1 (2.9)	0
Investigations			
-Total	1 (2.9)	0	1 (2.9)
Blood uric acid increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	4 (11.4)	2 (5.7)	2 (5.7)
Decreased appetite	1 (2.9)	0	1 (2.9)
Hypokalaemia	1 (2.9)	1 (2.9)	0
Malnutrition	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	1 (2.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (5.7)	2 (5.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone giant cell tumour benign	1 (2.9)	1 (2.9)	0
Myelodysplastic syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	4 (11.4)	3 (8.6)	1 (2.9)
Headache	2 (5.7)	2 (5.7)	0
Hydrocephalus	1 (2.9)	0	1 (2.9)
Nervous system disorder	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	2 (5.7)	1 (2.9)	0
Mental status changes	2 (5.7)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (17.1)	1 (2.9)	3 (8.6)
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Bronchial oedema	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (2.9)	0	0
Hypoxia	1 (2.9)	1 (2.9)	0
Laryngeal oedema	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210a
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	25 (61.0)	15 (36.6)	10 (24.4)
Blood and lymphatic system disorders			
-Total	13 (31.7)	11 (26.8)	2 (4.9)
Febrile neutropenia	10 (24.4)	10 (24.4)	0
Anaemia	1 (2.4)	0	0
Haemolytic anaemia	1 (2.4)	0	1 (2.4)
Hyperleukocytosis	1 (2.4)	1 (2.4)	0
Neutropenia	1 (2.4)	0	1 (2.4)
Thrombocytopenia	1 (2.4)	1 (2.4)	0
Endocrine disorders			
-Total	1 (2.4)	1 (2.4)	0
Adrenal insufficiency	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (7.3)	3 (7.3)	0
Anal inflammation	1 (2.4)	1 (2.4)	0
Neutropenic colitis	1 (2.4)	1 (2.4)	0
Stomatitis	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions			
-Total	4 (9.8)	3 (7.3)	0
Pyrexia	2 (4.9)	1 (2.4)	0
Mucosal inflammation	1 (2.4)	1 (2.4)	0
Pain	1 (2.4)	1 (2.4)	0
Infections and infestations			
-Total	11 (26.8)	8 (19.5)	3 (7.3)
Aspergillus infection	1 (2.4)	0	1 (2.4)
Bronchiolitis	1 (2.4)	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	1 (2.4)	0
Device related infection	1 (2.4)	1 (2.4)	0
Escherichia bacteraemia	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (2.4)	1 (2.4)	0
Gastroenteritis adenovirus	1 (2.4)	1 (2.4)	0
Haemophilus bacteraemia	1 (2.4)	0	1 (2.4)
Parainfluenzae virus infection	1 (2.4)	1 (2.4)	0
Pneumonia	1 (2.4)	1 (2.4)	0
Pneumonia fungal	1 (2.4)	0	1 (2.4)
Respiratory tract infection	1 (2.4)	1 (2.4)	0
Sialoadenitis	1 (2.4)	1 (2.4)	0
Sinusitis	1 (2.4)	1 (2.4)	0
Systemic mycosis	1 (2.4)	1 (2.4)	0
Injury, poisoning and procedural complications			
-Total	2 (4.9)	1 (2.4)	1 (2.4)
Infusion related reaction	1 (2.4)	1 (2.4)	0
Tracheal obstruction	1 (2.4)	0	1 (2.4)
Investigations			
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Neutrophil count decreased	2 (4.9)	1 (2.4)	1 (2.4)

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amylase increased	1 (2.4)	0	1 (2.4)
Metabolism and nutrition disorders			
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Hyponatraemia	1 (2.4)	0	1 (2.4)
Hypophagia	1 (2.4)	1 (2.4)	0
Tumour lysis syndrome	1 (2.4)	0	1 (2.4)
Nervous system disorders			
-Total	2 (4.9)	1 (2.4)	1 (2.4)
Encephalopathy	1 (2.4)	1 (2.4)	0
Haemorrhage intracranial	1 (2.4)	0	1 (2.4)
Psychiatric disorders			
-Total	1 (2.4)	1 (2.4)	0
Mental status changes	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Respiratory failure	2 (4.9)	0	2 (4.9)
Epistaxis	1 (2.4)	1 (2.4)	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemothorax	1 (2.4)	0	1 (2.4)
Pneumothorax	1 (2.4)	0	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210a
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	20 (50.0)	9 (22.5)	9 (22.5)
Blood and lymphatic system disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Febrile neutropenia	2 (5.0)	2 (5.0)	0
Anaemia	1 (2.5)	0	1 (2.5)
Neutropenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	3 (7.5)	2 (5.0)	0
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Pericardial effusion	1 (2.5)	1 (2.5)	0
Tachycardia	1 (2.5)	0	0
Endocrine disorders			

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	0	0
Addison's disease	1 (2.5)	0	0
Gastrointestinal disorders			
-Total	6 (15.0)	4 (10.0)	1 (2.5)
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Abdominal pain	1 (2.5)	0	0
Colitis	1 (2.5)	1 (2.5)	0
Diarrhoea	1 (2.5)	0	0
Gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0
Haemoperitoneum	1 (2.5)	0	1 (2.5)
Ileus	1 (2.5)	1 (2.5)	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	1 (2.5)	0	0
Pyrexia	1 (2.5)	0	0
Hepatobiliary disorders			
-Total	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic cytolysis	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	16 (40.0)	10 (25.0)	6 (15.0)
Herpes zoster	2 (5.0)	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Staphylococcal sepsis	2 (5.0)	0	2 (5.0)
Abscess limb	1 (2.5)	1 (2.5)	0
Bacteraemia	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	1 (2.5)
Gastroenteritis viral	1 (2.5)	1 (2.5)	0
Klebsiella bacteraemia	1 (2.5)	1 (2.5)	0
Localised infection	1 (2.5)	1 (2.5)	0
Paronychia	1 (2.5)	1 (2.5)	0
Pharyngitis	1 (2.5)	1 (2.5)	0
Sepsis	1 (2.5)	0	1 (2.5)
Septic shock	1 (2.5)	0	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia sepsis	1 (2.5)	0	1 (2.5)
Injury, poisoning and procedural complications			
-Total	2 (5.0)	1 (2.5)	0
Post procedural haemorrhage	1 (2.5)	1 (2.5)	0
Transfusion reaction	1 (2.5)	0	0
Investigations			
-Total	1 (2.5)	0	1 (2.5)
Neutrophil count decreased	1 (2.5)	0	1 (2.5)
Platelet count decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	1 (2.5)	1 (2.5)	0
Hypervolaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	0	0
Pain in extremity	1 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	0	1 (2.5)
Acute lymphocytic leukaemia	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	1 (2.5)	0	0
Seizure	1 (2.5)	0	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory failure	2 (5.0)	0	2 (5.0)
Pulmonary oedema	1 (2.5)	0	1 (2.5)
Tachypnoea	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	4 (10.0)	1 (2.5)	1 (2.5)
Hypotension	3 (7.5)	1 (2.5)	1 (2.5)
Hypertension	1 (2.5)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210a
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (64.7)	6 (35.3)	3 (17.6)
Blood and lymphatic system disorders			
-Total	5 (29.4)	3 (17.6)	2 (11.8)
Febrile neutropenia	4 (23.5)	3 (17.6)	1 (5.9)
Pancytopenia	2 (11.8)	1 (5.9)	1 (5.9)
Cardiac disorders			
-Total	1 (5.9)	1 (5.9)	0
Cardiac failure	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	2 (11.8)	0	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	2 (11.8)	0	0
Pain	1 (5.9)	0	0
Hepatobiliary disorders			
-Total	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	9 (52.9)	5 (29.4)	3 (17.6)
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related sepsis	1 (5.9)	1 (5.9)	0
Fungal sepsis	1 (5.9)	0	1 (5.9)
Gastroenteritis	1 (5.9)	0	0
Pneumonia	1 (5.9)	0	1 (5.9)
Respiratory tract infection	1 (5.9)	1 (5.9)	0
Septic shock	1 (5.9)	0	1 (5.9)
Staphylococcal skin infection	1 (5.9)	1 (5.9)	0
Urinary tract infection	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Investigations			

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (11.8)	1 (5.9)	0
C-reactive protein increased	1 (5.9)	1 (5.9)	0
Electrocardiogram qt prolonged	1 (5.9)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.9)	0	0
Pain in extremity	1 (5.9)	0	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.9)	0	1 (5.9)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210b
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	33 (60.0)	16 (29.1)	14 (25.5)
Blood and lymphatic system disorders			
-Total	11 (20.0)	8 (14.5)	3 (5.5)
Febrile neutropenia	6 (10.9)	6 (10.9)	0
Anaemia	2 (3.6)	0	1 (1.8)
Neutropenia	2 (3.6)	1 (1.8)	1 (1.8)
Haemolytic anaemia	1 (1.8)	0	1 (1.8)
Hyperleukocytosis	1 (1.8)	1 (1.8)	0
Thrombocytopenia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	2 (3.6)	1 (1.8)	0
Left ventricular dysfunction	1 (1.8)	1 (1.8)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	1 (1.8)	0	0
Endocrine disorders			
-Total	2 (3.6)	1 (1.8)	0
Addison's disease	1 (1.8)	0	0
Adrenal insufficiency	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	6 (10.9)	4 (7.3)	1 (1.8)
Abdominal compartment syndrome	1 (1.8)	0	1 (1.8)
Abdominal pain	1 (1.8)	0	0
Anal inflammation	1 (1.8)	1 (1.8)	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0
Haemoperitoneum	1 (1.8)	0	1 (1.8)
Ileus	1 (1.8)	1 (1.8)	0
Stomatitis	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	5 (9.1)	2 (3.6)	0
Pyrexia	4 (7.3)	1 (1.8)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	2 (3.6)	1 (1.8)	0
Hepatobiliary disorders			
-Total	2 (3.6)	2 (3.6)	0
Drug-induced liver injury	1 (1.8)	1 (1.8)	0
Hepatic cytolysis	1 (1.8)	1 (1.8)	0
Infections and infestations			
-Total	19 (34.5)	14 (25.5)	5 (9.1)
Respiratory tract infection	2 (3.6)	2 (3.6)	0
Staphylococcal sepsis	2 (3.6)	0	2 (3.6)
Abscess limb	1 (1.8)	1 (1.8)	0
Bronchiolitis	1 (1.8)	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	1 (1.8)	0
Device related infection	1 (1.8)	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	1 (1.8)
Escherichia bacteraemia	1 (1.8)	1 (1.8)	0
Herpes zoster	1 (1.8)	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	1 (1.8)	0
Localised infection	1 (1.8)	1 (1.8)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0
Paronychia	1 (1.8)	1 (1.8)	0
Pharyngitis	1 (1.8)	1 (1.8)	0
Pneumonia	1 (1.8)	1 (1.8)	0
Sepsis	1 (1.8)	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	1 (1.8)
Sialoadenitis	1 (1.8)	1 (1.8)	0
Sinusitis	1 (1.8)	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	1 (1.8)
Vascular device infection	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	3 (5.5)	2 (3.6)	1 (1.8)
Infusion related reaction	1 (1.8)	1 (1.8)	0
Post procedural haemorrhage	1 (1.8)	1 (1.8)	0
Tracheal obstruction	1 (1.8)	0	1 (1.8)
Investigations			
-Total	2 (3.6)	0	2 (3.6)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Amylase increased	1 (1.8)	0	1 (1.8)
Neutrophil count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	3 (5.5)	1 (1.8)	2 (3.6)
Hyponatraemia	1 (1.8)	0	1 (1.8)
Hypophagia	1 (1.8)	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	2 (3.6)	0	0
Pain in extremity	2 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.8)	0	1 (1.8)
Acute lymphocytic leukaemia	1 (1.8)	0	1 (1.8)
Nervous system disorders			
-Total	3 (5.5)	1 (1.8)	1 (1.8)
Encephalopathy	1 (1.8)	1 (1.8)	0
Haemorrhage intracranial	1 (1.8)	0	1 (1.8)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (1.8)	0	0
Psychiatric disorders			
-Total	1 (1.8)	1 (1.8)	0
Mental status changes	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	1 (1.8)	1 (1.8)	0
Renal tubular necrosis	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (10.9)	2 (3.6)	4 (7.3)
Respiratory failure	4 (7.3)	0	4 (7.3)
Epistaxis	1 (1.8)	1 (1.8)	0
Haemothorax	1 (1.8)	0	1 (1.8)
Pneumothorax	1 (1.8)	0	1 (1.8)
Pulmonary oedema	1 (1.8)	0	1 (1.8)
Tachypnoea	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	3 (5.5)	1 (1.8)	1 (1.8)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (5.5)	1 (1.8)	1 (1.8)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210b
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	23 (53.5)	14 (32.6)	8 (18.6)
Blood and lymphatic system disorders			
-Total	11 (25.6)	9 (20.9)	2 (4.7)
Febrile neutropenia	10 (23.3)	9 (20.9)	1 (2.3)
Pancytopenia	2 (4.7)	1 (2.3)	1 (2.3)
Cardiac disorders			
-Total	2 (4.7)	2 (4.7)	0
Cardiac failure	1 (2.3)	1 (2.3)	0
Pericardial effusion	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	3 (7.0)	3 (7.0)	0
Neutropenic colitis	2 (4.7)	2 (4.7)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Colitis	1 (2.3)	1 (2.3)	0
Diarrhoea	1 (2.3)	0	0
General disorders and administration site conditions			
-Total	2 (4.7)	1 (2.3)	0
Mucosal inflammation	1 (2.3)	1 (2.3)	0
Pyrexia	1 (2.3)	0	0
Infections and infestations			
-Total	17 (39.5)	9 (20.9)	7 (16.3)
Septic shock	2 (4.7)	0	2 (4.7)
Staphylococcal bacteraemia	2 (4.7)	2 (4.7)	0
Aspergillus infection	1 (2.3)	0	1 (2.3)
Bacteraemia	1 (2.3)	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	1 (2.3)
Device related infection	1 (2.3)	1 (2.3)	0
Device related sepsis	1 (2.3)	1 (2.3)	0
Fungal sepsis	1 (2.3)	0	1 (2.3)
Fungal skin infection	1 (2.3)	1 (2.3)	0

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (2.3)	0	0
Gastroenteritis adenovirus	1 (2.3)	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0
Haemophilus bacteraemia	1 (2.3)	0	1 (2.3)
Herpes zoster	1 (2.3)	1 (2.3)	0
Pneumonia	1 (2.3)	0	1 (2.3)
Pneumonia fungal	1 (2.3)	0	1 (2.3)
Staphylococcal infection	1 (2.3)	1 (2.3)	0
Staphylococcal skin infection	1 (2.3)	1 (2.3)	0
Systemic mycosis	1 (2.3)	1 (2.3)	0
Urinary tract infection	1 (2.3)	1 (2.3)	0
Injury, poisoning and procedural complications			
-Total	1 (2.3)	0	0
Transfusion reaction	1 (2.3)	0	0
Investigations			
-Total	4 (9.3)	2 (4.7)	1 (2.3)
Neutrophil count decreased	2 (4.7)	1 (2.3)	1 (2.3)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
C-reactive protein increased	1 (2.3)	1 (2.3)	0
Electrocardiogram qt prolonged	1 (2.3)	0	0
Platelet count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypervolaemia	1 (2.3)	1 (2.3)	0
Psychiatric disorders			
-Total	1 (2.3)	1 (2.3)	0
Mental status changes	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.3)	0	1 (2.3)
Acute respiratory distress syndrome	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	1 (2.3)	0	0
Hypertension	1 (2.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210c
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	45 (64.3)	24 (34.3)	18 (25.7)
Blood and lymphatic system disorders			
-Total	18 (25.7)	14 (20.0)	4 (5.7)
Febrile neutropenia	12 (17.1)	12 (17.1)	0
Anaemia	2 (2.9)	0	1 (1.4)
Neutropenia	2 (2.9)	1 (1.4)	1 (1.4)
Pancytopenia	2 (2.9)	1 (1.4)	1 (1.4)
Haemolytic anaemia	1 (1.4)	0	1 (1.4)
Hyperleukocytosis	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	3 (4.3)	2 (2.9)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	1 (1.4)	1 (1.4)	0
Pericardial effusion	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	0
Endocrine disorders			
-Total	2 (2.9)	1 (1.4)	0
Addison's disease	1 (1.4)	0	0
Adrenal insufficiency	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	8 (11.4)	6 (8.6)	1 (1.4)
Neutropenic colitis	2 (2.9)	2 (2.9)	0
Abdominal compartment syndrome	1 (1.4)	0	1 (1.4)
Abdominal pain	1 (1.4)	0	0
Colitis	1 (1.4)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
Haemoperitoneum	1 (1.4)	0	1 (1.4)
Ileus	1 (1.4)	1 (1.4)	0
Stomatitis	1 (1.4)	1 (1.4)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	7 (10.0)	3 (4.3)	0
Pyrexia	5 (7.1)	1 (1.4)	0
Pain	2 (2.9)	1 (1.4)	0
Mucosal inflammation	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.9)	2 (2.9)	0
Drug-induced liver injury	1 (1.4)	1 (1.4)	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	30 (42.9)	20 (28.6)	10 (14.3)
Device related infection	2 (2.9)	2 (2.9)	0
Herpes zoster	2 (2.9)	2 (2.9)	0
Septic shock	2 (2.9)	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	2 (2.9)	0
Staphylococcal infection	2 (2.9)	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	2 (2.9)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.4)	1 (1.4)	0
Aspergillus infection	1 (1.4)	0	1 (1.4)
Bacteraemia	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchiolitis	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	1 (1.4)
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	1 (1.4)
Fungal skin infection	1 (1.4)	1 (1.4)	0
Gastroenteritis adenovirus	1 (1.4)	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	1 (1.4)
Localised infection	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Paronychia	1 (1.4)	1 (1.4)	0
Pharyngitis	1 (1.4)	1 (1.4)	0
Pneumonia	1 (1.4)	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	1 (1.4)	1 (1.4)	0
Sepsis	1 (1.4)	0	1 (1.4)
Serratia sepsis	1 (1.4)	0	1 (1.4)
Sialoadenitis	1 (1.4)	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0
Staphylococcal skin infection	1 (1.4)	1 (1.4)	0
Systemic mycosis	1 (1.4)	1 (1.4)	0
Urinary tract infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	3 (4.3)	1 (1.4)	1 (1.4)
Infusion related reaction	1 (1.4)	1 (1.4)	0
Tracheal obstruction	1 (1.4)	0	1 (1.4)
Transfusion reaction	1 (1.4)	0	0
Investigations			
-Total	5 (7.1)	2 (2.9)	2 (2.9)
Neutrophil count decreased	2 (2.9)	1 (1.4)	1 (1.4)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Amylase increased	1 (1.4)	0	1 (1.4)
C-reactive protein increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	0	0
Platelet count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	4 (5.7)	2 (2.9)	2 (2.9)
Hypervolaemia	1 (1.4)	1 (1.4)	0
Hyponatraemia	1 (1.4)	0	1 (1.4)
Hypophagia	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.9)	0	0
Pain in extremity	2 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	0	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)	0	1 (1.4)
Nervous system disorders			

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (2.9)	1 (1.4)	0
Encephalopathy	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	0	0
Psychiatric disorders			
-Total	2 (2.9)	2 (2.9)	0
Mental status changes	2 (2.9)	2 (2.9)	0
Renal and urinary disorders			
-Total	1 (1.4)	1 (1.4)	0
Renal tubular necrosis	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.6)	2 (2.9)	4 (5.7)
Respiratory failure	3 (4.3)	0	3 (4.3)
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Haemothorax	1 (1.4)	0	1 (1.4)
Pneumothorax	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	0	1 (1.4)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	3 (4.3)	0	1 (1.4)
Hypotension	2 (2.9)	0	1 (1.4)
Hypertension	1 (1.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210c
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (33.3)	3 (20.0)	2 (13.3)
Blood and lymphatic system disorders			
-Total	1 (6.7)	1 (6.7)	0
Febrile neutropenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
-Total	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	1 (6.7)	1 (6.7)	0
Anal inflammation	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	3 (20.0)	2 (13.3)	1 (6.7)

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	1 (6.7)	0	1 (6.7)
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Vascular disorders			
-Total	1 (6.7)	1 (6.7)	0
Hypotension	1 (6.7)	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210c
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Number of patients with at least one SAE	6 (46.2)	3 (23.1)	2 (15.4)
Blood and lymphatic system disorders			
-Total	3 (23.1)	2 (15.4)	1 (7.7)
Febrile neutropenia	3 (23.1)	2 (15.4)	1 (7.7)
Infections and infestations			
-Total	3 (23.1)	1 (7.7)	1 (7.7)
Gastroenteritis	1 (7.7)	0	0
Pneumonia	1 (7.7)	0	1 (7.7)
Respiratory tract infection	1 (7.7)	1 (7.7)	0
Investigations			
-Total	1 (7.7)	0	1 (7.7)

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (7.7)	0	1 (7.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.7)	0	1 (7.7)
Respiratory failure	1 (7.7)	0	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210d
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (61.1)	5 (27.8)	4 (22.2)
Blood and lymphatic system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Anaemia	2 (11.1)	0	1 (5.6)
Thrombocytopenia	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
General disorders and administration site conditions			
-Total	2 (11.1)	0	0

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (11.1)	0	0
Pain	1 (5.6)	0	0
Infections and infestations			
-Total	9 (50.0)	6 (33.3)	2 (11.1)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Escherichia bacteraemia	1 (5.6)	1 (5.6)	0
Gastroenteritis	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Sinusitis	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	0	1 (5.6)
Electrocardiogram qt prolonged	1 (5.6)	0	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (5.6)	0	0
Pain in extremity	1 (5.6)	0	0
Psychiatric disorders			
-Total	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.6)	0	1 (5.6)
Respiratory failure	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	1 (5.6)	0	0
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210d
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	45 (56.3)	25 (31.3)	18 (22.5)
Blood and lymphatic system disorders			
-Total	20 (25.0)	16 (20.0)	4 (5.0)
Febrile neutropenia	16 (20.0)	15 (18.8)	1 (1.3)
Neutropenia	2 (2.5)	1 (1.3)	1 (1.3)
Pancytopenia	2 (2.5)	1 (1.3)	1 (1.3)
Haemolytic anaemia	1 (1.3)	0	1 (1.3)
Hyperleukocytosis	1 (1.3)	1 (1.3)	0
Cardiac disorders			
-Total	4 (5.0)	3 (3.8)	0
Cardiac failure	1 (1.3)	1 (1.3)	0
Left ventricular dysfunction	1 (1.3)	1 (1.3)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	0
Endocrine disorders			
-Total	2 (2.5)	1 (1.3)	0
Addison's disease	1 (1.3)	0	0
Adrenal insufficiency	1 (1.3)	1 (1.3)	0
Gastrointestinal disorders			
-Total	8 (10.0)	6 (7.5)	1 (1.3)
Neutropenic colitis	2 (2.5)	2 (2.5)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Abdominal pain	1 (1.3)	0	0
Anal inflammation	1 (1.3)	1 (1.3)	0
Gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0
Haemoperitoneum	1 (1.3)	0	1 (1.3)
Ileus	1 (1.3)	1 (1.3)	0
Stomatitis	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.3)	3 (3.8)	0
Pyrexia	3 (3.8)	1 (1.3)	0
Mucosal inflammation	1 (1.3)	1 (1.3)	0
Pain	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.5)	2 (2.5)	0
Drug-induced liver injury	1 (1.3)	1 (1.3)	0
Hepatic cytolysis	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	27 (33.8)	17 (21.3)	10 (12.5)
Device related infection	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Pneumonia	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory tract infection	2 (2.5)	2 (2.5)	0
Septic shock	2 (2.5)	0	2 (2.5)
Staphylococcal bacteraemia	2 (2.5)	2 (2.5)	0
Staphylococcal infection	2 (2.5)	1 (1.3)	1 (1.3)
Staphylococcal sepsis	2 (2.5)	0	2 (2.5)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (1.3)	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	1 (1.3)
Bronchiolitis	1 (1.3)	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	1 (1.3)	0
Device related sepsis	1 (1.3)	1 (1.3)	0
Fungal sepsis	1 (1.3)	0	1 (1.3)
Fungal skin infection	1 (1.3)	1 (1.3)	0
Gastroenteritis adenovirus	1 (1.3)	1 (1.3)	0
Haemophilus bacteraemia	1 (1.3)	0	1 (1.3)
Klebsiella bacteraemia	1 (1.3)	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	1 (1.3)	0
Paronychia	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	1 (1.3)
Sepsis	1 (1.3)	0	1 (1.3)
Serratia sepsis	1 (1.3)	0	1 (1.3)
Sialoadenitis	1 (1.3)	1 (1.3)	0
Staphylococcal skin infection	1 (1.3)	1 (1.3)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (1.3)	1 (1.3)	0
Vascular device infection	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	4 (5.0)	2 (2.5)	1 (1.3)
Infusion related reaction	1 (1.3)	1 (1.3)	0
Post procedural haemorrhage	1 (1.3)	1 (1.3)	0
Tracheal obstruction	1 (1.3)	0	1 (1.3)
Transfusion reaction	1 (1.3)	0	0
Investigations			
-Total	4 (5.0)	2 (2.5)	2 (2.5)
Neutrophil count decreased	2 (2.5)	1 (1.3)	1 (1.3)
Amylase increased	1 (1.3)	0	1 (1.3)
C-reactive protein increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			
-Total	4 (5.0)	2 (2.5)	2 (2.5)
Hypervolaemia	1 (1.3)	1 (1.3)	0
Hyponatraemia	1 (1.3)	0	1 (1.3)

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophagia	1 (1.3)	1 (1.3)	0
Tumour lysis syndrome	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.3)	0	0
Pain in extremity	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.3)	0	1 (1.3)
Acute lymphocytic leukaemia	1 (1.3)	0	1 (1.3)
Nervous system disorders			
-Total	3 (3.8)	1 (1.3)	1 (1.3)
Encephalopathy	1 (1.3)	1 (1.3)	0
Haemorrhage intracranial	1 (1.3)	0	1 (1.3)
Seizure	1 (1.3)	0	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Mental status changes	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.3)	1 (1.3)	0
Renal tubular necrosis	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (7.5)	2 (2.5)	4 (5.0)
Respiratory failure	3 (3.8)	0	3 (3.8)
Acute respiratory distress syndrome	1 (1.3)	0	1 (1.3)
Epistaxis	1 (1.3)	1 (1.3)	0
Haemothorax	1 (1.3)	0	1 (1.3)
Pneumothorax	1 (1.3)	0	1 (1.3)
Pulmonary oedema	1 (1.3)	0	1 (1.3)
Tachypnoea	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	3 (3.8)	1 (1.3)	1 (1.3)
Hypotension	3 (3.8)	1 (1.3)	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210e
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (50.0)	2 (25.0)	2 (25.0)
Blood and lymphatic system disorders			
-Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Haemoperitoneum	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0
Infections and infestations			

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210e
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	52 (57.8)	28 (31.1)	20 (22.2)
Blood and lymphatic system disorders			
-Total	21 (23.3)	16 (17.8)	5 (5.6)
Febrile neutropenia	15 (16.7)	14 (15.6)	1 (1.1)
Anaemia	2 (2.2)	0	1 (1.1)
Neutropenia	2 (2.2)	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.2)	1 (1.1)	1 (1.1)
Haemolytic anaemia	1 (1.1)	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	1 (1.1)	0
Thrombocytopenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	4 (4.4)	3 (3.3)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.1)	1 (1.1)	0
Left ventricular dysfunction	1 (1.1)	1 (1.1)	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	0
Endocrine disorders			
-Total	2 (2.2)	1 (1.1)	0
Addison's disease	1 (1.1)	0	0
Adrenal insufficiency	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders			
-Total	8 (8.9)	7 (7.8)	0
Neutropenic colitis	2 (2.2)	2 (2.2)	0
Abdominal pain	1 (1.1)	0	0
Anal inflammation	1 (1.1)	1 (1.1)	0
Colitis	1 (1.1)	1 (1.1)	0
Diarrhoea	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Ileus	1 (1.1)	1 (1.1)	0
Stomatitis	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (6.7)	3 (3.3)	0
Pyrexia	4 (4.4)	1 (1.1)	0
Pain	2 (2.2)	1 (1.1)	0
Mucosal inflammation	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	2 (2.2)	2 (2.2)	0
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatic cytolysis	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	32 (35.6)	21 (23.3)	10 (11.1)
Device related infection	2 (2.2)	2 (2.2)	0
Herpes zoster	2 (2.2)	2 (2.2)	0
Pneumonia	2 (2.2)	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	2 (2.2)	0
Septic shock	2 (2.2)	0	2 (2.2)
Staphylococcal sepsis	2 (2.2)	0	2 (2.2)
Abscess limb	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bacteraemia	1 (1.1)	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Escherichia bacteraemia	1 (1.1)	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	1 (1.1)
Klebsiella bacteraemia	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	1 (1.1)	0
Paronychia	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	1 (1.1)
Sepsis	1 (1.1)	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	1 (1.1)	1 (1.1)	0
Sinusitis	1 (1.1)	1 (1.1)	0
Staphylococcal bacteraemia	1 (1.1)	1 (1.1)	0
Staphylococcal infection	1 (1.1)	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	1 (1.1)	0
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Injury, poisoning and procedural complications			
-Total	4 (4.4)	2 (2.2)	1 (1.1)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Post procedural haemorrhage	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Investigations			
-Total	6 (6.7)	2 (2.2)	3 (3.3)
Neutrophil count decreased	3 (3.3)	1 (1.1)	2 (2.2)
Amylase increased	1 (1.1)	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	0
Platelet count decreased	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	4 (4.4)	2 (2.2)	2 (2.2)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Hypophagia	1 (1.1)	1 (1.1)	0
Tumour lysis syndrome	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.2)	0	0
Pain in extremity	2 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.1)	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	1 (1.1)
Nervous system disorders			
-Total	3 (3.3)	1 (1.1)	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (1.1)	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	1 (1.1)
Seizure	1 (1.1)	0	0
Psychiatric disorders			
-Total	2 (2.2)	2 (2.2)	0
Mental status changes	2 (2.2)	2 (2.2)	0
Renal and urinary disorders			
-Total	1 (1.1)	1 (1.1)	0
Renal tubular necrosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (5.6)	2 (2.2)	3 (3.3)
Respiratory failure	2 (2.2)	0	2 (2.2)
Acute respiratory distress syndrome	1 (1.1)	0	1 (1.1)
Epistaxis	1 (1.1)	1 (1.1)	0
Haemothorax	1 (1.1)	0	1 (1.1)
Pneumothorax	1 (1.1)	0	1 (1.1)
Tachypnoea	1 (1.1)	1 (1.1)	0
Vascular disorders			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (4.4)	1 (1.1)	1 (1.1)
Hypotension	3 (3.3)	1 (1.1)	1 (1.1)
Hypertension	1 (1.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210f
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Abscess limb	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210f
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	55 (57.3)	29 (30.2)	22 (22.9)
Blood and lymphatic system disorders			
-Total	22 (22.9)	17 (17.7)	5 (5.2)
Febrile neutropenia	16 (16.7)	15 (15.6)	1 (1.0)
Anaemia	2 (2.1)	0	1 (1.0)
Neutropenia	2 (2.1)	1 (1.0)	1 (1.0)
Pancytopenia	2 (2.1)	1 (1.0)	1 (1.0)
Haemolytic anaemia	1 (1.0)	0	1 (1.0)
Hyperleukocytosis	1 (1.0)	1 (1.0)	0
Thrombocytopenia	1 (1.0)	1 (1.0)	0
Cardiac disorders			
-Total	4 (4.2)	3 (3.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.0)	1 (1.0)	0
Left ventricular dysfunction	1 (1.0)	1 (1.0)	0
Pericardial effusion	1 (1.0)	1 (1.0)	0
Tachycardia	1 (1.0)	0	0
Endocrine disorders			
-Total	2 (2.1)	1 (1.0)	0
Addison's disease	1 (1.0)	0	0
Adrenal insufficiency	1 (1.0)	1 (1.0)	0
Gastrointestinal disorders			
-Total	9 (9.4)	7 (7.3)	1 (1.0)
Neutropenic colitis	2 (2.1)	2 (2.1)	0
Abdominal compartment syndrome	1 (1.0)	0	1 (1.0)
Abdominal pain	1 (1.0)	0	0
Anal inflammation	1 (1.0)	1 (1.0)	0
Colitis	1 (1.0)	1 (1.0)	0
Diarrhoea	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	1 (1.0)
Ileus	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.0)	1 (1.0)	0
General disorders and administration site conditions			
-Total	7 (7.3)	3 (3.1)	0
Pyrexia	5 (5.2)	1 (1.0)	0
Pain	2 (2.1)	1 (1.0)	0
Mucosal inflammation	1 (1.0)	1 (1.0)	0
Hepatobiliary disorders			
-Total	2 (2.1)	2 (2.1)	0
Drug-induced liver injury	1 (1.0)	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	1 (1.0)	0
Infections and infestations			
-Total	35 (36.5)	22 (22.9)	12 (12.5)
Device related infection	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Pneumonia	2 (2.1)	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	2 (2.1)	0
Septic shock	2 (2.1)	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (2.1)	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	2 (2.1)
Aspergillus infection	1 (1.0)	0	1 (1.0)
Bacteraemia	1 (1.0)	1 (1.0)	0
Bacterial sepsis	1 (1.0)	0	1 (1.0)
Bronchiolitis	1 (1.0)	1 (1.0)	0
Bronchopulmonary aspergillosis	1 (1.0)	1 (1.0)	0
Device related sepsis	1 (1.0)	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	1 (1.0)
Escherichia bacteraemia	1 (1.0)	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	1 (1.0)
Fungal skin infection	1 (1.0)	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	1 (1.0)
Klebsiella bacteraemia	1 (1.0)	1 (1.0)	0
Localised infection	1 (1.0)	1 (1.0)	0
Parainfluenzae virus infection	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.0)	1 (1.0)	0
Pharyngitis	1 (1.0)	1 (1.0)	0
Pneumonia fungal	1 (1.0)	0	1 (1.0)
Sepsis	1 (1.0)	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	1 (1.0)
Sialoadenitis	1 (1.0)	1 (1.0)	0
Sinusitis	1 (1.0)	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	1 (1.0)	0
Systemic mycosis	1 (1.0)	1 (1.0)	0
Urinary tract infection	1 (1.0)	1 (1.0)	0
Vascular device infection	1 (1.0)	1 (1.0)	0
Injury, poisoning and procedural complications			
-Total	4 (4.2)	2 (2.1)	1 (1.0)
Infusion related reaction	1 (1.0)	1 (1.0)	0
Post procedural haemorrhage	1 (1.0)	1 (1.0)	0
Tracheal obstruction	1 (1.0)	0	1 (1.0)
Transfusion reaction	1 (1.0)	0	0
Investigations			

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (6.3)	2 (2.1)	3 (3.1)
Neutrophil count decreased	3 (3.1)	1 (1.0)	2 (2.1)
Amylase increased	1 (1.0)	0	1 (1.0)
C-reactive protein increased	1 (1.0)	1 (1.0)	0
Electrocardiogram qt prolonged	1 (1.0)	0	0
Platelet count decreased	1 (1.0)	0	1 (1.0)
Metabolism and nutrition disorders			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Hypervolaemia	1 (1.0)	1 (1.0)	0
Hyponatraemia	1 (1.0)	0	1 (1.0)
Hypophagia	1 (1.0)	1 (1.0)	0
Tumour lysis syndrome	1 (1.0)	0	1 (1.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.1)	0	0
Pain in extremity	2 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.0)	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute lymphocytic leukaemia	1 (1.0)	0	1 (1.0)
Nervous system disorders			
-Total	3 (3.1)	1 (1.0)	1 (1.0)
Encephalopathy	1 (1.0)	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	1 (1.0)
Seizure	1 (1.0)	0	0
Psychiatric disorders			
-Total	2 (2.1)	2 (2.1)	0
Mental status changes	2 (2.1)	2 (2.1)	0
Renal and urinary disorders			
-Total	1 (1.0)	1 (1.0)	0
Renal tubular necrosis	1 (1.0)	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (7.3)	2 (2.1)	5 (5.2)
Respiratory failure	4 (4.2)	0	4 (4.2)
Acute respiratory distress syndrome	1 (1.0)	0	1 (1.0)
Epistaxis	1 (1.0)	1 (1.0)	0
Haemothorax	1 (1.0)	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive			
		All patients N=96	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumothorax	1 (1.0)	0	1 (1.0)
Pulmonary oedema	1 (1.0)	0	1 (1.0)
Tachypnoea	1 (1.0)	1 (1.0)	0
Vascular disorders			
-Total	4 (4.2)	1 (1.0)	1 (1.0)
Hypotension	3 (3.1)	1 (1.0)	1 (1.0)
Hypertension	1 (1.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210g
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	56 (57.7)	30 (30.9)	22 (22.7)
Blood and lymphatic system disorders			
-Total	22 (22.7)	17 (17.5)	5 (5.2)
Febrile neutropenia	16 (16.5)	15 (15.5)	1 (1.0)
Anaemia	2 (2.1)	0	1 (1.0)
Neutropenia	2 (2.1)	1 (1.0)	1 (1.0)
Pancytopenia	2 (2.1)	1 (1.0)	1 (1.0)
Haemolytic anaemia	1 (1.0)	0	1 (1.0)
Hyperleukocytosis	1 (1.0)	1 (1.0)	0
Thrombocytopenia	1 (1.0)	1 (1.0)	0
Cardiac disorders			
-Total	4 (4.1)	3 (3.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.0)	1 (1.0)	0
Left ventricular dysfunction	1 (1.0)	1 (1.0)	0
Pericardial effusion	1 (1.0)	1 (1.0)	0
Tachycardia	1 (1.0)	0	0
Endocrine disorders			
-Total	2 (2.1)	1 (1.0)	0
Addison's disease	1 (1.0)	0	0
Adrenal insufficiency	1 (1.0)	1 (1.0)	0
Gastrointestinal disorders			
-Total	9 (9.3)	7 (7.2)	1 (1.0)
Neutropenic colitis	2 (2.1)	2 (2.1)	0
Abdominal compartment syndrome	1 (1.0)	0	1 (1.0)
Abdominal pain	1 (1.0)	0	0
Anal inflammation	1 (1.0)	1 (1.0)	0
Colitis	1 (1.0)	1 (1.0)	0
Diarrhoea	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	1 (1.0)
Ileus	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.0)	1 (1.0)	0
General disorders and administration site conditions			
-Total	7 (7.2)	3 (3.1)	0
Pyrexia	5 (5.2)	1 (1.0)	0
Pain	2 (2.1)	1 (1.0)	0
Mucosal inflammation	1 (1.0)	1 (1.0)	0
Hepatobiliary disorders			
-Total	2 (2.1)	2 (2.1)	0
Drug-induced liver injury	1 (1.0)	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	1 (1.0)	0
Infections and infestations			
-Total	36 (37.1)	23 (23.7)	12 (12.4)
Device related infection	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Pneumonia	2 (2.1)	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	2 (2.1)	0
Septic shock	2 (2.1)	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	2 (2.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (2.1)	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	2 (2.1)
Abscess limb	1 (1.0)	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	1 (1.0)
Bacteraemia	1 (1.0)	1 (1.0)	0
Bacterial sepsis	1 (1.0)	0	1 (1.0)
Bronchiolitis	1 (1.0)	1 (1.0)	0
Bronchopulmonary aspergillosis	1 (1.0)	1 (1.0)	0
Device related sepsis	1 (1.0)	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	1 (1.0)
Escherichia bacteraemia	1 (1.0)	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	1 (1.0)
Fungal skin infection	1 (1.0)	1 (1.0)	0
Gastroenteritis	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	1 (1.0)
Klebsiella bacteraemia	1 (1.0)	1 (1.0)	0
Localised infection	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.0)	1 (1.0)	0
Paronychia	1 (1.0)	1 (1.0)	0
Pharyngitis	1 (1.0)	1 (1.0)	0
Pneumonia fungal	1 (1.0)	0	1 (1.0)
Sepsis	1 (1.0)	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	1 (1.0)
Sialoadenitis	1 (1.0)	1 (1.0)	0
Sinusitis	1 (1.0)	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	1 (1.0)	0
Systemic mycosis	1 (1.0)	1 (1.0)	0
Urinary tract infection	1 (1.0)	1 (1.0)	0
Vascular device infection	1 (1.0)	1 (1.0)	0
Injury, poisoning and procedural complications			
-Total	4 (4.1)	2 (2.1)	1 (1.0)
Infusion related reaction	1 (1.0)	1 (1.0)	0
Post procedural haemorrhage	1 (1.0)	1 (1.0)	0
Tracheal obstruction	1 (1.0)	0	1 (1.0)
Transfusion reaction	1 (1.0)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	6 (6.2)	2 (2.1)	3 (3.1)
Neutrophil count decreased	3 (3.1)	1 (1.0)	2 (2.1)
Amylase increased	1 (1.0)	0	1 (1.0)
C-reactive protein increased	1 (1.0)	1 (1.0)	0
Electrocardiogram qt prolonged	1 (1.0)	0	0
Platelet count decreased	1 (1.0)	0	1 (1.0)
Metabolism and nutrition disorders			
-Total	4 (4.1)	2 (2.1)	2 (2.1)
Hypervolaemia	1 (1.0)	1 (1.0)	0
Hyponatraemia	1 (1.0)	0	1 (1.0)
Hypophagia	1 (1.0)	1 (1.0)	0
Tumour lysis syndrome	1 (1.0)	0	1 (1.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.1)	0	0
Pain in extremity	2 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.0)	0	1 (1.0)
Acute lymphocytic leukaemia	1 (1.0)	0	1 (1.0)
Nervous system disorders			
-Total	3 (3.1)	1 (1.0)	1 (1.0)
Encephalopathy	1 (1.0)	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	1 (1.0)
Seizure	1 (1.0)	0	0
Psychiatric disorders			
-Total	2 (2.1)	2 (2.1)	0
Mental status changes	2 (2.1)	2 (2.1)	0
Renal and urinary disorders			
-Total	1 (1.0)	1 (1.0)	0
Renal tubular necrosis	1 (1.0)	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (7.2)	2 (2.1)	5 (5.2)
Respiratory failure	4 (4.1)	0	4 (4.1)
Acute respiratory distress syndrome	1 (1.0)	0	1 (1.0)
Epistaxis	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=97 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Haemothorax	1 (1.0)	0	1 (1.0)
Pneumothorax	1 (1.0)	0	1 (1.0)
Pulmonary oedema	1 (1.0)	0	1 (1.0)
Tachypnoea	1 (1.0)	1 (1.0)	0
Vascular disorders			
-Total	4 (4.1)	1 (1.0)	1 (1.0)
Hypotension	3 (3.1)	1 (1.0)	1 (1.0)
Hypertension	1 (1.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210h
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (100)	1 (33.3)	2 (66.7)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)
Haemoperitoneum	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Gastroenteritis adenovirus	1 (33.3)	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0
Post procedural haemorrhage	1 (33.3)	1 (33.3)	0
Investigations			
-Total	1 (33.3)	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypotension	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210h
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	53 (55.8)	29 (30.5)	20 (21.1)
Blood and lymphatic system disorders			
-Total	22 (23.2)	17 (17.9)	5 (5.3)
Febrile neutropenia	16 (16.8)	15 (15.8)	1 (1.1)
Anaemia	2 (2.1)	0	1 (1.1)
Neutropenia	2 (2.1)	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.1)	1 (1.1)	1 (1.1)
Haemolytic anaemia	1 (1.1)	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	1 (1.1)	0
Thrombocytopenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	3 (3.2)	2 (2.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.1)	1 (1.1)	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	0
Endocrine disorders			
-Total	2 (2.1)	1 (1.1)	0
Addison's disease	1 (1.1)	0	0
Adrenal insufficiency	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders			
-Total	8 (8.4)	7 (7.4)	0
Neutropenic colitis	2 (2.1)	2 (2.1)	0
Abdominal pain	1 (1.1)	0	0
Anal inflammation	1 (1.1)	1 (1.1)	0
Colitis	1 (1.1)	1 (1.1)	0
Diarrhoea	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Ileus	1 (1.1)	1 (1.1)	0
Stomatitis	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (6.3)	3 (3.2)	0
Pyrexia	4 (4.2)	1 (1.1)	0
Pain	2 (2.1)	1 (1.1)	0
Mucosal inflammation	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	2 (2.1)	2 (2.1)	0
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatic cytolysis	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	33 (34.7)	22 (23.2)	10 (10.5)
Device related infection	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Pneumonia	2 (2.1)	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.1)	2 (2.1)	0
Septic shock	2 (2.1)	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	2 (2.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	2 (2.1)	0	2 (2.1)
Abscess limb	1 (1.1)	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bacteraemia	1 (1.1)	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	1 (1.1)
Escherichia bacteraemia	1 (1.1)	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	0
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	1 (1.1)	0
Paronychia	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (1.1)	0	1 (1.1)
Sepsis	1 (1.1)	0	1 (1.1)
Sialoadenitis	1 (1.1)	1 (1.1)	0
Sinusitis	1 (1.1)	1 (1.1)	0
Staphylococcal infection	1 (1.1)	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	1 (1.1)	0
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Injury, poisoning and procedural complications			
-Total	3 (3.2)	1 (1.1)	1 (1.1)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Investigations			
-Total	5 (5.3)	1 (1.1)	3 (3.2)
Neutrophil count decreased	2 (2.1)	0	2 (2.1)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amylase increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	0
Platelet count decreased	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Hypophagia	1 (1.1)	1 (1.1)	0
Tumour lysis syndrome	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.1)	0	0
Pain in extremity	2 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.1)	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	1 (1.1)
Nervous system disorders			

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (3.2)	1 (1.1)	1 (1.1)
Encephalopathy	1 (1.1)	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	1 (1.1)
Seizure	1 (1.1)	0	0
Psychiatric disorders			
-Total	2 (2.1)	2 (2.1)	0
Mental status changes	2 (2.1)	2 (2.1)	0
Renal and urinary disorders			
-Total	1 (1.1)	1 (1.1)	0
Renal tubular necrosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (6.3)	2 (2.1)	4 (4.2)
Respiratory failure	3 (3.2)	0	3 (3.2)
Acute respiratory distress syndrome	1 (1.1)	0	1 (1.1)
Epistaxis	1 (1.1)	1 (1.1)	0
Haemothorax	1 (1.1)	0	1 (1.1)
Pneumothorax	1 (1.1)	0	1 (1.1)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	3 (3.2)	0	1 (1.1)
Hypotension	2 (2.1)	0	1 (1.1)
Hypertension	1 (1.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210i
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	2 (100)	0
Blood and lymphatic system disorders			
-Total	2 (100)	2 (100)	0
Febrile neutropenia	2 (100)	2 (100)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Fungal skin infection	1 (50.0)	1 (50.0)	0
Systemic mycosis	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210i
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	54 (56.3)	28 (29.2)	22 (22.9)
Blood and lymphatic system disorders			
-Total	20 (20.8)	15 (15.6)	5 (5.2)
Febrile neutropenia	14 (14.6)	13 (13.5)	1 (1.0)
Anaemia	2 (2.1)	0	1 (1.0)
Neutropenia	2 (2.1)	1 (1.0)	1 (1.0)
Pancytopenia	2 (2.1)	1 (1.0)	1 (1.0)
Haemolytic anaemia	1 (1.0)	0	1 (1.0)
Hyperleukocytosis	1 (1.0)	1 (1.0)	0
Thrombocytopenia	1 (1.0)	1 (1.0)	0
Cardiac disorders			
-Total	4 (4.2)	3 (3.1)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.0)	1 (1.0)	0
Left ventricular dysfunction	1 (1.0)	1 (1.0)	0
Pericardial effusion	1 (1.0)	1 (1.0)	0
Tachycardia	1 (1.0)	0	0
Endocrine disorders			
-Total	2 (2.1)	1 (1.0)	0
Addison's disease	1 (1.0)	0	0
Adrenal insufficiency	1 (1.0)	1 (1.0)	0
Gastrointestinal disorders			
-Total	9 (9.4)	7 (7.3)	1 (1.0)
Neutropenic colitis	2 (2.1)	2 (2.1)	0
Abdominal compartment syndrome	1 (1.0)	0	1 (1.0)
Abdominal pain	1 (1.0)	0	0
Anal inflammation	1 (1.0)	1 (1.0)	0
Colitis	1 (1.0)	1 (1.0)	0
Diarrhoea	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	1 (1.0)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (1.0)	1 (1.0)	0
Stomatitis	1 (1.0)	1 (1.0)	0
General disorders and administration site conditions			
-Total	7 (7.3)	3 (3.1)	0
Pyrexia	5 (5.2)	1 (1.0)	0
Pain	2 (2.1)	1 (1.0)	0
Mucosal inflammation	1 (1.0)	1 (1.0)	0
Hepatobiliary disorders			
-Total	2 (2.1)	2 (2.1)	0
Drug-induced liver injury	1 (1.0)	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	1 (1.0)	0
Infections and infestations			
-Total	35 (36.5)	22 (22.9)	12 (12.5)
Device related infection	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Pneumonia	2 (2.1)	1 (1.0)	1 (1.0)
Respiratory tract infection	2 (2.1)	2 (2.1)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	2 (2.1)	0	2 (2.1)
Staphylococcal bacteraemia	2 (2.1)	2 (2.1)	0
Staphylococcal infection	2 (2.1)	1 (1.0)	1 (1.0)
Staphylococcal sepsis	2 (2.1)	0	2 (2.1)
Abscess limb	1 (1.0)	1 (1.0)	0
Aspergillus infection	1 (1.0)	0	1 (1.0)
Bacteraemia	1 (1.0)	1 (1.0)	0
Bacterial sepsis	1 (1.0)	0	1 (1.0)
Bronchiolitis	1 (1.0)	1 (1.0)	0
Bronchopulmonary aspergillosis	1 (1.0)	1 (1.0)	0
Device related sepsis	1 (1.0)	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	1 (1.0)
Escherichia bacteraemia	1 (1.0)	1 (1.0)	0
Fungal sepsis	1 (1.0)	0	1 (1.0)
Gastroenteritis	1 (1.0)	0	0
Gastroenteritis adenovirus	1 (1.0)	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	1 (1.0)	0
Haemophilus bacteraemia	1 (1.0)	0	1 (1.0)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (1.0)	1 (1.0)	0
Localised infection	1 (1.0)	1 (1.0)	0
Parainfluenzae virus infection	1 (1.0)	1 (1.0)	0
Paronychia	1 (1.0)	1 (1.0)	0
Pharyngitis	1 (1.0)	1 (1.0)	0
Pneumonia fungal	1 (1.0)	0	1 (1.0)
Sepsis	1 (1.0)	0	1 (1.0)
Serratia sepsis	1 (1.0)	0	1 (1.0)
Sialoadenitis	1 (1.0)	1 (1.0)	0
Sinusitis	1 (1.0)	1 (1.0)	0
Staphylococcal skin infection	1 (1.0)	1 (1.0)	0
Urinary tract infection	1 (1.0)	1 (1.0)	0
Vascular device infection	1 (1.0)	1 (1.0)	0
Injury, poisoning and procedural complications			
-Total	4 (4.2)	2 (2.1)	1 (1.0)
Infusion related reaction	1 (1.0)	1 (1.0)	0
Post procedural haemorrhage	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal obstruction	1 (1.0)	0	1 (1.0)
Transfusion reaction	1 (1.0)	0	0
Investigations			
-Total	6 (6.3)	2 (2.1)	3 (3.1)
Neutrophil count decreased	3 (3.1)	1 (1.0)	2 (2.1)
Amylase increased	1 (1.0)	0	1 (1.0)
C-reactive protein increased	1 (1.0)	1 (1.0)	0
Electrocardiogram qt prolonged	1 (1.0)	0	0
Platelet count decreased	1 (1.0)	0	1 (1.0)
Metabolism and nutrition disorders			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Hypervolaemia	1 (1.0)	1 (1.0)	0
Hyponatraemia	1 (1.0)	0	1 (1.0)
Hypophagia	1 (1.0)	1 (1.0)	0
Tumour lysis syndrome	1 (1.0)	0	1 (1.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.1)	0	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (2.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.0)	0	1 (1.0)
Acute lymphocytic leukaemia	1 (1.0)	0	1 (1.0)
Nervous system disorders			
-Total	3 (3.1)	1 (1.0)	1 (1.0)
Encephalopathy	1 (1.0)	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	1 (1.0)
Seizure	1 (1.0)	0	0
Psychiatric disorders			
-Total	2 (2.1)	2 (2.1)	0
Mental status changes	2 (2.1)	2 (2.1)	0
Renal and urinary disorders			
-Total	1 (1.0)	1 (1.0)	0
Renal tubular necrosis	1 (1.0)	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (7.3)	2 (2.1)	5 (5.2)

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	4 (4.2)	0	4 (4.2)
Acute respiratory distress syndrome	1 (1.0)	0	1 (1.0)
Epistaxis	1 (1.0)	1 (1.0)	0
Haemothorax	1 (1.0)	0	1 (1.0)
Pneumothorax	1 (1.0)	0	1 (1.0)
Pulmonary oedema	1 (1.0)	0	1 (1.0)
Tachypnoea	1 (1.0)	1 (1.0)	0
Vascular disorders			
-Total	4 (4.2)	1 (1.0)	1 (1.0)
Hypotension	3 (3.1)	1 (1.0)	1 (1.0)
Hypertension	1 (1.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210j
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (43.3)	4 (13.3)	8 (26.7)
Blood and lymphatic system disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Febrile neutropenia	3 (10.0)	3 (10.0)	0
Haemolytic anaemia	1 (3.3)	0	1 (3.3)
Cardiac disorders			
-Total	1 (3.3)	0	0
Tachycardia	1 (3.3)	0	0
Endocrine disorders			
-Total	1 (3.3)	0	0
Addison's disease	1 (3.3)	0	0
Gastrointestinal disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.0)	1 (3.3)	1 (3.3)
Abdominal compartment syndrome	1 (3.3)	0	1 (3.3)
Abdominal pain	1 (3.3)	0	0
Haemoperitoneum	1 (3.3)	0	1 (3.3)
Neutropenic colitis	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	2 (6.7)	0	0
Pyrexia	2 (6.7)	0	0
Hepatobiliary disorders			
-Total	1 (3.3)	1 (3.3)	0
Hepatic cytolysis	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	8 (26.7)	4 (13.3)	4 (13.3)
Staphylococcal infection	2 (6.7)	1 (3.3)	1 (3.3)
Staphylococcal sepsis	2 (6.7)	0	2 (6.7)
Aspergillus infection	1 (3.3)	0	1 (3.3)
Bronchiolitis	1 (3.3)	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (3.3)	1 (3.3)	0
Pneumonia	1 (3.3)	1 (3.3)	0
Respiratory tract infection	1 (3.3)	1 (3.3)	0
Serratia sepsis	1 (3.3)	0	1 (3.3)
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Urinary tract infection	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	3 (10.0)	1 (3.3)	1 (3.3)
Infusion related reaction	1 (3.3)	1 (3.3)	0
Tracheal obstruction	1 (3.3)	0	1 (3.3)
Transfusion reaction	1 (3.3)	0	0
Investigations			
-Total	3 (10.0)	0	2 (6.7)
Neutrophil count decreased	2 (6.7)	0	2 (6.7)
Electrocardiogram qt prolonged	1 (3.3)	0	0
Platelet count decreased	1 (3.3)	0	1 (3.3)
Musculoskeletal and connective tissue disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.3)	0	0
Pain in extremity	1 (3.3)	0	0
Psychiatric disorders			
-Total	1 (3.3)	1 (3.3)	0
Mental status changes	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.0)	0	3 (10.0)
Respiratory failure	3 (10.0)	0	3 (10.0)
Haemothorax	1 (3.3)	0	1 (3.3)
Pneumothorax	1 (3.3)	0	1 (3.3)
Pulmonary oedema	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	1 (3.3)	0	0
Hypotension	1 (3.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210j
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	43 (63.2)	26 (38.2)	14 (20.6)
Blood and lymphatic system disorders			
-Total	19 (27.9)	15 (22.1)	4 (5.9)
Febrile neutropenia	13 (19.1)	12 (17.6)	1 (1.5)
Anaemia	2 (2.9)	0	1 (1.5)
Neutropenia	2 (2.9)	1 (1.5)	1 (1.5)
Pancytopenia	2 (2.9)	1 (1.5)	1 (1.5)
Hyperleukocytosis	1 (1.5)	1 (1.5)	0
Thrombocytopenia	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	3 (4.4)	3 (4.4)	0
Cardiac failure	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.5)	1 (1.5)	0
Pericardial effusion	1 (1.5)	1 (1.5)	0
Endocrine disorders			
-Total	1 (1.5)	1 (1.5)	0
Adrenal insufficiency	1 (1.5)	1 (1.5)	0
Gastrointestinal disorders			
-Total	6 (8.8)	6 (8.8)	0
Anal inflammation	1 (1.5)	1 (1.5)	0
Colitis	1 (1.5)	1 (1.5)	0
Diarrhoea	1 (1.5)	0	0
Gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0
Ileus	1 (1.5)	1 (1.5)	0
Neutropenic colitis	1 (1.5)	1 (1.5)	0
Stomatitis	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	5 (7.4)	3 (4.4)	0
Pyrexia	3 (4.4)	1 (1.5)	0
Pain	2 (2.9)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mucosal inflammation	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	1 (1.5)	1 (1.5)	0
Drug-induced liver injury	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	28 (41.2)	19 (27.9)	8 (11.8)
Device related infection	2 (2.9)	2 (2.9)	0
Herpes zoster	2 (2.9)	2 (2.9)	0
Septic shock	2 (2.9)	0	2 (2.9)
Abscess limb	1 (1.5)	1 (1.5)	0
Bacteraemia	1 (1.5)	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	1 (1.5)
Bronchopulmonary aspergillosis	1 (1.5)	1 (1.5)	0
Device related sepsis	1 (1.5)	1 (1.5)	0
Disseminated trichosporonosis	1 (1.5)	0	1 (1.5)
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0
Fungal sepsis	1 (1.5)	0	1 (1.5)
Fungal skin infection	1 (1.5)	1 (1.5)	0
Gastroenteritis	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis adenovirus	1 (1.5)	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	1 (1.5)	0
Haemophilus bacteraemia	1 (1.5)	0	1 (1.5)
Klebsiella bacteraemia	1 (1.5)	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0
Pharyngitis	1 (1.5)	1 (1.5)	0
Pneumonia	1 (1.5)	0	1 (1.5)
Pneumonia fungal	1 (1.5)	0	1 (1.5)
Respiratory tract infection	1 (1.5)	1 (1.5)	0
Sepsis	1 (1.5)	0	1 (1.5)
Sialoadenitis	1 (1.5)	1 (1.5)	0
Sinusitis	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	1 (1.5)	0
Staphylococcal skin infection	1 (1.5)	1 (1.5)	0
Systemic mycosis	1 (1.5)	1 (1.5)	0
Vascular device infection	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (1.5)	1 (1.5)	0
Investigations			
-Total	3 (4.4)	2 (2.9)	1 (1.5)
Amylase increased	1 (1.5)	0	1 (1.5)
C-reactive protein increased	1 (1.5)	1 (1.5)	0
Neutrophil count decreased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	4 (5.9)	2 (2.9)	2 (2.9)
Hypervolaemia	1 (1.5)	1 (1.5)	0
Hyponatraemia	1 (1.5)	0	1 (1.5)
Hypophagia	1 (1.5)	1 (1.5)	0
Tumour lysis syndrome	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.5)	0	0
Pain in extremity	1 (1.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.5)	0	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute lymphocytic leukaemia	1 (1.5)	0	1 (1.5)
Nervous system disorders			
-Total	3 (4.4)	1 (1.5)	1 (1.5)
Encephalopathy	1 (1.5)	1 (1.5)	0
Haemorrhage intracranial	1 (1.5)	0	1 (1.5)
Seizure	1 (1.5)	0	0
Psychiatric disorders			
-Total	1 (1.5)	1 (1.5)	0
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	1 (1.5)	1 (1.5)	0
Renal tubular necrosis	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.9)	2 (2.9)	2 (2.9)
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Epistaxis	1 (1.5)	1 (1.5)	0
Respiratory failure	1 (1.5)	0	1 (1.5)
Tachypnoea	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=68 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	3 (4.4)	1 (1.5)	1 (1.5)
Hypotension	2 (2.9)	1 (1.5)	1 (1.5)
Hypertension	1 (1.5)	0	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210k
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	21 (65.6)	11 (34.4)	9 (28.1)
Blood and lymphatic system disorders			
-Total	9 (28.1)	6 (18.8)	3 (9.4)
Febrile neutropenia	7 (21.9)	6 (18.8)	1 (3.1)
Haemolytic anaemia	1 (3.1)	0	1 (3.1)
Neutropenia	1 (3.1)	0	1 (3.1)
Pancytopenia	1 (3.1)	1 (3.1)	0
Cardiac disorders			
-Total	1 (3.1)	0	0
Tachycardia	1 (3.1)	0	0
Endocrine disorders			
-Total	2 (6.3)	1 (3.1)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Addison's disease	1 (3.1)	0	0
Adrenal insufficiency	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders			
-Total	3 (9.4)	2 (6.3)	0
Abdominal pain	1 (3.1)	0	0
Ileus	1 (3.1)	1 (3.1)	0
Neutropenic colitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	4 (12.5)	3 (9.4)	0
Pyrexia	2 (6.3)	1 (3.1)	0
Mucosal inflammation	1 (3.1)	1 (3.1)	0
Pain	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	1 (3.1)	1 (3.1)	0
Hepatic cytolysis	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	15 (46.9)	10 (31.3)	4 (12.5)

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (6.3)	2 (6.3)	0
Herpes zoster	2 (6.3)	2 (6.3)	0
Pneumonia	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory tract infection	2 (6.3)	2 (6.3)	0
Staphylococcal sepsis	2 (6.3)	0	2 (6.3)
Abscess limb	1 (3.1)	1 (3.1)	0
Bronchiolitis	1 (3.1)	1 (3.1)	0
Device related sepsis	1 (3.1)	1 (3.1)	0
Gastroenteritis	1 (3.1)	0	0
Gastroenteritis adenovirus	1 (3.1)	1 (3.1)	0
Haemophilus bacteraemia	1 (3.1)	0	1 (3.1)
Localised infection	1 (3.1)	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	1 (3.1)	0
Paronychia	1 (3.1)	1 (3.1)	0
Sialoadenitis	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	1 (3.1)	1 (3.1)	0

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (3.1)	1 (3.1)	0
Investigations			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Amylase increased	1 (3.1)	0	1 (3.1)
C-reactive protein increased	1 (3.1)	1 (3.1)	0
Neutrophil count decreased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Hyponatraemia	1 (3.1)	0	1 (3.1)
Hypophagia	1 (3.1)	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	1 (3.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.1)	0	1 (3.1)
Acute lymphocytic leukaemia	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	1 (3.1)	1 (3.1)	0
Encephalopathy	1 (3.1)	1 (3.1)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	1 (3.1)	0	0
Hypotension	1 (3.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210k
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	32 (56.1)	17 (29.8)	12 (21.1)
Blood and lymphatic system disorders			
-Total	12 (21.1)	10 (17.5)	2 (3.5)
Febrile neutropenia	8 (14.0)	8 (14.0)	0
Anaemia	2 (3.5)	0	1 (1.8)
Hyperleukocytosis	1 (1.8)	1 (1.8)	0
Neutropenia	1 (1.8)	1 (1.8)	0
Pancytopenia	1 (1.8)	0	1 (1.8)
Thrombocytopenia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	3 (5.3)	3 (5.3)	0
Cardiac failure	1 (1.8)	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Left ventricular dysfunction	1 (1.8)	1 (1.8)	0
Pericardial effusion	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	6 (10.5)	5 (8.8)	1 (1.8)
Abdominal compartment syndrome	1 (1.8)	0	1 (1.8)
Anal inflammation	1 (1.8)	1 (1.8)	0
Colitis	1 (1.8)	1 (1.8)	0
Diarrhoea	1 (1.8)	0	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0
Haemoperitoneum	1 (1.8)	0	1 (1.8)
Neutropenic colitis	1 (1.8)	1 (1.8)	0
Stomatitis	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	3 (5.3)	0	0
Pyrexia	3 (5.3)	0	0
Pain	1 (1.8)	0	0
Hepatobiliary disorders			

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.8)	1 (1.8)	0
Drug-induced liver injury	1 (1.8)	1 (1.8)	0
Infections and infestations			
-Total	20 (35.1)	12 (21.1)	8 (14.0)
Septic shock	2 (3.5)	0	2 (3.5)
Staphylococcal bacteraemia	2 (3.5)	2 (3.5)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	1 (1.8)
Aspergillus infection	1 (1.8)	0	1 (1.8)
Bacteraemia	1 (1.8)	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	1 (1.8)
Bronchopulmonary aspergillosis	1 (1.8)	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	1 (1.8)
Escherichia bacteraemia	1 (1.8)	1 (1.8)	0
Fungal sepsis	1 (1.8)	0	1 (1.8)
Fungal skin infection	1 (1.8)	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	1 (1.8)	0
Pharyngitis	1 (1.8)	1 (1.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (1.8)	0	1 (1.8)
Sepsis	1 (1.8)	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	1 (1.8)
Sinusitis	1 (1.8)	1 (1.8)	0
Systemic mycosis	1 (1.8)	1 (1.8)	0
Urinary tract infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	3 (5.3)	1 (1.8)	1 (1.8)
Post procedural haemorrhage	1 (1.8)	1 (1.8)	0
Tracheal obstruction	1 (1.8)	0	1 (1.8)
Transfusion reaction	1 (1.8)	0	0
Investigations			
-Total	3 (5.3)	0	2 (3.5)
Neutrophil count decreased	2 (3.5)	0	2 (3.5)
Electrocardiogram qt prolonged	1 (1.8)	0	0
Platelet count decreased	1 (1.8)	0	1 (1.8)

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (1.8)	1 (1.8)	0
Hypervolaemia	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.5)	0	0
Pain in extremity	2 (3.5)	0	0
Nervous system disorders			
-Total	1 (1.8)	0	0
Seizure	1 (1.8)	0	0
Psychiatric disorders			
-Total	2 (3.5)	2 (3.5)	0
Mental status changes	2 (3.5)	2 (3.5)	0
Renal and urinary disorders			
-Total	1 (1.8)	1 (1.8)	0
Renal tubular necrosis	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (12.3)	2 (3.5)	5 (8.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	4 (7.0)	0	4 (7.0)
Acute respiratory distress syndrome	1 (1.8)	0	1 (1.8)
Epistaxis	1 (1.8)	1 (1.8)	0
Haemothorax	1 (1.8)	0	1 (1.8)
Pneumothorax	1 (1.8)	0	1 (1.8)
Pulmonary oedema	1 (1.8)	0	1 (1.8)
Tachypnoea	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	3 (5.3)	1 (1.8)	1 (1.8)
Hypotension	2 (3.5)	1 (1.8)	1 (1.8)
Hypertension	1 (1.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210k
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (33.3)	2 (22.2)	1 (11.1)
Blood and lymphatic system disorders			
-Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	1 (11.1)	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	1 (11.1)	0	1 (11.1)
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210l
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	35 (60.3)	18 (31.0)	15 (25.9)
Blood and lymphatic system disorders			
-Total	14 (24.1)	10 (17.2)	4 (6.9)
Febrile neutropenia	11 (19.0)	10 (17.2)	1 (1.7)
Pancytopenia	2 (3.4)	1 (1.7)	1 (1.7)
Anaemia	1 (1.7)	0	0
Haemolytic anaemia	1 (1.7)	0	1 (1.7)
Neutropenia	1 (1.7)	0	1 (1.7)
Thrombocytopenia	1 (1.7)	1 (1.7)	0
Cardiac disorders			
-Total	4 (6.9)	3 (5.2)	0
Cardiac failure	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.7)	1 (1.7)	0
Pericardial effusion	1 (1.7)	1 (1.7)	0
Tachycardia	1 (1.7)	0	0
Endocrine disorders			
-Total	2 (3.4)	1 (1.7)	0
Addison's disease	1 (1.7)	0	0
Adrenal insufficiency	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	5 (8.6)	4 (6.9)	0
Abdominal pain	1 (1.7)	0	0
Anal inflammation	1 (1.7)	1 (1.7)	0
Colitis	1 (1.7)	1 (1.7)	0
Diarrhoea	1 (1.7)	0	0
Neutropenic colitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	4 (6.9)	3 (5.2)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (3.4)	1 (1.7)	0
Mucosal inflammation	1 (1.7)	1 (1.7)	0
Pain	1 (1.7)	1 (1.7)	0
Hepatobiliary disorders			
-Total	2 (3.4)	2 (3.4)	0
Drug-induced liver injury	1 (1.7)	1 (1.7)	0
Hepatic cytolysis	1 (1.7)	1 (1.7)	0
Infections and infestations			
-Total	21 (36.2)	13 (22.4)	7 (12.1)
Device related infection	2 (3.4)	2 (3.4)	0
Herpes zoster	2 (3.4)	2 (3.4)	0
Pneumonia	2 (3.4)	1 (1.7)	1 (1.7)
Septic shock	2 (3.4)	0	2 (3.4)
Staphylococcal sepsis	2 (3.4)	0	2 (3.4)
Abscess limb	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	1 (1.7)
Bronchiolitis	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (1.7)	1 (1.7)	0
Device related sepsis	1 (1.7)	1 (1.7)	0
Fungal sepsis	1 (1.7)	0	1 (1.7)
Gastroenteritis	1 (1.7)	0	0
Gastroenteritis adenovirus	1 (1.7)	1 (1.7)	0
Haemophilus bacteraemia	1 (1.7)	0	1 (1.7)
Klebsiella bacteraemia	1 (1.7)	1 (1.7)	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0
Paronychia	1 (1.7)	1 (1.7)	0
Respiratory tract infection	1 (1.7)	1 (1.7)	0
Sinusitis	1 (1.7)	1 (1.7)	0
Staphylococcal skin infection	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	3 (5.2)	2 (3.4)	1 (1.7)
Infusion related reaction	1 (1.7)	1 (1.7)	0
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal obstruction	1 (1.7)	0	1 (1.7)
Investigations			
-Total	4 (6.9)	2 (3.4)	2 (3.4)
Neutrophil count decreased	3 (5.2)	1 (1.7)	2 (3.4)
C-reactive protein increased	1 (1.7)	1 (1.7)	0
Platelet count decreased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	3 (5.2)	2 (3.4)	1 (1.7)
Hypervolaemia	1 (1.7)	1 (1.7)	0
Hypophagia	1 (1.7)	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	1 (1.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.7)	0	1 (1.7)
Acute lymphocytic leukaemia	1 (1.7)	0	1 (1.7)
Nervous system disorders			
-Total	3 (5.2)	1 (1.7)	1 (1.7)
Encephalopathy	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemorrhage intracranial	1 (1.7)	0	1 (1.7)
Seizure	1 (1.7)	0	0
Renal and urinary disorders			
-Total	1 (1.7)	1 (1.7)	0
Renal tubular necrosis	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (6.9)	1 (1.7)	3 (5.2)
Respiratory failure	2 (3.4)	0	2 (3.4)
Acute respiratory distress syndrome	1 (1.7)	0	1 (1.7)
Epistaxis	1 (1.7)	1 (1.7)	0
Haemothorax	1 (1.7)	0	1 (1.7)
Pneumothorax	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	3 (5.2)	1 (1.7)	0
Hypotension	2 (3.4)	1 (1.7)	0
Hypertension	1 (1.7)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210l
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	21 (52.5)	12 (30.0)	7 (17.5)
Blood and lymphatic system disorders			
-Total	8 (20.0)	7 (17.5)	1 (2.5)
Febrile neutropenia	5 (12.5)	5 (12.5)	0
Anaemia	1 (2.5)	0	1 (2.5)
Hyperleukocytosis	1 (2.5)	1 (2.5)	0
Neutropenia	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0
Haemoperitoneum	1 (2.5)	0	1 (2.5)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (2.5)	1 (2.5)	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	3 (7.5)	0	0
Pyrexia	3 (7.5)	0	0
Pain	1 (2.5)	0	0
Infections and infestations			
-Total	15 (37.5)	10 (25.0)	5 (12.5)
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Aspergillus infection	1 (2.5)	0	1 (2.5)
Disseminated trichosporonosis	1 (2.5)	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	1 (2.5)	0
Fungal skin infection	1 (2.5)	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	1 (2.5)	0
Localised infection	1 (2.5)	1 (2.5)	0
Pharyngitis	1 (2.5)	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (2.5)	0	1 (2.5)
Respiratory tract infection	1 (2.5)	1 (2.5)	0
Sepsis	1 (2.5)	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	1 (2.5)
Sialoadenitis	1 (2.5)	1 (2.5)	0
Systemic mycosis	1 (2.5)	1 (2.5)	0
Urinary tract infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	1 (2.5)	0	0
Transfusion reaction	1 (2.5)	0	0
Investigations			
-Total	2 (5.0)	0	1 (2.5)
Amylase increased	1 (2.5)	0	1 (2.5)
Electrocardiogram qt prolonged	1 (2.5)	0	0
Metabolism and nutrition disorders			
-Total	1 (2.5)	0	1 (2.5)
Hyponatraemia	1 (2.5)	0	1 (2.5)

Prior SCT therapy: No			
	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	0	0
Pain in extremity	2 (5.0)	0	0
Psychiatric disorders			
-Total	2 (5.0)	2 (5.0)	0
Mental status changes	2 (5.0)	2 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory failure	2 (5.0)	0	2 (5.0)
Pulmonary oedema	1 (2.5)	0	1 (2.5)
Tachypnoea	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypotension	1 (2.5)	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210m
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (52.9)	7 (41.2)	2 (11.8)
Blood and lymphatic system disorders			
-Total	6 (35.3)	6 (35.3)	0
Febrile neutropenia	6 (35.3)	6 (35.3)	0
Gastrointestinal disorders			
-Total	2 (11.8)	2 (11.8)	0
Neutropenic colitis	1 (5.9)	1 (5.9)	0
Stomatitis	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders			
-Total	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Infections and infestations			

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (23.5)	3 (17.6)	1 (5.9)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Fungal skin infection	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Staphylococcal infection	1 (5.9)	1 (5.9)	0
Systemic mycosis	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	1 (5.9)	0	0
Transfusion reaction	1 (5.9)	0	0
Nervous system disorders			
-Total	1 (5.9)	0	1 (5.9)
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	1 (5.9)	1 (5.9)	0
Mental status changes	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	1 (5.9)	0
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.9)	1 (5.9)	0
Epistaxis	1 (5.9)	1 (5.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210m
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	47 (58.0)	23 (28.4)	20 (24.7)
Blood and lymphatic system disorders			
-Total	16 (19.8)	11 (13.6)	5 (6.2)
Febrile neutropenia	10 (12.3)	9 (11.1)	1 (1.2)
Anaemia	2 (2.5)	0	1 (1.2)
Neutropenia	2 (2.5)	1 (1.2)	1 (1.2)
Pancytopenia	2 (2.5)	1 (1.2)	1 (1.2)
Haemolytic anaemia	1 (1.2)	0	1 (1.2)
Hyperleukocytosis	1 (1.2)	1 (1.2)	0
Thrombocytopenia	1 (1.2)	1 (1.2)	0
Cardiac disorders			
-Total	4 (4.9)	3 (3.7)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.2)	1 (1.2)	0
Left ventricular dysfunction	1 (1.2)	1 (1.2)	0
Pericardial effusion	1 (1.2)	1 (1.2)	0
Tachycardia	1 (1.2)	0	0
Endocrine disorders			
-Total	2 (2.5)	1 (1.2)	0
Addison's disease	1 (1.2)	0	0
Adrenal insufficiency	1 (1.2)	1 (1.2)	0
Gastrointestinal disorders			
-Total	7 (8.6)	5 (6.2)	1 (1.2)
Abdominal compartment syndrome	1 (1.2)	0	1 (1.2)
Abdominal pain	1 (1.2)	0	0
Anal inflammation	1 (1.2)	1 (1.2)	0
Colitis	1 (1.2)	1 (1.2)	0
Diarrhoea	1 (1.2)	0	0
Gastrointestinal haemorrhage	1 (1.2)	1 (1.2)	0
Haemoperitoneum	1 (1.2)	0	1 (1.2)
Ileus	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic colitis	1 (1.2)	1 (1.2)	0
General disorders and administration site conditions			
-Total	7 (8.6)	3 (3.7)	0
Pyrexia	5 (6.2)	1 (1.2)	0
Pain	2 (2.5)	1 (1.2)	0
Mucosal inflammation	1 (1.2)	1 (1.2)	0
Hepatobiliary disorders			
-Total	1 (1.2)	1 (1.2)	0
Hepatic cytolysis	1 (1.2)	1 (1.2)	0
Infections and infestations			
-Total	32 (39.5)	20 (24.7)	11 (13.6)
Device related infection	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Pneumonia	2 (2.5)	1 (1.2)	1 (1.2)
Respiratory tract infection	2 (2.5)	2 (2.5)	0
Septic shock	2 (2.5)	0	2 (2.5)
Staphylococcal sepsis	2 (2.5)	0	2 (2.5)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.2)	1 (1.2)	0
Bacteraemia	1 (1.2)	1 (1.2)	0
Bacterial sepsis	1 (1.2)	0	1 (1.2)
Bronchiolitis	1 (1.2)	1 (1.2)	0
Bronchopulmonary aspergillosis	1 (1.2)	1 (1.2)	0
Device related sepsis	1 (1.2)	1 (1.2)	0
Disseminated trichosporonosis	1 (1.2)	0	1 (1.2)
Escherichia bacteraemia	1 (1.2)	1 (1.2)	0
Fungal sepsis	1 (1.2)	0	1 (1.2)
Gastroenteritis	1 (1.2)	0	0
Gastroenteritis adenovirus	1 (1.2)	1 (1.2)	0
Gastroenteritis viral	1 (1.2)	1 (1.2)	0
Haemophilus bacteraemia	1 (1.2)	0	1 (1.2)
Klebsiella bacteraemia	1 (1.2)	1 (1.2)	0
Localised infection	1 (1.2)	1 (1.2)	0
Parainfluenzae virus infection	1 (1.2)	1 (1.2)	0
Paronychia	1 (1.2)	1 (1.2)	0
Pharyngitis	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (1.2)	0	1 (1.2)
Sepsis	1 (1.2)	0	1 (1.2)
Serratia sepsis	1 (1.2)	0	1 (1.2)
Sialoadenitis	1 (1.2)	1 (1.2)	0
Sinusitis	1 (1.2)	1 (1.2)	0
Staphylococcal bacteraemia	1 (1.2)	1 (1.2)	0
Staphylococcal infection	1 (1.2)	0	1 (1.2)
Staphylococcal skin infection	1 (1.2)	1 (1.2)	0
Urinary tract infection	1 (1.2)	1 (1.2)	0
Injury, poisoning and procedural complications			
-Total	3 (3.7)	2 (2.5)	1 (1.2)
Infusion related reaction	1 (1.2)	1 (1.2)	0
Post procedural haemorrhage	1 (1.2)	1 (1.2)	0
Tracheal obstruction	1 (1.2)	0	1 (1.2)
Investigations			
-Total	6 (7.4)	2 (2.5)	3 (3.7)
Neutrophil count decreased	3 (3.7)	1 (1.2)	2 (2.5)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Amylase increased	1 (1.2)	0	1 (1.2)
C-reactive protein increased	1 (1.2)	1 (1.2)	0
Electrocardiogram qt prolonged	1 (1.2)	0	0
Platelet count decreased	1 (1.2)	0	1 (1.2)
Metabolism and nutrition disorders			
-Total	4 (4.9)	2 (2.5)	2 (2.5)
Hypervolaemia	1 (1.2)	1 (1.2)	0
Hyponatraemia	1 (1.2)	0	1 (1.2)
Hypophagia	1 (1.2)	1 (1.2)	0
Tumour lysis syndrome	1 (1.2)	0	1 (1.2)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.5)	0	0
Pain in extremity	2 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.2)	0	1 (1.2)
Acute lymphocytic leukaemia	1 (1.2)	0	1 (1.2)
Nervous system disorders			

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.5)	1 (1.2)	0
Encephalopathy	1 (1.2)	1 (1.2)	0
Seizure	1 (1.2)	0	0
Psychiatric disorders			
-Total	1 (1.2)	1 (1.2)	0
Mental status changes	1 (1.2)	1 (1.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (7.4)	1 (1.2)	5 (6.2)
Respiratory failure	4 (4.9)	0	4 (4.9)
Acute respiratory distress syndrome	1 (1.2)	0	1 (1.2)
Haemothorax	1 (1.2)	0	1 (1.2)
Pneumothorax	1 (1.2)	0	1 (1.2)
Pulmonary oedema	1 (1.2)	0	1 (1.2)
Tachypnoea	1 (1.2)	1 (1.2)	0
Vascular disorders			
-Total	4 (4.9)	1 (1.2)	1 (1.2)
Hypotension	3 (3.7)	1 (1.2)	1 (1.2)

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (1.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210n
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	10 (35.7)	8 (28.6)	0
Blood and lymphatic system disorders			
-Total	5 (17.9)	5 (17.9)	0
Febrile neutropenia	4 (14.3)	4 (14.3)	0
Anaemia	1 (3.6)	0	0
Thrombocytopenia	1 (3.6)	1 (3.6)	0
Gastrointestinal disorders			
-Total	1 (3.6)	1 (3.6)	0
Ileus	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	1 (3.6)	0	0
Pyrexia	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	5 (17.9)	5 (17.9)	0
Abscess limb	1 (3.6)	1 (3.6)	0
Localised infection	1 (3.6)	1 (3.6)	0
Sinusitis	1 (3.6)	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	1 (3.6)	0
Staphylococcal skin infection	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	1 (3.6)	1 (3.6)	0
Hypophagia	1 (3.6)	1 (3.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.6)	0	0
Pain in extremity	1 (3.6)	0	0
Nervous system disorders			
-Total	1 (3.6)	0	0
Seizure	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210n
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	46 (65.7)	22 (31.4)	22 (31.4)
Blood and lymphatic system disorders			
-Total	17 (24.3)	12 (17.1)	5 (7.1)
Febrile neutropenia	12 (17.1)	11 (15.7)	1 (1.4)
Neutropenia	2 (2.9)	1 (1.4)	1 (1.4)
Pancytopenia	2 (2.9)	1 (1.4)	1 (1.4)
Anaemia	1 (1.4)	0	1 (1.4)
Haemolytic anaemia	1 (1.4)	0	1 (1.4)
Hyperleukocytosis	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	4 (5.7)	3 (4.3)	0
Cardiac failure	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Pericardial effusion	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	0
Endocrine disorders			
-Total	2 (2.9)	1 (1.4)	0
Addison's disease	1 (1.4)	0	0
Adrenal insufficiency	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	8 (11.4)	6 (8.6)	1 (1.4)
Neutropenic colitis	2 (2.9)	2 (2.9)	0
Abdominal compartment syndrome	1 (1.4)	0	1 (1.4)
Abdominal pain	1 (1.4)	0	0
Anal inflammation	1 (1.4)	1 (1.4)	0
Colitis	1 (1.4)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
Haemoperitoneum	1 (1.4)	0	1 (1.4)
Stomatitis	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (8.6)	3 (4.3)	0
Pyrexia	4 (5.7)	1 (1.4)	0
Pain	2 (2.9)	1 (1.4)	0
Mucosal inflammation	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.9)	2 (2.9)	0
Drug-induced liver injury	1 (1.4)	1 (1.4)	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	31 (44.3)	18 (25.7)	12 (17.1)
Device related infection	2 (2.9)	2 (2.9)	0
Herpes zoster	2 (2.9)	2 (2.9)	0
Pneumonia	2 (2.9)	1 (1.4)	1 (1.4)
Respiratory tract infection	2 (2.9)	2 (2.9)	0
Septic shock	2 (2.9)	0	2 (2.9)
Staphylococcal infection	2 (2.9)	1 (1.4)	1 (1.4)
Staphylococcal sepsis	2 (2.9)	0	2 (2.9)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (1.4)	0	1 (1.4)
Bacteraemia	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchiolitis	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	1 (1.4)
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Fungal sepsis	1 (1.4)	0	1 (1.4)
Fungal skin infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	0	0
Gastroenteritis adenovirus	1 (1.4)	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0
Haemophilus bacteraemia	1 (1.4)	0	1 (1.4)
Klebsiella bacteraemia	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Paronychia	1 (1.4)	1 (1.4)	0
Pharyngitis	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.4)	0	1 (1.4)
Serratia sepsis	1 (1.4)	0	1 (1.4)
Sialoadenitis	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Systemic mycosis	1 (1.4)	1 (1.4)	0
Urinary tract infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	4 (5.7)	2 (2.9)	1 (1.4)
Infusion related reaction	1 (1.4)	1 (1.4)	0
Post procedural haemorrhage	1 (1.4)	1 (1.4)	0
Tracheal obstruction	1 (1.4)	0	1 (1.4)
Transfusion reaction	1 (1.4)	0	0
Investigations			
-Total	6 (8.6)	2 (2.9)	3 (4.3)
Neutrophil count decreased	3 (4.3)	1 (1.4)	2 (2.9)
Amylase increased	1 (1.4)	0	1 (1.4)
C-reactive protein increased	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (1.4)	0	0
Platelet count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	3 (4.3)	1 (1.4)	2 (2.9)
Hypervolaemia	1 (1.4)	1 (1.4)	0
Hyponatraemia	1 (1.4)	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.4)	0	0
Pain in extremity	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	0	1 (1.4)
Acute lymphocytic leukaemia	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	2 (2.9)	1 (1.4)	1 (1.4)
Encephalopathy	1 (1.4)	1 (1.4)	0
Haemorrhage intracranial	1 (1.4)	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (2.9)	2 (2.9)	0
Mental status changes	2 (2.9)	2 (2.9)	0
Renal and urinary disorders			
-Total	1 (1.4)	1 (1.4)	0
Renal tubular necrosis	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (10.0)	2 (2.9)	5 (7.1)
Respiratory failure	4 (5.7)	0	4 (5.7)
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Haemothorax	1 (1.4)	0	1 (1.4)
Pneumothorax	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Tachypnoea	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	4 (5.7)	1 (1.4)	1 (1.4)
Hypotension	3 (4.3)	1 (1.4)	1 (1.4)

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=70 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypertension	1 (1.4)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210o
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (81.8)	7 (63.6)	1 (9.1)
Blood and lymphatic system disorders			
-Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	3 (27.3)	3 (27.3)	0
General disorders and administration site conditions			
-Total	2 (18.2)	0	0
Pyrexia	2 (18.2)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0
Hepatic cytolysis	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	5 (45.5)	4 (36.4)	1 (9.1)

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (9.1)	1 (9.1)	0
Device related infection	1 (9.1)	1 (9.1)	0
Herpes zoster	1 (9.1)	1 (9.1)	0
Paronychia	1 (9.1)	1 (9.1)	0
Staphylococcal sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	1 (9.1)	0	0
Electrocardiogram qt prolonged	1 (9.1)	0	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	1 (9.1)	0
Hypophagia	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	1 (9.1)	0	0
Seizure	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210o
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	47 (54.0)	23 (26.4)	21 (24.1)
Blood and lymphatic system disorders			
-Total	19 (21.8)	14 (16.1)	5 (5.7)
Febrile neutropenia	13 (14.9)	12 (13.8)	1 (1.1)
Anaemia	2 (2.3)	0	1 (1.1)
Neutropenia	2 (2.3)	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.3)	1 (1.1)	1 (1.1)
Haemolytic anaemia	1 (1.1)	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	1 (1.1)	0
Thrombocytopenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	4 (4.6)	3 (3.4)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac failure	1 (1.1)	1 (1.1)	0
Left ventricular dysfunction	1 (1.1)	1 (1.1)	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	0
Endocrine disorders			
-Total	2 (2.3)	1 (1.1)	0
Addison's disease	1 (1.1)	0	0
Adrenal insufficiency	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders			
-Total	9 (10.3)	7 (8.0)	1 (1.1)
Neutropenic colitis	2 (2.3)	2 (2.3)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
Abdominal pain	1 (1.1)	0	0
Anal inflammation	1 (1.1)	1 (1.1)	0
Colitis	1 (1.1)	1 (1.1)	0
Diarrhoea	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Haemoperitoneum	1 (1.1)	0	1 (1.1)
Ileus	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.1)	1 (1.1)	0
General disorders and administration site conditions			
-Total	5 (5.7)	3 (3.4)	0
Pyrexia	3 (3.4)	1 (1.1)	0
Pain	2 (2.3)	1 (1.1)	0
Mucosal inflammation	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	1 (1.1)	1 (1.1)	0
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	31 (35.6)	19 (21.8)	11 (12.6)
Pneumonia	2 (2.3)	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.3)	2 (2.3)	0
Septic shock	2 (2.3)	0	2 (2.3)
Staphylococcal bacteraemia	2 (2.3)	2 (2.3)	0
Staphylococcal infection	2 (2.3)	1 (1.1)	1 (1.1)
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bacteraemia	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	1 (1.1)	0
Device related infection	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	1 (1.1)
Escherichia bacteraemia	1 (1.1)	1 (1.1)	0
Fungal sepsis	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	1 (1.1)
Herpes zoster	1 (1.1)	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.1)	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	1 (1.1)
Sialoadenitis	1 (1.1)	1 (1.1)	0
Sinusitis	1 (1.1)	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	1 (1.1)
Systemic mycosis	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Injury, poisoning and procedural complications			
-Total	4 (4.6)	2 (2.3)	1 (1.1)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Post procedural haemorrhage	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Investigations			
-Total	5 (5.7)	2 (2.3)	3 (3.4)
Neutrophil count decreased	3 (3.4)	1 (1.1)	2 (2.3)
Amylase increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	3 (3.4)	1 (1.1)	2 (2.3)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Tumour lysis syndrome	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (2.3)	0	0
Pain in extremity	2 (2.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.1)	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	1 (1.1)
Nervous system disorders			
-Total	2 (2.3)	1 (1.1)	1 (1.1)
Encephalopathy	1 (1.1)	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	1 (1.1)
Psychiatric disorders			

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.3)	2 (2.3)	0
Mental status changes	2 (2.3)	2 (2.3)	0
Renal and urinary disorders			
-Total	1 (1.1)	1 (1.1)	0
Renal tubular necrosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (8.0)	2 (2.3)	5 (5.7)
Respiratory failure	4 (4.6)	0	4 (4.6)
Acute respiratory distress syndrome	1 (1.1)	0	1 (1.1)
Epistaxis	1 (1.1)	1 (1.1)	0
Haemothorax	1 (1.1)	0	1 (1.1)
Pneumothorax	1 (1.1)	0	1 (1.1)
Pulmonary oedema	1 (1.1)	0	1 (1.1)
Tachypnoea	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	4 (4.6)	1 (1.1)	1 (1.1)
Hypotension	3 (3.4)	1 (1.1)	1 (1.1)
Hypertension	1 (1.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210p
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (28.6)	1 (14.3)	1 (14.3)
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	0	1 (14.3)
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210p
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	54 (59.3)	29 (31.9)	21 (23.1)
Blood and lymphatic system disorders			
-Total	22 (24.2)	17 (18.7)	5 (5.5)
Febrile neutropenia	16 (17.6)	15 (16.5)	1 (1.1)
Anaemia	2 (2.2)	0	1 (1.1)
Neutropenia	2 (2.2)	1 (1.1)	1 (1.1)
Pancytopenia	2 (2.2)	1 (1.1)	1 (1.1)
Haemolytic anaemia	1 (1.1)	0	1 (1.1)
Hyperleukocytosis	1 (1.1)	1 (1.1)	0
Thrombocytopenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	4 (4.4)	3 (3.3)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.1)	1 (1.1)	0
Left ventricular dysfunction	1 (1.1)	1 (1.1)	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	0
Endocrine disorders			
-Total	2 (2.2)	1 (1.1)	0
Addison's disease	1 (1.1)	0	0
Adrenal insufficiency	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders			
-Total	9 (9.9)	7 (7.7)	1 (1.1)
Neutropenic colitis	2 (2.2)	2 (2.2)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
Abdominal pain	1 (1.1)	0	0
Anal inflammation	1 (1.1)	1 (1.1)	0
Colitis	1 (1.1)	1 (1.1)	0
Diarrhoea	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Haemoperitoneum	1 (1.1)	0	1 (1.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (1.1)	1 (1.1)	0
Stomatitis	1 (1.1)	1 (1.1)	0
General disorders and administration site conditions			
-Total	7 (7.7)	3 (3.3)	0
Pyrexia	5 (5.5)	1 (1.1)	0
Pain	2 (2.2)	1 (1.1)	0
Mucosal inflammation	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	2 (2.2)	2 (2.2)	0
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatic cytolysis	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	35 (38.5)	22 (24.2)	12 (13.2)
Device related infection	2 (2.2)	2 (2.2)	0
Herpes zoster	2 (2.2)	2 (2.2)	0
Pneumonia	2 (2.2)	1 (1.1)	1 (1.1)
Respiratory tract infection	2 (2.2)	2 (2.2)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic shock	2 (2.2)	0	2 (2.2)
Staphylococcal bacteraemia	2 (2.2)	2 (2.2)	0
Staphylococcal infection	2 (2.2)	1 (1.1)	1 (1.1)
Staphylococcal sepsis	2 (2.2)	0	2 (2.2)
Abscess limb	1 (1.1)	1 (1.1)	0
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bacteraemia	1 (1.1)	1 (1.1)	0
Bacterial sepsis	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Bronchopulmonary aspergillosis	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	1 (1.1)
Fungal sepsis	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis	1 (1.1)	0	0
Gastroenteritis adenovirus	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Haemophilus bacteraemia	1 (1.1)	0	1 (1.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	1 (1.1)	0
Paronychia	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0
Pneumonia fungal	1 (1.1)	0	1 (1.1)
Sepsis	1 (1.1)	0	1 (1.1)
Serratia sepsis	1 (1.1)	0	1 (1.1)
Sialoadenitis	1 (1.1)	1 (1.1)	0
Sinusitis	1 (1.1)	1 (1.1)	0
Staphylococcal skin infection	1 (1.1)	1 (1.1)	0
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Injury, poisoning and procedural complications			
-Total	4 (4.4)	2 (2.2)	1 (1.1)
Infusion related reaction	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Investigations			
-Total	6 (6.6)	2 (2.2)	3 (3.3)
Neutrophil count decreased	3 (3.3)	1 (1.1)	2 (2.2)
Amylase increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	0
Platelet count decreased	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	4 (4.4)	2 (2.2)	2 (2.2)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Hypophagia	1 (1.1)	1 (1.1)	0
Tumour lysis syndrome	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.2)	0	0
Pain in extremity	2 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.1)	0	1 (1.1)
Acute lymphocytic leukaemia	1 (1.1)	0	1 (1.1)
Nervous system disorders			
-Total	2 (2.2)	1 (1.1)	0
Encephalopathy	1 (1.1)	1 (1.1)	0
Seizure	1 (1.1)	0	0
Psychiatric disorders			
-Total	2 (2.2)	2 (2.2)	0
Mental status changes	2 (2.2)	2 (2.2)	0
Renal and urinary disorders			
-Total	1 (1.1)	1 (1.1)	0
Renal tubular necrosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (7.7)	2 (2.2)	5 (5.5)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	4 (4.4)	0	4 (4.4)
Acute respiratory distress syndrome	1 (1.1)	0	1 (1.1)
Epistaxis	1 (1.1)	1 (1.1)	0
Haemothorax	1 (1.1)	0	1 (1.1)
Pneumothorax	1 (1.1)	0	1 (1.1)
Pulmonary oedema	1 (1.1)	0	1 (1.1)
Tachypnoea	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	4 (4.4)	1 (1.1)	1 (1.1)
Hypotension	3 (3.3)	1 (1.1)	1 (1.1)
Hypertension	1 (1.1)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210q
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	21 (52.5)	14 (35.0)	6 (15.0)
Blood and lymphatic system disorders			
-Total	9 (22.5)	7 (17.5)	2 (5.0)
Febrile neutropenia	8 (20.0)	8 (20.0)	0
Neutropenia	1 (2.5)	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)
Endocrine disorders			
-Total	1 (2.5)	1 (2.5)	0
Adrenal insufficiency	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	3 (7.5)	3 (7.5)	0
Anal inflammation	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (2.5)	1 (2.5)	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	2 (5.0)	1 (2.5)	0
Mucosal inflammation	1 (2.5)	1 (2.5)	0
Pyrexia	1 (2.5)	0	0
Hepatobiliary disorders			
-Total	2 (5.0)	2 (5.0)	0
Drug-induced liver injury	1 (2.5)	1 (2.5)	0
Hepatic cytolysis	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	15 (37.5)	11 (27.5)	3 (7.5)
Herpes zoster	2 (5.0)	2 (5.0)	0
Respiratory tract infection	2 (5.0)	2 (5.0)	0
Abscess limb	1 (2.5)	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis adenovirus	1 (2.5)	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	1 (2.5)	0
Haemophilus bacteraemia	1 (2.5)	0	1 (2.5)
Localised infection	1 (2.5)	1 (2.5)	0
Paronychia	1 (2.5)	1 (2.5)	0
Septic shock	1 (2.5)	0	1 (2.5)
Sialoadenitis	1 (2.5)	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	1 (2.5)
Staphylococcal skin infection	1 (2.5)	1 (2.5)	0
Vascular device infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Amylase increased	1 (2.5)	0	1 (2.5)
Neutrophil count decreased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Hyponatraemia	1 (2.5)	0	1 (2.5)
Hypophagia	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.5)	0	1 (2.5)
Acute lymphocytic leukaemia	1 (2.5)	0	1 (2.5)
Renal and urinary disorders			
-Total	1 (2.5)	1 (2.5)	0
Renal tubular necrosis	1 (2.5)	1 (2.5)	0

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- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210q
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	19 (47.5)	10 (25.0)	6 (15.0)
Blood and lymphatic system disorders			
-Total	9 (22.5)	7 (17.5)	2 (5.0)
Febrile neutropenia	6 (15.0)	6 (15.0)	0
Anaemia	2 (5.0)	0	1 (2.5)
Haemolytic anaemia	1 (2.5)	0	1 (2.5)
Neutropenia	1 (2.5)	1 (2.5)	0
Thrombocytopenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	2 (5.0)	1 (2.5)	0
Pericardial effusion	1 (2.5)	1 (2.5)	0
Tachycardia	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders			
-Total	1 (2.5)	0	0
Addison's disease	1 (2.5)	0	0
Gastrointestinal disorders			
-Total	3 (7.5)	2 (5.0)	0
Abdominal pain	1 (2.5)	0	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
Stomatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	2 (5.0)	0	0
Pyrexia	2 (5.0)	0	0
Pain	1 (2.5)	0	0
Infections and infestations			
-Total	9 (22.5)	7 (17.5)	2 (5.0)
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Bronchiolitis	1 (2.5)	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0
Septic shock	1 (2.5)	0	1 (2.5)
Sinusitis	1 (2.5)	1 (2.5)	0
Staphylococcal infection	1 (2.5)	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	1 (2.5)
Urinary tract infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	3 (7.5)	1 (2.5)	1 (2.5)
Infusion related reaction	1 (2.5)	1 (2.5)	0
Tracheal obstruction	1 (2.5)	0	1 (2.5)
Transfusion reaction	1 (2.5)	0	0
Investigations			
-Total	2 (5.0)	0	1 (2.5)
Electrocardiogram qt prolonged	1 (2.5)	0	0
Neutrophil count decreased	1 (2.5)	0	1 (2.5)
Platelet count decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	1 (2.5)	0
Hypervolaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	0	0
Pain in extremity	2 (5.0)	0	0
Nervous system disorders			
-Total	1 (2.5)	0	0
Seizure	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Epistaxis	1 (2.5)	1 (2.5)	0
Haemothorax	1 (2.5)	0	1 (2.5)
Pneumothorax	1 (2.5)	0	1 (2.5)
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	0
Hypotension	1 (2.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210q
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	12 (66.7)	5 (27.8)	7 (38.9)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (50.0)	2 (25.0)	2 (25.0)
Blood and lymphatic system disorders			
-Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Haemoperitoneum	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (53.3)	10 (33.3)	4 (13.3)
Blood and lymphatic system disorders			
-Total	5 (16.7)	5 (16.7)	0
Febrile neutropenia	2 (6.7)	2 (6.7)	0
Hyperleukocytosis	1 (3.3)	1 (3.3)	0
Neutropenia	1 (3.3)	1 (3.3)	0
Pancytopenia	1 (3.3)	1 (3.3)	0
Cardiac disorders			
-Total	1 (3.3)	1 (3.3)	0
Left ventricular dysfunction	1 (3.3)	1 (3.3)	0
Gastrointestinal disorders			
-Total	3 (10.0)	3 (10.0)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (3.3)	1 (3.3)	0
Ileus	1 (3.3)	1 (3.3)	0
Stomatitis	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	3 (10.0)	1 (3.3)	0
Pyrexia	3 (10.0)	1 (3.3)	0
Pain	1 (3.3)	0	0
Infections and infestations			
-Total	10 (33.3)	7 (23.3)	3 (10.0)
Device related infection	1 (3.3)	1 (3.3)	0
Device related sepsis	1 (3.3)	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	1 (3.3)	0
Fungal skin infection	1 (3.3)	1 (3.3)	0
Gastroenteritis adenovirus	1 (3.3)	1 (3.3)	0
Haemophilus bacteraemia	1 (3.3)	0	1 (3.3)
Klebsiella bacteraemia	1 (3.3)	1 (3.3)	0
Localised infection	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (3.3)	0	1 (3.3)
Sepsis	1 (3.3)	0	1 (3.3)
Sialoadenitis	1 (3.3)	1 (3.3)	0
Systemic mycosis	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	1 (3.3)	1 (3.3)	0
Post procedural haemorrhage	1 (3.3)	1 (3.3)	0
Investigations			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Amylase increased	1 (3.3)	0	1 (3.3)
C-reactive protein increased	1 (3.3)	1 (3.3)	0
Neutrophil count decreased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Hyponatraemia	1 (3.3)	0	1 (3.3)
Hypophagia	1 (3.3)	1 (3.3)	0
Musculoskeletal and connective tissue disorders			

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.7)	0	0
Pain in extremity	2 (6.7)	0	0
Psychiatric disorders			
-Total	1 (3.3)	1 (3.3)	0
Mental status changes	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	2 (6.7)	0
Epistaxis	1 (3.3)	1 (3.3)	0
Tachypnoea	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Hypotension	2 (6.7)	1 (3.3)	1 (3.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (61.1)	9 (50.0)	2 (11.1)
Blood and lymphatic system disorders			
-Total	7 (38.9)	6 (33.3)	1 (5.6)
Febrile neutropenia	5 (27.8)	5 (27.8)	0
Anaemia	2 (11.1)	0	1 (5.6)
Thrombocytopenia	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	2 (11.1)	2 (11.1)	0
Anal inflammation	1 (5.6)	1 (5.6)	0
Neutropenic colitis	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (5.6)	0	0
Pyrexia	1 (5.6)	0	0
Infections and infestations			
-Total	7 (38.9)	6 (33.3)	1 (5.6)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Respiratory tract infection	1 (5.6)	1 (5.6)	0
Sinusitis	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	1 (5.6)	0
Staphylococcal infection	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	0	0
Transfusion reaction	1 (5.6)	0	0
Investigations			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	0	0
Electrocardiogram qt prolonged	1 (5.6)	0	0
Psychiatric disorders			
-Total	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 210r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	25 (59.5)	9 (21.4)	14 (33.3)
Blood and lymphatic system disorders			
-Total	9 (21.4)	5 (11.9)	4 (9.5)
Febrile neutropenia	8 (19.0)	7 (16.7)	1 (2.4)
Haemolytic anaemia	1 (2.4)	0	1 (2.4)
Neutropenia	1 (2.4)	0	1 (2.4)
Pancytopenia	1 (2.4)	0	1 (2.4)
Cardiac disorders			
-Total	3 (7.1)	2 (4.8)	0
Cardiac failure	1 (2.4)	1 (2.4)	0
Pericardial effusion	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (2.4)	0	0
Endocrine disorders			
-Total	2 (4.8)	1 (2.4)	0
Addison's disease	1 (2.4)	0	0
Adrenal insufficiency	1 (2.4)	1 (2.4)	0
Gastrointestinal disorders			
-Total	3 (7.1)	2 (4.8)	0
Abdominal pain	1 (2.4)	0	0
Colitis	1 (2.4)	1 (2.4)	0
Diarrhoea	1 (2.4)	0	0
Neutropenic colitis	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions			
-Total	2 (4.8)	2 (4.8)	0
Mucosal inflammation	1 (2.4)	1 (2.4)	0
Pain	1 (2.4)	1 (2.4)	0
Hepatobiliary disorders			
-Total	2 (4.8)	2 (4.8)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug-induced liver injury	1 (2.4)	1 (2.4)	0
Hepatic cytolysis	1 (2.4)	1 (2.4)	0
Infections and infestations			
-Total	15 (35.7)	8 (19.0)	6 (14.3)
Herpes zoster	2 (4.8)	2 (4.8)	0
Pneumonia	2 (4.8)	1 (2.4)	1 (2.4)
Septic shock	2 (4.8)	0	2 (4.8)
Staphylococcal sepsis	2 (4.8)	0	2 (4.8)
Abscess limb	1 (2.4)	1 (2.4)	0
Bacteraemia	1 (2.4)	1 (2.4)	0
Bacterial sepsis	1 (2.4)	0	1 (2.4)
Bronchiolitis	1 (2.4)	1 (2.4)	0
Device related infection	1 (2.4)	1 (2.4)	0
Fungal sepsis	1 (2.4)	0	1 (2.4)
Gastroenteritis	1 (2.4)	0	0
Parainfluenzae virus infection	1 (2.4)	1 (2.4)	0
Paronychia	1 (2.4)	1 (2.4)	0
Respiratory tract infection	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (2.4)	1 (2.4)	0
Vascular device infection	1 (2.4)	1 (2.4)	0
Injury, poisoning and procedural complications			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Infusion related reaction	1 (2.4)	1 (2.4)	0
Tracheal obstruction	1 (2.4)	0	1 (2.4)
Investigations			
-Total	2 (4.8)	0	2 (4.8)
Neutrophil count decreased	2 (4.8)	0	2 (4.8)
Platelet count decreased	1 (2.4)	0	1 (2.4)
Metabolism and nutrition disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Hypervolaemia	1 (2.4)	1 (2.4)	0
Tumour lysis syndrome	1 (2.4)	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.4)	0	1 (2.4)
Acute lymphocytic leukaemia	1 (2.4)	0	1 (2.4)

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders			
-Total	3 (7.1)	1 (2.4)	1 (2.4)
Encephalopathy	1 (2.4)	1 (2.4)	0
Haemorrhage intracranial	1 (2.4)	0	1 (2.4)
Seizure	1 (2.4)	0	0
Renal and urinary disorders			
-Total	1 (2.4)	1 (2.4)	0
Renal tubular necrosis	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.1)	0	3 (7.1)
Respiratory failure	2 (4.8)	0	2 (4.8)
Acute respiratory distress syndrome	1 (2.4)	0	1 (2.4)
Haemothorax	1 (2.4)	0	1 (2.4)
Pneumothorax	1 (2.4)	0	1 (2.4)
Vascular disorders			
-Total	2 (4.8)	0	0
Hypertension	1 (2.4)	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (2.4)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211a
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (8.8)	1 (2.9)	1 (2.9)
General disorders and administration site conditions			
-Total	2 (5.9)	0	0
Pyrexia	2 (5.9)	0	0
Infections and infestations			
-Total	1 (2.9)	0	1 (2.9)
Fungaemia	1 (2.9)	0	1 (2.9)
Renal and urinary disorders			
-Total	1 (2.9)	0	0
Acute kidney injury	1 (2.9)	0	0

Age: <10 years

Group term Preferred term	All patients N=34 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.9)	0	1 (2.9)
Pulmonary haemorrhage	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	1 (2.9)	1 (2.9)	0
Flushing	1 (2.9)	0	0
Hypotension	1 (2.9)	1 (2.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211a
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (9.7)	1 (3.2)	1 (3.2)
Blood and lymphatic system disorders			
-Total	1 (3.2)	1 (3.2)	0
Febrile neutropenia	1 (3.2)	1 (3.2)	0
General disorders and administration site conditions			
-Total	1 (3.2)	0	0
Oedema peripheral	1 (3.2)	0	0
Investigations			
-Total	1 (3.2)	0	1 (3.2)
Neutrophil count decreased	1 (3.2)	0	1 (3.2)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=31 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.2)	0	0
Pleural effusion	1 (3.2)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211a
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (15.4)	1 (7.7)	1 (7.7)
Blood and lymphatic system disorders			
-Total	1 (7.7)	1 (7.7)	0
Febrile neutropenia	1 (7.7)	1 (7.7)	0
Infections and infestations			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Bacteraemia	1 (7.7)	1 (7.7)	0
Escherichia bacteraemia	1 (7.7)	0	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211b
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (10.9)	2 (4.3)	1 (2.2)
Blood and lymphatic system disorders			
-Total	1 (2.2)	1 (2.2)	0
Febrile neutropenia	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	3 (6.5)	0	0
Pyrexia	2 (4.3)	0	0
Oedema peripheral	1 (2.2)	0	0
Infections and infestations			
-Total	1 (2.2)	0	1 (2.2)

Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungaemia	1 (2.2)	0	1 (2.2)
Renal and urinary disorders			
-Total	1 (2.2)	0	0
Acute kidney injury	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.3)	0	1 (2.2)
Pleural effusion	1 (2.2)	0	0
Pulmonary haemorrhage	1 (2.2)	0	1 (2.2)
Respiratory failure	1 (2.2)	0	1 (2.2)
Vascular disorders			
-Total	1 (2.2)	1 (2.2)	0
Flushing	1 (2.2)	0	0
Hypotension	1 (2.2)	1 (2.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211b
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (9.4)	1 (3.1)	2 (6.3)
Blood and lymphatic system disorders			
-Total	1 (3.1)	1 (3.1)	0
Febrile neutropenia	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	1 (3.1)
Investigations			
-Total	1 (3.1)	0	1 (3.1)
Neutrophil count decreased	1 (3.1)	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211c
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (10.5)	3 (5.3)	1 (1.8)
Blood and lymphatic system disorders			
-Total	2 (3.5)	2 (3.5)	0
Febrile neutropenia	2 (3.5)	2 (3.5)	0
General disorders and administration site conditions			
-Total	3 (5.3)	0	0
Pyrexia	2 (3.5)	0	0
Oedema peripheral	1 (1.8)	0	0
Infections and infestations			
-Total	1 (1.8)	1 (1.8)	0

Race: White

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (1.8)	1 (1.8)	0
Investigations			
-Total	1 (1.8)	0	1 (1.8)
Neutrophil count decreased	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.8)	0	0
Pleural effusion	1 (1.8)	0	0
Vascular disorders			
-Total	1 (1.8)	1 (1.8)	0
Flushing	1 (1.8)	0	0
Hypotension	1 (1.8)	1 (1.8)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211c
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (18.2)	0	2 (18.2)
Infections and infestations			
-Total	2 (18.2)	0	2 (18.2)
Escherichia bacteraemia	1 (9.1)	0	1 (9.1)
Fungaemia	1 (9.1)	0	1 (9.1)
Renal and urinary disorders			
-Total	1 (9.1)	0	0
Acute kidney injury	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	0	1 (9.1)

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary haemorrhage	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211d
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (21.4)	1 (7.1)	2 (14.3)
General disorders and administration site conditions			
-Total	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	0
Infections and infestations			
-Total	1 (7.1)	0	1 (7.1)
Escherichia bacteraemia	1 (7.1)	0	1 (7.1)
Investigations			
-Total	1 (7.1)	0	1 (7.1)
Neutrophil count decreased	1 (7.1)	0	1 (7.1)

Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (7.1)	1 (7.1)	0
Flushing	1 (7.1)	0	0
Hypotension	1 (7.1)	1 (7.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211d
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (7.8)	2 (3.1)	1 (1.6)
Blood and lymphatic system disorders			
-Total	2 (3.1)	2 (3.1)	0
Febrile neutropenia	2 (3.1)	2 (3.1)	0
General disorders and administration site conditions			
-Total	2 (3.1)	0	0
Oedema peripheral	1 (1.6)	0	0
Pyrexia	1 (1.6)	0	0
Infections and infestations			
-Total	2 (3.1)	1 (1.6)	1 (1.6)

Ethnicity: Other

Group term Preferred term	All patients N=64 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (1.6)	1 (1.6)	0
Fungaemia	1 (1.6)	0	1 (1.6)
Renal and urinary disorders			
-Total	1 (1.6)	0	0
Acute kidney injury	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.1)	0	1 (1.6)
Pleural effusion	1 (1.6)	0	0
Pulmonary haemorrhage	1 (1.6)	0	1 (1.6)
Respiratory failure	1 (1.6)	0	1 (1.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211e
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (11.1)	3 (4.2)	3 (4.2)
Blood and lymphatic system disorders			
-Total	2 (2.8)	2 (2.8)	0
Febrile neutropenia	2 (2.8)	2 (2.8)	0
General disorders and administration site conditions			
-Total	3 (4.2)	0	0
Pyrexia	2 (2.8)	0	0
Oedema peripheral	1 (1.4)	0	0
Infections and infestations			
-Total	3 (4.2)	1 (1.4)	2 (2.8)
Bacteraemia	1 (1.4)	1 (1.4)	0

Response status at study entry: Relapsed disease

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (1.4)	0	1 (1.4)
Fungaemia	1 (1.4)	0	1 (1.4)
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Neutrophil count decreased	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	0
Acute kidney injury	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (2.8)	0	1 (1.4)
Pleural effusion	1 (1.4)	0	0
Pulmonary haemorrhage	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	1 (1.4)	1 (1.4)	0
Flushing	1 (1.4)	0	0
Hypotension	1 (1.4)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211f
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (100)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	0
Pleural effusion	1 (100)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211f
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=77	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (9.1)	3 (3.9)	3 (3.9)
Blood and lymphatic system disorders			
-Total	2 (2.6)	2 (2.6)	0
Febrile neutropenia	2 (2.6)	2 (2.6)	0
General disorders and administration site conditions			
-Total	3 (3.9)	0	0
Pyrexia	2 (2.6)	0	0
Oedema peripheral	1 (1.3)	0	0
Infections and infestations			
-Total	3 (3.9)	1 (1.3)	2 (2.6)
Bacteraemia	1 (1.3)	1 (1.3)	0

Philadelphia chromosome/BCR-ABL: Non-Positive			
		All patients N=77	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (1.3)	0	1 (1.3)
Fungaemia	1 (1.3)	0	1 (1.3)
Investigations			
-Total	1 (1.3)	0	1 (1.3)
Neutrophil count decreased	1 (1.3)	0	1 (1.3)
Renal and urinary disorders			
-Total	1 (1.3)	0	0
Acute kidney injury	1 (1.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.3)	0	1 (1.3)
Pulmonary haemorrhage	1 (1.3)	0	1 (1.3)
Respiratory failure	1 (1.3)	0	1 (1.3)
Vascular disorders			
-Total	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	0	0
Hypotension	1 (1.3)	1 (1.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211g
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (10.4)	3 (3.9)	3 (3.9)
Blood and lymphatic system disorders			
-Total	2 (2.6)	2 (2.6)	0
Febrile neutropenia	2 (2.6)	2 (2.6)	0
General disorders and administration site conditions			
-Total	3 (3.9)	0	0
Pyrexia	2 (2.6)	0	0
Oedema peripheral	1 (1.3)	0	0
Infections and infestations			
-Total	3 (3.9)	1 (1.3)	2 (2.6)
Bacteraemia	1 (1.3)	1 (1.3)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (1.3)	0	1 (1.3)
Fungaemia	1 (1.3)	0	1 (1.3)
Investigations			
-Total	1 (1.3)	0	1 (1.3)
Neutrophil count decreased	1 (1.3)	0	1 (1.3)
Renal and urinary disorders			
-Total	1 (1.3)	0	0
Acute kidney injury	1 (1.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (2.6)	0	1 (1.3)
Pleural effusion	1 (1.3)	0	0
Pulmonary haemorrhage	1 (1.3)	0	1 (1.3)
Respiratory failure	1 (1.3)	0	1 (1.3)
Vascular disorders			
-Total	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	0	0
Hypotension	1 (1.3)	1 (1.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211h
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (10.4)	3 (3.9)	3 (3.9)
Blood and lymphatic system disorders			
-Total	2 (2.6)	2 (2.6)	0
Febrile neutropenia	2 (2.6)	2 (2.6)	0
General disorders and administration site conditions			
-Total	3 (3.9)	0	0
Pyrexia	2 (2.6)	0	0
Oedema peripheral	1 (1.3)	0	0
Infections and infestations			
-Total	3 (3.9)	1 (1.3)	2 (2.6)

Hypodiploidy: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.3)	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	1 (1.3)
Fungaemia	1 (1.3)	0	1 (1.3)
Investigations			
-Total	1 (1.3)	0	1 (1.3)
Neutrophil count decreased	1 (1.3)	0	1 (1.3)
Renal and urinary disorders			
-Total	1 (1.3)	0	0
Acute kidney injury	1 (1.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (2.6)	0	1 (1.3)
Pleural effusion	1 (1.3)	0	0
Pulmonary haemorrhage	1 (1.3)	0	1 (1.3)
Respiratory failure	1 (1.3)	0	1 (1.3)
Vascular disorders			
-Total	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=77 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (1.3)	1 (1.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211i
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (10.4)	3 (3.9)	3 (3.9)
Blood and lymphatic system disorders			
-Total	2 (2.6)	2 (2.6)	0
Febrile neutropenia	2 (2.6)	2 (2.6)	0
General disorders and administration site conditions			
-Total	3 (3.9)	0	0
Pyrexia	2 (2.6)	0	0
Oedema peripheral	1 (1.3)	0	0
Infections and infestations			
-Total	3 (3.9)	1 (1.3)	2 (2.6)

BCR-ABL1-like: No

	All patients N=77		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.3)	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	0	1 (1.3)
Fungaemia	1 (1.3)	0	1 (1.3)
Investigations			
-Total	1 (1.3)	0	1 (1.3)
Neutrophil count decreased	1 (1.3)	0	1 (1.3)
Renal and urinary disorders			
-Total	1 (1.3)	0	0
Acute kidney injury	1 (1.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (2.6)	0	1 (1.3)
Pleural effusion	1 (1.3)	0	0
Pulmonary haemorrhage	1 (1.3)	0	1 (1.3)
Respiratory failure	1 (1.3)	0	1 (1.3)
Vascular disorders			
-Total	1 (1.3)	1 (1.3)	0
Flushing	1 (1.3)	0	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=77 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (1.3)	1 (1.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211j
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (14.8)	2 (7.4)	2 (7.4)
Blood and lymphatic system disorders			
-Total	2 (7.4)	2 (7.4)	0
Febrile neutropenia	2 (7.4)	2 (7.4)	0
General disorders and administration site conditions			
-Total	1 (3.7)	0	0
Oedema peripheral	1 (3.7)	0	0
Infections and infestations			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Bacteraemia	1 (3.7)	1 (3.7)	0
Fungaemia	1 (3.7)	0	1 (3.7)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (3.7)	0	1 (3.7)
Neutrophil count decreased	1 (3.7)	0	1 (3.7)
Renal and urinary disorders			
-Total	1 (3.7)	0	0
Acute kidney injury	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.7)	0	1 (3.7)
Pulmonary haemorrhage	1 (3.7)	0	1 (3.7)
Respiratory failure	1 (3.7)	0	1 (3.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211j
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (7.8)	1 (2.0)	1 (2.0)
General disorders and administration site conditions			
-Total	2 (3.9)	0	0
Pyrexia	2 (3.9)	0	0
Infections and infestations			
-Total	1 (2.0)	0	1 (2.0)
Escherichia bacteraemia	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.0)	0	0
Pleural effusion	1 (2.0)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=51 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	1 (2.0)	1 (2.0)	0
Flushing	1 (2.0)	0	0
Hypotension	1 (2.0)	1 (2.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211k
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (14.8)	1 (3.7)	1 (3.7)
Blood and lymphatic system disorders			
-Total	1 (3.7)	1 (3.7)	0
Febrile neutropenia	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			
-Total	1 (3.7)	0	0
Pyrexia	1 (3.7)	0	0
Infections and infestations			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Bacteraemia	1 (3.7)	1 (3.7)	0

Region: Europe

Group term Preferred term	All patients N=27 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (3.7)	0	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.7)	0	0
Pleural effusion	1 (3.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211k
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (9.1)	2 (4.5)	2 (4.5)
Blood and lymphatic system disorders			
-Total	1 (2.3)	1 (2.3)	0
Febrile neutropenia	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	2 (4.5)	0	0
Oedema peripheral	1 (2.3)	0	0
Pyrexia	1 (2.3)	0	0
Infections and infestations			
-Total	1 (2.3)	0	1 (2.3)

Region: US

Group term Preferred term	All patients N=44 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungaemia	1 (2.3)	0	1 (2.3)
Investigations			
-Total	1 (2.3)	0	1 (2.3)
Neutrophil count decreased	1 (2.3)	0	1 (2.3)
Renal and urinary disorders			
-Total	1 (2.3)	0	0
Acute kidney injury	1 (2.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.3)	0	1 (2.3)
Pulmonary haemorrhage	1 (2.3)	0	1 (2.3)
Respiratory failure	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	1 (2.3)	1 (2.3)	0
Flushing	1 (2.3)	0	0
Hypotension	1 (2.3)	1 (2.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211l
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (13.0)	2 (4.3)	3 (6.5)
Blood and lymphatic system disorders			
-Total	1 (2.2)	1 (2.2)	0
Febrile neutropenia	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	1 (2.2)	0	0
Pyrexia	1 (2.2)	0	0
Infections and infestations			
-Total	3 (6.5)	1 (2.2)	2 (4.3)
Bacteraemia	1 (2.2)	1 (2.2)	0

Prior SCT therapy: Yes

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (2.2)	0	1 (2.2)
Fungaemia	1 (2.2)	0	1 (2.2)
Investigations			
-Total	1 (2.2)	0	1 (2.2)
Neutrophil count decreased	1 (2.2)	0	1 (2.2)
Renal and urinary disorders			
-Total	1 (2.2)	0	0
Acute kidney injury	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.3)	0	1 (2.2)
Pleural effusion	1 (2.2)	0	0
Pulmonary haemorrhage	1 (2.2)	0	1 (2.2)
Respiratory failure	1 (2.2)	0	1 (2.2)
Vascular disorders			
-Total	1 (2.2)	1 (2.2)	0
Flushing	1 (2.2)	0	0
Hypotension	1 (2.2)	1 (2.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211l
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (6.3)	1 (3.1)	0
Blood and lymphatic system disorders			
-Total	1 (3.1)	1 (3.1)	0
Febrile neutropenia	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	2 (6.3)	0	0
Oedema peripheral	1 (3.1)	0	0
Pyrexia	1 (3.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211m
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (12.3)	3 (4.6)	3 (4.6)
Blood and lymphatic system disorders			
-Total	2 (3.1)	2 (3.1)	0
Febrile neutropenia	2 (3.1)	2 (3.1)	0
General disorders and administration site conditions			
-Total	3 (4.6)	0	0
Pyrexia	2 (3.1)	0	0
Oedema peripheral	1 (1.5)	0	0
Infections and infestations			
-Total	3 (4.6)	1 (1.5)	2 (3.1)

Eligibility for SCT: No

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	1 (1.5)
Fungaemia	1 (1.5)	0	1 (1.5)
Investigations			
-Total	1 (1.5)	0	1 (1.5)
Neutrophil count decreased	1 (1.5)	0	1 (1.5)
Renal and urinary disorders			
-Total	1 (1.5)	0	0
Acute kidney injury	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.1)	0	1 (1.5)
Pleural effusion	1 (1.5)	0	0
Pulmonary haemorrhage	1 (1.5)	0	1 (1.5)
Respiratory failure	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	1 (1.5)	1 (1.5)	0
Flushing	1 (1.5)	0	0

Eligibility for SCT: No

Group term Preferred term	All patients N=65 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (1.5)	1 (1.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211n
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (12.0)	2 (8.0)	0
Blood and lymphatic system disorders			
-Total	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	2 (8.0)	0	0
Oedema peripheral	1 (4.0)	0	0
Pyrexia	1 (4.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.0)	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=25 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pleural effusion	1 (4.0)	0	0
Vascular disorders			
-Total	1 (4.0)	1 (4.0)	0
Flushing	1 (4.0)	0	0
Hypotension	1 (4.0)	1 (4.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211n
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (9.4)	1 (1.9)	3 (5.7)
Blood and lymphatic system disorders			
-Total	1 (1.9)	1 (1.9)	0
Febrile neutropenia	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	1 (1.9)	0	0
Pyrexia	1 (1.9)	0	0
Infections and infestations			
-Total	3 (5.7)	1 (1.9)	2 (3.8)
Bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	1 (1.9)

Baseline bone marrow tumor burden: High			
		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	1 (1.9)	0	1 (1.9)
Investigations			
-Total	1 (1.9)	0	1 (1.9)
Neutrophil count decreased	1 (1.9)	0	1 (1.9)
Renal and urinary disorders			
-Total	1 (1.9)	0	0
Acute kidney injury	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.9)	0	1 (1.9)
Pulmonary haemorrhage	1 (1.9)	0	1 (1.9)
Respiratory failure	1 (1.9)	0	1 (1.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211o
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	0	0
Pleural effusion	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211o
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (10.4)	3 (4.5)	3 (4.5)
Blood and lymphatic system disorders			
-Total	2 (3.0)	2 (3.0)	0
Febrile neutropenia	2 (3.0)	2 (3.0)	0
General disorders and administration site conditions			
-Total	3 (4.5)	0	0
Pyrexia	2 (3.0)	0	0
Oedema peripheral	1 (1.5)	0	0
Infections and infestations			
-Total	3 (4.5)	1 (1.5)	2 (3.0)
Bacteraemia	1 (1.5)	1 (1.5)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=67 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (1.5)	0	1 (1.5)
Fungaemia	1 (1.5)	0	1 (1.5)
Investigations			
-Total	1 (1.5)	0	1 (1.5)
Neutrophil count decreased	1 (1.5)	0	1 (1.5)
Renal and urinary disorders			
-Total	1 (1.5)	0	0
Acute kidney injury	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.5)	0	1 (1.5)
Pulmonary haemorrhage	1 (1.5)	0	1 (1.5)
Respiratory failure	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	1 (1.5)	1 (1.5)	0
Flushing	1 (1.5)	0	0
Hypotension	1 (1.5)	1 (1.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211p
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (11.1)	3 (4.2)	3 (4.2)
Blood and lymphatic system disorders			
-Total	2 (2.8)	2 (2.8)	0
Febrile neutropenia	2 (2.8)	2 (2.8)	0
General disorders and administration site conditions			
-Total	3 (4.2)	0	0
Pyrexia	2 (2.8)	0	0
Oedema peripheral	1 (1.4)	0	0
Infections and infestations			
-Total	3 (4.2)	1 (1.4)	2 (2.8)

Down syndrome: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	1 (1.4)
Fungaemia	1 (1.4)	0	1 (1.4)
Investigations			
-Total	1 (1.4)	0	1 (1.4)
Neutrophil count decreased	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	0
Acute kidney injury	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (2.8)	0	1 (1.4)
Pleural effusion	1 (1.4)	0	0
Pulmonary haemorrhage	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	1 (1.4)	1 (1.4)	0
Flushing	1 (1.4)	0	0

Down syndrome: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (1.4)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211q
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (10.5)	1 (2.6)	1 (2.6)
Blood and lymphatic system disorders			
-Total	1 (2.6)	1 (2.6)	0
Febrile neutropenia	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	1 (2.6)	0	0
Pyrexia	1 (2.6)	0	0
Infections and infestations			
-Total	2 (5.3)	1 (2.6)	1 (2.6)
Bacteraemia	1 (2.6)	1 (2.6)	0
Escherichia bacteraemia	1 (2.6)	0	1 (2.6)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=38 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.6)	0	0
Pleural effusion	1 (2.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211q
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (7.7)	2 (5.1)	1 (2.6)
Blood and lymphatic system disorders			
-Total	1 (2.6)	1 (2.6)	0
Febrile neutropenia	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	2 (5.1)	0	0
Oedema peripheral	1 (2.6)	0	0
Pyrexia	1 (2.6)	0	0
Investigations			
-Total	1 (2.6)	0	1 (2.6)
Neutrophil count decreased	1 (2.6)	0	1 (2.6)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=39 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	1 (2.6)	1 (2.6)	0
Flushing	1 (2.6)	0	0
Hypotension	1 (2.6)	1 (2.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211q
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Fungaemia	1 (100)	0	1 (100)
Renal and urinary disorders			
-Total	1 (100)	0	0
Acute kidney injury	1 (100)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Pulmonary haemorrhage	1 (100)	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211r
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (13.6)	2 (9.1)	0
Blood and lymphatic system disorders			
-Total	1 (4.5)	1 (4.5)	0
Febrile neutropenia	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	3 (13.6)	0	0
Pyrexia	2 (9.1)	0	0
Oedema peripheral	1 (4.5)	0	0
Vascular disorders			
-Total	1 (4.5)	1 (4.5)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Flushing	1 (4.5)	0	0
Hypotension	1 (4.5)	1 (4.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 211r
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (14.3)	1 (2.9)	3 (8.6)
Blood and lymphatic system disorders			
-Total	1 (2.9)	1 (2.9)	0
Febrile neutropenia	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	3 (8.6)	1 (2.9)	2 (5.7)
Bacteraemia	1 (2.9)	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	0	1 (2.9)
Fungaemia	1 (2.9)	0	1 (2.9)
Investigations			
-Total	1 (2.9)	0	1 (2.9)

Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (2.9)	0	1 (2.9)
Renal and urinary disorders			
-Total	1 (2.9)	0	0
Acute kidney injury	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.7)	0	1 (2.9)
Pleural effusion	1 (2.9)	0	0
Pulmonary haemorrhage	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212a
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	8 (100)	3 (37.5)	5 (62.5)
Blood and lymphatic system disorders			
-Total	2 (25.0)	2 (25.0)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	2 (25.0)	2 (25.0)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	5 (62.5)	2 (25.0)	3 (37.5)

Age: <10 years

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspergillus infection	1 (12.5)	0	1 (12.5)
Device related infection	1 (12.5)	1 (12.5)	0
Fungaemia	1 (12.5)	0	1 (12.5)
Fungal skin infection	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Investigations			
-Total	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	1 (12.5)	0	1 (12.5)
Tumour lysis syndrome	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Encephalopathy	1 (12.5)	1 (12.5)	0
Haemorrhage intracranial	1 (12.5)	0	1 (12.5)
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0

Age: <10 years

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	1 (12.5)	0	0
Acute kidney injury	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Pulmonary haemorrhage	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212a
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	5 (71.4)	2 (28.6)	3 (42.9)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	1 (14.3)
Colitis	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Haemoperitoneum	1 (14.3)	0	1 (14.3)

Age: >=10 years to <18 years

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Infections and infestations			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	1 (14.3)	0
Disseminated trichosporonosis	1 (14.3)	0	1 (14.3)
Klebsiella bacteraemia	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Serratia sepsis	1 (14.3)	0	1 (14.3)
Staphylococcal infection	1 (14.3)	0	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Respiratory failure	2 (28.6)	0	2 (28.6)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	3 (42.9)	1 (14.3)	1 (14.3)
Hypotension	2 (28.6)	1 (14.3)	1 (14.3)
Hypertension	1 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212a
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	1 (33.3)
Pancytopenia	1 (33.3)	1 (33.3)	0
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Cardiac failure	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Bacterial sepsis	1 (33.3)	0	1 (33.3)

Age: >=18

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related sepsis	1 (33.3)	1 (33.3)	0
Fungal sepsis	1 (33.3)	0	1 (33.3)
Pneumonia	1 (33.3)	0	1 (33.3)
Investigations			
-Total	1 (33.3)	1 (33.3)	0
C-reactive protein increased	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Acute respiratory distress syndrome	1 (33.3)	0	1 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212b
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (100)	3 (33.3)	6 (66.7)
Blood and lymphatic system disorders			
-Total	1 (11.1)	1 (11.1)	0
Hyperleukocytosis	1 (11.1)	1 (11.1)	0
Cardiac disorders			
-Total	1 (11.1)	1 (11.1)	0
Left ventricular dysfunction	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Abdominal compartment syndrome	1 (11.1)	0	1 (11.1)
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
Haemoperitoneum	1 (11.1)	0	1 (11.1)

Gender: Male

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (33.3)	2 (22.2)	0
Pyrexia	2 (22.2)	1 (11.1)	0
Pain	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	6 (66.7)	2 (22.2)	4 (44.4)
Device related infection	1 (11.1)	1 (11.1)	0
Disseminated trichosporonosis	1 (11.1)	0	1 (11.1)
Fungaemia	1 (11.1)	0	1 (11.1)
Klebsiella bacteraemia	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Serratia sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal infection	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			
-Total	1 (11.1)	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	1 (11.1)	0
Investigations			

Gender: Male

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Tumour lysis syndrome	1 (11.1)	0	1 (11.1)
Nervous system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Encephalopathy	1 (11.1)	1 (11.1)	0
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	1 (11.1)	0	0
Acute kidney injury	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)

Gender: Male

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	3 (33.3)	0	3 (33.3)
Pulmonary haemorrhage	1 (11.1)	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Hypotension	2 (22.2)	1 (11.1)	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212b
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (77.8)	3 (33.3)	4 (44.4)
Blood and lymphatic system disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Febrile neutropenia	2 (22.2)	1 (11.1)	1 (11.1)
Pancytopenia	1 (11.1)	1 (11.1)	0
Cardiac disorders			
-Total	1 (11.1)	1 (11.1)	0
Cardiac failure	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	1 (11.1)	1 (11.1)	0
Colitis	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	0	0

Gender: Female

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	7 (77.8)	3 (33.3)	4 (44.4)
Aspergillus infection	1 (11.1)	0	1 (11.1)
Bacteraemia	1 (11.1)	1 (11.1)	0
Bacterial sepsis	1 (11.1)	0	1 (11.1)
Device related sepsis	1 (11.1)	1 (11.1)	0
Fungal sepsis	1 (11.1)	0	1 (11.1)
Fungal skin infection	1 (11.1)	1 (11.1)	0
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)
Systemic mycosis	1 (11.1)	1 (11.1)	0
Investigations			
-Total	1 (11.1)	1 (11.1)	0
C-reactive protein increased	1 (11.1)	1 (11.1)	0
Psychiatric disorders			
-Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0

Gender: Female

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (11.1)	0	1 (11.1)
Acute respiratory distress syndrome	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	1 (11.1)	0	0
Hypertension	1 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212c
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (100)	5 (45.5)	6 (54.5)
Blood and lymphatic system disorders			
-Total	3 (27.3)	3 (27.3)	0
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Hyperleukocytosis	1 (9.1)	1 (9.1)	0
Pancytopenia	1 (9.1)	1 (9.1)	0
Cardiac disorders			
-Total	1 (9.1)	1 (9.1)	0
Cardiac failure	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Abdominal compartment syndrome	1 (9.1)	0	1 (9.1)

Race: White

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	0	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haemoperitoneum	1 (9.1)	0	1 (9.1)
General disorders and administration site conditions			
-Total	3 (27.3)	2 (18.2)	0
Pyrexia	2 (18.2)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	9 (81.8)	4 (36.4)	5 (45.5)
Aspergillus infection	1 (9.1)	0	1 (9.1)
Bacteraemia	1 (9.1)	1 (9.1)	0
Bacterial sepsis	1 (9.1)	0	1 (9.1)
Device related infection	1 (9.1)	1 (9.1)	0
Device related sepsis	1 (9.1)	1 (9.1)	0
Disseminated trichosporonosis	1 (9.1)	0	1 (9.1)
Fungal sepsis	1 (9.1)	0	1 (9.1)

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Serratia sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Systemic mycosis	1 (9.1)	1 (9.1)	0
Investigations			
-Total	1 (9.1)	1 (9.1)	0
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Tumour lysis syndrome	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Encephalopathy	1 (9.1)	1 (9.1)	0
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Mental status changes	2 (18.2)	2 (18.2)	0

Race: White

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Respiratory failure	2 (18.2)	0	2 (18.2)
Acute respiratory distress syndrome	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	2 (18.2)	0	1 (9.1)
Hypertension	1 (9.1)	0	0
Hypotension	1 (9.1)	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212c
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (60.0)	1 (20.0)	2 (40.0)
Cardiac disorders			
-Total	1 (20.0)	1 (20.0)	0
Left ventricular dysfunction	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Klebsiella bacteraemia	1 (20.0)	1 (20.0)	0
Pneumonia fungal	1 (20.0)	0	1 (20.0)
Injury, poisoning and procedural complications			
-Total	1 (20.0)	1 (20.0)	0
Post procedural haemorrhage	1 (20.0)	1 (20.0)	0

Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders			
-Total	1 (20.0)	0	1 (20.0)
Haemorrhage intracranial	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	1 (20.0)	1 (20.0)	0
Hypotension	1 (20.0)	1 (20.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212c
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Febrile neutropenia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	2 (100)	0	2 (100)
Fungaemia	1 (50.0)	0	1 (50.0)
Pneumonia	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	1 (50.0)

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders			
-Total	1 (50.0)	0	0
Acute kidney injury	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pulmonary haemorrhage	1 (50.0)	0	1 (50.0)
Respiratory failure	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212d
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (100)	1 (33.3)	2 (66.7)
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Colitis	1 (33.3)	1 (33.3)	0
Diarrhoea	1 (33.3)	0	0
Infections and infestations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Aspergillus infection	1 (33.3)	0	1 (33.3)
Bacteraemia	1 (33.3)	1 (33.3)	0
Disseminated trichosporonosis	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
-Total	1 (33.3)	1 (33.3)	0

Ethnicity: Hispanic or Latino

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	0	0
Hypertension	1 (33.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212d
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (86.7)	5 (33.3)	8 (53.3)
Blood and lymphatic system disorders			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Febrile neutropenia	2 (13.3)	1 (6.7)	1 (6.7)
Hyperleukocytosis	1 (6.7)	1 (6.7)	0
Pancytopenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
-Total	2 (13.3)	2 (13.3)	0
Cardiac failure	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)
Gastrointestinal haemorrhage	1 (6.7)	1 (6.7)	0
Haemoperitoneum	1 (6.7)	0	1 (6.7)
General disorders and administration site conditions			
-Total	3 (20.0)	2 (13.3)	0
Pyrexia	2 (13.3)	1 (6.7)	0
Pain	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	10 (66.7)	4 (26.7)	6 (40.0)
Bacterial sepsis	1 (6.7)	0	1 (6.7)
Device related infection	1 (6.7)	1 (6.7)	0
Device related sepsis	1 (6.7)	1 (6.7)	0
Fungaemia	1 (6.7)	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	1 (6.7)
Fungal skin infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	0	1 (6.7)

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Sepsis	1 (6.7)	0	1 (6.7)
Serratia sepsis	1 (6.7)	0	1 (6.7)
Staphylococcal infection	1 (6.7)	0	1 (6.7)
Systemic mycosis	1 (6.7)	1 (6.7)	0
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
C-reactive protein increased	1 (6.7)	1 (6.7)	0
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
Metabolism and nutrition disorders			
-Total	1 (6.7)	0	1 (6.7)
Tumour lysis syndrome	1 (6.7)	0	1 (6.7)
Nervous system disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)

Ethnicity: Other

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (6.7)	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
-Total	1 (6.7)	1 (6.7)	0
Mental status changes	1 (6.7)	1 (6.7)	0
Renal and urinary disorders			
-Total	1 (6.7)	0	0
Acute kidney injury	1 (6.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Respiratory failure	2 (13.3)	0	2 (13.3)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Pulmonary haemorrhage	1 (6.7)	0	1 (6.7)
Pulmonary oedema	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)

Ethnicity: Other

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212e
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	0	2 (100)
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
-Total	2 (100)	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	1 (50.0)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=2 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	0	2 (100)
Respiratory failure	2 (100)	0	2 (100)
Pulmonary oedema	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212e
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (87.5)	6 (37.5)	8 (50.0)
Blood and lymphatic system disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Pancytopenia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
-Total	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
-Total	2 (12.5)	2 (12.5)	0

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	2 (12.5)	2 (12.5)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	11 (68.8)	5 (31.3)	6 (37.5)
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	1 (6.3)	0

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
-Total	1 (6.3)	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	1 (6.3)	0
Investigations			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
C-reactive protein increased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	1 (6.3)	0	1 (6.3)
Tumour lysis syndrome	1 (6.3)	0	1 (6.3)
Nervous system disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)

Response status at study entry: Relapsed disease

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Renal and urinary disorders			
-Total	1 (6.3)	0	0
Acute kidney injury	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Respiratory failure	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	3 (18.8)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	1 (6.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212f
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
-Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212g
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
-Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212h
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	1 (50.0)	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	1 (50.0)	0
Left ventricular dysfunction	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0

Hypodiploidy: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Klebsiella bacteraemia	1 (50.0)	1 (50.0)	0
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Injury, poisoning and procedural complications			
-Total	1 (50.0)	1 (50.0)	0
Post procedural haemorrhage	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Respiratory failure	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212h
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	14 (87.5)	5 (31.3)	9 (56.3)
Blood and lymphatic system disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Pancytopenia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
-Total	1 (6.3)	1 (6.3)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
-Total	2 (12.5)	2 (12.5)	0
Colitis	1 (6.3)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	2 (12.5)	2 (12.5)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	11 (68.8)	4 (25.0)	7 (43.8)
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	1 (6.3)
Fungaemia	1 (6.3)	0	1 (6.3)
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Investigations			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
C-reactive protein increased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	1 (6.3)	0	1 (6.3)
Tumour lysis syndrome	1 (6.3)	0	1 (6.3)
Nervous system disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
-Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0

Hypodiploidy: No

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	1 (6.3)	0	0
Acute kidney injury	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (25.0)	1 (6.3)	3 (18.8)
Respiratory failure	2 (12.5)	0	2 (12.5)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	2 (12.5)	0	1 (6.3)
Hypertension	1 (6.3)	0	0
Hypotension	1 (6.3)	0	1 (6.3)

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212i
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	1 (100)	0
Fungal skin infection	1 (100)	1 (100)	0
Systemic mycosis	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212i
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (88.2)	5 (29.4)	10 (58.8)
Blood and lymphatic system disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Febrile neutropenia	1 (5.9)	0	1 (5.9)
Hyperleukocytosis	1 (5.9)	1 (5.9)	0
Pancytopenia	1 (5.9)	1 (5.9)	0
Cardiac disorders			
-Total	2 (11.8)	2 (11.8)	0
Cardiac failure	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.9)	0	1 (5.9)
Colitis	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	0	0
Gastrointestinal haemorrhage	1 (5.9)	1 (5.9)	0
Haemoperitoneum	1 (5.9)	0	1 (5.9)
General disorders and administration site conditions			
-Total	3 (17.6)	2 (11.8)	0
Pyrexia	2 (11.8)	1 (5.9)	0
Pain	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	12 (70.6)	4 (23.5)	8 (47.1)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Bacteraemia	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	1 (5.9)

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	1 (5.9)	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	1 (5.9)
Klebsiella bacteraemia	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	1 (5.9)
Sepsis	1 (5.9)	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	1 (5.9)
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	1 (5.9)	0
Investigations			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
C-reactive protein increased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
-Total	1 (5.9)	0	1 (5.9)

BCR-ABL1-like: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.9)	0	1 (5.9)
Nervous system disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Encephalopathy	1 (5.9)	1 (5.9)	0
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	2 (11.8)	2 (11.8)	0
Mental status changes	2 (11.8)	2 (11.8)	0
Renal and urinary disorders			
-Total	1 (5.9)	0	0
Acute kidney injury	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Pulmonary haemorrhage	1 (5.9)	0	1 (5.9)
Pulmonary oedema	1 (5.9)	0	1 (5.9)

BCR-ABL1-like: No

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	3 (17.6)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212j
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (100)	0	3 (100)
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)
Haemoperitoneum	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0
Infections and infestations			
-Total	3 (100)	0	3 (100)
Aspergillus infection	1 (33.3)	0	1 (33.3)
Fungaemia	1 (33.3)	0	1 (33.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia sepsis	1 (33.3)	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Investigations			
-Total	1 (33.3)	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	1 (33.3)
Psychiatric disorders			
-Total	1 (33.3)	1 (33.3)	0
Mental status changes	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	1 (33.3)	0	0
Acute kidney injury	1 (33.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Respiratory failure	2 (66.7)	0	2 (66.7)
Pulmonary haemorrhage	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212j
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (86.7)	6 (40.0)	7 (46.7)
Blood and lymphatic system disorders			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Febrile neutropenia	2 (13.3)	1 (6.7)	1 (6.7)
Hyperleukocytosis	1 (6.7)	1 (6.7)	0
Pancytopenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
-Total	2 (13.3)	2 (13.3)	0
Cardiac failure	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	2 (13.3)	2 (13.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (6.7)	1 (6.7)	0
Diarrhoea	1 (6.7)	0	0
Gastrointestinal haemorrhage	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	2 (13.3)	2 (13.3)	0
Pain	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	10 (66.7)	5 (33.3)	5 (33.3)
Bacteraemia	1 (6.7)	1 (6.7)	0
Bacterial sepsis	1 (6.7)	0	1 (6.7)
Device related infection	1 (6.7)	1 (6.7)	0
Device related sepsis	1 (6.7)	1 (6.7)	0
Disseminated trichosporonosis	1 (6.7)	0	1 (6.7)
Fungal sepsis	1 (6.7)	0	1 (6.7)
Fungal skin infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Pneumonia	1 (6.7)	0	1 (6.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Sepsis	1 (6.7)	0	1 (6.7)
Systemic mycosis	1 (6.7)	1 (6.7)	0
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
-Total	1 (6.7)	1 (6.7)	0
C-reactive protein increased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	1 (6.7)	0	1 (6.7)
Tumour lysis syndrome	1 (6.7)	0	1 (6.7)
Nervous system disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Encephalopathy	1 (6.7)	1 (6.7)	0
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
-Total	1 (6.7)	1 (6.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	3 (20.0)	1 (6.7)	1 (6.7)
Hypotension	2 (13.3)	1 (6.7)	1 (6.7)
Hypertension	1 (6.7)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212k
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Europe

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	4 (100)	2 (50.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	1 (25.0)
Pancytopenia	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	2 (50.0)	2 (50.0)	0
Pain	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	3 (75.0)	2 (50.0)	1 (25.0)

Region: Europe

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Device related infection	1 (25.0)	1 (25.0)	0
Device related sepsis	1 (25.0)	1 (25.0)	0
Pneumonia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	1 (25.0)	1 (25.0)	0
C-reactive protein increased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	0	1 (25.0)
Tumour lysis syndrome	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	1 (25.0)	1 (25.0)	0
Encephalopathy	1 (25.0)	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212k
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	11 (91.7)	4 (33.3)	7 (58.3)
Blood and lymphatic system disorders			
-Total	2 (16.7)	2 (16.7)	0
Febrile neutropenia	1 (8.3)	1 (8.3)	0
Hyperleukocytosis	1 (8.3)	1 (8.3)	0
Cardiac disorders			
-Total	2 (16.7)	2 (16.7)	0
Cardiac failure	1 (8.3)	1 (8.3)	0
Left ventricular dysfunction	1 (8.3)	1 (8.3)	0
Gastrointestinal disorders			
-Total	3 (25.0)	2 (16.7)	1 (8.3)
Abdominal compartment syndrome	1 (8.3)	0	1 (8.3)

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Colitis	1 (8.3)	1 (8.3)	0
Diarrhoea	1 (8.3)	0	0
Gastrointestinal haemorrhage	1 (8.3)	1 (8.3)	0
Haemoperitoneum	1 (8.3)	0	1 (8.3)
General disorders and administration site conditions			
-Total	1 (8.3)	0	0
Pyrexia	1 (8.3)	0	0
Infections and infestations			
-Total	10 (83.3)	3 (25.0)	7 (58.3)
Aspergillus infection	1 (8.3)	0	1 (8.3)
Bacteraemia	1 (8.3)	1 (8.3)	0
Bacterial sepsis	1 (8.3)	0	1 (8.3)
Disseminated trichosporonosis	1 (8.3)	0	1 (8.3)
Fungaemia	1 (8.3)	0	1 (8.3)
Fungal sepsis	1 (8.3)	0	1 (8.3)
Fungal skin infection	1 (8.3)	1 (8.3)	0
Klebsiella bacteraemia	1 (8.3)	1 (8.3)	0

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia fungal	1 (8.3)	0	1 (8.3)
Sepsis	1 (8.3)	0	1 (8.3)
Serratia sepsis	1 (8.3)	0	1 (8.3)
Staphylococcal infection	1 (8.3)	0	1 (8.3)
Systemic mycosis	1 (8.3)	1 (8.3)	0
Injury, poisoning and procedural complications			
-Total	1 (8.3)	1 (8.3)	0
Post procedural haemorrhage	1 (8.3)	1 (8.3)	0
Investigations			
-Total	1 (8.3)	0	1 (8.3)
Neutrophil count decreased	1 (8.3)	0	1 (8.3)
Psychiatric disorders			
-Total	2 (16.7)	2 (16.7)	0
Mental status changes	2 (16.7)	2 (16.7)	0
Renal and urinary disorders			
-Total	1 (8.3)	0	0
Acute kidney injury	1 (8.3)	0	0

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (41.7)	1 (8.3)	4 (33.3)
Respiratory failure	3 (25.0)	0	3 (25.0)
Acute respiratory distress syndrome	1 (8.3)	0	1 (8.3)
Pulmonary haemorrhage	1 (8.3)	0	1 (8.3)
Pulmonary oedema	1 (8.3)	0	1 (8.3)
Tachypnoea	1 (8.3)	1 (8.3)	0
Vascular disorders			
-Total	3 (25.0)	1 (8.3)	1 (8.3)
Hypotension	2 (16.7)	1 (8.3)	1 (8.3)
Hypertension	1 (8.3)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212k
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Rest of World

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (50.0)	0	1 (50.0)
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Haemorrhage intracranial	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212l
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (90.0)	4 (40.0)	5 (50.0)
Blood and lymphatic system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Febrile neutropenia	1 (10.0)	0	1 (10.0)
Pancytopenia	1 (10.0)	1 (10.0)	0
Cardiac disorders			
-Total	2 (20.0)	2 (20.0)	0
Cardiac failure	1 (10.0)	1 (10.0)	0
Left ventricular dysfunction	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
-Total	1 (10.0)	1 (10.0)	0
Colitis	1 (10.0)	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (10.0)	0	0
General disorders and administration site conditions			
-Total	2 (20.0)	2 (20.0)	0
Pain	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	1 (10.0)	0
Infections and infestations			
-Total	7 (70.0)	4 (40.0)	3 (30.0)
Bacteraemia	1 (10.0)	1 (10.0)	0
Bacterial sepsis	1 (10.0)	0	1 (10.0)
Device related infection	1 (10.0)	1 (10.0)	0
Device related sepsis	1 (10.0)	1 (10.0)	0
Fungaemia	1 (10.0)	0	1 (10.0)
Fungal sepsis	1 (10.0)	0	1 (10.0)
Klebsiella bacteraemia	1 (10.0)	1 (10.0)	0
Pneumonia	1 (10.0)	0	1 (10.0)
Injury, poisoning and procedural complications			
-Total	1 (10.0)	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (10.0)	1 (10.0)	0
Investigations			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
C-reactive protein increased	1 (10.0)	1 (10.0)	0
Neutrophil count decreased	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
-Total	1 (10.0)	0	1 (10.0)
Tumour lysis syndrome	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Encephalopathy	1 (10.0)	1 (10.0)	0
Haemorrhage intracranial	1 (10.0)	0	1 (10.0)
Renal and urinary disorders			
-Total	1 (10.0)	0	0
Acute kidney injury	1 (10.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	2 (20.0)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute respiratory distress syndrome	1 (10.0)	0	1 (10.0)
Pulmonary haemorrhage	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	2 (20.0)	1 (10.0)	0
Hypertension	1 (10.0)	0	0
Hypotension	1 (10.0)	1 (10.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 212l
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (87.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders			
-Total	2 (25.0)	2 (25.0)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0
Haemoperitoneum	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			

Prior SCT therapy: No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	0	0
Pyrexia	1 (12.5)	0	0
Infections and infestations			
-Total	6 (75.0)	1 (12.5)	5 (62.5)
Aspergillus infection	1 (12.5)	0	1 (12.5)
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Fungal skin infection	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Sepsis	1 (12.5)	0	1 (12.5)
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	2 (25.0)	2 (25.0)	0
Mental status changes	2 (25.0)	2 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)

Prior SCT therapy: No

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Tachypnoea	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212m
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Aspergillus infection	1 (25.0)	0	1 (25.0)
Fungal skin infection	1 (25.0)	1 (25.0)	0
Systemic mycosis	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Haemorrhage intracranial	1 (25.0)	0	1 (25.0)

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	1 (25.0)	1 (25.0)	0
Mental status changes	1 (25.0)	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212m
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (92.9)	5 (35.7)	8 (57.1)
Blood and lymphatic system disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Febrile neutropenia	1 (7.1)	0	1 (7.1)
Hyperleukocytosis	1 (7.1)	1 (7.1)	0
Pancytopenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	2 (14.3)	2 (14.3)	0
Cardiac failure	1 (7.1)	1 (7.1)	0
Left ventricular dysfunction	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (7.1)	0	1 (7.1)
Colitis	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	0	0
Gastrointestinal haemorrhage	1 (7.1)	1 (7.1)	0
Haemoperitoneum	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	3 (21.4)	2 (14.3)	0
Pyrexia	2 (14.3)	1 (7.1)	0
Pain	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	11 (78.6)	4 (28.6)	7 (50.0)
Bacteraemia	1 (7.1)	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	1 (7.1)
Device related infection	1 (7.1)	1 (7.1)	0
Device related sepsis	1 (7.1)	1 (7.1)	0
Disseminated trichosporonosis	1 (7.1)	0	1 (7.1)
Fungaemia	1 (7.1)	0	1 (7.1)

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (7.1)	0	1 (7.1)
Klebsiella bacteraemia	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	1 (7.1)
Sepsis	1 (7.1)	0	1 (7.1)
Serratia sepsis	1 (7.1)	0	1 (7.1)
Staphylococcal infection	1 (7.1)	0	1 (7.1)
Injury, poisoning and procedural complications			
-Total	1 (7.1)	1 (7.1)	0
Post procedural haemorrhage	1 (7.1)	1 (7.1)	0
Investigations			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
C-reactive protein increased	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	1 (7.1)	0	1 (7.1)
Tumour lysis syndrome	1 (7.1)	0	1 (7.1)

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (7.1)	1 (7.1)	0
Encephalopathy	1 (7.1)	1 (7.1)	0
Psychiatric disorders			
-Total	1 (7.1)	1 (7.1)	0
Mental status changes	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	1 (7.1)	0	0
Acute kidney injury	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (35.7)	1 (7.1)	4 (28.6)
Respiratory failure	3 (21.4)	0	3 (21.4)
Acute respiratory distress syndrome	1 (7.1)	0	1 (7.1)
Pulmonary haemorrhage	1 (7.1)	0	1 (7.1)
Pulmonary oedema	1 (7.1)	0	1 (7.1)
Tachypnoea	1 (7.1)	1 (7.1)	0
Vascular disorders			

Eligibility for SCT: No

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (21.4)	1 (7.1)	1 (7.1)
Hypotension	2 (14.3)	1 (7.1)	1 (7.1)
Hypertension	1 (7.1)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212n
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (100)	6 (37.5)	10 (62.5)
Blood and lymphatic system disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperleukocytosis	1 (6.3)	1 (6.3)	0
Pancytopenia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
-Total	2 (12.5)	2 (12.5)	0
Cardiac failure	1 (6.3)	1 (6.3)	0
Left ventricular dysfunction	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
-Total	3 (18.8)	2 (12.5)	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (6.3)	0	1 (6.3)
Colitis	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	0	0
Gastrointestinal haemorrhage	1 (6.3)	1 (6.3)	0
Haemoperitoneum	1 (6.3)	0	1 (6.3)
General disorders and administration site conditions			
-Total	3 (18.8)	2 (12.5)	0
Pyrexia	2 (12.5)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0
Infections and infestations			
-Total	13 (81.3)	5 (31.3)	8 (50.0)
Aspergillus infection	1 (6.3)	0	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bacterial sepsis	1 (6.3)	0	1 (6.3)
Device related infection	1 (6.3)	1 (6.3)	0
Device related sepsis	1 (6.3)	1 (6.3)	0
Disseminated trichosporonosis	1 (6.3)	0	1 (6.3)
Fungaemia	1 (6.3)	0	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (6.3)	0	1 (6.3)
Fungal skin infection	1 (6.3)	1 (6.3)	0
Klebsiella bacteraemia	1 (6.3)	1 (6.3)	0
Pneumonia	1 (6.3)	0	1 (6.3)
Pneumonia fungal	1 (6.3)	0	1 (6.3)
Sepsis	1 (6.3)	0	1 (6.3)
Serratia sepsis	1 (6.3)	0	1 (6.3)
Staphylococcal infection	1 (6.3)	0	1 (6.3)
Systemic mycosis	1 (6.3)	1 (6.3)	0
Injury, poisoning and procedural complications			
-Total	1 (6.3)	1 (6.3)	0
Post procedural haemorrhage	1 (6.3)	1 (6.3)	0
Investigations			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
C-reactive protein increased	1 (6.3)	1 (6.3)	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	1 (6.3)	0	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (6.3)	0	1 (6.3)
Nervous system disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Encephalopathy	1 (6.3)	1 (6.3)	0
Haemorrhage intracranial	1 (6.3)	0	1 (6.3)
Psychiatric disorders			
-Total	2 (12.5)	2 (12.5)	0
Mental status changes	2 (12.5)	2 (12.5)	0
Renal and urinary disorders			
-Total	1 (6.3)	0	0
Acute kidney injury	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (31.3)	1 (6.3)	4 (25.0)
Respiratory failure	3 (18.8)	0	3 (18.8)
Acute respiratory distress syndrome	1 (6.3)	0	1 (6.3)
Pulmonary haemorrhage	1 (6.3)	0	1 (6.3)
Pulmonary oedema	1 (6.3)	0	1 (6.3)
Tachypnoea	1 (6.3)	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	3 (18.8)	1 (6.3)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	1 (6.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212o
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)

Baseline extramedullary disease presence: No

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
-Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212p
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (100)	0	1 (100)
Nervous system disorders			
-Total	1 (100)	0	1 (100)
Haemorrhage intracranial	1 (100)	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212p
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (88.2)	6 (35.3)	9 (52.9)
Blood and lymphatic system disorders			
-Total	4 (23.5)	3 (17.6)	1 (5.9)
Febrile neutropenia	2 (11.8)	1 (5.9)	1 (5.9)
Hyperleukocytosis	1 (5.9)	1 (5.9)	0
Pancytopenia	1 (5.9)	1 (5.9)	0
Cardiac disorders			
-Total	2 (11.8)	2 (11.8)	0
Cardiac failure	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.9)	0	1 (5.9)
Colitis	1 (5.9)	1 (5.9)	0
Diarrhoea	1 (5.9)	0	0
Gastrointestinal haemorrhage	1 (5.9)	1 (5.9)	0
Haemoperitoneum	1 (5.9)	0	1 (5.9)
General disorders and administration site conditions			
-Total	3 (17.6)	2 (11.8)	0
Pyrexia	2 (11.8)	1 (5.9)	0
Pain	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	13 (76.5)	5 (29.4)	8 (47.1)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Bacteraemia	1 (5.9)	1 (5.9)	0
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Device related infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Disseminated trichosporonosis	1 (5.9)	0	1 (5.9)

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	1 (5.9)	0	1 (5.9)
Fungal sepsis	1 (5.9)	0	1 (5.9)
Fungal skin infection	1 (5.9)	1 (5.9)	0
Klebsiella bacteraemia	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	0	1 (5.9)
Sepsis	1 (5.9)	0	1 (5.9)
Serratia sepsis	1 (5.9)	0	1 (5.9)
Staphylococcal infection	1 (5.9)	0	1 (5.9)
Systemic mycosis	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Post procedural haemorrhage	1 (5.9)	1 (5.9)	0
Investigations			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
C-reactive protein increased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)

Down syndrome: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	0	1 (5.9)
Nervous system disorders			
-Total	1 (5.9)	1 (5.9)	0
Encephalopathy	1 (5.9)	1 (5.9)	0
Psychiatric disorders			
-Total	2 (11.8)	2 (11.8)	0
Mental status changes	2 (11.8)	2 (11.8)	0
Renal and urinary disorders			
-Total	1 (5.9)	0	0
Acute kidney injury	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (29.4)	1 (5.9)	4 (23.5)
Respiratory failure	3 (17.6)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Pulmonary haemorrhage	1 (5.9)	0	1 (5.9)

Down syndrome: No

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	3 (17.6)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212q
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (88.9)	6 (33.3)	10 (55.6)
Blood and lymphatic system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	3 (16.7)	2 (11.1)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	13 (72.2)	5 (27.8)	8 (44.4)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0
Renal and urinary disorders			
-Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	3 (16.7)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)
Hypertension	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	0	2 (100)
Gastrointestinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	1 (50.0)
Haemoperitoneum	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
-Total	2 (100)	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	1 (50.0)

Number of previous relapses: 0

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia sepsis	1 (50.0)	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	0	2 (100)
Respiratory failure	2 (100)	0	2 (100)
Pulmonary oedema	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (87.5)	5 (62.5)	2 (25.0)
Blood and lymphatic system disorders			
-Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	1 (12.5)	0
Pancytopenia	1 (12.5)	1 (12.5)	0
Cardiac disorders			
-Total	1 (12.5)	1 (12.5)	0
Left ventricular dysfunction	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	4 (50.0)	2 (25.0)
Device related infection	1 (12.5)	1 (12.5)	0
Device related sepsis	1 (12.5)	1 (12.5)	0
Fungal skin infection	1 (12.5)	1 (12.5)	0
Klebsiella bacteraemia	1 (12.5)	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	1 (12.5)
Sepsis	1 (12.5)	0	1 (12.5)
Systemic mycosis	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Post procedural haemorrhage	1 (12.5)	1 (12.5)	0
Investigations			
-Total	1 (12.5)	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0
Mental status changes	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Tachypnoea	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Aspergillus infection	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	1 (100)	0
Mental status changes	1 (100)	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 212r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (85.7)	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Febrile neutropenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Cardiac failure	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Colitis	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0

Number of previous relapses: >=3

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Pain	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Bacteraemia	1 (14.3)	1 (14.3)	0
Bacterial sepsis	1 (14.3)	0	1 (14.3)
Fungaemia	1 (14.3)	0	1 (14.3)
Fungal sepsis	1 (14.3)	0	1 (14.3)
Pneumonia	1 (14.3)	0	1 (14.3)
Investigations			
-Total	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)
Tumour lysis syndrome	1 (14.3)	0	1 (14.3)
Nervous system disorders			

Number of previous relapses: >=3

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Encephalopathy	1 (14.3)	1 (14.3)	0
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)
Renal and urinary disorders			
-Total	1 (14.3)	0	0
Acute kidney injury	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Acute respiratory distress syndrome	1 (14.3)	0	1 (14.3)
Pulmonary haemorrhage	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	1 (14.3)	0	0
Hypertension	1 (14.3)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213a
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	31 (75.6)	11 (26.8)	18 (43.9)
Blood and lymphatic system disorders			
-Total	12 (29.3)	12 (29.3)	0
Febrile neutropenia	12 (29.3)	12 (29.3)	0
Anaemia	1 (2.4)	0	0
Disseminated intravascular coagulation	1 (2.4)	0	0
Thrombocytopenia	1 (2.4)	1 (2.4)	0
Cardiac disorders			
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Cardiac arrest	1 (2.4)	0	1 (2.4)
Left ventricular dysfunction	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (2.4)	0	1 (2.4)
Gastrointestinal disorders			
-Total	5 (12.2)	4 (9.8)	1 (2.4)
Diarrhoea	2 (4.9)	1 (2.4)	0
Abdominal compartment syndrome	1 (2.4)	0	1 (2.4)
Anal inflammation	1 (2.4)	1 (2.4)	0
Neutropenic colitis	1 (2.4)	1 (2.4)	0
Pancreatitis	1 (2.4)	1 (2.4)	0
Stomatitis	1 (2.4)	1 (2.4)	0
Vomiting	1 (2.4)	0	0
General disorders and administration site conditions			
-Total	10 (24.4)	1 (2.4)	2 (4.9)
Pyrexia	8 (19.5)	1 (2.4)	0
Multiple organ dysfunction syndrome	2 (4.9)	0	2 (4.9)
Systemic inflammatory response syndrome	1 (2.4)	1 (2.4)	0
Hepatobiliary disorders			
-Total	1 (2.4)	0	1 (2.4)

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholestasis	1 (2.4)	0	1 (2.4)
Immune system disorders			
-Total	19 (46.3)	3 (7.3)	9 (22.0)
Cytokine release syndrome	18 (43.9)	3 (7.3)	8 (19.5)
Haemophagocytic lymphohistiocytosis	2 (4.9)	0	2 (4.9)
Infections and infestations			
-Total	16 (39.0)	8 (19.5)	8 (19.5)
Bronchopulmonary aspergillosis	2 (4.9)	1 (2.4)	1 (2.4)
Pneumonia	2 (4.9)	1 (2.4)	1 (2.4)
Aspergillus infection	1 (2.4)	0	1 (2.4)
Bronchiolitis	1 (2.4)	1 (2.4)	0
Candida infection	1 (2.4)	0	0
Covid-19 pneumonia	1 (2.4)	0	1 (2.4)
Cytomegalovirus infection reactivation	1 (2.4)	1 (2.4)	0
Device related infection	1 (2.4)	1 (2.4)	0
Encephalitis	1 (2.4)	0	1 (2.4)
Enterobacter infection	1 (2.4)	1 (2.4)	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia bacteraemia	1 (2.4)	1 (2.4)	0
Fungaemia	1 (2.4)	0	1 (2.4)
Fungal skin infection	1 (2.4)	1 (2.4)	0
Gastroenteritis	1 (2.4)	1 (2.4)	0
Herpes zoster	1 (2.4)	1 (2.4)	0
Human herpesvirus 6 infection	1 (2.4)	1 (2.4)	0
Klebsiella infection	1 (2.4)	1 (2.4)	0
Mastoiditis	1 (2.4)	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	0
Otitis externa	1 (2.4)	1 (2.4)	0
Otitis media	1 (2.4)	1 (2.4)	0
Parainfluenzae virus infection	1 (2.4)	1 (2.4)	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	1 (2.4)
Pneumonia viral	1 (2.4)	1 (2.4)	0
Sepsis	1 (2.4)	0	1 (2.4)
Sialoadenitis	1 (2.4)	1 (2.4)	0
Sinusitis	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Soft tissue infection	1 (2.4)	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Staphylococcal sepsis	1 (2.4)	0	1 (2.4)
Systemic mycosis	1 (2.4)	1 (2.4)	0
Injury, poisoning and procedural complications			
-Total	2 (4.9)	0	2 (4.9)
Tracheal obstruction	1 (2.4)	0	1 (2.4)
Vasoplegia syndrome	1 (2.4)	0	1 (2.4)
Investigations			
-Total	2 (4.9)	0	2 (4.9)
Amylase increased	1 (2.4)	0	1 (2.4)
Neutrophil count decreased	1 (2.4)	0	1 (2.4)
Metabolism and nutrition disorders			
-Total	5 (12.2)	1 (2.4)	3 (7.3)
Dehydration	1 (2.4)	0	0
Hypernatraemia	1 (2.4)	0	1 (2.4)
Hypokalaemia	1 (2.4)	1 (2.4)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (2.4)	0	1 (2.4)
Tumour lysis syndrome	1 (2.4)	0	1 (2.4)
Musculoskeletal and connective tissue disorders			
-Total	2 (4.9)	1 (2.4)	1 (2.4)
Back pain	1 (2.4)	1 (2.4)	0
Rhabdomyolysis	1 (2.4)	0	1 (2.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (4.9)	2 (4.9)	0
Bone giant cell tumour benign	1 (2.4)	1 (2.4)	0
Myelodysplastic syndrome	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	6 (14.6)	3 (7.3)	3 (7.3)
Encephalopathy	2 (4.9)	2 (4.9)	0
Cerebral haemorrhage	1 (2.4)	0	1 (2.4)
Haemorrhage intracranial	1 (2.4)	0	1 (2.4)
Headache	1 (2.4)	1 (2.4)	0
Hydrocephalus	1 (2.4)	0	1 (2.4)

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (4.9)	2 (4.9)	0
Mental status changes	2 (4.9)	2 (4.9)	0
Renal and urinary disorders			
-Total	3 (7.3)	0	2 (4.9)
Acute kidney injury	3 (7.3)	0	2 (4.9)
Renal tubular necrosis	1 (2.4)	0	1 (2.4)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (19.5)	2 (4.9)	5 (12.2)
Respiratory failure	3 (7.3)	0	3 (7.3)
Hypoxia	2 (4.9)	1 (2.4)	1 (2.4)
Acute respiratory distress syndrome	1 (2.4)	0	1 (2.4)
Dyspnoea	1 (2.4)	0	1 (2.4)
Dyspnoea exertional	1 (2.4)	0	0
Epistaxis	1 (2.4)	1 (2.4)	0
Pulmonary haemorrhage	1 (2.4)	0	1 (2.4)
Respiratory distress	1 (2.4)	0	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	4 (9.8)	1 (2.4)	3 (7.3)
Hypotension	4 (9.8)	1 (2.4)	3 (7.3)
Flushing	1 (2.4)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213a
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	33 (82.5)	13 (32.5)	20 (50.0)
Blood and lymphatic system disorders			
-Total	11 (27.5)	8 (20.0)	3 (7.5)
Febrile neutropenia	7 (17.5)	6 (15.0)	1 (2.5)
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Anaemia	1 (2.5)	0	1 (2.5)
Coagulopathy	1 (2.5)	1 (2.5)	0
Neutropenia	1 (2.5)	1 (2.5)	0
Pancytopenia	1 (2.5)	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.5)	2 (5.0)	2 (5.0)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Atrioventricular block first degree	1 (2.5)	0	0
Cardiac failure	1 (2.5)	1 (2.5)	0
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Pericardial effusion	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	5 (12.5)	3 (7.5)	1 (2.5)
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0
Haemoperitoneum	1 (2.5)	0	1 (2.5)
Ileus	1 (2.5)	1 (2.5)	0
Irritable bowel syndrome	1 (2.5)	0	0
Pancreatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	4 (10.0)	1 (2.5)	0
Pyrexia	3 (7.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (2.5)	0	0
Hepatobiliary disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Hepatic cytolysis	1 (2.5)	1 (2.5)	0
Hepatomegaly	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	23 (57.5)	10 (25.0)	9 (22.5)
Cytokine release syndrome	23 (57.5)	10 (25.0)	9 (22.5)
Drug hypersensitivity	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	24 (60.0)	16 (40.0)	8 (20.0)
Sepsis	3 (7.5)	1 (2.5)	2 (5.0)
Septic shock	2 (5.0)	0	2 (5.0)
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Upper respiratory tract infection	2 (5.0)	2 (5.0)	0
Clostridium difficile colitis	1 (2.5)	1 (2.5)	0
Covid-19	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (2.5)	1 (2.5)	0
Device related sepsis	1 (2.5)	1 (2.5)	0
Disseminated trichosporonosis	1 (2.5)	0	1 (2.5)
Encephalitis	1 (2.5)	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	1 (2.5)
Gastroenteritis escherichia coli	1 (2.5)	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	1 (2.5)	0
Herpes zoster	1 (2.5)	1 (2.5)	0
Klebsiella bacteraemia	1 (2.5)	1 (2.5)	0
Localised infection	1 (2.5)	1 (2.5)	0
Meningitis bacterial	1 (2.5)	1 (2.5)	0
Meningitis pneumococcal	1 (2.5)	1 (2.5)	0
Paronychia	1 (2.5)	1 (2.5)	0
Pharyngitis	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0
Pneumonia fungal	1 (2.5)	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Serratia sepsis	1 (2.5)	0	1 (2.5)
Sinusitis	1 (2.5)	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	2 (5.0)	1 (2.5)	0
Infusion related reaction	1 (2.5)	1 (2.5)	0
Transfusion reaction	1 (2.5)	0	0
Investigations			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Aspartate aminotransferase increased	1 (2.5)	1 (2.5)	0
Blood uric acid increased	1 (2.5)	0	1 (2.5)
Electrocardiogram qt prolonged	1 (2.5)	0	1 (2.5)
Neutrophil count decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Tumour lysis syndrome	2 (5.0)	1 (2.5)	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (2.5)	0	1 (2.5)
Hypercalcaemia	1 (2.5)	1 (2.5)	0
Hyperkalaemia	1 (2.5)	0	1 (2.5)
Hyperphosphataemia	1 (2.5)	0	1 (2.5)
Hypervolaemia	1 (2.5)	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	3 (7.5)	2 (5.0)	0
Back pain	1 (2.5)	1 (2.5)	0
Haemarthrosis	1 (2.5)	1 (2.5)	0
Pain in extremity	1 (2.5)	0	0
Nervous system disorders			
-Total	3 (7.5)	3 (7.5)	0
Seizure	2 (5.0)	1 (2.5)	0
Dysarthria	1 (2.5)	1 (2.5)	0
Headache	1 (2.5)	1 (2.5)	0
Nervous system disorder	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (5.0)	1 (2.5)	0
Delirium	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	0	0
Renal and urinary disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Acute kidney injury	3 (7.5)	2 (5.0)	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (30.0)	3 (7.5)	8 (20.0)
Respiratory failure	5 (12.5)	0	5 (12.5)
Hypoxia	3 (7.5)	2 (5.0)	1 (2.5)
Pleural effusion	3 (7.5)	1 (2.5)	1 (2.5)
Pulmonary oedema	2 (5.0)	1 (2.5)	1 (2.5)
Acute respiratory distress syndrome	1 (2.5)	0	1 (2.5)
Acute respiratory failure	1 (2.5)	1 (2.5)	0
Epistaxis	1 (2.5)	0	0
Respiratory distress	1 (2.5)	0	1 (2.5)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	6 (15.0)	2 (5.0)	4 (10.0)
Hypotension	6 (15.0)	2 (5.0)	4 (10.0)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213a
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	15 (88.2)	5 (29.4)	9 (52.9)
Blood and lymphatic system disorders			
-Total	5 (29.4)	4 (23.5)	1 (5.9)
Febrile neutropenia	4 (23.5)	3 (17.6)	1 (5.9)
Pancytopenia	1 (5.9)	1 (5.9)	0
Cardiac disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Cardiac failure	2 (11.8)	1 (5.9)	1 (5.9)
Gastrointestinal disorders			
-Total	1 (5.9)	0	0
Constipation	1 (5.9)	0	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Nausea	1 (5.9)	0	0
General disorders and administration site conditions			
-Total	4 (23.5)	0	1 (5.9)
Pyrexia	2 (11.8)	0	0
Multiple organ dysfunction syndrome	1 (5.9)	0	1 (5.9)
Non-cardiac chest pain	1 (5.9)	0	0
Pain	1 (5.9)	0	0
Hepatobiliary disorders			
-Total	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Immune system disorders			
-Total	9 (52.9)	3 (17.6)	4 (23.5)
Cytokine release syndrome	9 (52.9)	3 (17.6)	4 (23.5)
Allergy to immunoglobulin therapy	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	8 (47.1)	5 (29.4)	3 (17.6)
Bacteraemia	2 (11.8)	1 (5.9)	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	2 (11.8)	1 (5.9)	0
Candida infection	1 (5.9)	0	1 (5.9)
Encephalitis viral	1 (5.9)	1 (5.9)	0
Escherichia bacteraemia	1 (5.9)	0	1 (5.9)
Gastroenteritis	1 (5.9)	1 (5.9)	0
Parainfluenzae virus infection	1 (5.9)	1 (5.9)	0
Pharyngitis streptococcal	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Respiratory syncytial virus infection	1 (5.9)	1 (5.9)	0
Respiratory tract infection	1 (5.9)	1 (5.9)	0
Septic shock	1 (5.9)	0	1 (5.9)
Staphylococcal abscess	1 (5.9)	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	1 (5.9)	0
Urinary tract infection	1 (5.9)	1 (5.9)	0
Varicella zoster virus infection	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Viral upper respiratory tract infection	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Investigations			
-Total	2 (11.8)	2 (11.8)	0
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0
Blood bilirubin increased	1 (5.9)	1 (5.9)	0
C-reactive protein increased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	1 (5.9)	1 (5.9)	0
Malnutrition	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (11.8)	0	0
Back pain	1 (5.9)	0	0
Pain in extremity	1 (5.9)	0	0
Nervous system disorders			
-Total	1 (5.9)	0	0
Cognitive disorder	1 (5.9)	0	0
Renal and urinary disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal failure	1 (5.9)	0	1 (5.9)
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Reproductive system and breast disorders			
-Total	1 (5.9)	1 (5.9)	0
Endometriosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (23.5)	0	3 (17.6)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Bronchial oedema	1 (5.9)	0	0
Laryngeal oedema	1 (5.9)	0	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Vascular disorders			
-Total	2 (11.8)	0	2 (11.8)
Hypotension	1 (5.9)	0	1 (5.9)
Venoocclusive disease	1 (5.9)	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213b
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	44 (80.0)	15 (27.3)	27 (49.1)
Blood and lymphatic system disorders			
-Total	13 (23.6)	11 (20.0)	2 (3.6)
Febrile neutropenia	11 (20.0)	11 (20.0)	0
Anaemia	2 (3.6)	0	1 (1.8)
Disseminated intravascular coagulation	2 (3.6)	1 (1.8)	0
Thrombocytopenia	2 (3.6)	1 (1.8)	1 (1.8)
Neutropenia	1 (1.8)	1 (1.8)	0
Pancytopenia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	4 (7.3)	2 (3.6)	1 (1.8)

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	2 (3.6)	2 (3.6)	0
Atrioventricular block first degree	1 (1.8)	0	0
Cardiac arrest	1 (1.8)	0	1 (1.8)
Cardiac failure	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	10 (18.2)	7 (12.7)	2 (3.6)
Abdominal compartment syndrome	2 (3.6)	0	2 (3.6)
Diarrhoea	2 (3.6)	1 (1.8)	0
Pancreatitis	2 (3.6)	2 (3.6)	0
Anal inflammation	1 (1.8)	1 (1.8)	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0
Haemoperitoneum	1 (1.8)	0	1 (1.8)
Ileus	1 (1.8)	1 (1.8)	0
Irritable bowel syndrome	1 (1.8)	0	0
Neutropenic colitis	1 (1.8)	1 (1.8)	0
Stomatitis	1 (1.8)	1 (1.8)	0
Vomiting	1 (1.8)	0	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions			
-Total	13 (23.6)	2 (3.6)	1 (1.8)
Pyrexia	11 (20.0)	2 (3.6)	0
Multiple organ dysfunction syndrome	1 (1.8)	0	1 (1.8)
Oedema peripheral	1 (1.8)	0	0
Pain	1 (1.8)	0	0
Hepatobiliary disorders			
-Total	2 (3.6)	2 (3.6)	0
Drug-induced liver injury	1 (1.8)	1 (1.8)	0
Hepatic cytolysis	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	24 (43.6)	7 (12.7)	12 (21.8)
Cytokine release syndrome	23 (41.8)	7 (12.7)	11 (20.0)
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)
Infections and infestations			
-Total	26 (47.3)	17 (30.9)	9 (16.4)
Pneumonia	3 (5.5)	2 (3.6)	1 (1.8)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	3 (5.5)	1 (1.8)	2 (3.6)
Staphylococcal bacteraemia	2 (3.6)	2 (3.6)	0
Upper respiratory tract infection	2 (3.6)	2 (3.6)	0
Bronchiolitis	1 (1.8)	1 (1.8)	0
Bronchopulmonary aspergillosis	1 (1.8)	1 (1.8)	0
Candida infection	1 (1.8)	0	0
Clostridium difficile colitis	1 (1.8)	1 (1.8)	0
Covid-19	1 (1.8)	1 (1.8)	0
Covid-19 pneumonia	1 (1.8)	0	1 (1.8)
Cytomegalovirus infection reactivation	1 (1.8)	1 (1.8)	0
Device related infection	1 (1.8)	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	1 (1.8)
Encephalitis	1 (1.8)	0	1 (1.8)
Escherichia bacteraemia	1 (1.8)	1 (1.8)	0
Fungaemia	1 (1.8)	0	1 (1.8)
Gastroenteritis escherichia coli	1 (1.8)	1 (1.8)	0
Gastroenteritis salmonella	1 (1.8)	1 (1.8)	0
Herpes zoster	1 (1.8)	1 (1.8)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (1.8)	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	1 (1.8)	0
Localised infection	1 (1.8)	1 (1.8)	0
Metapneumovirus infection	1 (1.8)	1 (1.8)	0
Ophthalmic herpes zoster	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0
Paronychia	1 (1.8)	1 (1.8)	0
Pharyngitis	1 (1.8)	1 (1.8)	0
Pneumocystis jirovecii pneumonia	1 (1.8)	0	1 (1.8)
Pneumonia fungal	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Respiratory tract infection	1 (1.8)	1 (1.8)	0
Serratia sepsis	1 (1.8)	0	1 (1.8)
Sialoadenitis	1 (1.8)	1 (1.8)	0
Sinusitis	1 (1.8)	1 (1.8)	0
Soft tissue infection	1 (1.8)	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	1 (1.8)

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.8)	0	1 (1.8)
Varicella zoster virus infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Viral haemorrhagic cystitis	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Infusion related reaction	1 (1.8)	1 (1.8)	0
Tracheal obstruction	1 (1.8)	0	1 (1.8)
Investigations			
-Total	4 (7.3)	2 (3.6)	2 (3.6)
Aspartate aminotransferase increased	2 (3.6)	2 (3.6)	0
Amylase increased	1 (1.8)	0	1 (1.8)
Blood bilirubin increased	1 (1.8)	1 (1.8)	0
Neutrophil count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	5 (9.1)	1 (1.8)	3 (5.5)
Tumour lysis syndrome	2 (3.6)	1 (1.8)	1 (1.8)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Decreased appetite	1 (1.8)	0	1 (1.8)
Dehydration	1 (1.8)	0	0
Hyponatraemia	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	4 (7.3)	2 (3.6)	0
Back pain	2 (3.6)	2 (3.6)	0
Pain in extremity	2 (3.6)	0	0
Nervous system disorders			
-Total	7 (12.7)	4 (7.3)	3 (5.5)
Headache	2 (3.6)	2 (3.6)	0
Cerebral haemorrhage	1 (1.8)	0	1 (1.8)
Dysarthria	1 (1.8)	1 (1.8)	0
Encephalopathy	1 (1.8)	1 (1.8)	0
Haemorrhage intracranial	1 (1.8)	0	1 (1.8)
Hydrocephalus	1 (1.8)	0	1 (1.8)
Seizure	1 (1.8)	0	0
Psychiatric disorders			

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.8)	1 (1.8)	0
Delirium	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	4 (7.3)	1 (1.8)	2 (3.6)
Acute kidney injury	2 (3.6)	0	1 (1.8)
Renal failure	1 (1.8)	0	1 (1.8)
Renal tubular necrosis	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	14 (25.5)	2 (3.6)	11 (20.0)
Respiratory failure	7 (12.7)	0	7 (12.7)
Pleural effusion	3 (5.5)	1 (1.8)	1 (1.8)
Epistaxis	2 (3.6)	1 (1.8)	0
Hypoxia	2 (3.6)	1 (1.8)	1 (1.8)
Pulmonary oedema	2 (3.6)	1 (1.8)	1 (1.8)
Respiratory distress	2 (3.6)	0	1 (1.8)
Laryngeal oedema	1 (1.8)	0	1 (1.8)
Pulmonary haemorrhage	1 (1.8)	0	1 (1.8)

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	6 (10.9)	2 (3.6)	4 (7.3)
Hypotension	5 (9.1)	2 (3.6)	3 (5.5)
Flushing	1 (1.8)	0	0
Venoocclusive disease	1 (1.8)	0	1 (1.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213b
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	35 (81.4)	14 (32.6)	20 (46.5)
Blood and lymphatic system disorders			
-Total	15 (34.9)	13 (30.2)	2 (4.7)
Febrile neutropenia	12 (27.9)	10 (23.3)	2 (4.7)
Coagulopathy	1 (2.3)	1 (2.3)	0
Disseminated intravascular coagulation	1 (2.3)	1 (2.3)	0
Pancytopenia	1 (2.3)	1 (2.3)	0
Cardiac disorders			
-Total	6 (14.0)	2 (4.7)	4 (9.3)
Cardiac arrest	2 (4.7)	0	2 (4.7)
Cardiac failure	2 (4.7)	1 (2.3)	1 (2.3)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pericardial effusion	1 (2.3)	1 (2.3)	0
Tachycardia	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	1 (2.3)	0	0
Constipation	1 (2.3)	0	0
Nausea	1 (2.3)	0	0
General disorders and administration site conditions			
-Total	5 (11.6)	0	2 (4.7)
Multiple organ dysfunction syndrome	2 (4.7)	0	2 (4.7)
Pyrexia	2 (4.7)	0	0
Non-cardiac chest pain	1 (2.3)	0	0
Systemic inflammatory response syndrome	1 (2.3)	1 (2.3)	0
Hepatobiliary disorders			
-Total	2 (4.7)	0	2 (4.7)
Cholestasis	1 (2.3)	0	1 (2.3)
Hepatomegaly	1 (2.3)	0	1 (2.3)
Immune system disorders			

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	27 (62.8)	9 (20.9)	10 (23.3)
Cytokine release syndrome	27 (62.8)	9 (20.9)	10 (23.3)
Allergy to immunoglobulin therapy	1 (2.3)	1 (2.3)	0
Drug hypersensitivity	1 (2.3)	1 (2.3)	0
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)
Infections and infestations			
-Total	22 (51.2)	12 (27.9)	10 (23.3)
Septic shock	3 (7.0)	0	3 (7.0)
Bacteraemia	2 (4.7)	1 (2.3)	1 (2.3)
Encephalitis viral	2 (4.7)	1 (2.3)	1 (2.3)
Gastroenteritis	2 (4.7)	2 (4.7)	0
Rhinovirus infection	2 (4.7)	1 (2.3)	0
Aspergillus infection	1 (2.3)	0	1 (2.3)
Bronchopulmonary aspergillosis	1 (2.3)	0	1 (2.3)
Candida infection	1 (2.3)	0	1 (2.3)
Device related infection	1 (2.3)	1 (2.3)	0
Device related sepsis	1 (2.3)	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalitis	1 (2.3)	0	1 (2.3)
Enterobacter infection	1 (2.3)	1 (2.3)	0
Escherichia bacteraemia	1 (2.3)	0	1 (2.3)
Fungal skin infection	1 (2.3)	1 (2.3)	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0
Herpes zoster	1 (2.3)	1 (2.3)	0
Klebsiella infection	1 (2.3)	1 (2.3)	0
Mastoiditis	1 (2.3)	1 (2.3)	0
Meningitis bacterial	1 (2.3)	1 (2.3)	0
Meningitis pneumococcal	1 (2.3)	1 (2.3)	0
Otitis externa	1 (2.3)	1 (2.3)	0
Otitis media	1 (2.3)	1 (2.3)	0
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0
Pharyngitis streptococcal	1 (2.3)	1 (2.3)	0
Pneumonia	1 (2.3)	0	1 (2.3)
Pneumonia respiratory syncytial viral	1 (2.3)	1 (2.3)	0
Pneumonia viral	1 (2.3)	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	1 (2.3)	0	1 (2.3)
Sinusitis	1 (2.3)	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	1 (2.3)	0
Staphylococcal infection	1 (2.3)	1 (2.3)	0
Staphylococcal skin infection	1 (2.3)	1 (2.3)	0
Systemic mycosis	1 (2.3)	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Urinary tract infection	1 (2.3)	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Injury, poisoning and procedural complications			
-Total	2 (4.7)	0	1 (2.3)
Transfusion reaction	1 (2.3)	0	0
Vasoplegia syndrome	1 (2.3)	0	1 (2.3)
Investigations			
-Total	3 (7.0)	1 (2.3)	2 (4.7)
Blood uric acid increased	1 (2.3)	0	1 (2.3)
C-reactive protein increased	1 (2.3)	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	1 (2.3)	0	1 (2.3)
Neutrophil count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	6 (14.0)	3 (7.0)	3 (7.0)
Hypercalcaemia	1 (2.3)	1 (2.3)	0
Hyperkalaemia	1 (2.3)	0	1 (2.3)
Hypernatraemia	1 (2.3)	0	1 (2.3)
Hyperphosphataemia	1 (2.3)	0	1 (2.3)
Hypervolaemia	1 (2.3)	1 (2.3)	0
Hypokalaemia	1 (2.3)	1 (2.3)	0
Malnutrition	1 (2.3)	1 (2.3)	0
Metabolic acidosis	1 (2.3)	0	1 (2.3)
Tumour lysis syndrome	1 (2.3)	0	1 (2.3)
Musculoskeletal and connective tissue disorders			
-Total	3 (7.0)	1 (2.3)	1 (2.3)
Back pain	1 (2.3)	0	0
Haemarthrosis	1 (2.3)	1 (2.3)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhabdomyolysis	1 (2.3)	0	1 (2.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (4.7)	2 (4.7)	0
Bone giant cell tumour benign	1 (2.3)	1 (2.3)	0
Myelodysplastic syndrome	1 (2.3)	1 (2.3)	0
Nervous system disorders			
-Total	3 (7.0)	2 (4.7)	0
Cognitive disorder	1 (2.3)	0	0
Encephalopathy	1 (2.3)	1 (2.3)	0
Nervous system disorder	1 (2.3)	1 (2.3)	0
Seizure	1 (2.3)	1 (2.3)	0
Psychiatric disorders			
-Total	3 (7.0)	2 (4.7)	0
Mental status changes	3 (7.0)	2 (4.7)	0
Renal and urinary disorders			
-Total	4 (9.3)	2 (4.7)	2 (4.7)
Acute kidney injury	4 (9.3)	2 (4.7)	2 (4.7)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal tubular necrosis	1 (2.3)	0	1 (2.3)
Reproductive system and breast disorders			
-Total	1 (2.3)	1 (2.3)	0
Endometriosis	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (23.3)	3 (7.0)	5 (11.6)
Acute respiratory distress syndrome	3 (7.0)	0	3 (7.0)
Hypoxia	3 (7.0)	2 (4.7)	1 (2.3)
Respiratory failure	2 (4.7)	0	2 (4.7)
Acute respiratory failure	1 (2.3)	1 (2.3)	0
Bronchial oedema	1 (2.3)	0	0
Dyspnoea	1 (2.3)	0	1 (2.3)
Dyspnoea exertional	1 (2.3)	0	0
Vascular disorders			
-Total	6 (14.0)	1 (2.3)	5 (11.6)
Hypotension	6 (14.0)	1 (2.3)	5 (11.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213c
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	57 (81.4)	24 (34.3)	30 (42.9)
Blood and lymphatic system disorders			
-Total	21 (30.0)	18 (25.7)	3 (4.3)
Febrile neutropenia	17 (24.3)	16 (22.9)	1 (1.4)
Anaemia	2 (2.9)	0	1 (1.4)
Disseminated intravascular coagulation	2 (2.9)	1 (1.4)	0
Pancytopenia	2 (2.9)	2 (2.9)	0
Thrombocytopenia	2 (2.9)	1 (1.4)	1 (1.4)
Coagulopathy	1 (1.4)	1 (1.4)	0
Neutropenia	1 (1.4)	1 (1.4)	0
Cardiac disorders			

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (10.0)	3 (4.3)	3 (4.3)
Cardiac failure	3 (4.3)	2 (2.9)	1 (1.4)
Atrioventricular block first degree	1 (1.4)	0	0
Cardiac arrest	1 (1.4)	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	1 (1.4)	0
Pericardial effusion	1 (1.4)	1 (1.4)	0
Tachycardia	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	8 (11.4)	5 (7.1)	2 (2.9)
Abdominal compartment syndrome	2 (2.9)	0	2 (2.9)
Diarrhoea	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
Haemoperitoneum	1 (1.4)	0	1 (1.4)
Ileus	1 (1.4)	1 (1.4)	0
Irritable bowel syndrome	1 (1.4)	0	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Stomatitis	1 (1.4)	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions			
-Total	12 (17.1)	1 (1.4)	1 (1.4)
Pyrexia	10 (14.3)	1 (1.4)	0
Multiple organ dysfunction syndrome	1 (1.4)	0	1 (1.4)
Oedema peripheral	1 (1.4)	0	0
Pain	1 (1.4)	0	0
Systemic inflammatory response syndrome	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Cholestasis	1 (1.4)	0	1 (1.4)
Drug-induced liver injury	1 (1.4)	1 (1.4)	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	37 (52.9)	14 (20.0)	12 (17.1)
Cytokine release syndrome	37 (52.9)	14 (20.0)	12 (17.1)
Drug hypersensitivity	1 (1.4)	1 (1.4)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)
Infections and infestations			
-Total	36 (51.4)	22 (31.4)	14 (20.0)
Sepsis	4 (5.7)	1 (1.4)	3 (4.3)
Pneumonia	3 (4.3)	2 (2.9)	1 (1.4)
Septic shock	3 (4.3)	0	3 (4.3)
Staphylococcal bacteraemia	3 (4.3)	3 (4.3)	0
Candida infection	2 (2.9)	0	1 (1.4)
Device related infection	2 (2.9)	2 (2.9)	0
Encephalitis	2 (2.9)	0	2 (2.9)
Gastroenteritis	2 (2.9)	2 (2.9)	0
Parainfluenzae virus infection	2 (2.9)	2 (2.9)	0
Sinusitis	2 (2.9)	2 (2.9)	0
Staphylococcal infection	2 (2.9)	1 (1.4)	1 (1.4)
Aspergillus infection	1 (1.4)	0	1 (1.4)
Bacteraemia	1 (1.4)	1 (1.4)	0
Bronchiolitis	1 (1.4)	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	1 (1.4)	0	1 (1.4)
Clostridium difficile colitis	1 (1.4)	1 (1.4)	0
Covid-19	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	1 (1.4)
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Fungal skin infection	1 (1.4)	1 (1.4)	0
Gastroenteritis escherichia coli	1 (1.4)	1 (1.4)	0
Gastroenteritis salmonella	1 (1.4)	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Localised infection	1 (1.4)	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0
Pharyngitis	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Pneumonia respiratory syncytial viral	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Serratia sepsis	1 (1.4)	0	1 (1.4)
Sialoadenitis	1 (1.4)	1 (1.4)	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Staphylococcal skin infection	1 (1.4)	1 (1.4)	0
Systemic mycosis	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral haemorrhagic cystitis	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (5.7)	1 (1.4)	2 (2.9)
Infusion related reaction	1 (1.4)	1 (1.4)	0
Tracheal obstruction	1 (1.4)	0	1 (1.4)
Transfusion reaction	1 (1.4)	0	0
Vasoplegia syndrome	1 (1.4)	0	1 (1.4)
Investigations			
-Total	5 (7.1)	3 (4.3)	2 (2.9)
Aspartate aminotransferase increased	2 (2.9)	2 (2.9)	0
Amylase increased	1 (1.4)	0	1 (1.4)
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Blood uric acid increased	1 (1.4)	0	1 (1.4)
C-reactive protein increased	1 (1.4)	1 (1.4)	0
Neutrophil count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	7 (10.0)	1 (1.4)	5 (7.1)
Tumour lysis syndrome	2 (2.9)	0	2 (2.9)
Decreased appetite	1 (1.4)	0	1 (1.4)

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (1.4)	0	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypervolaemia	1 (1.4)	1 (1.4)	0
Hyponatraemia	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	4 (5.7)	1 (1.4)	1 (1.4)
Pain in extremity	2 (2.9)	0	0
Back pain	1 (1.4)	1 (1.4)	0
Rhabdomyolysis	1 (1.4)	0	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.9)	2 (2.9)	0
Bone giant cell tumour benign	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	8 (11.4)	6 (8.6)	2 (2.9)
Encephalopathy	2 (2.9)	2 (2.9)	0
Headache	2 (2.9)	2 (2.9)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (2.9)	1 (1.4)	0
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Dysarthria	1 (1.4)	1 (1.4)	0
Hydrocephalus	1 (1.4)	0	1 (1.4)
Nervous system disorder	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	3 (4.3)	2 (2.9)	0
Mental status changes	2 (2.9)	1 (1.4)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (10.0)	3 (4.3)	4 (5.7)
Acute kidney injury	5 (7.1)	2 (2.9)	3 (4.3)
Renal tubular necrosis	2 (2.9)	1 (1.4)	1 (1.4)
Renal failure	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (27.1)	4 (5.7)	13 (18.6)
Respiratory failure	7 (10.0)	0	7 (10.0)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute respiratory distress syndrome	3 (4.3)	0	3 (4.3)
Hypoxia	3 (4.3)	2 (2.9)	1 (1.4)
Epistaxis	2 (2.9)	1 (1.4)	0
Pleural effusion	2 (2.9)	1 (1.4)	0
Pulmonary oedema	2 (2.9)	1 (1.4)	1 (1.4)
Respiratory distress	2 (2.9)	0	1 (1.4)
Acute respiratory failure	1 (1.4)	1 (1.4)	0
Dyspnoea	1 (1.4)	0	1 (1.4)
Dyspnoea exertional	1 (1.4)	0	0
Laryngeal oedema	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	8 (11.4)	2 (2.9)	6 (8.6)
Hypotension	8 (11.4)	2 (2.9)	6 (8.6)
Flushing	1 (1.4)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213c
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (60.0)	4 (26.7)	5 (33.3)
Blood and lymphatic system disorders			
-Total	3 (20.0)	3 (20.0)	0
Febrile neutropenia	2 (13.3)	2 (13.3)	0
Disseminated intravascular coagulation	1 (6.7)	1 (6.7)	0
Cardiac disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Cardiac arrest	1 (6.7)	0	1 (6.7)
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	1 (6.7)	1 (6.7)	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal inflammation	1 (6.7)	1 (6.7)	0
Diarrhoea	1 (6.7)	0	0
Vomiting	1 (6.7)	0	0
General disorders and administration site conditions			
-Total	1 (6.7)	0	0
Pyrexia	1 (6.7)	0	0
Hepatobiliary disorders			
-Total	1 (6.7)	0	1 (6.7)
Hepatomegaly	1 (6.7)	0	1 (6.7)
Immune system disorders			
-Total	4 (26.7)	1 (6.7)	3 (20.0)
Cytokine release syndrome	4 (26.7)	1 (6.7)	3 (20.0)
Infections and infestations			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Bronchopulmonary aspergillosis	1 (6.7)	1 (6.7)	0
Cytomegalovirus infection reactivation	1 (6.7)	1 (6.7)	0
Encephalitis viral	1 (6.7)	0	1 (6.7)

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Meningitis bacterial	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypercalcaemia	1 (6.7)	1 (6.7)	0
Hyperkalaemia	1 (6.7)	0	1 (6.7)
Hyperphosphataemia	1 (6.7)	0	1 (6.7)
Metabolic acidosis	1 (6.7)	0	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (6.7)	1 (6.7)	0
Back pain	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	1 (6.7)	0	1 (6.7)
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Reproductive system and breast disorders			

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (6.7)	1 (6.7)	0
Endometriosis	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypoxia	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Vascular disorders			
-Total	1 (6.7)	1 (6.7)	0
Hypotension	1 (6.7)	1 (6.7)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213c
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (100)	1 (7.7)	12 (92.3)
Blood and lymphatic system disorders			
-Total	4 (30.8)	3 (23.1)	1 (7.7)
Febrile neutropenia	4 (30.8)	3 (23.1)	1 (7.7)
Cardiac disorders			
-Total	1 (7.7)	0	1 (7.7)
Cardiac arrest	1 (7.7)	0	1 (7.7)
Gastrointestinal disorders			
-Total	2 (15.4)	1 (7.7)	0
Constipation	1 (7.7)	0	0
Nausea	1 (7.7)	0	0

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (7.7)	1 (7.7)	0
General disorders and administration site conditions			
-Total	5 (38.5)	1 (7.7)	2 (15.4)
Multiple organ dysfunction syndrome	2 (15.4)	0	2 (15.4)
Pyrexia	2 (15.4)	1 (7.7)	0
Non-cardiac chest pain	1 (7.7)	0	0
Immune system disorders			
-Total	10 (76.9)	1 (7.7)	7 (53.8)
Cytokine release syndrome	9 (69.2)	1 (7.7)	6 (46.2)
Allergy to immunoglobulin therapy	1 (7.7)	1 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	1 (7.7)
Infections and infestations			
-Total	8 (61.5)	4 (30.8)	4 (30.8)
Bacteraemia	1 (7.7)	0	1 (7.7)
Covid-19 pneumonia	1 (7.7)	0	1 (7.7)
Encephalitis viral	1 (7.7)	1 (7.7)	0
Enterobacter infection	1 (7.7)	1 (7.7)	0

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (7.7)	0	1 (7.7)
Fungaemia	1 (7.7)	0	1 (7.7)
Herpes zoster	1 (7.7)	1 (7.7)	0
Klebsiella infection	1 (7.7)	1 (7.7)	0
Mastoiditis	1 (7.7)	1 (7.7)	0
Otitis externa	1 (7.7)	1 (7.7)	0
Otitis media	1 (7.7)	1 (7.7)	0
Pharyngitis streptococcal	1 (7.7)	1 (7.7)	0
Pneumonia	1 (7.7)	0	1 (7.7)
Respiratory syncytial virus infection	1 (7.7)	1 (7.7)	0
Respiratory tract infection	1 (7.7)	1 (7.7)	0
Rhinovirus infection	1 (7.7)	0	0
Upper respiratory tract infection	1 (7.7)	1 (7.7)	0
Urinary tract infection	1 (7.7)	1 (7.7)	0
Viral upper respiratory tract infection	1 (7.7)	1 (7.7)	0
Investigations			
-Total	2 (15.4)	0	2 (15.4)
Electrocardiogram qt prolonged	1 (7.7)	0	1 (7.7)

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	1 (7.7)	0	1 (7.7)
Metabolism and nutrition disorders			
-Total	3 (23.1)	3 (23.1)	0
Hypokalaemia	1 (7.7)	1 (7.7)	0
Malnutrition	1 (7.7)	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	1 (7.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (15.4)	1 (7.7)	0
Back pain	1 (7.7)	0	0
Haemarthrosis	1 (7.7)	1 (7.7)	0
Nervous system disorders			
-Total	1 (7.7)	0	0
Cognitive disorder	1 (7.7)	0	0
Psychiatric disorders			
-Total	1 (7.7)	1 (7.7)	0
Mental status changes	1 (7.7)	1 (7.7)	0
Renal and urinary disorders			

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.7)	0	0
Acute kidney injury	1 (7.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (30.8)	1 (7.7)	2 (15.4)
Bronchial oedema	1 (7.7)	0	0
Hypoxia	1 (7.7)	1 (7.7)	0
Pleural effusion	1 (7.7)	0	1 (7.7)
Pulmonary haemorrhage	1 (7.7)	0	1 (7.7)
Respiratory failure	1 (7.7)	0	1 (7.7)
Vascular disorders			
-Total	3 (23.1)	0	3 (23.1)
Hypotension	2 (15.4)	0	2 (15.4)
Venoocclusive disease	1 (7.7)	0	1 (7.7)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213d
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	17 (94.4)	3 (16.7)	13 (72.2)
Blood and lymphatic system disorders			
-Total	7 (38.9)	5 (27.8)	2 (11.1)
Febrile neutropenia	5 (27.8)	4 (22.2)	1 (5.6)
Anaemia	2 (11.1)	0	1 (5.6)
Coagulopathy	1 (5.6)	1 (5.6)	0
Disseminated intravascular coagulation	1 (5.6)	0	0
Thrombocytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	1 (5.6)	0	1 (5.6)
Cardiac arrest	1 (5.6)	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	2 (11.1)	0	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Constipation	1 (5.6)	0	0
Nausea	1 (5.6)	0	0
General disorders and administration site conditions			
-Total	5 (27.8)	1 (5.6)	1 (5.6)
Pyrexia	3 (16.7)	1 (5.6)	0
Multiple organ dysfunction syndrome	1 (5.6)	0	1 (5.6)
Non-cardiac chest pain	1 (5.6)	0	0
Pain	1 (5.6)	0	0
Immune system disorders			
-Total	13 (72.2)	1 (5.6)	8 (44.4)
Cytokine release syndrome	13 (72.2)	1 (5.6)	8 (44.4)
Allergy to immunoglobulin therapy	1 (5.6)	1 (5.6)	0
Infections and infestations			

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (55.6)	6 (33.3)	4 (22.2)
Escherichia bacteraemia	2 (11.1)	1 (5.6)	1 (5.6)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	0	1 (5.6)
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Encephalitis viral	1 (5.6)	1 (5.6)	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Pharyngitis streptococcal	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Rhinovirus infection	1 (5.6)	0	0
Septic shock	1 (5.6)	0	1 (5.6)
Sinusitis	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	1 (5.6)	0
Upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	1 (5.6)	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Investigations			

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
Blood bilirubin increased	1 (5.6)	1 (5.6)	0
Blood uric acid increased	1 (5.6)	0	1 (5.6)
Electrocardiogram qt prolonged	1 (5.6)	0	1 (5.6)
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Tumour lysis syndrome	2 (11.1)	1 (5.6)	1 (5.6)
Malnutrition	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (22.2)	2 (11.1)	0
Back pain	2 (11.1)	1 (5.6)	0
Haemarthrosis	1 (5.6)	1 (5.6)	0
Pain in extremity	1 (5.6)	0	0
Nervous system disorders			
-Total	2 (11.1)	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (5.6)	0	1 (5.6)
Cognitive disorder	1 (5.6)	0	0
Psychiatric disorders			
-Total	2 (11.1)	1 (5.6)	0
Mental status changes	2 (11.1)	1 (5.6)	0
Renal and urinary disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Acute kidney injury	3 (16.7)	1 (5.6)	2 (11.1)
Renal failure	1 (5.6)	0	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (38.9)	1 (5.6)	5 (27.8)
Respiratory failure	2 (11.1)	0	2 (11.1)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Acute respiratory failure	1 (5.6)	1 (5.6)	0
Bronchial oedema	1 (5.6)	0	0
Hypoxia	1 (5.6)	0	1 (5.6)
Pleural effusion	1 (5.6)	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Hypotension	4 (22.2)	1 (5.6)	3 (16.7)
Flushing	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213d
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	62 (77.5)	26 (32.5)	34 (42.5)
Blood and lymphatic system disorders			
-Total	21 (26.3)	19 (23.8)	2 (2.5)
Febrile neutropenia	18 (22.5)	17 (21.3)	1 (1.3)
Disseminated intravascular coagulation	2 (2.5)	2 (2.5)	0
Pancytopenia	2 (2.5)	2 (2.5)	0
Neutropenia	1 (1.3)	1 (1.3)	0
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	9 (11.3)	4 (5.0)	4 (5.0)
Cardiac arrest	2 (2.5)	0	2 (2.5)

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (2.5)	1 (1.3)	1 (1.3)
Left ventricular dysfunction	2 (2.5)	2 (2.5)	0
Atrioventricular block first degree	1 (1.3)	0	0
Pericardial effusion	1 (1.3)	1 (1.3)	0
Tachycardia	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	9 (11.3)	7 (8.8)	1 (1.3)
Diarrhoea	2 (2.5)	1 (1.3)	0
Pancreatitis	2 (2.5)	2 (2.5)	0
Abdominal compartment syndrome	1 (1.3)	0	1 (1.3)
Anal inflammation	1 (1.3)	1 (1.3)	0
Gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0
Haemoperitoneum	1 (1.3)	0	1 (1.3)
Ileus	1 (1.3)	1 (1.3)	0
Irritable bowel syndrome	1 (1.3)	0	0
Neutropenic colitis	1 (1.3)	1 (1.3)	0
Stomatitis	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions			
-Total	13 (16.3)	1 (1.3)	2 (2.5)
Pyrexia	10 (12.5)	1 (1.3)	0
Multiple organ dysfunction syndrome	2 (2.5)	0	2 (2.5)
Oedema peripheral	1 (1.3)	0	0
Systemic inflammatory response syndrome	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	4 (5.0)	2 (2.5)	2 (2.5)
Cholestasis	1 (1.3)	0	1 (1.3)
Drug-induced liver injury	1 (1.3)	1 (1.3)	0
Hepatic cytolysis	1 (1.3)	1 (1.3)	0
Hepatomegaly	1 (1.3)	0	1 (1.3)
Immune system disorders			
-Total	38 (47.5)	15 (18.8)	14 (17.5)
Cytokine release syndrome	37 (46.3)	15 (18.8)	13 (16.3)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	2 (2.5)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Drug hypersensitivity	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	38 (47.5)	23 (28.8)	15 (18.8)
Pneumonia	4 (5.0)	2 (2.5)	2 (2.5)
Sepsis	4 (5.0)	1 (1.3)	3 (3.8)
Bronchopulmonary aspergillosis	2 (2.5)	1 (1.3)	1 (1.3)
Candida infection	2 (2.5)	0	1 (1.3)
Device related infection	2 (2.5)	2 (2.5)	0
Encephalitis	2 (2.5)	0	2 (2.5)
Gastroenteritis	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Parainfluenzae virus infection	2 (2.5)	2 (2.5)	0
Septic shock	2 (2.5)	0	2 (2.5)
Staphylococcal bacteraemia	2 (2.5)	2 (2.5)	0
Staphylococcal infection	2 (2.5)	1 (1.3)	1 (1.3)
Upper respiratory tract infection	2 (2.5)	2 (2.5)	0
Bacteraemia	1 (1.3)	1 (1.3)	0
Bronchiolitis	1 (1.3)	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	1 (1.3)	1 (1.3)	0
Covid-19	1 (1.3)	1 (1.3)	0
Covid-19 pneumonia	1 (1.3)	0	1 (1.3)
Cytomegalovirus infection reactivation	1 (1.3)	1 (1.3)	0
Device related sepsis	1 (1.3)	1 (1.3)	0
Encephalitis viral	1 (1.3)	0	1 (1.3)
Enterobacter infection	1 (1.3)	1 (1.3)	0
Fungaemia	1 (1.3)	0	1 (1.3)
Fungal skin infection	1 (1.3)	1 (1.3)	0
Gastroenteritis escherichia coli	1 (1.3)	1 (1.3)	0
Gastroenteritis salmonella	1 (1.3)	1 (1.3)	0
Human herpesvirus 6 infection	1 (1.3)	1 (1.3)	0
Klebsiella bacteraemia	1 (1.3)	1 (1.3)	0
Klebsiella infection	1 (1.3)	1 (1.3)	0
Localised infection	1 (1.3)	1 (1.3)	0
Mastoiditis	1 (1.3)	1 (1.3)	0
Meningitis bacterial	1 (1.3)	1 (1.3)	0
Meningitis pneumococcal	1 (1.3)	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metapneumovirus infection	1 (1.3)	1 (1.3)	0
Ophthalmic herpes zoster	1 (1.3)	0	0
Otitis externa	1 (1.3)	1 (1.3)	0
Otitis media	1 (1.3)	1 (1.3)	0
Paronychia	1 (1.3)	1 (1.3)	0
Pneumocystis jirovecii pneumonia	1 (1.3)	0	1 (1.3)
Pneumonia fungal	1 (1.3)	1 (1.3)	0
Pneumonia respiratory syncytial viral	1 (1.3)	1 (1.3)	0
Pneumonia viral	1 (1.3)	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	1 (1.3)	0
Respiratory tract infection	1 (1.3)	1 (1.3)	0
Rhinovirus infection	1 (1.3)	1 (1.3)	0
Serratia sepsis	1 (1.3)	0	1 (1.3)
Sialoadenitis	1 (1.3)	1 (1.3)	0
Sinusitis	1 (1.3)	1 (1.3)	0
Soft tissue infection	1 (1.3)	1 (1.3)	0
Staphylococcal abscess	1 (1.3)	1 (1.3)	0
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (1.3)	1 (1.3)	0
Systemic mycosis	1 (1.3)	1 (1.3)	0
Varicella zoster virus infection	1 (1.3)	1 (1.3)	0
Vascular device infection	1 (1.3)	1 (1.3)	0
Viral haemorrhagic cystitis	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	4 (5.0)	1 (1.3)	2 (2.5)
Infusion related reaction	1 (1.3)	1 (1.3)	0
Tracheal obstruction	1 (1.3)	0	1 (1.3)
Transfusion reaction	1 (1.3)	0	0
Vasoplegia syndrome	1 (1.3)	0	1 (1.3)
Investigations			
-Total	4 (5.0)	2 (2.5)	2 (2.5)
Amylase increased	1 (1.3)	0	1 (1.3)
Aspartate aminotransferase increased	1 (1.3)	1 (1.3)	0
C-reactive protein increased	1 (1.3)	1 (1.3)	0
Neutrophil count decreased	1 (1.3)	0	1 (1.3)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	8 (10.0)	2 (2.5)	5 (6.3)
Decreased appetite	1 (1.3)	0	1 (1.3)
Dehydration	1 (1.3)	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0
Hyperkalaemia	1 (1.3)	0	1 (1.3)
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hyperphosphataemia	1 (1.3)	0	1 (1.3)
Hypervolaemia	1 (1.3)	1 (1.3)	0
Hypokalaemia	1 (1.3)	1 (1.3)	0
Hyponatraemia	1 (1.3)	0	1 (1.3)
Metabolic acidosis	1 (1.3)	0	1 (1.3)
Tumour lysis syndrome	1 (1.3)	0	1 (1.3)
Musculoskeletal and connective tissue disorders			
-Total	3 (3.8)	1 (1.3)	1 (1.3)
Back pain	1 (1.3)	1 (1.3)	0
Pain in extremity	1 (1.3)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhabdomyolysis	1 (1.3)	0	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.5)	2 (2.5)	0
Bone giant cell tumour benign	1 (1.3)	1 (1.3)	0
Myelodysplastic syndrome	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	8 (10.0)	6 (7.5)	2 (2.5)
Encephalopathy	2 (2.5)	2 (2.5)	0
Headache	2 (2.5)	2 (2.5)	0
Seizure	2 (2.5)	1 (1.3)	0
Dysarthria	1 (1.3)	1 (1.3)	0
Haemorrhage intracranial	1 (1.3)	0	1 (1.3)
Hydrocephalus	1 (1.3)	0	1 (1.3)
Nervous system disorder	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	2 (2.5)	2 (2.5)	0
Delirium	1 (1.3)	1 (1.3)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	4 (5.0)	2 (2.5)	1 (1.3)
Acute kidney injury	3 (3.8)	1 (1.3)	1 (1.3)
Renal tubular necrosis	2 (2.5)	1 (1.3)	1 (1.3)
Reproductive system and breast disorders			
-Total	1 (1.3)	1 (1.3)	0
Endometriosis	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (21.3)	4 (5.0)	11 (13.8)
Respiratory failure	7 (8.8)	0	7 (8.8)
Hypoxia	4 (5.0)	3 (3.8)	1 (1.3)
Acute respiratory distress syndrome	2 (2.5)	0	2 (2.5)
Epistaxis	2 (2.5)	1 (1.3)	0
Pleural effusion	2 (2.5)	1 (1.3)	0
Pulmonary oedema	2 (2.5)	1 (1.3)	1 (1.3)
Respiratory distress	2 (2.5)	0	1 (1.3)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Dyspnoea	1 (1.3)	0	1 (1.3)
Dyspnoea exertional	1 (1.3)	0	0
Laryngeal oedema	1 (1.3)	0	1 (1.3)
Pulmonary haemorrhage	1 (1.3)	0	1 (1.3)
Vascular disorders			
-Total	8 (10.0)	2 (2.5)	6 (7.5)
Hypotension	7 (8.8)	2 (2.5)	5 (6.3)
Venoocclusive disease	1 (1.3)	0	1 (1.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213e
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (87.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Febrile neutropenia	2 (25.0)	1 (12.5)	1 (12.5)
Coagulopathy	1 (12.5)	1 (12.5)	0
Cardiac disorders			
-Total	1 (12.5)	0	1 (12.5)
Tachycardia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	0	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Haemoperitoneum	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (12.5)	0	0
General disorders and administration site conditions			
-Total	3 (37.5)	0	1 (12.5)
Pyrexia	2 (25.0)	0	0
Multiple organ dysfunction syndrome	1 (12.5)	0	1 (12.5)
Systemic inflammatory response syndrome	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Cholestasis	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	4 (50.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	6 (75.0)	3 (37.5)	3 (37.5)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (12.5)	0	1 (12.5)
Gastroenteritis escherichia coli	1 (12.5)	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	0	1 (12.5)
Vasoplegia syndrome	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	0	1 (12.5)
Rhabdomyolysis	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Encephalopathy	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	2 (25.0)	1 (12.5)	1 (12.5)
Renal tubular necrosis	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Respiratory failure	2 (25.0)	0	2 (25.0)
Acute respiratory distress syndrome	1 (12.5)	0	1 (12.5)
Acute respiratory failure	1 (12.5)	1 (12.5)	0
Dyspnoea	1 (12.5)	0	1 (12.5)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213e
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	72 (80.0)	27 (30.0)	42 (46.7)
Blood and lymphatic system disorders			
-Total	25 (27.8)	22 (24.4)	3 (3.3)
Febrile neutropenia	21 (23.3)	20 (22.2)	1 (1.1)
Disseminated intravascular coagulation	3 (3.3)	2 (2.2)	0
Anaemia	2 (2.2)	0	1 (1.1)
Pancytopenia	2 (2.2)	2 (2.2)	0
Thrombocytopenia	2 (2.2)	1 (1.1)	1 (1.1)
Neutropenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	9 (10.0)	4 (4.4)	4 (4.4)
Cardiac arrest	3 (3.3)	0	3 (3.3)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	3 (3.3)	2 (2.2)	1 (1.1)
Left ventricular dysfunction	2 (2.2)	2 (2.2)	0
Atrioventricular block first degree	1 (1.1)	0	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders			
-Total	9 (10.0)	7 (7.8)	1 (1.1)
Diarrhoea	2 (2.2)	1 (1.1)	0
Pancreatitis	2 (2.2)	2 (2.2)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
Anal inflammation	1 (1.1)	1 (1.1)	0
Constipation	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Ileus	1 (1.1)	1 (1.1)	0
Nausea	1 (1.1)	0	0
Neutropenic colitis	1 (1.1)	1 (1.1)	0
Stomatitis	1 (1.1)	1 (1.1)	0
Vomiting	1 (1.1)	0	0
General disorders and administration site conditions			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (16.7)	2 (2.2)	2 (2.2)
Pyrexia	11 (12.2)	2 (2.2)	0
Multiple organ dysfunction syndrome	2 (2.2)	0	2 (2.2)
Non-cardiac chest pain	1 (1.1)	0	0
Oedema peripheral	1 (1.1)	0	0
Pain	1 (1.1)	0	0
Hepatobiliary disorders			
-Total	3 (3.3)	2 (2.2)	1 (1.1)
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatic cytolysis	1 (1.1)	1 (1.1)	0
Hepatomegaly	1 (1.1)	0	1 (1.1)
Immune system disorders			
-Total	47 (52.2)	16 (17.8)	20 (22.2)
Cytokine release syndrome	46 (51.1)	16 (17.8)	19 (21.1)
Allergy to immunoglobulin therapy	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	1 (1.1)	1 (1.1)	0
Haemophagocytic lymphohistiocytosis	1 (1.1)	0	1 (1.1)
Infections and infestations			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	42 (46.7)	26 (28.9)	16 (17.8)
Sepsis	4 (4.4)	1 (1.1)	3 (3.3)
Pneumonia	3 (3.3)	1 (1.1)	2 (2.2)
Septic shock	3 (3.3)	0	3 (3.3)
Upper respiratory tract infection	3 (3.3)	3 (3.3)	0
Bacteraemia	2 (2.2)	1 (1.1)	1 (1.1)
Bronchopulmonary aspergillosis	2 (2.2)	1 (1.1)	1 (1.1)
Candida infection	2 (2.2)	0	1 (1.1)
Device related infection	2 (2.2)	2 (2.2)	0
Encephalitis viral	2 (2.2)	1 (1.1)	1 (1.1)
Escherichia bacteraemia	2 (2.2)	1 (1.1)	1 (1.1)
Gastroenteritis	2 (2.2)	2 (2.2)	0
Herpes zoster	2 (2.2)	2 (2.2)	0
Parainfluenzae virus infection	2 (2.2)	2 (2.2)	0
Respiratory syncytial virus infection	2 (2.2)	2 (2.2)	0
Rhinovirus infection	2 (2.2)	1 (1.1)	0
Sinusitis	2 (2.2)	2 (2.2)	0
Staphylococcal bacteraemia	2 (2.2)	2 (2.2)	0
Aspergillus infection	1 (1.1)	0	1 (1.1)

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (1.1)	1 (1.1)	0
Covid-19	1 (1.1)	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Encephalitis	1 (1.1)	0	1 (1.1)
Enterobacter infection	1 (1.1)	1 (1.1)	0
Fungaemia	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	1 (1.1)	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	1 (1.1)	0
Klebsiella infection	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Mastoiditis	1 (1.1)	1 (1.1)	0
Meningitis bacterial	1 (1.1)	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	1 (1.1)	0
Metapneumovirus infection	1 (1.1)	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	0
Otitis externa	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (1.1)	1 (1.1)	0
Paronychia	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	1 (1.1)
Pneumonia fungal	1 (1.1)	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	1 (1.1)	0
Pneumonia viral	1 (1.1)	1 (1.1)	0
Respiratory tract infection	1 (1.1)	1 (1.1)	0
Sialoadenitis	1 (1.1)	1 (1.1)	0
Soft tissue infection	1 (1.1)	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	1 (1.1)	0
Staphylococcal infection	1 (1.1)	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	1 (1.1)
Staphylococcal skin infection	1 (1.1)	1 (1.1)	0
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Varicella zoster virus infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral haemorrhagic cystitis	1 (1.1)	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	1 (1.1)	0
Injury, poisoning and procedural complications			
-Total	3 (3.3)	1 (1.1)	1 (1.1)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Investigations			
-Total	7 (7.8)	3 (3.3)	4 (4.4)
Aspartate aminotransferase increased	2 (2.2)	2 (2.2)	0
Neutrophil count decreased	2 (2.2)	0	2 (2.2)
Amylase increased	1 (1.1)	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	1 (1.1)	0
Blood uric acid increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (11.1)	4 (4.4)	5 (5.6)
Tumour lysis syndrome	3 (3.3)	1 (1.1)	2 (2.2)
Decreased appetite	1 (1.1)	0	1 (1.1)
Dehydration	1 (1.1)	0	0
Hypercalcaemia	1 (1.1)	1 (1.1)	0
Hyperkalaemia	1 (1.1)	0	1 (1.1)
Hyperphosphataemia	1 (1.1)	0	1 (1.1)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hypokalaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Malnutrition	1 (1.1)	1 (1.1)	0
Metabolic acidosis	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	6 (6.7)	3 (3.3)	0
Back pain	3 (3.3)	2 (2.2)	0
Pain in extremity	2 (2.2)	0	0
Haemarthrosis	1 (1.1)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.2)	2 (2.2)	0
Bone giant cell tumour benign	1 (1.1)	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	1 (1.1)	0
Nervous system disorders			
-Total	9 (10.0)	5 (5.6)	3 (3.3)
Headache	2 (2.2)	2 (2.2)	0
Seizure	2 (2.2)	1 (1.1)	0
Cerebral haemorrhage	1 (1.1)	0	1 (1.1)
Cognitive disorder	1 (1.1)	0	0
Dysarthria	1 (1.1)	1 (1.1)	0
Encephalopathy	1 (1.1)	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	1 (1.1)
Hydrocephalus	1 (1.1)	0	1 (1.1)
Nervous system disorder	1 (1.1)	1 (1.1)	0
Psychiatric disorders			
-Total	4 (4.4)	3 (3.3)	0
Mental status changes	3 (3.3)	2 (2.2)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (1.1)	1 (1.1)	0
Renal and urinary disorders			
-Total	6 (6.7)	2 (2.2)	3 (3.3)
Acute kidney injury	4 (4.4)	1 (1.1)	2 (2.2)
Renal failure	1 (1.1)	0	1 (1.1)
Renal tubular necrosis	1 (1.1)	1 (1.1)	0
Reproductive system and breast disorders			
-Total	1 (1.1)	1 (1.1)	0
Endometriosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	20 (22.2)	4 (4.4)	13 (14.4)
Respiratory failure	7 (7.8)	0	7 (7.8)
Hypoxia	5 (5.6)	3 (3.3)	2 (2.2)
Pleural effusion	3 (3.3)	1 (1.1)	1 (1.1)
Acute respiratory distress syndrome	2 (2.2)	0	2 (2.2)
Epistaxis	2 (2.2)	1 (1.1)	0
Respiratory distress	2 (2.2)	0	1 (1.1)

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=90 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Bronchial oedema	1 (1.1)	0	0
Dyspnoea exertional	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	1 (1.1)
Pulmonary haemorrhage	1 (1.1)	0	1 (1.1)
Pulmonary oedema	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	11 (12.2)	3 (3.3)	8 (8.9)
Hypotension	10 (11.1)	3 (3.3)	7 (7.8)
Flushing	1 (1.1)	0	0
Venoocclusive disease	1 (1.1)	0	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213f
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
Pancytopenia	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	1 (50.0)	0
Sepsis	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)
Tumour lysis syndrome	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	0	1 (50.0)
Pleural effusion	2 (100)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213f
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	77 (80.2)	29 (30.2)	45 (46.9)
Blood and lymphatic system disorders			
-Total	27 (28.1)	23 (24.0)	4 (4.2)
Febrile neutropenia	23 (24.0)	21 (21.9)	2 (2.1)
Anaemia	2 (2.1)	0	1 (1.0)
Disseminated intravascular coagulation	2 (2.1)	1 (1.0)	0
Thrombocytopenia	2 (2.1)	1 (1.0)	1 (1.0)
Coagulopathy	1 (1.0)	1 (1.0)	0
Neutropenia	1 (1.0)	1 (1.0)	0
Pancytopenia	1 (1.0)	1 (1.0)	0
Cardiac disorders			
-Total	10 (10.4)	4 (4.2)	5 (5.2)

Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=96	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	3 (3.1)	0	3 (3.1)
Cardiac failure	3 (3.1)	2 (2.1)	1 (1.0)
Left ventricular dysfunction	2 (2.1)	2 (2.1)	0
Atrioventricular block first degree	1 (1.0)	0	0
Pericardial effusion	1 (1.0)	1 (1.0)	0
Tachycardia	1 (1.0)	0	1 (1.0)
Gastrointestinal disorders			
-Total	11 (11.5)	7 (7.3)	2 (2.1)
Abdominal compartment syndrome	2 (2.1)	0	2 (2.1)
Diarrhoea	2 (2.1)	1 (1.0)	0
Pancreatitis	2 (2.1)	2 (2.1)	0
Anal inflammation	1 (1.0)	1 (1.0)	0
Constipation	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	1 (1.0)
Ileus	1 (1.0)	1 (1.0)	0
Irritable bowel syndrome	1 (1.0)	0	0
Nausea	1 (1.0)	0	0
Neutropenic colitis	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.0)	1 (1.0)	0
Vomiting	1 (1.0)	0	0
General disorders and administration site conditions			
-Total	17 (17.7)	1 (1.0)	3 (3.1)
Pyrexia	12 (12.5)	1 (1.0)	0
Multiple organ dysfunction syndrome	3 (3.1)	0	3 (3.1)
Non-cardiac chest pain	1 (1.0)	0	0
Oedema peripheral	1 (1.0)	0	0
Pain	1 (1.0)	0	0
Systemic inflammatory response syndrome	1 (1.0)	1 (1.0)	0
Hepatobiliary disorders			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Cholestasis	1 (1.0)	0	1 (1.0)
Drug-induced liver injury	1 (1.0)	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	1 (1.0)	0
Hepatomegaly	1 (1.0)	0	1 (1.0)
Immune system disorders			

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	49 (51.0)	15 (15.6)	21 (21.9)
Cytokine release syndrome	48 (50.0)	15 (15.6)	20 (20.8)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	2 (2.1)
Allergy to immunoglobulin therapy	1 (1.0)	1 (1.0)	0
Drug hypersensitivity	1 (1.0)	1 (1.0)	0
Infections and infestations			
-Total	46 (47.9)	28 (29.2)	18 (18.8)
Pneumonia	4 (4.2)	2 (2.1)	2 (2.1)
Sepsis	3 (3.1)	0	3 (3.1)
Septic shock	3 (3.1)	0	3 (3.1)
Staphylococcal bacteraemia	3 (3.1)	3 (3.1)	0
Bacteraemia	2 (2.1)	1 (1.0)	1 (1.0)
Bronchopulmonary aspergillosis	2 (2.1)	1 (1.0)	1 (1.0)
Candida infection	2 (2.1)	0	1 (1.0)
Device related infection	2 (2.1)	2 (2.1)	0
Encephalitis viral	2 (2.1)	1 (1.0)	1 (1.0)
Escherichia bacteraemia	2 (2.1)	1 (1.0)	1 (1.0)
Gastroenteritis	2 (2.1)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	2 (2.1)	2 (2.1)	0
Parainfluenzae virus infection	2 (2.1)	2 (2.1)	0
Rhinovirus infection	2 (2.1)	1 (1.0)	0
Sinusitis	2 (2.1)	2 (2.1)	0
Staphylococcal infection	2 (2.1)	1 (1.0)	1 (1.0)
Upper respiratory tract infection	2 (2.1)	2 (2.1)	0
Aspergillus infection	1 (1.0)	0	1 (1.0)
Bronchiolitis	1 (1.0)	1 (1.0)	0
Clostridium difficile colitis	1 (1.0)	1 (1.0)	0
Covid-19	1 (1.0)	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	1 (1.0)
Cytomegalovirus infection reactivation	1 (1.0)	1 (1.0)	0
Device related sepsis	1 (1.0)	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	1 (1.0)
Encephalitis	1 (1.0)	0	1 (1.0)
Enterobacter infection	1 (1.0)	1 (1.0)	0
Fungaemia	1 (1.0)	0	1 (1.0)
Fungal skin infection	1 (1.0)	1 (1.0)	0
Gastroenteritis escherichia coli	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis salmonella	1 (1.0)	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	1 (1.0)	1 (1.0)	0
Klebsiella bacteraemia	1 (1.0)	1 (1.0)	0
Klebsiella infection	1 (1.0)	1 (1.0)	0
Localised infection	1 (1.0)	1 (1.0)	0
Mastoiditis	1 (1.0)	1 (1.0)	0
Meningitis bacterial	1 (1.0)	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	1 (1.0)	0
Metapneumovirus infection	1 (1.0)	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	0
Otitis externa	1 (1.0)	1 (1.0)	0
Otitis media	1 (1.0)	1 (1.0)	0
Paronychia	1 (1.0)	1 (1.0)	0
Pharyngitis	1 (1.0)	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	1 (1.0)	0
Pneumocystis jirovecii pneumonia	1 (1.0)	0	1 (1.0)
Pneumonia fungal	1 (1.0)	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.0)	1 (1.0)	0
Respiratory syncytial virus infection	1 (1.0)	1 (1.0)	0
Respiratory tract infection	1 (1.0)	1 (1.0)	0
Serratia sepsis	1 (1.0)	0	1 (1.0)
Sialoadenitis	1 (1.0)	1 (1.0)	0
Soft tissue infection	1 (1.0)	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	1 (1.0)	0
Staphylococcal sepsis	1 (1.0)	0	1 (1.0)
Staphylococcal skin infection	1 (1.0)	1 (1.0)	0
Systemic mycosis	1 (1.0)	1 (1.0)	0
Urinary tract infection	1 (1.0)	1 (1.0)	0
Varicella zoster virus infection	1 (1.0)	1 (1.0)	0
Vascular device infection	1 (1.0)	1 (1.0)	0
Viral upper respiratory tract infection	1 (1.0)	1 (1.0)	0
Injury, poisoning and procedural complications			
-Total	4 (4.2)	1 (1.0)	2 (2.1)
Infusion related reaction	1 (1.0)	1 (1.0)	0
Tracheal obstruction	1 (1.0)	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	1 (1.0)	0	0
Vasoplegia syndrome	1 (1.0)	0	1 (1.0)
Investigations			
-Total	7 (7.3)	3 (3.1)	4 (4.2)
Aspartate aminotransferase increased	2 (2.1)	2 (2.1)	0
Neutrophil count decreased	2 (2.1)	0	2 (2.1)
Amylase increased	1 (1.0)	0	1 (1.0)
Blood bilirubin increased	1 (1.0)	1 (1.0)	0
Blood uric acid increased	1 (1.0)	0	1 (1.0)
C-reactive protein increased	1 (1.0)	1 (1.0)	0
Electrocardiogram qt prolonged	1 (1.0)	0	1 (1.0)
Metabolism and nutrition disorders			
-Total	9 (9.4)	3 (3.1)	5 (5.2)
Tumour lysis syndrome	2 (2.1)	0	2 (2.1)
Dehydration	1 (1.0)	0	0
Hypercalcaemia	1 (1.0)	1 (1.0)	0
Hyperkalaemia	1 (1.0)	0	1 (1.0)
Hypernatraemia	1 (1.0)	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (1.0)	0	1 (1.0)
Hypervolaemia	1 (1.0)	1 (1.0)	0
Hypokalaemia	1 (1.0)	1 (1.0)	0
Hyponatraemia	1 (1.0)	0	1 (1.0)
Malnutrition	1 (1.0)	1 (1.0)	0
Metabolic acidosis	1 (1.0)	0	1 (1.0)
Musculoskeletal and connective tissue disorders			
-Total	7 (7.3)	3 (3.1)	1 (1.0)
Back pain	3 (3.1)	2 (2.1)	0
Pain in extremity	2 (2.1)	0	0
Haemarthrosis	1 (1.0)	1 (1.0)	0
Rhabdomyolysis	1 (1.0)	0	1 (1.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.1)	2 (2.1)	0
Bone giant cell tumour benign	1 (1.0)	1 (1.0)	0
Myelodysplastic syndrome	1 (1.0)	1 (1.0)	0
Nervous system disorders			

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (10.4)	6 (6.3)	3 (3.1)
Encephalopathy	2 (2.1)	2 (2.1)	0
Headache	2 (2.1)	2 (2.1)	0
Seizure	2 (2.1)	1 (1.0)	0
Cerebral haemorrhage	1 (1.0)	0	1 (1.0)
Cognitive disorder	1 (1.0)	0	0
Dysarthria	1 (1.0)	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	1 (1.0)
Hydrocephalus	1 (1.0)	0	1 (1.0)
Nervous system disorder	1 (1.0)	1 (1.0)	0
Psychiatric disorders			
-Total	4 (4.2)	3 (3.1)	0
Mental status changes	3 (3.1)	2 (2.1)	0
Delirium	1 (1.0)	1 (1.0)	0
Renal and urinary disorders			
-Total	8 (8.3)	3 (3.1)	4 (4.2)
Acute kidney injury	6 (6.3)	2 (2.1)	3 (3.1)
Renal tubular necrosis	2 (2.1)	1 (1.0)	1 (1.0)
Renal failure	1 (1.0)	0	1 (1.0)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (1.0)	1 (1.0)	0
Endometriosis	1 (1.0)	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	22 (22.9)	5 (5.2)	15 (15.6)
Respiratory failure	9 (9.4)	0	9 (9.4)
Hypoxia	5 (5.2)	3 (3.1)	2 (2.1)
Acute respiratory distress syndrome	3 (3.1)	0	3 (3.1)
Epistaxis	2 (2.1)	1 (1.0)	0
Pulmonary oedema	2 (2.1)	1 (1.0)	1 (1.0)
Respiratory distress	2 (2.1)	0	1 (1.0)
Acute respiratory failure	1 (1.0)	1 (1.0)	0
Bronchial oedema	1 (1.0)	0	0
Dyspnoea	1 (1.0)	0	1 (1.0)
Dyspnoea exertional	1 (1.0)	0	0
Laryngeal oedema	1 (1.0)	0	1 (1.0)
Pleural effusion	1 (1.0)	1 (1.0)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary haemorrhage	1 (1.0)	0	1 (1.0)
Vascular disorders			
-Total	12 (12.5)	3 (3.1)	9 (9.4)
Hypotension	11 (11.5)	3 (3.1)	8 (8.3)
Flushing	1 (1.0)	0	0
Venoocclusive disease	1 (1.0)	0	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213g
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	79 (81.4)	29 (29.9)	47 (48.5)
Blood and lymphatic system disorders			
-Total	28 (28.9)	24 (24.7)	4 (4.1)
Febrile neutropenia	23 (23.7)	21 (21.6)	2 (2.1)
Disseminated intravascular coagulation	3 (3.1)	2 (2.1)	0
Anaemia	2 (2.1)	0	1 (1.0)
Pancytopenia	2 (2.1)	2 (2.1)	0
Thrombocytopenia	2 (2.1)	1 (1.0)	1 (1.0)
Coagulopathy	1 (1.0)	1 (1.0)	0
Neutropenia	1 (1.0)	1 (1.0)	0
Cardiac disorders			
-Total	10 (10.3)	4 (4.1)	5 (5.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	3 (3.1)	0	3 (3.1)
Cardiac failure	3 (3.1)	2 (2.1)	1 (1.0)
Left ventricular dysfunction	2 (2.1)	2 (2.1)	0
Atrioventricular block first degree	1 (1.0)	0	0
Pericardial effusion	1 (1.0)	1 (1.0)	0
Tachycardia	1 (1.0)	0	1 (1.0)
Gastrointestinal disorders			
-Total	11 (11.3)	7 (7.2)	2 (2.1)
Abdominal compartment syndrome	2 (2.1)	0	2 (2.1)
Diarrhoea	2 (2.1)	1 (1.0)	0
Pancreatitis	2 (2.1)	2 (2.1)	0
Anal inflammation	1 (1.0)	1 (1.0)	0
Constipation	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	1 (1.0)
Ileus	1 (1.0)	1 (1.0)	0
Irritable bowel syndrome	1 (1.0)	0	0
Nausea	1 (1.0)	0	0
Neutropenic colitis	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.0)	1 (1.0)	0
Vomiting	1 (1.0)	0	0
General disorders and administration site conditions			
-Total	18 (18.6)	2 (2.1)	3 (3.1)
Pyrexia	13 (13.4)	2 (2.1)	0
Multiple organ dysfunction syndrome	3 (3.1)	0	3 (3.1)
Non-cardiac chest pain	1 (1.0)	0	0
Oedema peripheral	1 (1.0)	0	0
Pain	1 (1.0)	0	0
Systemic inflammatory response syndrome	1 (1.0)	1 (1.0)	0
Hepatobiliary disorders			
-Total	4 (4.1)	2 (2.1)	2 (2.1)
Cholestasis	1 (1.0)	0	1 (1.0)
Drug-induced liver injury	1 (1.0)	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	1 (1.0)	0
Hepatomegaly	1 (1.0)	0	1 (1.0)
Immune system disorders			

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	51 (52.6)	16 (16.5)	22 (22.7)
Cytokine release syndrome	50 (51.5)	16 (16.5)	21 (21.6)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	2 (2.1)
Allergy to immunoglobulin therapy	1 (1.0)	1 (1.0)	0
Drug hypersensitivity	1 (1.0)	1 (1.0)	0
Infections and infestations			
-Total	48 (49.5)	29 (29.9)	19 (19.6)
Pneumonia	4 (4.1)	2 (2.1)	2 (2.1)
Sepsis	4 (4.1)	1 (1.0)	3 (3.1)
Septic shock	3 (3.1)	0	3 (3.1)
Staphylococcal bacteraemia	3 (3.1)	3 (3.1)	0
Upper respiratory tract infection	3 (3.1)	3 (3.1)	0
Bacteraemia	2 (2.1)	1 (1.0)	1 (1.0)
Bronchopulmonary aspergillosis	2 (2.1)	1 (1.0)	1 (1.0)
Candida infection	2 (2.1)	0	1 (1.0)
Device related infection	2 (2.1)	2 (2.1)	0
Encephalitis	2 (2.1)	0	2 (2.1)
Encephalitis viral	2 (2.1)	1 (1.0)	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	2 (2.1)	1 (1.0)	1 (1.0)
Gastroenteritis	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Parainfluenzae virus infection	2 (2.1)	2 (2.1)	0
Respiratory syncytial virus infection	2 (2.1)	2 (2.1)	0
Rhinovirus infection	2 (2.1)	1 (1.0)	0
Sinusitis	2 (2.1)	2 (2.1)	0
Staphylococcal infection	2 (2.1)	1 (1.0)	1 (1.0)
Aspergillus infection	1 (1.0)	0	1 (1.0)
Bronchiolitis	1 (1.0)	1 (1.0)	0
Clostridium difficile colitis	1 (1.0)	1 (1.0)	0
Covid-19	1 (1.0)	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	1 (1.0)
Cytomegalovirus infection reactivation	1 (1.0)	1 (1.0)	0
Device related sepsis	1 (1.0)	1 (1.0)	0
Disseminated trichosporonosis	1 (1.0)	0	1 (1.0)
Enterobacter infection	1 (1.0)	1 (1.0)	0
Fungaemia	1 (1.0)	0	1 (1.0)
Fungal skin infection	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis escherichia coli	1 (1.0)	1 (1.0)	0
Gastroenteritis salmonella	1 (1.0)	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	1 (1.0)	1 (1.0)	0
Klebsiella bacteraemia	1 (1.0)	1 (1.0)	0
Klebsiella infection	1 (1.0)	1 (1.0)	0
Localised infection	1 (1.0)	1 (1.0)	0
Mastoiditis	1 (1.0)	1 (1.0)	0
Meningitis bacterial	1 (1.0)	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	1 (1.0)	0
Metapneumovirus infection	1 (1.0)	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	0
Otitis externa	1 (1.0)	1 (1.0)	0
Otitis media	1 (1.0)	1 (1.0)	0
Paronychia	1 (1.0)	1 (1.0)	0
Pharyngitis	1 (1.0)	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	1 (1.0)	0
Pneumocystis jirovecii pneumonia	1 (1.0)	0	1 (1.0)
Pneumonia fungal	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (1.0)	1 (1.0)	0
Pneumonia viral	1 (1.0)	1 (1.0)	0
Respiratory tract infection	1 (1.0)	1 (1.0)	0
Serratia sepsis	1 (1.0)	0	1 (1.0)
Sialoadenitis	1 (1.0)	1 (1.0)	0
Soft tissue infection	1 (1.0)	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	1 (1.0)	0
Staphylococcal sepsis	1 (1.0)	0	1 (1.0)
Staphylococcal skin infection	1 (1.0)	1 (1.0)	0
Systemic mycosis	1 (1.0)	1 (1.0)	0
Urinary tract infection	1 (1.0)	1 (1.0)	0
Varicella zoster virus infection	1 (1.0)	1 (1.0)	0
Vascular device infection	1 (1.0)	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	1 (1.0)	0
Viral upper respiratory tract infection	1 (1.0)	1 (1.0)	0
Injury, poisoning and procedural complications			
-Total	4 (4.1)	1 (1.0)	2 (2.1)
Infusion related reaction	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal obstruction	1 (1.0)	0	1 (1.0)
Transfusion reaction	1 (1.0)	0	0
Vasoplegia syndrome	1 (1.0)	0	1 (1.0)
Investigations			
-Total	7 (7.2)	3 (3.1)	4 (4.1)
Aspartate aminotransferase increased	2 (2.1)	2 (2.1)	0
Neutrophil count decreased	2 (2.1)	0	2 (2.1)
Amylase increased	1 (1.0)	0	1 (1.0)
Blood bilirubin increased	1 (1.0)	1 (1.0)	0
Blood uric acid increased	1 (1.0)	0	1 (1.0)
C-reactive protein increased	1 (1.0)	1 (1.0)	0
Electrocardiogram qt prolonged	1 (1.0)	0	1 (1.0)
Metabolism and nutrition disorders			
-Total	11 (11.3)	4 (4.1)	6 (6.2)
Tumour lysis syndrome	3 (3.1)	1 (1.0)	2 (2.1)
Decreased appetite	1 (1.0)	0	1 (1.0)
Dehydration	1 (1.0)	0	0
Hypercalcaemia	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (1.0)	0	1 (1.0)
Hypernatraemia	1 (1.0)	0	1 (1.0)
Hyperphosphataemia	1 (1.0)	0	1 (1.0)
Hypervolaemia	1 (1.0)	1 (1.0)	0
Hypokalaemia	1 (1.0)	1 (1.0)	0
Hyponatraemia	1 (1.0)	0	1 (1.0)
Malnutrition	1 (1.0)	1 (1.0)	0
Metabolic acidosis	1 (1.0)	0	1 (1.0)
Musculoskeletal and connective tissue disorders			
-Total	7 (7.2)	3 (3.1)	1 (1.0)
Back pain	3 (3.1)	2 (2.1)	0
Pain in extremity	2 (2.1)	0	0
Haemarthrosis	1 (1.0)	1 (1.0)	0
Rhabdomyolysis	1 (1.0)	0	1 (1.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.1)	2 (2.1)	0
Bone giant cell tumour benign	1 (1.0)	1 (1.0)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.0)	1 (1.0)	0
Nervous system disorders			
-Total	10 (10.3)	6 (6.2)	3 (3.1)
Encephalopathy	2 (2.1)	2 (2.1)	0
Headache	2 (2.1)	2 (2.1)	0
Seizure	2 (2.1)	1 (1.0)	0
Cerebral haemorrhage	1 (1.0)	0	1 (1.0)
Cognitive disorder	1 (1.0)	0	0
Dysarthria	1 (1.0)	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	1 (1.0)
Hydrocephalus	1 (1.0)	0	1 (1.0)
Nervous system disorder	1 (1.0)	1 (1.0)	0
Psychiatric disorders			
-Total	4 (4.1)	3 (3.1)	0
Mental status changes	3 (3.1)	2 (2.1)	0
Delirium	1 (1.0)	1 (1.0)	0
Renal and urinary disorders			
-Total	8 (8.2)	3 (3.1)	4 (4.1)
Acute kidney injury	6 (6.2)	2 (2.1)	3 (3.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=97		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	2 (2.1)	1 (1.0)	1 (1.0)
Renal failure	1 (1.0)	0	1 (1.0)
Reproductive system and breast disorders			
-Total	1 (1.0)	1 (1.0)	0
Endometriosis	1 (1.0)	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	24 (24.7)	5 (5.2)	16 (16.5)
Respiratory failure	9 (9.3)	0	9 (9.3)
Hypoxia	5 (5.2)	3 (3.1)	2 (2.1)
Acute respiratory distress syndrome	3 (3.1)	0	3 (3.1)
Pleural effusion	3 (3.1)	1 (1.0)	1 (1.0)
Epistaxis	2 (2.1)	1 (1.0)	0
Pulmonary oedema	2 (2.1)	1 (1.0)	1 (1.0)
Respiratory distress	2 (2.1)	0	1 (1.0)
Acute respiratory failure	1 (1.0)	1 (1.0)	0
Bronchial oedema	1 (1.0)	0	0
Dyspnoea	1 (1.0)	0	1 (1.0)

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=97 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Dyspnoea exertional	1 (1.0)	0	0
Laryngeal oedema	1 (1.0)	0	1 (1.0)
Pulmonary haemorrhage	1 (1.0)	0	1 (1.0)
Vascular disorders			
-Total	12 (12.4)	3 (3.1)	9 (9.3)
Hypotension	11 (11.3)	3 (3.1)	8 (8.2)
Flushing	1 (1.0)	0	0
Venoocclusive disease	1 (1.0)	0	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213h
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	2 (66.7)	1 (33.3)	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)
Haemoperitoneum	1 (33.3)	0	1 (33.3)
General disorders and administration site conditions			
-Total	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypotension	1 (33.3)	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213h
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	77 (81.1)	28 (29.5)	46 (48.4)
Blood and lymphatic system disorders			
-Total	28 (29.5)	24 (25.3)	4 (4.2)
Febrile neutropenia	23 (24.2)	21 (22.1)	2 (2.1)
Disseminated intravascular coagulation	3 (3.2)	2 (2.1)	0
Anaemia	2 (2.1)	0	1 (1.1)
Pancytopenia	2 (2.1)	2 (2.1)	0
Thrombocytopenia	2 (2.1)	1 (1.1)	1 (1.1)
Coagulopathy	1 (1.1)	1 (1.1)	0
Neutropenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (9.5)	3 (3.2)	5 (5.3)
Cardiac arrest	3 (3.2)	0	3 (3.2)
Cardiac failure	3 (3.2)	2 (2.1)	1 (1.1)
Atrioventricular block first degree	1 (1.1)	0	0
Left ventricular dysfunction	1 (1.1)	1 (1.1)	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	1 (1.1)
Gastrointestinal disorders			
-Total	10 (10.5)	7 (7.4)	1 (1.1)
Diarrhoea	2 (2.1)	1 (1.1)	0
Pancreatitis	2 (2.1)	2 (2.1)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
Anal inflammation	1 (1.1)	1 (1.1)	0
Constipation	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Ileus	1 (1.1)	1 (1.1)	0
Irritable bowel syndrome	1 (1.1)	0	0
Nausea	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic colitis	1 (1.1)	1 (1.1)	0
Stomatitis	1 (1.1)	1 (1.1)	0
Vomiting	1 (1.1)	0	0
General disorders and administration site conditions			
-Total	17 (17.9)	2 (2.1)	3 (3.2)
Pyrexia	12 (12.6)	2 (2.1)	0
Multiple organ dysfunction syndrome	3 (3.2)	0	3 (3.2)
Non-cardiac chest pain	1 (1.1)	0	0
Oedema peripheral	1 (1.1)	0	0
Pain	1 (1.1)	0	0
Systemic inflammatory response syndrome	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Cholestasis	1 (1.1)	0	1 (1.1)
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatic cytolysis	1 (1.1)	1 (1.1)	0
Hepatomegaly	1 (1.1)	0	1 (1.1)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	51 (53.7)	16 (16.8)	22 (23.2)
Cytokine release syndrome	50 (52.6)	16 (16.8)	21 (22.1)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	2 (2.1)
Allergy to immunoglobulin therapy	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	46 (48.4)	28 (29.5)	18 (18.9)
Pneumonia	4 (4.2)	2 (2.1)	2 (2.1)
Sepsis	4 (4.2)	1 (1.1)	3 (3.2)
Septic shock	3 (3.2)	0	3 (3.2)
Staphylococcal bacteraemia	3 (3.2)	3 (3.2)	0
Upper respiratory tract infection	3 (3.2)	3 (3.2)	0
Bacteraemia	2 (2.1)	1 (1.1)	1 (1.1)
Bronchopulmonary aspergillosis	2 (2.1)	1 (1.1)	1 (1.1)
Candida infection	2 (2.1)	0	1 (1.1)
Device related infection	2 (2.1)	2 (2.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	2 (2.1)	0	2 (2.1)
Encephalitis viral	2 (2.1)	1 (1.1)	1 (1.1)
Escherichia bacteraemia	2 (2.1)	1 (1.1)	1 (1.1)
Gastroenteritis	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Parainfluenzae virus infection	2 (2.1)	2 (2.1)	0
Respiratory syncytial virus infection	2 (2.1)	2 (2.1)	0
Rhinovirus infection	2 (2.1)	1 (1.1)	0
Sinusitis	2 (2.1)	2 (2.1)	0
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Clostridium difficile colitis	1 (1.1)	1 (1.1)	0
Covid-19	1 (1.1)	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	1 (1.1)
Enterobacter infection	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungaemia	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis escherichia coli	1 (1.1)	1 (1.1)	0
Gastroenteritis salmonella	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	1 (1.1)	1 (1.1)	0
Klebsiella infection	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Mastoiditis	1 (1.1)	1 (1.1)	0
Meningitis bacterial	1 (1.1)	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	1 (1.1)	0
Metapneumovirus infection	1 (1.1)	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	0
Otitis externa	1 (1.1)	1 (1.1)	0
Otitis media	1 (1.1)	1 (1.1)	0
Paronychia	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumocystis jirovecii pneumonia	1 (1.1)	0	1 (1.1)
Pneumonia fungal	1 (1.1)	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	1 (1.1)	0
Pneumonia viral	1 (1.1)	1 (1.1)	0
Respiratory tract infection	1 (1.1)	1 (1.1)	0
Sialoadenitis	1 (1.1)	1 (1.1)	0
Soft tissue infection	1 (1.1)	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	1 (1.1)	0
Staphylococcal infection	1 (1.1)	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	1 (1.1)
Staphylococcal skin infection	1 (1.1)	1 (1.1)	0
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Varicella zoster virus infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	4 (4.2)	1 (1.1)	2 (2.1)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Vasoplegia syndrome	1 (1.1)	0	1 (1.1)
Investigations			
-Total	7 (7.4)	3 (3.2)	4 (4.2)
Aspartate aminotransferase increased	2 (2.1)	2 (2.1)	0
Neutrophil count decreased	2 (2.1)	0	2 (2.1)
Amylase increased	1 (1.1)	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	1 (1.1)	0
Blood uric acid increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	11 (11.6)	4 (4.2)	6 (6.3)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (3.2)	1 (1.1)	2 (2.1)
Decreased appetite	1 (1.1)	0	1 (1.1)
Dehydration	1 (1.1)	0	0
Hypercalcaemia	1 (1.1)	1 (1.1)	0
Hyperkalaemia	1 (1.1)	0	1 (1.1)
Hypernatraemia	1 (1.1)	0	1 (1.1)
Hyperphosphataemia	1 (1.1)	0	1 (1.1)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hypokalaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Malnutrition	1 (1.1)	1 (1.1)	0
Metabolic acidosis	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	7 (7.4)	3 (3.2)	1 (1.1)
Back pain	3 (3.2)	2 (2.1)	0
Pain in extremity	2 (2.1)	0	0
Haemarthrosis	1 (1.1)	1 (1.1)	0

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (1.1)	0	1 (1.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.1)	2 (2.1)	0
Bone giant cell tumour benign	1 (1.1)	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	1 (1.1)	0
Nervous system disorders			
-Total	10 (10.5)	6 (6.3)	3 (3.2)
Encephalopathy	2 (2.1)	2 (2.1)	0
Headache	2 (2.1)	2 (2.1)	0
Seizure	2 (2.1)	1 (1.1)	0
Cerebral haemorrhage	1 (1.1)	0	1 (1.1)
Cognitive disorder	1 (1.1)	0	0
Dysarthria	1 (1.1)	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	1 (1.1)
Hydrocephalus	1 (1.1)	0	1 (1.1)
Nervous system disorder	1 (1.1)	1 (1.1)	0
Psychiatric disorders			

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (4.2)	3 (3.2)	0
Mental status changes	3 (3.2)	2 (2.1)	0
Delirium	1 (1.1)	1 (1.1)	0
Renal and urinary disorders			
-Total	8 (8.4)	3 (3.2)	4 (4.2)
Acute kidney injury	6 (6.3)	2 (2.1)	3 (3.2)
Renal tubular necrosis	2 (2.1)	1 (1.1)	1 (1.1)
Renal failure	1 (1.1)	0	1 (1.1)
Reproductive system and breast disorders			
-Total	1 (1.1)	1 (1.1)	0
Endometriosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	23 (24.2)	5 (5.3)	15 (15.8)
Respiratory failure	8 (8.4)	0	8 (8.4)
Hypoxia	5 (5.3)	3 (3.2)	2 (2.1)
Acute respiratory distress syndrome	3 (3.2)	0	3 (3.2)
Pleural effusion	3 (3.2)	1 (1.1)	1 (1.1)

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (2.1)	1 (1.1)	0
Respiratory distress	2 (2.1)	0	1 (1.1)
Acute respiratory failure	1 (1.1)	1 (1.1)	0
Bronchial oedema	1 (1.1)	0	0
Dyspnoea	1 (1.1)	0	1 (1.1)
Dyspnoea exertional	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	1 (1.1)
Pulmonary haemorrhage	1 (1.1)	0	1 (1.1)
Pulmonary oedema	1 (1.1)	1 (1.1)	0
Vascular disorders			
-Total	11 (11.6)	2 (2.1)	9 (9.5)
Hypotension	10 (10.5)	2 (2.1)	8 (8.4)
Flushing	1 (1.1)	0	0
Venoocclusive disease	1 (1.1)	0	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213i
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	1 (50.0)	1 (50.0)	0
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Fungal skin infection	1 (50.0)	1 (50.0)	0
Systemic mycosis	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213i
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	78 (81.3)	28 (29.2)	47 (49.0)
Blood and lymphatic system disorders			
-Total	27 (28.1)	23 (24.0)	4 (4.2)
Febrile neutropenia	22 (22.9)	20 (20.8)	2 (2.1)
Disseminated intravascular coagulation	3 (3.1)	2 (2.1)	0
Anaemia	2 (2.1)	0	1 (1.0)
Pancytopenia	2 (2.1)	2 (2.1)	0
Thrombocytopenia	2 (2.1)	1 (1.0)	1 (1.0)
Coagulopathy	1 (1.0)	1 (1.0)	0
Neutropenia	1 (1.0)	1 (1.0)	0
Cardiac disorders			

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (10.4)	4 (4.2)	5 (5.2)
Cardiac arrest	3 (3.1)	0	3 (3.1)
Cardiac failure	3 (3.1)	2 (2.1)	1 (1.0)
Left ventricular dysfunction	2 (2.1)	2 (2.1)	0
Atrioventricular block first degree	1 (1.0)	0	0
Pericardial effusion	1 (1.0)	1 (1.0)	0
Tachycardia	1 (1.0)	0	1 (1.0)
Gastrointestinal disorders			
-Total	11 (11.5)	7 (7.3)	2 (2.1)
Abdominal compartment syndrome	2 (2.1)	0	2 (2.1)
Diarrhoea	2 (2.1)	1 (1.0)	0
Pancreatitis	2 (2.1)	2 (2.1)	0
Anal inflammation	1 (1.0)	1 (1.0)	0
Constipation	1 (1.0)	0	0
Gastrointestinal haemorrhage	1 (1.0)	1 (1.0)	0
Haemoperitoneum	1 (1.0)	0	1 (1.0)
Ileus	1 (1.0)	1 (1.0)	0
Irritable bowel syndrome	1 (1.0)	0	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (1.0)	0	0
Neutropenic colitis	1 (1.0)	1 (1.0)	0
Stomatitis	1 (1.0)	1 (1.0)	0
Vomiting	1 (1.0)	0	0
General disorders and administration site conditions			
-Total	18 (18.8)	2 (2.1)	3 (3.1)
Pyrexia	13 (13.5)	2 (2.1)	0
Multiple organ dysfunction syndrome	3 (3.1)	0	3 (3.1)
Non-cardiac chest pain	1 (1.0)	0	0
Oedema peripheral	1 (1.0)	0	0
Pain	1 (1.0)	0	0
Systemic inflammatory response syndrome	1 (1.0)	1 (1.0)	0
Hepatobiliary disorders			
-Total	4 (4.2)	2 (2.1)	2 (2.1)
Cholestasis	1 (1.0)	0	1 (1.0)
Drug-induced liver injury	1 (1.0)	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.0)	0	1 (1.0)
Immune system disorders			
-Total	51 (53.1)	16 (16.7)	22 (22.9)
Cytokine release syndrome	50 (52.1)	16 (16.7)	21 (21.9)
Haemophagocytic lymphohistiocytosis	2 (2.1)	0	2 (2.1)
Allergy to immunoglobulin therapy	1 (1.0)	1 (1.0)	0
Drug hypersensitivity	1 (1.0)	1 (1.0)	0
Infections and infestations			
-Total	47 (49.0)	28 (29.2)	19 (19.8)
Pneumonia	4 (4.2)	2 (2.1)	2 (2.1)
Sepsis	4 (4.2)	1 (1.0)	3 (3.1)
Septic shock	3 (3.1)	0	3 (3.1)
Staphylococcal bacteraemia	3 (3.1)	3 (3.1)	0
Upper respiratory tract infection	3 (3.1)	3 (3.1)	0
Bacteraemia	2 (2.1)	1 (1.0)	1 (1.0)
Bronchopulmonary aspergillosis	2 (2.1)	1 (1.0)	1 (1.0)
Candida infection	2 (2.1)	0	1 (1.0)

BCR-ABL1-like: No

Group term Preferred term	All patients N=96 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (2.1)	2 (2.1)	0
Encephalitis	2 (2.1)	0	2 (2.1)
Encephalitis viral	2 (2.1)	1 (1.0)	1 (1.0)
Escherichia bacteraemia	2 (2.1)	1 (1.0)	1 (1.0)
Gastroenteritis	2 (2.1)	2 (2.1)	0
Herpes zoster	2 (2.1)	2 (2.1)	0
Parainfluenzae virus infection	2 (2.1)	2 (2.1)	0
Respiratory syncytial virus infection	2 (2.1)	2 (2.1)	0
Rhinovirus infection	2 (2.1)	1 (1.0)	0
Sinusitis	2 (2.1)	2 (2.1)	0
Staphylococcal infection	2 (2.1)	1 (1.0)	1 (1.0)
Aspergillus infection	1 (1.0)	0	1 (1.0)
Bronchiolitis	1 (1.0)	1 (1.0)	0
Clostridium difficile colitis	1 (1.0)	1 (1.0)	0
Covid-19	1 (1.0)	1 (1.0)	0
Covid-19 pneumonia	1 (1.0)	0	1 (1.0)
Cytomegalovirus infection reactivation	1 (1.0)	1 (1.0)	0
Device related sepsis	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (1.0)	0	1 (1.0)
Enterobacter infection	1 (1.0)	1 (1.0)	0
Fungaemia	1 (1.0)	0	1 (1.0)
Gastroenteritis escherichia coli	1 (1.0)	1 (1.0)	0
Gastroenteritis salmonella	1 (1.0)	1 (1.0)	0
Gastroenteritis viral	1 (1.0)	1 (1.0)	0
Human herpesvirus 6 infection	1 (1.0)	1 (1.0)	0
Klebsiella bacteraemia	1 (1.0)	1 (1.0)	0
Klebsiella infection	1 (1.0)	1 (1.0)	0
Localised infection	1 (1.0)	1 (1.0)	0
Mastoiditis	1 (1.0)	1 (1.0)	0
Meningitis bacterial	1 (1.0)	1 (1.0)	0
Meningitis pneumococcal	1 (1.0)	1 (1.0)	0
Metapneumovirus infection	1 (1.0)	1 (1.0)	0
Ophthalmic herpes zoster	1 (1.0)	0	0
Otitis externa	1 (1.0)	1 (1.0)	0
Otitis media	1 (1.0)	1 (1.0)	0
Paronychia	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (1.0)	1 (1.0)	0
Pharyngitis streptococcal	1 (1.0)	1 (1.0)	0
Pneumocystis jirovecii pneumonia	1 (1.0)	0	1 (1.0)
Pneumonia fungal	1 (1.0)	1 (1.0)	0
Pneumonia respiratory syncytial viral	1 (1.0)	1 (1.0)	0
Pneumonia viral	1 (1.0)	1 (1.0)	0
Respiratory tract infection	1 (1.0)	1 (1.0)	0
Serratia sepsis	1 (1.0)	0	1 (1.0)
Sialoadenitis	1 (1.0)	1 (1.0)	0
Soft tissue infection	1 (1.0)	1 (1.0)	0
Staphylococcal abscess	1 (1.0)	1 (1.0)	0
Staphylococcal sepsis	1 (1.0)	0	1 (1.0)
Staphylococcal skin infection	1 (1.0)	1 (1.0)	0
Urinary tract infection	1 (1.0)	1 (1.0)	0
Varicella zoster virus infection	1 (1.0)	1 (1.0)	0
Vascular device infection	1 (1.0)	1 (1.0)	0
Viral haemorrhagic cystitis	1 (1.0)	1 (1.0)	0
Viral upper respiratory tract infection	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	4 (4.2)	1 (1.0)	2 (2.1)
Infusion related reaction	1 (1.0)	1 (1.0)	0
Tracheal obstruction	1 (1.0)	0	1 (1.0)
Transfusion reaction	1 (1.0)	0	0
Vasoplegia syndrome	1 (1.0)	0	1 (1.0)
Investigations			
-Total	7 (7.3)	3 (3.1)	4 (4.2)
Aspartate aminotransferase increased	2 (2.1)	2 (2.1)	0
Neutrophil count decreased	2 (2.1)	0	2 (2.1)
Amylase increased	1 (1.0)	0	1 (1.0)
Blood bilirubin increased	1 (1.0)	1 (1.0)	0
Blood uric acid increased	1 (1.0)	0	1 (1.0)
C-reactive protein increased	1 (1.0)	1 (1.0)	0
Electrocardiogram qt prolonged	1 (1.0)	0	1 (1.0)
Metabolism and nutrition disorders			
-Total	11 (11.5)	4 (4.2)	6 (6.3)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (3.1)	1 (1.0)	2 (2.1)
Decreased appetite	1 (1.0)	0	1 (1.0)
Dehydration	1 (1.0)	0	0
Hypercalcaemia	1 (1.0)	1 (1.0)	0
Hyperkalaemia	1 (1.0)	0	1 (1.0)
Hypernatraemia	1 (1.0)	0	1 (1.0)
Hyperphosphataemia	1 (1.0)	0	1 (1.0)
Hypervolaemia	1 (1.0)	1 (1.0)	0
Hypokalaemia	1 (1.0)	1 (1.0)	0
Hyponatraemia	1 (1.0)	0	1 (1.0)
Malnutrition	1 (1.0)	1 (1.0)	0
Metabolic acidosis	1 (1.0)	0	1 (1.0)
Musculoskeletal and connective tissue disorders			
-Total	7 (7.3)	3 (3.1)	1 (1.0)
Back pain	3 (3.1)	2 (2.1)	0
Pain in extremity	2 (2.1)	0	0
Haemarthrosis	1 (1.0)	1 (1.0)	0

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (1.0)	0	1 (1.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.1)	2 (2.1)	0
Bone giant cell tumour benign	1 (1.0)	1 (1.0)	0
Myelodysplastic syndrome	1 (1.0)	1 (1.0)	0
Nervous system disorders			
-Total	10 (10.4)	6 (6.3)	3 (3.1)
Encephalopathy	2 (2.1)	2 (2.1)	0
Headache	2 (2.1)	2 (2.1)	0
Seizure	2 (2.1)	1 (1.0)	0
Cerebral haemorrhage	1 (1.0)	0	1 (1.0)
Cognitive disorder	1 (1.0)	0	0
Dysarthria	1 (1.0)	1 (1.0)	0
Haemorrhage intracranial	1 (1.0)	0	1 (1.0)
Hydrocephalus	1 (1.0)	0	1 (1.0)
Nervous system disorder	1 (1.0)	1 (1.0)	0
Psychiatric disorders			

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (4.2)	3 (3.1)	0
Mental status changes	3 (3.1)	2 (2.1)	0
Delirium	1 (1.0)	1 (1.0)	0
Renal and urinary disorders			
-Total	8 (8.3)	3 (3.1)	4 (4.2)
Acute kidney injury	6 (6.3)	2 (2.1)	3 (3.1)
Renal tubular necrosis	2 (2.1)	1 (1.0)	1 (1.0)
Renal failure	1 (1.0)	0	1 (1.0)
Reproductive system and breast disorders			
-Total	1 (1.0)	1 (1.0)	0
Endometriosis	1 (1.0)	1 (1.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	24 (25.0)	5 (5.2)	16 (16.7)
Respiratory failure	9 (9.4)	0	9 (9.4)
Hypoxia	5 (5.2)	3 (3.1)	2 (2.1)
Acute respiratory distress syndrome	3 (3.1)	0	3 (3.1)
Pleural effusion	3 (3.1)	1 (1.0)	1 (1.0)

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (2.1)	1 (1.0)	0
Pulmonary oedema	2 (2.1)	1 (1.0)	1 (1.0)
Respiratory distress	2 (2.1)	0	1 (1.0)
Acute respiratory failure	1 (1.0)	1 (1.0)	0
Bronchial oedema	1 (1.0)	0	0
Dyspnoea	1 (1.0)	0	1 (1.0)
Dyspnoea exertional	1 (1.0)	0	0
Laryngeal oedema	1 (1.0)	0	1 (1.0)
Pulmonary haemorrhage	1 (1.0)	0	1 (1.0)
Vascular disorders			
-Total	12 (12.5)	3 (3.1)	9 (9.4)
Hypotension	11 (11.5)	3 (3.1)	8 (8.3)
Flushing	1 (1.0)	0	0
Venoocclusive disease	1 (1.0)	0	1 (1.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213j
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	26 (86.7)	8 (26.7)	17 (56.7)
Blood and lymphatic system disorders			
-Total	6 (20.0)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	6 (20.0)	0
Cardiac disorders			
-Total	1 (3.3)	0	1 (3.3)
Tachycardia	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	4 (13.3)	3 (10.0)	1 (3.3)
Pancreatitis	2 (6.7)	2 (6.7)	0
Abdominal compartment syndrome	1 (3.3)	0	1 (3.3)
Diarrhoea	1 (3.3)	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (3.3)	0	1 (3.3)
General disorders and administration site conditions			
-Total	3 (10.0)	0	1 (3.3)
Multiple organ dysfunction syndrome	1 (3.3)	0	1 (3.3)
Oedema peripheral	1 (3.3)	0	0
Pyrexia	1 (3.3)	0	0
Systemic inflammatory response syndrome	1 (3.3)	1 (3.3)	0
Hepatobiliary disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Cholestasis	1 (3.3)	0	1 (3.3)
Hepatic cytolysis	1 (3.3)	1 (3.3)	0
Immune system disorders			
-Total	19 (63.3)	7 (23.3)	9 (30.0)
Cytokine release syndrome	19 (63.3)	7 (23.3)	9 (30.0)
Drug hypersensitivity	1 (3.3)	1 (3.3)	0
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	1 (3.3)
Infections and infestations			

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (60.0)	9 (30.0)	9 (30.0)
Sepsis	2 (6.7)	0	2 (6.7)
Staphylococcal infection	2 (6.7)	1 (3.3)	1 (3.3)
Aspergillus infection	1 (3.3)	0	1 (3.3)
Bacteraemia	1 (3.3)	1 (3.3)	0
Bronchiolitis	1 (3.3)	1 (3.3)	0
Candida infection	1 (3.3)	0	0
Covid-19	1 (3.3)	1 (3.3)	0
Device related infection	1 (3.3)	1 (3.3)	0
Device related sepsis	1 (3.3)	1 (3.3)	0
Encephalitis	1 (3.3)	0	1 (3.3)
Encephalitis viral	1 (3.3)	0	1 (3.3)
Fungaemia	1 (3.3)	0	1 (3.3)
Gastroenteritis	1 (3.3)	1 (3.3)	0
Herpes zoster	1 (3.3)	1 (3.3)	0
Meningitis bacterial	1 (3.3)	1 (3.3)	0
Ophthalmic herpes zoster	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	1 (3.3)	0
Paronychia	1 (3.3)	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumocystis jirovecii pneumonia	1 (3.3)	0	1 (3.3)
Pneumonia	1 (3.3)	1 (3.3)	0
Pneumonia respiratory syncytial viral	1 (3.3)	1 (3.3)	0
Respiratory tract infection	1 (3.3)	1 (3.3)	0
Septic shock	1 (3.3)	0	1 (3.3)
Serratia sepsis	1 (3.3)	0	1 (3.3)
Sinusitis	1 (3.3)	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Staphylococcal sepsis	1 (3.3)	0	1 (3.3)
Upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	4 (13.3)	1 (3.3)	2 (6.7)
Infusion related reaction	1 (3.3)	1 (3.3)	0
Tracheal obstruction	1 (3.3)	0	1 (3.3)
Transfusion reaction	1 (3.3)	0	0
Vasoplegia syndrome	1 (3.3)	0	1 (3.3)
Investigations			
-Total	2 (6.7)	0	2 (6.7)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (6.7)	0	2 (6.7)
Blood uric acid increased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	2 (6.7)	0	2 (6.7)
Hypernatraemia	1 (3.3)	0	1 (3.3)
Tumour lysis syndrome	1 (3.3)	0	1 (3.3)
Musculoskeletal and connective tissue disorders			
-Total	2 (6.7)	0	1 (3.3)
Pain in extremity	1 (3.3)	0	0
Rhabdomyolysis	1 (3.3)	0	1 (3.3)
Nervous system disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Encephalopathy	1 (3.3)	1 (3.3)	0
Headache	1 (3.3)	1 (3.3)	0
Hydrocephalus	1 (3.3)	0	1 (3.3)
Psychiatric disorders			
-Total	2 (6.7)	1 (3.3)	0
Mental status changes	2 (6.7)	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	4 (13.3)	1 (3.3)	2 (6.7)
Acute kidney injury	4 (13.3)	1 (3.3)	2 (6.7)
Renal tubular necrosis	1 (3.3)	0	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (26.7)	2 (6.7)	6 (20.0)
Respiratory failure	3 (10.0)	0	3 (10.0)
Acute respiratory distress syndrome	2 (6.7)	0	2 (6.7)
Hypoxia	2 (6.7)	2 (6.7)	0
Pulmonary oedema	2 (6.7)	1 (3.3)	1 (3.3)
Dyspnoea	1 (3.3)	0	1 (3.3)
Epistaxis	1 (3.3)	0	0
Pleural effusion	1 (3.3)	1 (3.3)	0
Pulmonary haemorrhage	1 (3.3)	0	1 (3.3)
Respiratory distress	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	6 (20.0)	1 (3.3)	5 (16.7)
Hypotension	5 (16.7)	1 (3.3)	4 (13.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Venoocclusive disease	1 (3.3)	0	1 (3.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213j
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	53 (77.9)	21 (30.9)	30 (44.1)
Blood and lymphatic system disorders			
-Total	22 (32.4)	18 (26.5)	4 (5.9)
Febrile neutropenia	17 (25.0)	15 (22.1)	2 (2.9)
Disseminated intravascular coagulation	3 (4.4)	2 (2.9)	0
Anaemia	2 (2.9)	0	1 (1.5)
Pancytopenia	2 (2.9)	2 (2.9)	0
Thrombocytopenia	2 (2.9)	1 (1.5)	1 (1.5)
Coagulopathy	1 (1.5)	1 (1.5)	0
Neutropenia	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	9 (13.2)	4 (5.9)	4 (5.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	3 (4.4)	0	3 (4.4)
Cardiac failure	3 (4.4)	2 (2.9)	1 (1.5)
Left ventricular dysfunction	2 (2.9)	2 (2.9)	0
Atrioventricular block first degree	1 (1.5)	0	0
Pericardial effusion	1 (1.5)	1 (1.5)	0
Gastrointestinal disorders			
-Total	7 (10.3)	4 (5.9)	1 (1.5)
Abdominal compartment syndrome	1 (1.5)	0	1 (1.5)
Anal inflammation	1 (1.5)	1 (1.5)	0
Constipation	1 (1.5)	0	0
Diarrhoea	1 (1.5)	0	0
Gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0
Ileus	1 (1.5)	1 (1.5)	0
Irritable bowel syndrome	1 (1.5)	0	0
Nausea	1 (1.5)	0	0
Neutropenic colitis	1 (1.5)	1 (1.5)	0
Stomatitis	1 (1.5)	1 (1.5)	0
Vomiting	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	15 (22.1)	2 (2.9)	2 (2.9)
Pyrexia	12 (17.6)	2 (2.9)	0
Multiple organ dysfunction syndrome	2 (2.9)	0	2 (2.9)
Non-cardiac chest pain	1 (1.5)	0	0
Pain	1 (1.5)	0	0
Hepatobiliary disorders			
-Total	2 (2.9)	1 (1.5)	1 (1.5)
Drug-induced liver injury	1 (1.5)	1 (1.5)	0
Hepatomegaly	1 (1.5)	0	1 (1.5)
Immune system disorders			
-Total	32 (47.1)	9 (13.2)	13 (19.1)
Cytokine release syndrome	31 (45.6)	9 (13.2)	12 (17.6)
Allergy to immunoglobulin therapy	1 (1.5)	1 (1.5)	0
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)
Infections and infestations			
-Total	30 (44.1)	20 (29.4)	10 (14.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	3 (4.4)	1 (1.5)	2 (2.9)
Bronchopulmonary aspergillosis	2 (2.9)	1 (1.5)	1 (1.5)
Escherichia bacteraemia	2 (2.9)	1 (1.5)	1 (1.5)
Respiratory syncytial virus infection	2 (2.9)	2 (2.9)	0
Rhinovirus infection	2 (2.9)	1 (1.5)	0
Sepsis	2 (2.9)	1 (1.5)	1 (1.5)
Septic shock	2 (2.9)	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	2 (2.9)	0
Bacteraemia	1 (1.5)	0	1 (1.5)
Candida infection	1 (1.5)	0	1 (1.5)
Clostridium difficile colitis	1 (1.5)	1 (1.5)	0
Covid-19 pneumonia	1 (1.5)	0	1 (1.5)
Cytomegalovirus infection reactivation	1 (1.5)	1 (1.5)	0
Device related infection	1 (1.5)	1 (1.5)	0
Disseminated trichosporonosis	1 (1.5)	0	1 (1.5)
Encephalitis	1 (1.5)	0	1 (1.5)
Encephalitis viral	1 (1.5)	1 (1.5)	0
Enterobacter infection	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (1.5)	1 (1.5)	0
Gastroenteritis	1 (1.5)	1 (1.5)	0
Gastroenteritis escherichia coli	1 (1.5)	1 (1.5)	0
Gastroenteritis salmonella	1 (1.5)	1 (1.5)	0
Gastroenteritis viral	1 (1.5)	1 (1.5)	0
Herpes zoster	1 (1.5)	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	1 (1.5)	0
Klebsiella bacteraemia	1 (1.5)	1 (1.5)	0
Klebsiella infection	1 (1.5)	1 (1.5)	0
Localised infection	1 (1.5)	1 (1.5)	0
Mastoiditis	1 (1.5)	1 (1.5)	0
Meningitis pneumococcal	1 (1.5)	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	1 (1.5)	0
Otitis externa	1 (1.5)	1 (1.5)	0
Otitis media	1 (1.5)	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	1 (1.5)	0
Pharyngitis	1 (1.5)	1 (1.5)	0
Pharyngitis streptococcal	1 (1.5)	1 (1.5)	0
Pneumonia fungal	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.5)	1 (1.5)	0
Sialoadenitis	1 (1.5)	1 (1.5)	0
Sinusitis	1 (1.5)	1 (1.5)	0
Soft tissue infection	1 (1.5)	1 (1.5)	0
Staphylococcal abscess	1 (1.5)	1 (1.5)	0
Staphylococcal skin infection	1 (1.5)	1 (1.5)	0
Systemic mycosis	1 (1.5)	1 (1.5)	0
Urinary tract infection	1 (1.5)	1 (1.5)	0
Varicella zoster virus infection	1 (1.5)	1 (1.5)	0
Vascular device infection	1 (1.5)	1 (1.5)	0
Viral haemorrhagic cystitis	1 (1.5)	1 (1.5)	0
Viral upper respiratory tract infection	1 (1.5)	1 (1.5)	0
Investigations			
-Total	5 (7.4)	3 (4.4)	2 (2.9)
Aspartate aminotransferase increased	2 (2.9)	2 (2.9)	0
Amylase increased	1 (1.5)	0	1 (1.5)
Blood bilirubin increased	1 (1.5)	1 (1.5)	0
C-reactive protein increased	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	9 (13.2)	4 (5.9)	4 (5.9)
Tumour lysis syndrome	2 (2.9)	1 (1.5)	1 (1.5)
Decreased appetite	1 (1.5)	0	1 (1.5)
Dehydration	1 (1.5)	0	0
Hypercalcaemia	1 (1.5)	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	1 (1.5)
Hyperphosphataemia	1 (1.5)	0	1 (1.5)
Hypervolaemia	1 (1.5)	1 (1.5)	0
Hypokalaemia	1 (1.5)	1 (1.5)	0
Hyponatraemia	1 (1.5)	0	1 (1.5)
Malnutrition	1 (1.5)	1 (1.5)	0
Metabolic acidosis	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	5 (7.4)	3 (4.4)	0
Back pain	3 (4.4)	2 (2.9)	0
Haemarthrosis	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (1.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.9)	2 (2.9)	0
Bone giant cell tumour benign	1 (1.5)	1 (1.5)	0
Myelodysplastic syndrome	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	7 (10.3)	4 (5.9)	2 (2.9)
Seizure	2 (2.9)	1 (1.5)	0
Cerebral haemorrhage	1 (1.5)	0	1 (1.5)
Cognitive disorder	1 (1.5)	0	0
Dysarthria	1 (1.5)	1 (1.5)	0
Encephalopathy	1 (1.5)	1 (1.5)	0
Haemorrhage intracranial	1 (1.5)	0	1 (1.5)
Headache	1 (1.5)	1 (1.5)	0
Nervous system disorder	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	2 (2.9)	2 (2.9)	0
Delirium	1 (1.5)	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	4 (5.9)	2 (2.9)	2 (2.9)
Acute kidney injury	2 (2.9)	1 (1.5)	1 (1.5)
Renal failure	1 (1.5)	0	1 (1.5)
Renal tubular necrosis	1 (1.5)	1 (1.5)	0
Reproductive system and breast disorders			
-Total	1 (1.5)	1 (1.5)	0
Endometriosis	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (23.5)	3 (4.4)	10 (14.7)
Respiratory failure	6 (8.8)	0	6 (8.8)
Hypoxia	3 (4.4)	1 (1.5)	2 (2.9)
Pleural effusion	2 (2.9)	0	1 (1.5)
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Acute respiratory failure	1 (1.5)	1 (1.5)	0
Bronchial oedema	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea exertional	1 (1.5)	0	0
Epistaxis	1 (1.5)	1 (1.5)	0
Laryngeal oedema	1 (1.5)	0	1 (1.5)
Respiratory distress	1 (1.5)	0	0
Vascular disorders			
-Total	6 (8.8)	2 (2.9)	4 (5.9)
Hypotension	6 (8.8)	2 (2.9)	4 (5.9)
Flushing	1 (1.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213k
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	25 (78.1)	9 (28.1)	15 (46.9)
Blood and lymphatic system disorders			
-Total	7 (21.9)	6 (18.8)	1 (3.1)
Febrile neutropenia	5 (15.6)	4 (12.5)	1 (3.1)
Pancytopenia	2 (6.3)	2 (6.3)	0
Disseminated intravascular coagulation	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders			
-Total	2 (6.3)	2 (6.3)	0
Ileus	1 (3.1)	1 (3.1)	0
Pancreatitis	1 (3.1)	1 (3.1)	0

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	5 (15.6)	1 (3.1)	1 (3.1)
Pyrexia	3 (9.4)	1 (3.1)	0
Multiple organ dysfunction syndrome	1 (3.1)	0	1 (3.1)
Non-cardiac chest pain	1 (3.1)	0	0
Hepatobiliary disorders			
-Total	1 (3.1)	1 (3.1)	0
Hepatic cytolysis	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	16 (50.0)	5 (15.6)	9 (28.1)
Cytokine release syndrome	15 (46.9)	5 (15.6)	8 (25.0)
Drug hypersensitivity	1 (3.1)	1 (3.1)	0
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)
Infections and infestations			
-Total	18 (56.3)	9 (28.1)	9 (28.1)
Pneumonia	3 (9.4)	1 (3.1)	2 (6.3)
Sepsis	3 (9.4)	1 (3.1)	2 (6.3)

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	2 (6.3)	1 (3.1)	1 (3.1)
Device related infection	2 (6.3)	2 (6.3)	0
Gastroenteritis	2 (6.3)	2 (6.3)	0
Herpes zoster	2 (6.3)	2 (6.3)	0
Bronchiolitis	1 (3.1)	1 (3.1)	0
Bronchopulmonary aspergillosis	1 (3.1)	0	1 (3.1)
Candida infection	1 (3.1)	0	0
Covid-19	1 (3.1)	1 (3.1)	0
Covid-19 pneumonia	1 (3.1)	0	1 (3.1)
Device related sepsis	1 (3.1)	1 (3.1)	0
Encephalitis	1 (3.1)	0	1 (3.1)
Encephalitis viral	1 (3.1)	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	1 (3.1)
Localised infection	1 (3.1)	1 (3.1)	0
Ophthalmic herpes zoster	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	1 (3.1)	0
Paronychia	1 (3.1)	1 (3.1)	0
Pneumocystis jirovecii pneumonia	1 (3.1)	0	1 (3.1)

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (3.1)	1 (3.1)	0
Pneumonia viral	1 (3.1)	1 (3.1)	0
Respiratory tract infection	1 (3.1)	1 (3.1)	0
Sialoadenitis	1 (3.1)	1 (3.1)	0
Sinusitis	1 (3.1)	1 (3.1)	0
Staphylococcal sepsis	1 (3.1)	0	1 (3.1)
Urinary tract infection	1 (3.1)	1 (3.1)	0
Viral haemorrhagic cystitis	1 (3.1)	1 (3.1)	0
Investigations			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Amylase increased	1 (3.1)	0	1 (3.1)
C-reactive protein increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	4 (12.5)	1 (3.1)	3 (9.4)
Decreased appetite	1 (3.1)	0	1 (3.1)
Hyponatraemia	1 (3.1)	0	1 (3.1)
Malnutrition	1 (3.1)	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	0	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (6.3)	2 (6.3)	0
Bone giant cell tumour benign	1 (3.1)	1 (3.1)	0
Myelodysplastic syndrome	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Encephalopathy	1 (3.1)	1 (3.1)	0
Headache	1 (3.1)	1 (3.1)	0
Hydrocephalus	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (12.5)	0	1 (3.1)
Bronchial oedema	1 (3.1)	0	0
Dyspnoea exertional	1 (3.1)	0	0
Pleural effusion	1 (3.1)	0	0
Respiratory failure	1 (3.1)	0	1 (3.1)
Vascular disorders			
-Total	1 (3.1)	0	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Venoocclusive disease	1 (3.1)	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213k
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	48 (84.2)	18 (31.6)	28 (49.1)
Blood and lymphatic system disorders			
-Total	20 (35.1)	17 (29.8)	3 (5.3)
Febrile neutropenia	17 (29.8)	16 (28.1)	1 (1.8)
Anaemia	2 (3.5)	0	1 (1.8)
Disseminated intravascular coagulation	2 (3.5)	1 (1.8)	0
Thrombocytopenia	2 (3.5)	1 (1.8)	1 (1.8)
Coagulopathy	1 (1.8)	1 (1.8)	0
Neutropenia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	10 (17.5)	4 (7.0)	5 (8.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac arrest	3 (5.3)	0	3 (5.3)
Cardiac failure	3 (5.3)	2 (3.5)	1 (1.8)
Left ventricular dysfunction	2 (3.5)	2 (3.5)	0
Atrioventricular block first degree	1 (1.8)	0	0
Pericardial effusion	1 (1.8)	1 (1.8)	0
Tachycardia	1 (1.8)	0	1 (1.8)
Gastrointestinal disorders			
-Total	9 (15.8)	5 (8.8)	2 (3.5)
Abdominal compartment syndrome	2 (3.5)	0	2 (3.5)
Diarrhoea	2 (3.5)	1 (1.8)	0
Anal inflammation	1 (1.8)	1 (1.8)	0
Constipation	1 (1.8)	0	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0
Haemoperitoneum	1 (1.8)	0	1 (1.8)
Irritable bowel syndrome	1 (1.8)	0	0
Nausea	1 (1.8)	0	0
Neutropenic colitis	1 (1.8)	1 (1.8)	0
Pancreatitis	1 (1.8)	1 (1.8)	0

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.8)	1 (1.8)	0
Vomiting	1 (1.8)	0	0
General disorders and administration site conditions			
-Total	12 (21.1)	1 (1.8)	2 (3.5)
Pyrexia	9 (15.8)	1 (1.8)	0
Multiple organ dysfunction syndrome	2 (3.5)	0	2 (3.5)
Oedema peripheral	1 (1.8)	0	0
Pain	1 (1.8)	0	0
Systemic inflammatory response syndrome	1 (1.8)	1 (1.8)	0
Hepatobiliary disorders			
-Total	3 (5.3)	1 (1.8)	2 (3.5)
Cholestasis	1 (1.8)	0	1 (1.8)
Drug-induced liver injury	1 (1.8)	1 (1.8)	0
Hepatomegaly	1 (1.8)	0	1 (1.8)
Immune system disorders			
-Total	31 (54.4)	10 (17.5)	10 (17.5)
Cytokine release syndrome	31 (54.4)	10 (17.5)	10 (17.5)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Allergy to immunoglobulin therapy	1 (1.8)	1 (1.8)	0
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)
Infections and infestations			
-Total	27 (47.4)	18 (31.6)	9 (15.8)
Septic shock	3 (5.3)	0	3 (5.3)
Staphylococcal bacteraemia	3 (5.3)	3 (5.3)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	1 (1.8)
Aspergillus infection	1 (1.8)	0	1 (1.8)
Bronchopulmonary aspergillosis	1 (1.8)	1 (1.8)	0
Candida infection	1 (1.8)	0	1 (1.8)
Clostridium difficile colitis	1 (1.8)	1 (1.8)	0
Cytomegalovirus infection reactivation	1 (1.8)	1 (1.8)	0
Disseminated trichosporonosis	1 (1.8)	0	1 (1.8)
Encephalitis	1 (1.8)	0	1 (1.8)
Enterobacter infection	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	1 (1.8)	1 (1.8)	0
Fungaemia	1 (1.8)	0	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (1.8)	1 (1.8)	0
Gastroenteritis escherichia coli	1 (1.8)	1 (1.8)	0
Gastroenteritis salmonella	1 (1.8)	1 (1.8)	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0
Human herpesvirus 6 infection	1 (1.8)	1 (1.8)	0
Klebsiella bacteraemia	1 (1.8)	1 (1.8)	0
Klebsiella infection	1 (1.8)	1 (1.8)	0
Mastoiditis	1 (1.8)	1 (1.8)	0
Meningitis pneumococcal	1 (1.8)	1 (1.8)	0
Metapneumovirus infection	1 (1.8)	1 (1.8)	0
Otitis externa	1 (1.8)	1 (1.8)	0
Otitis media	1 (1.8)	1 (1.8)	0
Pharyngitis	1 (1.8)	1 (1.8)	0
Pharyngitis streptococcal	1 (1.8)	1 (1.8)	0
Pneumonia	1 (1.8)	1 (1.8)	0
Pneumonia respiratory syncytial viral	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Rhinovirus infection	1 (1.8)	0	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Sepsis	1 (1.8)	0	1 (1.8)
Serratia sepsis	1 (1.8)	0	1 (1.8)
Sinusitis	1 (1.8)	1 (1.8)	0
Soft tissue infection	1 (1.8)	1 (1.8)	0
Staphylococcal abscess	1 (1.8)	1 (1.8)	0
Systemic mycosis	1 (1.8)	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Varicella zoster virus infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	4 (7.0)	1 (1.8)	2 (3.5)
Infusion related reaction	1 (1.8)	1 (1.8)	0
Tracheal obstruction	1 (1.8)	0	1 (1.8)
Transfusion reaction	1 (1.8)	0	0
Vasoplegia syndrome	1 (1.8)	0	1 (1.8)
Investigations			

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (8.8)	2 (3.5)	3 (5.3)
Aspartate aminotransferase increased	2 (3.5)	2 (3.5)	0
Neutrophil count decreased	2 (3.5)	0	2 (3.5)
Blood bilirubin increased	1 (1.8)	1 (1.8)	0
Blood uric acid increased	1 (1.8)	0	1 (1.8)
Electrocardiogram qt prolonged	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	7 (12.3)	3 (5.3)	3 (5.3)
Tumour lysis syndrome	2 (3.5)	1 (1.8)	1 (1.8)
Dehydration	1 (1.8)	0	0
Hypercalcaemia	1 (1.8)	1 (1.8)	0
Hyperkalaemia	1 (1.8)	0	1 (1.8)
Hypernatraemia	1 (1.8)	0	1 (1.8)
Hyperphosphataemia	1 (1.8)	0	1 (1.8)
Hypervolaemia	1 (1.8)	1 (1.8)	0
Hypokalaemia	1 (1.8)	1 (1.8)	0
Metabolic acidosis	1 (1.8)	0	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders			
-Total	7 (12.3)	3 (5.3)	1 (1.8)
Back pain	3 (5.3)	2 (3.5)	0
Pain in extremity	2 (3.5)	0	0
Haemarthrosis	1 (1.8)	1 (1.8)	0
Rhabdomyolysis	1 (1.8)	0	1 (1.8)
Nervous system disorders			
-Total	6 (10.5)	4 (7.0)	1 (1.8)
Seizure	2 (3.5)	1 (1.8)	0
Cerebral haemorrhage	1 (1.8)	0	1 (1.8)
Cognitive disorder	1 (1.8)	0	0
Dysarthria	1 (1.8)	1 (1.8)	0
Encephalopathy	1 (1.8)	1 (1.8)	0
Headache	1 (1.8)	1 (1.8)	0
Nervous system disorder	1 (1.8)	1 (1.8)	0
Psychiatric disorders			
-Total	4 (7.0)	3 (5.3)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Mental status changes	3 (5.3)	2 (3.5)	0
Delirium	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	8 (14.0)	3 (5.3)	4 (7.0)
Acute kidney injury	6 (10.5)	2 (3.5)	3 (5.3)
Renal tubular necrosis	2 (3.5)	1 (1.8)	1 (1.8)
Renal failure	1 (1.8)	0	1 (1.8)
Reproductive system and breast disorders			
-Total	1 (1.8)	1 (1.8)	0
Endometriosis	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	20 (35.1)	5 (8.8)	15 (26.3)
Respiratory failure	8 (14.0)	0	8 (14.0)
Hypoxia	5 (8.8)	3 (5.3)	2 (3.5)
Acute respiratory distress syndrome	3 (5.3)	0	3 (5.3)
Epistaxis	2 (3.5)	1 (1.8)	0
Pleural effusion	2 (3.5)	1 (1.8)	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	2 (3.5)	1 (1.8)	1 (1.8)
Respiratory distress	2 (3.5)	0	1 (1.8)
Acute respiratory failure	1 (1.8)	1 (1.8)	0
Dyspnoea	1 (1.8)	0	1 (1.8)
Laryngeal oedema	1 (1.8)	0	1 (1.8)
Pulmonary haemorrhage	1 (1.8)	0	1 (1.8)
Vascular disorders			
-Total	11 (19.3)	3 (5.3)	8 (14.0)
Hypotension	11 (19.3)	3 (5.3)	8 (14.0)
Flushing	1 (1.8)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213k
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (66.7)	2 (22.2)	4 (44.4)
Blood and lymphatic system disorders			
-Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	0
Immune system disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Cytokine release syndrome	4 (44.4)	1 (11.1)	3 (33.3)

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Upper respiratory tract infection	2 (22.2)	2 (22.2)	0
Encephalitis viral	1 (11.1)	0	1 (11.1)
Meningitis bacterial	1 (11.1)	1 (11.1)	0
Parainfluenzae virus infection	1 (11.1)	1 (11.1)	0
Respiratory syncytial virus infection	1 (11.1)	1 (11.1)	0
Rhinovirus infection	1 (11.1)	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	1 (11.1)	0	1 (11.1)
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213l
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	47 (81.0)	20 (34.5)	26 (44.8)
Blood and lymphatic system disorders			
-Total	14 (24.1)	13 (22.4)	1 (1.7)
Febrile neutropenia	12 (20.7)	11 (19.0)	1 (1.7)
Pancytopenia	2 (3.4)	2 (3.4)	0
Anaemia	1 (1.7)	0	0
Disseminated intravascular coagulation	1 (1.7)	1 (1.7)	0
Thrombocytopenia	1 (1.7)	1 (1.7)	0
Cardiac disorders			
-Total	5 (8.6)	4 (6.9)	1 (1.7)
Left ventricular dysfunction	2 (3.4)	2 (3.4)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (1.7)	0	1 (1.7)
Cardiac failure	1 (1.7)	1 (1.7)	0
Pericardial effusion	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	4 (6.9)	4 (6.9)	0
Diarrhoea	2 (3.4)	1 (1.7)	0
Anal inflammation	1 (1.7)	1 (1.7)	0
Neutropenic colitis	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	1 (1.7)	0
Vomiting	1 (1.7)	0	0
General disorders and administration site conditions			
-Total	9 (15.5)	2 (3.4)	0
Pyrexia	8 (13.8)	2 (3.4)	0
Non-cardiac chest pain	1 (1.7)	0	0
Hepatobiliary disorders			
-Total	2 (3.4)	2 (3.4)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug-induced liver injury	1 (1.7)	1 (1.7)	0
Hepatic cytolysis	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	29 (50.0)	11 (19.0)	11 (19.0)
Cytokine release syndrome	29 (50.0)	11 (19.0)	11 (19.0)
Drug hypersensitivity	1 (1.7)	1 (1.7)	0
Infections and infestations			
-Total	28 (48.3)	17 (29.3)	11 (19.0)
Sepsis	3 (5.2)	1 (1.7)	2 (3.4)
Septic shock	3 (5.2)	0	3 (5.2)
Upper respiratory tract infection	3 (5.2)	3 (5.2)	0
Bacteraemia	2 (3.4)	1 (1.7)	1 (1.7)
Bronchopulmonary aspergillosis	2 (3.4)	1 (1.7)	1 (1.7)
Candida infection	2 (3.4)	0	1 (1.7)
Device related infection	2 (3.4)	2 (3.4)	0
Gastroenteritis	2 (3.4)	2 (3.4)	0
Parainfluenzae virus infection	2 (3.4)	2 (3.4)	0
Pneumonia	2 (3.4)	1 (1.7)	1 (1.7)

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (3.4)	2 (3.4)	0
Sinusitis	2 (3.4)	2 (3.4)	0
Bronchiolitis	1 (1.7)	1 (1.7)	0
Covid-19	1 (1.7)	1 (1.7)	0
Cytomegalovirus infection reactivation	1 (1.7)	1 (1.7)	0
Device related sepsis	1 (1.7)	1 (1.7)	0
Encephalitis	1 (1.7)	0	1 (1.7)
Encephalitis viral	1 (1.7)	1 (1.7)	0
Enterobacter infection	1 (1.7)	1 (1.7)	0
Escherichia bacteraemia	1 (1.7)	0	1 (1.7)
Fungaemia	1 (1.7)	0	1 (1.7)
Herpes zoster	1 (1.7)	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	1 (1.7)	0
Klebsiella bacteraemia	1 (1.7)	1 (1.7)	0
Klebsiella infection	1 (1.7)	1 (1.7)	0
Mastoiditis	1 (1.7)	1 (1.7)	0
Meningitis pneumococcal	1 (1.7)	1 (1.7)	0
Metapneumovirus infection	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ophthalmic herpes zoster	1 (1.7)	0	0
Otitis externa	1 (1.7)	1 (1.7)	0
Otitis media	1 (1.7)	1 (1.7)	0
Paronychia	1 (1.7)	1 (1.7)	0
Pneumocystis jirovecii pneumonia	1 (1.7)	0	1 (1.7)
Pneumonia fungal	1 (1.7)	1 (1.7)	0
Pneumonia viral	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0
Soft tissue infection	1 (1.7)	1 (1.7)	0
Staphylococcal abscess	1 (1.7)	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	1 (1.7)	0
Staphylococcal sepsis	1 (1.7)	0	1 (1.7)
Staphylococcal skin infection	1 (1.7)	1 (1.7)	0
Urinary tract infection	1 (1.7)	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	1 (1.7)	0
Viral haemorrhagic cystitis	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Tracheal obstruction	1 (1.7)	0	1 (1.7)
Investigations			
-Total	3 (5.2)	1 (1.7)	2 (3.4)
Neutrophil count decreased	2 (3.4)	0	2 (3.4)
Blood uric acid increased	1 (1.7)	0	1 (1.7)
C-reactive protein increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	7 (12.1)	4 (6.9)	3 (5.2)
Tumour lysis syndrome	3 (5.2)	1 (1.7)	2 (3.4)
Decreased appetite	1 (1.7)	0	1 (1.7)
Hypervolaemia	1 (1.7)	1 (1.7)	0
Hypokalaemia	1 (1.7)	1 (1.7)	0
Malnutrition	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (1.7)	1 (1.7)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.4)	2 (3.4)	0
Bone giant cell tumour benign	1 (1.7)	1 (1.7)	0
Myelodysplastic syndrome	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	6 (10.3)	4 (6.9)	2 (3.4)
Headache	2 (3.4)	2 (3.4)	0
Seizure	2 (3.4)	1 (1.7)	0
Encephalopathy	1 (1.7)	1 (1.7)	0
Haemorrhage intracranial	1 (1.7)	0	1 (1.7)
Hydrocephalus	1 (1.7)	0	1 (1.7)
Nervous system disorder	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	2 (3.4)	1 (1.7)	0
Mental status changes	2 (3.4)	1 (1.7)	0
Renal and urinary disorders			

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.2)	1 (1.7)	1 (1.7)
Acute kidney injury	2 (3.4)	0	1 (1.7)
Renal tubular necrosis	1 (1.7)	1 (1.7)	0
Reproductive system and breast disorders			
-Total	1 (1.7)	1 (1.7)	0
Endometriosis	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (22.4)	2 (3.4)	8 (13.8)
Respiratory failure	3 (5.2)	0	3 (5.2)
Acute respiratory distress syndrome	2 (3.4)	0	2 (3.4)
Pleural effusion	2 (3.4)	0	1 (1.7)
Respiratory distress	2 (3.4)	0	1 (1.7)
Bronchial oedema	1 (1.7)	0	0
Dyspnoea exertional	1 (1.7)	0	0
Epistaxis	1 (1.7)	1 (1.7)	0
Hypoxia	1 (1.7)	1 (1.7)	0
Laryngeal oedema	1 (1.7)	0	1 (1.7)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary haemorrhage	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	5 (8.6)	2 (3.4)	3 (5.2)
Hypotension	5 (8.6)	2 (3.4)	3 (5.2)
Flushing	1 (1.7)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213l
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	32 (80.0)	9 (22.5)	21 (52.5)
Blood and lymphatic system disorders			
-Total	14 (35.0)	11 (27.5)	3 (7.5)
Febrile neutropenia	11 (27.5)	10 (25.0)	1 (2.5)
Disseminated intravascular coagulation	2 (5.0)	1 (2.5)	0
Anaemia	1 (2.5)	0	1 (2.5)
Coagulopathy	1 (2.5)	1 (2.5)	0
Neutropenia	1 (2.5)	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	5 (12.5)	0	4 (10.0)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	2 (5.0)	1 (2.5)	1 (2.5)
Atrioventricular block first degree	1 (2.5)	0	0
Tachycardia	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	7 (17.5)	3 (7.5)	2 (5.0)
Abdominal compartment syndrome	2 (5.0)	0	2 (5.0)
Constipation	1 (2.5)	0	0
Gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0
Haemoperitoneum	1 (2.5)	0	1 (2.5)
Ileus	1 (2.5)	1 (2.5)	0
Irritable bowel syndrome	1 (2.5)	0	0
Nausea	1 (2.5)	0	0
Pancreatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	9 (22.5)	0	3 (7.5)
Pyrexia	5 (12.5)	0	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (7.5)	0	3 (7.5)
Oedema peripheral	1 (2.5)	0	0
Pain	1 (2.5)	0	0
Systemic inflammatory response syndrome	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			
-Total	2 (5.0)	0	2 (5.0)
Cholestasis	1 (2.5)	0	1 (2.5)
Hepatomegaly	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	22 (55.0)	5 (12.5)	11 (27.5)
Cytokine release syndrome	21 (52.5)	5 (12.5)	10 (25.0)
Haemophagocytic lymphohistiocytosis	2 (5.0)	0	2 (5.0)
Allergy to immunoglobulin therapy	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	20 (50.0)	12 (30.0)	8 (20.0)
Pneumonia	2 (5.0)	1 (2.5)	1 (2.5)
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Aspergillus infection	1 (2.5)	0	1 (2.5)
Clostridium difficile colitis	1 (2.5)	1 (2.5)	0
Covid-19 pneumonia	1 (2.5)	0	1 (2.5)
Disseminated trichosporonosis	1 (2.5)	0	1 (2.5)
Encephalitis	1 (2.5)	0	1 (2.5)
Encephalitis viral	1 (2.5)	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	1 (2.5)	0
Fungal skin infection	1 (2.5)	1 (2.5)	0
Gastroenteritis escherichia coli	1 (2.5)	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	1 (2.5)	0
Gastroenteritis viral	1 (2.5)	1 (2.5)	0
Herpes zoster	1 (2.5)	1 (2.5)	0
Localised infection	1 (2.5)	1 (2.5)	0
Meningitis bacterial	1 (2.5)	1 (2.5)	0
Pharyngitis	1 (2.5)	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	1 (2.5)	0
Pneumonia respiratory syncytial viral	1 (2.5)	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (2.5)	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	0
Sepsis	1 (2.5)	0	1 (2.5)
Serratia sepsis	1 (2.5)	0	1 (2.5)
Sialoadenitis	1 (2.5)	1 (2.5)	0
Systemic mycosis	1 (2.5)	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	3 (7.5)	1 (2.5)	1 (2.5)
Infusion related reaction	1 (2.5)	1 (2.5)	0
Transfusion reaction	1 (2.5)	0	0
Vasoplegia syndrome	1 (2.5)	0	1 (2.5)
Investigations			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Aspartate aminotransferase increased	2 (5.0)	2 (5.0)	0
Amylase increased	1 (2.5)	0	1 (2.5)
Blood bilirubin increased	1 (2.5)	1 (2.5)	0

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	4 (10.0)	0	3 (7.5)
Dehydration	1 (2.5)	0	0
Hypercalcaemia	1 (2.5)	1 (2.5)	0
Hyperkalaemia	1 (2.5)	0	1 (2.5)
Hypernatraemia	1 (2.5)	0	1 (2.5)
Hyperphosphataemia	1 (2.5)	0	1 (2.5)
Hyponatraemia	1 (2.5)	0	1 (2.5)
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	6 (15.0)	2 (5.0)	1 (2.5)
Back pain	2 (5.0)	1 (2.5)	0
Pain in extremity	2 (5.0)	0	0
Haemarthrosis	1 (2.5)	1 (2.5)	0
Rhabdomyolysis	1 (2.5)	0	1 (2.5)
Nervous system disorders			

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.0)	2 (5.0)	1 (2.5)
Cerebral haemorrhage	1 (2.5)	0	1 (2.5)
Cognitive disorder	1 (2.5)	0	0
Dysarthria	1 (2.5)	1 (2.5)	0
Encephalopathy	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	2 (5.0)	2 (5.0)	0
Delirium	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)
Acute kidney injury	4 (10.0)	2 (5.0)	2 (5.0)
Renal failure	1 (2.5)	0	1 (2.5)
Renal tubular necrosis	1 (2.5)	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (27.5)	3 (7.5)	8 (20.0)
Respiratory failure	6 (15.0)	0	6 (15.0)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (10.0)	2 (5.0)	2 (5.0)
Pulmonary oedema	2 (5.0)	1 (2.5)	1 (2.5)
Acute respiratory distress syndrome	1 (2.5)	0	1 (2.5)
Acute respiratory failure	1 (2.5)	1 (2.5)	0
Dyspnoea	1 (2.5)	0	1 (2.5)
Epistaxis	1 (2.5)	0	0
Pleural effusion	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	7 (17.5)	1 (2.5)	6 (15.0)
Hypotension	6 (15.0)	1 (2.5)	5 (12.5)
Venoocclusive disease	1 (2.5)	0	1 (2.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213m
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (76.5)	7 (41.2)	5 (29.4)
Blood and lymphatic system disorders			
-Total	8 (47.1)	8 (47.1)	0
Febrile neutropenia	8 (47.1)	8 (47.1)	0
Cardiac disorders			
-Total	1 (5.9)	1 (5.9)	0
Left ventricular dysfunction	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	1 (5.9)	1 (5.9)	0
Neutropenic colitis	1 (5.9)	1 (5.9)	0
Stomatitis	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (5.9)	0	0
Pyrexia	1 (5.9)	0	0
Hepatobiliary disorders			
-Total	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Immune system disorders			
-Total	10 (58.8)	4 (23.5)	1 (5.9)
Cytokine release syndrome	10 (58.8)	4 (23.5)	1 (5.9)
Infections and infestations			
-Total	5 (29.4)	4 (23.5)	1 (5.9)
Aspergillus infection	1 (5.9)	0	1 (5.9)
Fungal skin infection	1 (5.9)	1 (5.9)	0
Staphylococcal abscess	1 (5.9)	1 (5.9)	0
Staphylococcal infection	1 (5.9)	1 (5.9)	0
Systemic mycosis	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	1 (5.9)	0	0
Transfusion reaction	1 (5.9)	0	0
Metabolism and nutrition disorders			
-Total	1 (5.9)	0	0
Dehydration	1 (5.9)	0	0
Nervous system disorders			
-Total	1 (5.9)	0	1 (5.9)
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	1 (5.9)	1 (5.9)	0
Mental status changes	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Renal tubular necrosis	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Epistaxis	1 (5.9)	1 (5.9)	0
Hypoxia	1 (5.9)	1 (5.9)	0
Laryngeal oedema	1 (5.9)	0	1 (5.9)
Respiratory distress	1 (5.9)	0	0
Vascular disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Hypotension	2 (11.8)	1 (5.9)	1 (5.9)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213m
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	66 (81.5)	22 (27.2)	42 (51.9)
Blood and lymphatic system disorders			
-Total	20 (24.7)	16 (19.8)	4 (4.9)
Febrile neutropenia	15 (18.5)	13 (16.0)	2 (2.5)
Disseminated intravascular coagulation	3 (3.7)	2 (2.5)	0
Anaemia	2 (2.5)	0	1 (1.2)
Pancytopenia	2 (2.5)	2 (2.5)	0
Thrombocytopenia	2 (2.5)	1 (1.2)	1 (1.2)
Coagulopathy	1 (1.2)	1 (1.2)	0
Neutropenia	1 (1.2)	1 (1.2)	0
Cardiac disorders			

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (11.1)	3 (3.7)	5 (6.2)
Cardiac arrest	3 (3.7)	0	3 (3.7)
Cardiac failure	3 (3.7)	2 (2.5)	1 (1.2)
Atrioventricular block first degree	1 (1.2)	0	0
Left ventricular dysfunction	1 (1.2)	1 (1.2)	0
Pericardial effusion	1 (1.2)	1 (1.2)	0
Tachycardia	1 (1.2)	0	1 (1.2)
Gastrointestinal disorders			
-Total	10 (12.3)	6 (7.4)	2 (2.5)
Abdominal compartment syndrome	2 (2.5)	0	2 (2.5)
Diarrhoea	2 (2.5)	1 (1.2)	0
Pancreatitis	2 (2.5)	2 (2.5)	0
Anal inflammation	1 (1.2)	1 (1.2)	0
Constipation	1 (1.2)	0	0
Gastrointestinal haemorrhage	1 (1.2)	1 (1.2)	0
Haemoperitoneum	1 (1.2)	0	1 (1.2)
Ileus	1 (1.2)	1 (1.2)	0
Irritable bowel syndrome	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (1.2)	0	0
Vomiting	1 (1.2)	0	0
General disorders and administration site conditions			
-Total	17 (21.0)	2 (2.5)	3 (3.7)
Pyrexia	12 (14.8)	2 (2.5)	0
Multiple organ dysfunction syndrome	3 (3.7)	0	3 (3.7)
Non-cardiac chest pain	1 (1.2)	0	0
Oedema peripheral	1 (1.2)	0	0
Pain	1 (1.2)	0	0
Systemic inflammatory response syndrome	1 (1.2)	1 (1.2)	0
Hepatobiliary disorders			
-Total	3 (3.7)	1 (1.2)	2 (2.5)
Cholestasis	1 (1.2)	0	1 (1.2)
Hepatic cytolysis	1 (1.2)	1 (1.2)	0
Hepatomegaly	1 (1.2)	0	1 (1.2)
Immune system disorders			
-Total	41 (50.6)	12 (14.8)	21 (25.9)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	40 (49.4)	12 (14.8)	20 (24.7)
Haemophagocytic lymphohistiocytosis	2 (2.5)	0	2 (2.5)
Allergy to immunoglobulin therapy	1 (1.2)	1 (1.2)	0
Drug hypersensitivity	1 (1.2)	1 (1.2)	0
Infections and infestations			
-Total	43 (53.1)	25 (30.9)	18 (22.2)
Pneumonia	4 (4.9)	2 (2.5)	2 (2.5)
Sepsis	4 (4.9)	1 (1.2)	3 (3.7)
Septic shock	3 (3.7)	0	3 (3.7)
Staphylococcal bacteraemia	3 (3.7)	3 (3.7)	0
Bacteraemia	2 (2.5)	1 (1.2)	1 (1.2)
Bronchopulmonary aspergillosis	2 (2.5)	1 (1.2)	1 (1.2)
Candida infection	2 (2.5)	0	1 (1.2)
Device related infection	2 (2.5)	2 (2.5)	0
Encephalitis	2 (2.5)	0	2 (2.5)
Encephalitis viral	2 (2.5)	1 (1.2)	1 (1.2)
Escherichia bacteraemia	2 (2.5)	1 (1.2)	1 (1.2)

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (2.5)	2 (2.5)	0
Herpes zoster	2 (2.5)	2 (2.5)	0
Parainfluenzae virus infection	2 (2.5)	2 (2.5)	0
Respiratory syncytial virus infection	2 (2.5)	2 (2.5)	0
Rhinovirus infection	2 (2.5)	1 (1.2)	0
Sinusitis	2 (2.5)	2 (2.5)	0
Upper respiratory tract infection	2 (2.5)	2 (2.5)	0
Bronchiolitis	1 (1.2)	1 (1.2)	0
Clostridium difficile colitis	1 (1.2)	1 (1.2)	0
Covid-19	1 (1.2)	1 (1.2)	0
Covid-19 pneumonia	1 (1.2)	0	1 (1.2)
Cytomegalovirus infection reactivation	1 (1.2)	1 (1.2)	0
Device related sepsis	1 (1.2)	1 (1.2)	0
Disseminated trichosporonosis	1 (1.2)	0	1 (1.2)
Enterobacter infection	1 (1.2)	1 (1.2)	0
Fungaemia	1 (1.2)	0	1 (1.2)
Gastroenteritis escherichia coli	1 (1.2)	1 (1.2)	0
Gastroenteritis salmonella	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (1.2)	1 (1.2)	0
Human herpesvirus 6 infection	1 (1.2)	1 (1.2)	0
Klebsiella bacteraemia	1 (1.2)	1 (1.2)	0
Klebsiella infection	1 (1.2)	1 (1.2)	0
Localised infection	1 (1.2)	1 (1.2)	0
Mastoiditis	1 (1.2)	1 (1.2)	0
Meningitis bacterial	1 (1.2)	1 (1.2)	0
Meningitis pneumococcal	1 (1.2)	1 (1.2)	0
Metapneumovirus infection	1 (1.2)	1 (1.2)	0
Ophthalmic herpes zoster	1 (1.2)	0	0
Otitis externa	1 (1.2)	1 (1.2)	0
Otitis media	1 (1.2)	1 (1.2)	0
Paronychia	1 (1.2)	1 (1.2)	0
Pharyngitis	1 (1.2)	1 (1.2)	0
Pharyngitis streptococcal	1 (1.2)	1 (1.2)	0
Pneumocystis jirovecii pneumonia	1 (1.2)	0	1 (1.2)
Pneumonia fungal	1 (1.2)	1 (1.2)	0
Pneumonia respiratory syncytial viral	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia viral	1 (1.2)	1 (1.2)	0
Respiratory tract infection	1 (1.2)	1 (1.2)	0
Serratia sepsis	1 (1.2)	0	1 (1.2)
Sialoadenitis	1 (1.2)	1 (1.2)	0
Soft tissue infection	1 (1.2)	1 (1.2)	0
Staphylococcal infection	1 (1.2)	0	1 (1.2)
Staphylococcal sepsis	1 (1.2)	0	1 (1.2)
Staphylococcal skin infection	1 (1.2)	1 (1.2)	0
Urinary tract infection	1 (1.2)	1 (1.2)	0
Viral haemorrhagic cystitis	1 (1.2)	1 (1.2)	0
Viral upper respiratory tract infection	1 (1.2)	1 (1.2)	0
Injury, poisoning and procedural complications			
-Total	3 (3.7)	1 (1.2)	2 (2.5)
Infusion related reaction	1 (1.2)	1 (1.2)	0
Tracheal obstruction	1 (1.2)	0	1 (1.2)
Vasoplegia syndrome	1 (1.2)	0	1 (1.2)
Investigations			

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (8.6)	3 (3.7)	4 (4.9)
Aspartate aminotransferase increased	2 (2.5)	2 (2.5)	0
Neutrophil count decreased	2 (2.5)	0	2 (2.5)
Amylase increased	1 (1.2)	0	1 (1.2)
Blood bilirubin increased	1 (1.2)	1 (1.2)	0
Blood uric acid increased	1 (1.2)	0	1 (1.2)
C-reactive protein increased	1 (1.2)	1 (1.2)	0
Electrocardiogram qt prolonged	1 (1.2)	0	1 (1.2)
Metabolism and nutrition disorders			
-Total	10 (12.3)	4 (4.9)	6 (7.4)
Tumour lysis syndrome	3 (3.7)	1 (1.2)	2 (2.5)
Decreased appetite	1 (1.2)	0	1 (1.2)
Hypercalcaemia	1 (1.2)	1 (1.2)	0
Hyperkalaemia	1 (1.2)	0	1 (1.2)
Hypernatraemia	1 (1.2)	0	1 (1.2)
Hyperphosphataemia	1 (1.2)	0	1 (1.2)
Hypervolaemia	1 (1.2)	1 (1.2)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (1.2)	1 (1.2)	0
Hyponatraemia	1 (1.2)	0	1 (1.2)
Malnutrition	1 (1.2)	1 (1.2)	0
Metabolic acidosis	1 (1.2)	0	1 (1.2)
Musculoskeletal and connective tissue disorders			
-Total	7 (8.6)	3 (3.7)	1 (1.2)
Back pain	3 (3.7)	2 (2.5)	0
Pain in extremity	2 (2.5)	0	0
Haemarthrosis	1 (1.2)	1 (1.2)	0
Rhabdomyolysis	1 (1.2)	0	1 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.5)	2 (2.5)	0
Bone giant cell tumour benign	1 (1.2)	1 (1.2)	0
Myelodysplastic syndrome	1 (1.2)	1 (1.2)	0
Nervous system disorders			
-Total	9 (11.1)	6 (7.4)	2 (2.5)
Encephalopathy	2 (2.5)	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (2.5)	2 (2.5)	0
Seizure	2 (2.5)	1 (1.2)	0
Cerebral haemorrhage	1 (1.2)	0	1 (1.2)
Cognitive disorder	1 (1.2)	0	0
Dysarthria	1 (1.2)	1 (1.2)	0
Hydrocephalus	1 (1.2)	0	1 (1.2)
Nervous system disorder	1 (1.2)	1 (1.2)	0
Psychiatric disorders			
-Total	3 (3.7)	2 (2.5)	0
Mental status changes	2 (2.5)	1 (1.2)	0
Delirium	1 (1.2)	1 (1.2)	0
Renal and urinary disorders			
-Total	7 (8.6)	2 (2.5)	4 (4.9)
Acute kidney injury	6 (7.4)	2 (2.5)	3 (3.7)
Renal failure	1 (1.2)	0	1 (1.2)
Renal tubular necrosis	1 (1.2)	0	1 (1.2)
Reproductive system and breast disorders			

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.2)	1 (1.2)	0
Endometriosis	1 (1.2)	1 (1.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	21 (25.9)	3 (3.7)	15 (18.5)
Respiratory failure	9 (11.1)	0	9 (11.1)
Hypoxia	4 (4.9)	2 (2.5)	2 (2.5)
Acute respiratory distress syndrome	3 (3.7)	0	3 (3.7)
Pleural effusion	3 (3.7)	1 (1.2)	1 (1.2)
Pulmonary oedema	2 (2.5)	1 (1.2)	1 (1.2)
Acute respiratory failure	1 (1.2)	1 (1.2)	0
Bronchial oedema	1 (1.2)	0	0
Dyspnoea	1 (1.2)	0	1 (1.2)
Dyspnoea exertional	1 (1.2)	0	0
Epistaxis	1 (1.2)	0	0
Pulmonary haemorrhage	1 (1.2)	0	1 (1.2)
Respiratory distress	1 (1.2)	0	1 (1.2)
Vascular disorders			

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	10 (12.3)	2 (2.5)	8 (9.9)
Hypotension	9 (11.1)	2 (2.5)	7 (8.6)
Flushing	1 (1.2)	0	0
Venoocclusive disease	1 (1.2)	0	1 (1.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213n
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	19 (67.9)	11 (39.3)	6 (21.4)
Blood and lymphatic system disorders			
-Total	6 (21.4)	6 (21.4)	0
Febrile neutropenia	5 (17.9)	5 (17.9)	0
Anaemia	1 (3.6)	0	0
Disseminated intravascular coagulation	1 (3.6)	1 (3.6)	0
Pancytopenia	1 (3.6)	1 (3.6)	0
Thrombocytopenia	1 (3.6)	1 (3.6)	0
Cardiac disorders			
-Total	1 (3.6)	0	1 (3.6)
Tachycardia	1 (3.6)	0	1 (3.6)
Gastrointestinal disorders			

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.7)	2 (7.1)	0
Ileus	1 (3.6)	1 (3.6)	0
Irritable bowel syndrome	1 (3.6)	0	0
Pancreatitis	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	9 (32.1)	1 (3.6)	2 (7.1)
Pyrexia	6 (21.4)	1 (3.6)	0
Multiple organ dysfunction syndrome	2 (7.1)	0	2 (7.1)
Oedema peripheral	1 (3.6)	0	0
Systemic inflammatory response syndrome	1 (3.6)	1 (3.6)	0
Hepatobiliary disorders			
-Total	1 (3.6)	0	1 (3.6)
Cholestasis	1 (3.6)	0	1 (3.6)
Immune system disorders			
-Total	13 (46.4)	3 (10.7)	5 (17.9)
Cytokine release syndrome	12 (42.9)	3 (10.7)	4 (14.3)
Haemophagocytic lymphohistiocytosis	2 (7.1)	0	2 (7.1)

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	11 (39.3)	7 (25.0)	4 (14.3)
Staphylococcal bacteraemia	3 (10.7)	3 (10.7)	0
Encephalitis	2 (7.1)	0	2 (7.1)
Respiratory syncytial virus infection	2 (7.1)	2 (7.1)	0
Upper respiratory tract infection	2 (7.1)	2 (7.1)	0
Bronchopulmonary aspergillosis	1 (3.6)	0	1 (3.6)
Clostridium difficile colitis	1 (3.6)	1 (3.6)	0
Covid-19 pneumonia	1 (3.6)	0	1 (3.6)
Gastroenteritis	1 (3.6)	1 (3.6)	0
Gastroenteritis escherichia coli	1 (3.6)	1 (3.6)	0
Gastroenteritis salmonella	1 (3.6)	1 (3.6)	0
Herpes zoster	1 (3.6)	1 (3.6)	0
Localised infection	1 (3.6)	1 (3.6)	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0
Pneumonia	1 (3.6)	1 (3.6)	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0
Sepsis	1 (3.6)	1 (3.6)	0
Sinusitis	1 (3.6)	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (3.6)	1 (3.6)	0
Viral haemorrhagic cystitis	1 (3.6)	1 (3.6)	0
Injury, poisoning and procedural complications			
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Infusion related reaction	1 (3.6)	1 (3.6)	0
Vasoplegia syndrome	1 (3.6)	0	1 (3.6)
Investigations			
-Total	1 (3.6)	0	1 (3.6)
Electrocardiogram qt prolonged	1 (3.6)	0	1 (3.6)
Metabolism and nutrition disorders			
-Total	4 (14.3)	1 (3.6)	2 (7.1)
Decreased appetite	1 (3.6)	0	1 (3.6)
Dehydration	1 (3.6)	0	0
Hypernatraemia	1 (3.6)	0	1 (3.6)
Tumour lysis syndrome	1 (3.6)	1 (3.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (10.7)	1 (3.6)	1 (3.6)

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemarthrosis	1 (3.6)	1 (3.6)	0
Pain in extremity	1 (3.6)	0	0
Rhabdomyolysis	1 (3.6)	0	1 (3.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.6)	1 (3.6)	0
Bone giant cell tumour benign	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	2 (7.1)	2 (7.1)	0
Encephalopathy	1 (3.6)	1 (3.6)	0
Headache	1 (3.6)	1 (3.6)	0
Seizure	1 (3.6)	0	0
Renal and urinary disorders			
-Total	1 (3.6)	0	1 (3.6)
Acute kidney injury	1 (3.6)	0	1 (3.6)
Renal tubular necrosis	1 (3.6)	0	1 (3.6)
Reproductive system and breast disorders			
-Total	1 (3.6)	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endometriosis	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (17.9)	1 (3.6)	2 (7.1)
Pleural effusion	3 (10.7)	1 (3.6)	1 (3.6)
Acute respiratory distress syndrome	1 (3.6)	0	1 (3.6)
Dyspnoea	1 (3.6)	0	1 (3.6)
Dyspnoea exertional	1 (3.6)	0	0
Epistaxis	1 (3.6)	0	0
Hypoxia	1 (3.6)	1 (3.6)	0
Pulmonary oedema	1 (3.6)	1 (3.6)	0
Vascular disorders			
-Total	2 (7.1)	1 (3.6)	1 (3.6)
Hypotension	2 (7.1)	1 (3.6)	1 (3.6)
Flushing	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213n
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	60 (85.7)	18 (25.7)	41 (58.6)
Blood and lymphatic system disorders			
-Total	22 (31.4)	18 (25.7)	4 (5.7)
Febrile neutropenia	18 (25.7)	16 (22.9)	2 (2.9)
Disseminated intravascular coagulation	2 (2.9)	1 (1.4)	0
Anaemia	1 (1.4)	0	1 (1.4)
Coagulopathy	1 (1.4)	1 (1.4)	0
Neutropenia	1 (1.4)	1 (1.4)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	9 (12.9)	4 (5.7)	4 (5.7)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	3 (4.3)	0	3 (4.3)
Cardiac failure	3 (4.3)	2 (2.9)	1 (1.4)
Left ventricular dysfunction	2 (2.9)	2 (2.9)	0
Atrioventricular block first degree	1 (1.4)	0	0
Pericardial effusion	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	8 (11.4)	5 (7.1)	2 (2.9)
Abdominal compartment syndrome	2 (2.9)	0	2 (2.9)
Diarrhoea	2 (2.9)	1 (1.4)	0
Anal inflammation	1 (1.4)	1 (1.4)	0
Constipation	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
Haemoperitoneum	1 (1.4)	0	1 (1.4)
Nausea	1 (1.4)	0	0
Neutropenic colitis	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Stomatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	9 (12.9)	1 (1.4)	1 (1.4)
Pyrexia	7 (10.0)	1 (1.4)	0
Multiple organ dysfunction syndrome	1 (1.4)	0	1 (1.4)
Non-cardiac chest pain	1 (1.4)	0	0
Pain	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Drug-induced liver injury	1 (1.4)	1 (1.4)	0
Hepatic cytolysis	1 (1.4)	1 (1.4)	0
Hepatomegaly	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	38 (54.3)	13 (18.6)	17 (24.3)
Cytokine release syndrome	38 (54.3)	13 (18.6)	17 (24.3)
Allergy to immunoglobulin therapy	1 (1.4)	1 (1.4)	0
Drug hypersensitivity	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	37 (52.9)	22 (31.4)	15 (21.4)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	3 (4.3)	1 (1.4)	2 (2.9)
Sepsis	3 (4.3)	0	3 (4.3)
Septic shock	3 (4.3)	0	3 (4.3)
Bacteraemia	2 (2.9)	1 (1.4)	1 (1.4)
Candida infection	2 (2.9)	0	1 (1.4)
Device related infection	2 (2.9)	2 (2.9)	0
Encephalitis viral	2 (2.9)	1 (1.4)	1 (1.4)
Escherichia bacteraemia	2 (2.9)	1 (1.4)	1 (1.4)
Staphylococcal infection	2 (2.9)	1 (1.4)	1 (1.4)
Aspergillus infection	1 (1.4)	0	1 (1.4)
Bronchiolitis	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Covid-19	1 (1.4)	1 (1.4)	0
Cytomegalovirus infection reactivation	1 (1.4)	1 (1.4)	0
Device related sepsis	1 (1.4)	1 (1.4)	0
Disseminated trichosporonosis	1 (1.4)	0	1 (1.4)
Enterobacter infection	1 (1.4)	1 (1.4)	0
Fungaemia	1 (1.4)	0	1 (1.4)
Fungal skin infection	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.4)	1 (1.4)	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	1 (1.4)	0
Klebsiella bacteraemia	1 (1.4)	1 (1.4)	0
Klebsiella infection	1 (1.4)	1 (1.4)	0
Mastoiditis	1 (1.4)	1 (1.4)	0
Meningitis bacterial	1 (1.4)	1 (1.4)	0
Meningitis pneumococcal	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	1 (1.4)	0
Ophthalmic herpes zoster	1 (1.4)	0	0
Otitis externa	1 (1.4)	1 (1.4)	0
Otitis media	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	1 (1.4)	0
Paronychia	1 (1.4)	1 (1.4)	0
Pharyngitis	1 (1.4)	1 (1.4)	0
Pharyngitis streptococcal	1 (1.4)	1 (1.4)	0
Pneumocystis jirovecii pneumonia	1 (1.4)	0	1 (1.4)
Pneumonia fungal	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia respiratory syncytial viral	1 (1.4)	1 (1.4)	0
Pneumonia viral	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Serratia sepsis	1 (1.4)	0	1 (1.4)
Sialoadenitis	1 (1.4)	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0
Soft tissue infection	1 (1.4)	1 (1.4)	0
Staphylococcal abscess	1 (1.4)	1 (1.4)	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Systemic mycosis	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Urinary tract infection	1 (1.4)	1 (1.4)	0
Varicella zoster virus infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.9)	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal obstruction	1 (1.4)	0	1 (1.4)
Transfusion reaction	1 (1.4)	0	0
Investigations			
-Total	6 (8.6)	3 (4.3)	3 (4.3)
Aspartate aminotransferase increased	2 (2.9)	2 (2.9)	0
Neutrophil count decreased	2 (2.9)	0	2 (2.9)
Amylase increased	1 (1.4)	0	1 (1.4)
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Blood uric acid increased	1 (1.4)	0	1 (1.4)
C-reactive protein increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	7 (10.0)	3 (4.3)	4 (5.7)
Tumour lysis syndrome	2 (2.9)	0	2 (2.9)
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Hyperphosphataemia	1 (1.4)	0	1 (1.4)
Hypervolaemia	1 (1.4)	1 (1.4)	0
Hypokalaemia	1 (1.4)	1 (1.4)	0

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (1.4)	0	1 (1.4)
Malnutrition	1 (1.4)	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	4 (5.7)	2 (2.9)	0
Back pain	3 (4.3)	2 (2.9)	0
Pain in extremity	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.4)	1 (1.4)	0
Myelodysplastic syndrome	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	8 (11.4)	4 (5.7)	3 (4.3)
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Cognitive disorder	1 (1.4)	0	0
Dysarthria	1 (1.4)	1 (1.4)	0
Encephalopathy	1 (1.4)	1 (1.4)	0
Haemorrhage intracranial	1 (1.4)	0	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (1.4)	1 (1.4)	0
Hydrocephalus	1 (1.4)	0	1 (1.4)
Nervous system disorder	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	4 (5.7)	3 (4.3)	0
Mental status changes	3 (4.3)	2 (2.9)	0
Delirium	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (10.0)	3 (4.3)	3 (4.3)
Acute kidney injury	5 (7.1)	2 (2.9)	2 (2.9)
Renal failure	1 (1.4)	0	1 (1.4)
Renal tubular necrosis	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	19 (27.1)	4 (5.7)	14 (20.0)
Respiratory failure	9 (12.9)	0	9 (12.9)
Hypoxia	4 (5.7)	2 (2.9)	2 (2.9)
Acute respiratory distress syndrome	2 (2.9)	0	2 (2.9)

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=70 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory distress	2 (2.9)	0	1 (1.4)
Acute respiratory failure	1 (1.4)	1 (1.4)	0
Bronchial oedema	1 (1.4)	0	0
Epistaxis	1 (1.4)	1 (1.4)	0
Laryngeal oedema	1 (1.4)	0	1 (1.4)
Pulmonary haemorrhage	1 (1.4)	0	1 (1.4)
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	10 (14.3)	2 (2.9)	8 (11.4)
Hypotension	9 (12.9)	2 (2.9)	7 (10.0)
Venoocclusive disease	1 (1.4)	0	1 (1.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213o
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	9 (81.8)	5 (45.5)	2 (18.2)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Disseminated intravascular coagulation	1 (9.1)	1 (9.1)	0
Pancytopenia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	2 (18.2)	0	0
Pyrexia	2 (18.2)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0
Hepatic cytolysis	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	4 (36.4)	1 (9.1)	1 (9.1)
Cytokine release syndrome	4 (36.4)	1 (9.1)	1 (9.1)
Infections and infestations			
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Device related infection	1 (9.1)	1 (9.1)	0
Encephalitis	1 (9.1)	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0
Paronychia	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	1 (9.1)	0
Staphylococcal skin infection	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	0
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Endometriosis	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	0	0
Pleural effusion	1 (9.1)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213o
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	70 (80.5)	24 (27.6)	45 (51.7)
Blood and lymphatic system disorders			
-Total	27 (31.0)	23 (26.4)	4 (4.6)
Febrile neutropenia	23 (26.4)	21 (24.1)	2 (2.3)
Anaemia	2 (2.3)	0	1 (1.1)
Disseminated intravascular coagulation	2 (2.3)	1 (1.1)	0
Thrombocytopenia	2 (2.3)	1 (1.1)	1 (1.1)
Coagulopathy	1 (1.1)	1 (1.1)	0
Neutropenia	1 (1.1)	1 (1.1)	0
Pancytopenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			
-Total	10 (11.5)	4 (4.6)	5 (5.7)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	3 (3.4)	0	3 (3.4)
Cardiac failure	3 (3.4)	2 (2.3)	1 (1.1)
Left ventricular dysfunction	2 (2.3)	2 (2.3)	0
Atrioventricular block first degree	1 (1.1)	0	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	1 (1.1)
Gastrointestinal disorders			
-Total	10 (11.5)	6 (6.9)	2 (2.3)
Abdominal compartment syndrome	2 (2.3)	0	2 (2.3)
Diarrhoea	2 (2.3)	1 (1.1)	0
Anal inflammation	1 (1.1)	1 (1.1)	0
Constipation	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Haemoperitoneum	1 (1.1)	0	1 (1.1)
Ileus	1 (1.1)	1 (1.1)	0
Irritable bowel syndrome	1 (1.1)	0	0
Nausea	1 (1.1)	0	0
Neutropenic colitis	1 (1.1)	1 (1.1)	0
Pancreatitis	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.1)	1 (1.1)	0
Vomiting	1 (1.1)	0	0
General disorders and administration site conditions			
-Total	16 (18.4)	2 (2.3)	3 (3.4)
Pyrexia	11 (12.6)	2 (2.3)	0
Multiple organ dysfunction syndrome	3 (3.4)	0	3 (3.4)
Non-cardiac chest pain	1 (1.1)	0	0
Oedema peripheral	1 (1.1)	0	0
Pain	1 (1.1)	0	0
Systemic inflammatory response syndrome	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	3 (3.4)	1 (1.1)	2 (2.3)
Cholestasis	1 (1.1)	0	1 (1.1)
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatomegaly	1 (1.1)	0	1 (1.1)
Immune system disorders			
-Total	47 (54.0)	15 (17.2)	21 (24.1)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	46 (52.9)	15 (17.2)	20 (23.0)
Haemophagocytic lymphohistiocytosis	2 (2.3)	0	2 (2.3)
Allergy to immunoglobulin therapy	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	44 (50.6)	26 (29.9)	18 (20.7)
Pneumonia	4 (4.6)	2 (2.3)	2 (2.3)
Sepsis	3 (3.4)	0	3 (3.4)
Septic shock	3 (3.4)	0	3 (3.4)
Staphylococcal bacteraemia	3 (3.4)	3 (3.4)	0
Bacteraemia	2 (2.3)	1 (1.1)	1 (1.1)
Bronchopulmonary aspergillosis	2 (2.3)	1 (1.1)	1 (1.1)
Candida infection	2 (2.3)	0	1 (1.1)
Encephalitis viral	2 (2.3)	1 (1.1)	1 (1.1)
Escherichia bacteraemia	2 (2.3)	1 (1.1)	1 (1.1)
Gastroenteritis	2 (2.3)	2 (2.3)	0
Herpes zoster	2 (2.3)	2 (2.3)	0
Sinusitis	2 (2.3)	2 (2.3)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Staphylococcal infection	2 (2.3)	1 (1.1)	1 (1.1)
Upper respiratory tract infection	2 (2.3)	2 (2.3)	0
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Clostridium difficile colitis	1 (1.1)	1 (1.1)	0
Covid-19	1 (1.1)	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	1 (1.1)	0
Device related infection	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	1 (1.1)
Encephalitis	1 (1.1)	0	1 (1.1)
Enterobacter infection	1 (1.1)	1 (1.1)	0
Fungaemia	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis escherichia coli	1 (1.1)	1 (1.1)	0
Gastroenteritis salmonella	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Klebsiella bacteraemia	1 (1.1)	1 (1.1)	0
Klebsiella infection	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Mastoiditis	1 (1.1)	1 (1.1)	0
Meningitis bacterial	1 (1.1)	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	1 (1.1)	0
Metapneumovirus infection	1 (1.1)	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	0
Otitis externa	1 (1.1)	1 (1.1)	0
Otitis media	1 (1.1)	1 (1.1)	0
Parainfluenzae virus infection	1 (1.1)	1 (1.1)	0
Pharyngitis	1 (1.1)	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	1 (1.1)
Pneumonia fungal	1 (1.1)	1 (1.1)	0
Pneumonia respiratory syncytial viral	1 (1.1)	1 (1.1)	0
Pneumonia viral	1 (1.1)	1 (1.1)	0
Respiratory syncytial virus infection	1 (1.1)	1 (1.1)	0
Respiratory tract infection	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	1 (1.1)	0	0
Serratia sepsis	1 (1.1)	0	1 (1.1)
Sialoadenitis	1 (1.1)	1 (1.1)	0
Soft tissue infection	1 (1.1)	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	1 (1.1)
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Varicella zoster virus infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	1 (1.1)	0
Injury, poisoning and procedural complications			
-Total	4 (4.6)	1 (1.1)	2 (2.3)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Vasoplegia syndrome	1 (1.1)	0	1 (1.1)
Investigations			

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (8.0)	3 (3.4)	4 (4.6)
Aspartate aminotransferase increased	2 (2.3)	2 (2.3)	0
Neutrophil count decreased	2 (2.3)	0	2 (2.3)
Amylase increased	1 (1.1)	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	1 (1.1)	0
Blood uric acid increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	10 (11.5)	4 (4.6)	5 (5.7)
Tumour lysis syndrome	3 (3.4)	1 (1.1)	2 (2.3)
Dehydration	1 (1.1)	0	0
Hypercalcaemia	1 (1.1)	1 (1.1)	0
Hyperkalaemia	1 (1.1)	0	1 (1.1)
Hypernatraemia	1 (1.1)	0	1 (1.1)
Hyperphosphataemia	1 (1.1)	0	1 (1.1)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hypokalaemia	1 (1.1)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (1.1)	0	1 (1.1)
Malnutrition	1 (1.1)	1 (1.1)	0
Metabolic acidosis	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	7 (8.0)	3 (3.4)	1 (1.1)
Back pain	3 (3.4)	2 (2.3)	0
Pain in extremity	2 (2.3)	0	0
Haemarthrosis	1 (1.1)	1 (1.1)	0
Rhabdomyolysis	1 (1.1)	0	1 (1.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.3)	2 (2.3)	0
Bone giant cell tumour benign	1 (1.1)	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	1 (1.1)	0
Nervous system disorders			
-Total	9 (10.3)	5 (5.7)	3 (3.4)
Encephalopathy	2 (2.3)	2 (2.3)	0
Cerebral haemorrhage	1 (1.1)	0	1 (1.1)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	1 (1.1)	0	0
Dysarthria	1 (1.1)	1 (1.1)	0
Haemorrhage intracranial	1 (1.1)	0	1 (1.1)
Headache	1 (1.1)	1 (1.1)	0
Hydrocephalus	1 (1.1)	0	1 (1.1)
Nervous system disorder	1 (1.1)	1 (1.1)	0
Seizure	1 (1.1)	1 (1.1)	0
Psychiatric disorders			
-Total	4 (4.6)	3 (3.4)	0
Mental status changes	3 (3.4)	2 (2.3)	0
Delirium	1 (1.1)	1 (1.1)	0
Renal and urinary disorders			
-Total	8 (9.2)	3 (3.4)	4 (4.6)
Acute kidney injury	6 (6.9)	2 (2.3)	3 (3.4)
Renal tubular necrosis	2 (2.3)	1 (1.1)	1 (1.1)
Renal failure	1 (1.1)	0	1 (1.1)
Respiratory, thoracic and mediastinal disorders			
-Total	23 (26.4)	5 (5.7)	16 (18.4)

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	9 (10.3)	0	9 (10.3)
Hypoxia	5 (5.7)	3 (3.4)	2 (2.3)
Acute respiratory distress syndrome	3 (3.4)	0	3 (3.4)
Epistaxis	2 (2.3)	1 (1.1)	0
Pleural effusion	2 (2.3)	1 (1.1)	1 (1.1)
Pulmonary oedema	2 (2.3)	1 (1.1)	1 (1.1)
Respiratory distress	2 (2.3)	0	1 (1.1)
Acute respiratory failure	1 (1.1)	1 (1.1)	0
Bronchial oedema	1 (1.1)	0	0
Dyspnoea	1 (1.1)	0	1 (1.1)
Dyspnoea exertional	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	1 (1.1)
Pulmonary haemorrhage	1 (1.1)	0	1 (1.1)
Vascular disorders			
-Total	12 (13.8)	3 (3.4)	9 (10.3)
Hypotension	11 (12.6)	3 (3.4)	8 (9.2)
Flushing	1 (1.1)	0	0
Venoocclusive disease	1 (1.1)	0	1 (1.1)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213p
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	6 (85.7)	2 (28.6)	4 (57.1)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Disseminated intravascular coagulation	1 (14.3)	0	0
Gastrointestinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (14.3)	0	0
Immune system disorders			
-Total	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	4 (57.1)	0	3 (42.9)
Infections and infestations			
-Total	4 (57.1)	4 (57.1)	0
Escherichia bacteraemia	1 (14.3)	1 (14.3)	0
Metapneumovirus infection	1 (14.3)	1 (14.3)	0
Pneumonia respiratory syncytial viral	1 (14.3)	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	2 (28.6)	0	2 (28.6)
Cerebral haemorrhage	1 (14.3)	0	1 (14.3)
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)
Renal and urinary disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	2 (28.6)	1 (14.3)	1 (14.3)

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypoxia	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	2 (28.6)	0	2 (28.6)
Hypotension	2 (28.6)	0	2 (28.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213p
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	73 (80.2)	27 (29.7)	43 (47.3)
Blood and lymphatic system disorders			
-Total	26 (28.6)	22 (24.2)	4 (4.4)
Febrile neutropenia	21 (23.1)	19 (20.9)	2 (2.2)
Anaemia	2 (2.2)	0	1 (1.1)
Disseminated intravascular coagulation	2 (2.2)	2 (2.2)	0
Pancytopenia	2 (2.2)	2 (2.2)	0
Thrombocytopenia	2 (2.2)	1 (1.1)	1 (1.1)
Coagulopathy	1 (1.1)	1 (1.1)	0
Neutropenia	1 (1.1)	1 (1.1)	0
Cardiac disorders			

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (11.0)	4 (4.4)	5 (5.5)
Cardiac arrest	3 (3.3)	0	3 (3.3)
Cardiac failure	3 (3.3)	2 (2.2)	1 (1.1)
Left ventricular dysfunction	2 (2.2)	2 (2.2)	0
Atrioventricular block first degree	1 (1.1)	0	0
Pericardial effusion	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	0	1 (1.1)
Gastrointestinal disorders			
-Total	10 (11.0)	7 (7.7)	1 (1.1)
Diarrhoea	2 (2.2)	1 (1.1)	0
Pancreatitis	2 (2.2)	2 (2.2)	0
Abdominal compartment syndrome	1 (1.1)	0	1 (1.1)
Anal inflammation	1 (1.1)	1 (1.1)	0
Constipation	1 (1.1)	0	0
Gastrointestinal haemorrhage	1 (1.1)	1 (1.1)	0
Haemoperitoneum	1 (1.1)	0	1 (1.1)
Ileus	1 (1.1)	1 (1.1)	0
Irritable bowel syndrome	1 (1.1)	0	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (1.1)	0	0
Neutropenic colitis	1 (1.1)	1 (1.1)	0
Stomatitis	1 (1.1)	1 (1.1)	0
Vomiting	1 (1.1)	0	0
General disorders and administration site conditions			
-Total	17 (18.7)	2 (2.2)	3 (3.3)
Pyrexia	12 (13.2)	2 (2.2)	0
Multiple organ dysfunction syndrome	3 (3.3)	0	3 (3.3)
Non-cardiac chest pain	1 (1.1)	0	0
Oedema peripheral	1 (1.1)	0	0
Pain	1 (1.1)	0	0
Systemic inflammatory response syndrome	1 (1.1)	1 (1.1)	0
Hepatobiliary disorders			
-Total	4 (4.4)	2 (2.2)	2 (2.2)
Cholestasis	1 (1.1)	0	1 (1.1)
Drug-induced liver injury	1 (1.1)	1 (1.1)	0
Hepatic cytolysis	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (1.1)	0	1 (1.1)
Immune system disorders			
-Total	47 (51.6)	16 (17.6)	19 (20.9)
Cytokine release syndrome	46 (50.5)	16 (17.6)	18 (19.8)
Haemophagocytic lymphohistiocytosis	2 (2.2)	0	2 (2.2)
Allergy to immunoglobulin therapy	1 (1.1)	1 (1.1)	0
Drug hypersensitivity	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	44 (48.4)	25 (27.5)	19 (20.9)
Pneumonia	4 (4.4)	2 (2.2)	2 (2.2)
Sepsis	4 (4.4)	1 (1.1)	3 (3.3)
Septic shock	3 (3.3)	0	3 (3.3)
Staphylococcal bacteraemia	3 (3.3)	3 (3.3)	0
Bacteraemia	2 (2.2)	1 (1.1)	1 (1.1)
Bronchopulmonary aspergillosis	2 (2.2)	1 (1.1)	1 (1.1)
Candida infection	2 (2.2)	0	1 (1.1)
Device related infection	2 (2.2)	2 (2.2)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	2 (2.2)	0	2 (2.2)
Encephalitis viral	2 (2.2)	1 (1.1)	1 (1.1)
Gastroenteritis	2 (2.2)	2 (2.2)	0
Herpes zoster	2 (2.2)	2 (2.2)	0
Parainfluenzae virus infection	2 (2.2)	2 (2.2)	0
Respiratory syncytial virus infection	2 (2.2)	2 (2.2)	0
Rhinovirus infection	2 (2.2)	1 (1.1)	0
Sinusitis	2 (2.2)	2 (2.2)	0
Staphylococcal infection	2 (2.2)	1 (1.1)	1 (1.1)
Upper respiratory tract infection	2 (2.2)	2 (2.2)	0
Aspergillus infection	1 (1.1)	0	1 (1.1)
Bronchiolitis	1 (1.1)	1 (1.1)	0
Clostridium difficile colitis	1 (1.1)	1 (1.1)	0
Covid-19	1 (1.1)	1 (1.1)	0
Covid-19 pneumonia	1 (1.1)	0	1 (1.1)
Cytomegalovirus infection reactivation	1 (1.1)	1 (1.1)	0
Device related sepsis	1 (1.1)	1 (1.1)	0
Disseminated trichosporonosis	1 (1.1)	0	1 (1.1)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterobacter infection	1 (1.1)	1 (1.1)	0
Escherichia bacteraemia	1 (1.1)	0	1 (1.1)
Fungaemia	1 (1.1)	0	1 (1.1)
Fungal skin infection	1 (1.1)	1 (1.1)	0
Gastroenteritis escherichia coli	1 (1.1)	1 (1.1)	0
Gastroenteritis salmonella	1 (1.1)	1 (1.1)	0
Gastroenteritis viral	1 (1.1)	1 (1.1)	0
Human herpesvirus 6 infection	1 (1.1)	1 (1.1)	0
Klebsiella bacteraemia	1 (1.1)	1 (1.1)	0
Klebsiella infection	1 (1.1)	1 (1.1)	0
Localised infection	1 (1.1)	1 (1.1)	0
Mastoiditis	1 (1.1)	1 (1.1)	0
Meningitis bacterial	1 (1.1)	1 (1.1)	0
Meningitis pneumococcal	1 (1.1)	1 (1.1)	0
Ophthalmic herpes zoster	1 (1.1)	0	0
Otitis externa	1 (1.1)	1 (1.1)	0
Otitis media	1 (1.1)	1 (1.1)	0
Paronychia	1 (1.1)	1 (1.1)	0

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	1 (1.1)	1 (1.1)	0
Pharyngitis streptococcal	1 (1.1)	1 (1.1)	0
Pneumocystis jirovecii pneumonia	1 (1.1)	0	1 (1.1)
Pneumonia fungal	1 (1.1)	1 (1.1)	0
Pneumonia viral	1 (1.1)	1 (1.1)	0
Respiratory tract infection	1 (1.1)	1 (1.1)	0
Serratia sepsis	1 (1.1)	0	1 (1.1)
Sialoadenitis	1 (1.1)	1 (1.1)	0
Soft tissue infection	1 (1.1)	1 (1.1)	0
Staphylococcal abscess	1 (1.1)	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	1 (1.1)
Staphylococcal skin infection	1 (1.1)	1 (1.1)	0
Systemic mycosis	1 (1.1)	1 (1.1)	0
Urinary tract infection	1 (1.1)	1 (1.1)	0
Varicella zoster virus infection	1 (1.1)	1 (1.1)	0
Vascular device infection	1 (1.1)	1 (1.1)	0
Viral haemorrhagic cystitis	1 (1.1)	1 (1.1)	0
Viral upper respiratory tract infection	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	4 (4.4)	1 (1.1)	2 (2.2)
Infusion related reaction	1 (1.1)	1 (1.1)	0
Tracheal obstruction	1 (1.1)	0	1 (1.1)
Transfusion reaction	1 (1.1)	0	0
Vasoplegia syndrome	1 (1.1)	0	1 (1.1)
Investigations			
-Total	7 (7.7)	3 (3.3)	4 (4.4)
Aspartate aminotransferase increased	2 (2.2)	2 (2.2)	0
Neutrophil count decreased	2 (2.2)	0	2 (2.2)
Amylase increased	1 (1.1)	0	1 (1.1)
Blood bilirubin increased	1 (1.1)	1 (1.1)	0
Blood uric acid increased	1 (1.1)	0	1 (1.1)
C-reactive protein increased	1 (1.1)	1 (1.1)	0
Electrocardiogram qt prolonged	1 (1.1)	0	1 (1.1)
Metabolism and nutrition disorders			
-Total	11 (12.1)	4 (4.4)	6 (6.6)

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (3.3)	1 (1.1)	2 (2.2)
Decreased appetite	1 (1.1)	0	1 (1.1)
Dehydration	1 (1.1)	0	0
Hypercalcaemia	1 (1.1)	1 (1.1)	0
Hyperkalaemia	1 (1.1)	0	1 (1.1)
Hypernatraemia	1 (1.1)	0	1 (1.1)
Hyperphosphataemia	1 (1.1)	0	1 (1.1)
Hypervolaemia	1 (1.1)	1 (1.1)	0
Hypokalaemia	1 (1.1)	1 (1.1)	0
Hyponatraemia	1 (1.1)	0	1 (1.1)
Malnutrition	1 (1.1)	1 (1.1)	0
Metabolic acidosis	1 (1.1)	0	1 (1.1)
Musculoskeletal and connective tissue disorders			
-Total	7 (7.7)	3 (3.3)	1 (1.1)
Back pain	3 (3.3)	2 (2.2)	0
Pain in extremity	2 (2.2)	0	0
Haemarthrosis	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (1.1)	0	1 (1.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.2)	2 (2.2)	0
Bone giant cell tumour benign	1 (1.1)	1 (1.1)	0
Myelodysplastic syndrome	1 (1.1)	1 (1.1)	0
Nervous system disorders			
-Total	8 (8.8)	6 (6.6)	1 (1.1)
Encephalopathy	2 (2.2)	2 (2.2)	0
Headache	2 (2.2)	2 (2.2)	0
Seizure	2 (2.2)	1 (1.1)	0
Cognitive disorder	1 (1.1)	0	0
Dysarthria	1 (1.1)	1 (1.1)	0
Hydrocephalus	1 (1.1)	0	1 (1.1)
Nervous system disorder	1 (1.1)	1 (1.1)	0
Psychiatric disorders			
-Total	4 (4.4)	3 (3.3)	0
Mental status changes	3 (3.3)	2 (2.2)	0

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (1.1)	1 (1.1)	0
Renal and urinary disorders			
-Total	6 (6.6)	2 (2.2)	3 (3.3)
Acute kidney injury	4 (4.4)	1 (1.1)	2 (2.2)
Renal tubular necrosis	2 (2.2)	1 (1.1)	1 (1.1)
Renal failure	1 (1.1)	0	1 (1.1)
Reproductive system and breast disorders			
-Total	1 (1.1)	1 (1.1)	0
Endometriosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	23 (25.3)	5 (5.5)	15 (16.5)
Respiratory failure	9 (9.9)	0	9 (9.9)
Hypoxia	4 (4.4)	3 (3.3)	1 (1.1)
Acute respiratory distress syndrome	3 (3.3)	0	3 (3.3)
Pleural effusion	3 (3.3)	1 (1.1)	1 (1.1)
Epistaxis	2 (2.2)	1 (1.1)	0
Pulmonary oedema	2 (2.2)	1 (1.1)	1 (1.1)

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory distress	2 (2.2)	0	1 (1.1)
Acute respiratory failure	1 (1.1)	1 (1.1)	0
Bronchial oedema	1 (1.1)	0	0
Dyspnoea	1 (1.1)	0	1 (1.1)
Dyspnoea exertional	1 (1.1)	0	0
Laryngeal oedema	1 (1.1)	0	1 (1.1)
Pulmonary haemorrhage	1 (1.1)	0	1 (1.1)
Vascular disorders			
-Total	10 (11.0)	3 (3.3)	7 (7.7)
Hypotension	9 (9.9)	3 (3.3)	6 (6.6)
Flushing	1 (1.1)	0	0
Venoocclusive disease	1 (1.1)	0	1 (1.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213q
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	31 (77.5)	12 (30.0)	18 (45.0)
Blood and lymphatic system disorders			
-Total	9 (22.5)	8 (20.0)	1 (2.5)
Febrile neutropenia	7 (17.5)	6 (15.0)	1 (2.5)
Coagulopathy	1 (2.5)	1 (2.5)	0
Disseminated intravascular coagulation	1 (2.5)	1 (2.5)	0
Pancytopenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	1 (2.5)	0	1 (2.5)
Cardiac arrest	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	2 (5.0)	2 (5.0)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal inflammation	1 (2.5)	1 (2.5)	0
Diarrhoea	1 (2.5)	0	0
Ileus	1 (2.5)	1 (2.5)	0
Vomiting	1 (2.5)	0	0
General disorders and administration site conditions			
-Total	8 (20.0)	0	1 (2.5)
Pyrexia	6 (15.0)	0	0
Multiple organ dysfunction syndrome	1 (2.5)	0	1 (2.5)
Non-cardiac chest pain	1 (2.5)	0	0
Hepatobiliary disorders			
-Total	2 (5.0)	2 (5.0)	0
Drug-induced liver injury	1 (2.5)	1 (2.5)	0
Hepatic cytolysis	1 (2.5)	1 (2.5)	0
Immune system disorders			
-Total	24 (60.0)	9 (22.5)	11 (27.5)
Cytokine release syndrome	23 (57.5)	9 (22.5)	10 (25.0)
Drug hypersensitivity	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	24 (60.0)	16 (40.0)	8 (20.0)
Bacteraemia	2 (5.0)	1 (2.5)	1 (2.5)
Bronchopulmonary aspergillosis	2 (5.0)	1 (2.5)	1 (2.5)
Encephalitis viral	2 (5.0)	1 (2.5)	1 (2.5)
Gastroenteritis	2 (5.0)	2 (5.0)	0
Herpes zoster	2 (5.0)	2 (5.0)	0
Sepsis	2 (5.0)	1 (2.5)	1 (2.5)
Upper respiratory tract infection	2 (5.0)	2 (5.0)	0
Candida infection	1 (2.5)	0	1 (2.5)
Covid-19 pneumonia	1 (2.5)	0	1 (2.5)
Cytomegalovirus infection reactivation	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Device related sepsis	1 (2.5)	1 (2.5)	0
Encephalitis	1 (2.5)	0	1 (2.5)
Enterobacter infection	1 (2.5)	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (2.5)	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	1 (2.5)	0
Klebsiella infection	1 (2.5)	1 (2.5)	0
Localised infection	1 (2.5)	1 (2.5)	0
Mastoiditis	1 (2.5)	1 (2.5)	0
Meningitis bacterial	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0
Otitis externa	1 (2.5)	1 (2.5)	0
Otitis media	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0
Paronychia	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	0	1 (2.5)
Pneumonia fungal	1 (2.5)	1 (2.5)	0
Pneumonia viral	1 (2.5)	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Respiratory tract infection	1 (2.5)	1 (2.5)	0
Rhinovirus infection	1 (2.5)	1 (2.5)	0
Septic shock	1 (2.5)	0	1 (2.5)
Sialoadenitis	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (2.5)	1 (2.5)	0
Soft tissue infection	1 (2.5)	1 (2.5)	0
Staphylococcal abscess	1 (2.5)	1 (2.5)	0
Staphylococcal skin infection	1 (2.5)	1 (2.5)	0
Urinary tract infection	1 (2.5)	1 (2.5)	0
Varicella zoster virus infection	1 (2.5)	1 (2.5)	0
Vascular device infection	1 (2.5)	1 (2.5)	0
Viral haemorrhagic cystitis	1 (2.5)	1 (2.5)	0
Investigations			
-Total	1 (2.5)	0	1 (2.5)
Amylase increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Decreased appetite	1 (2.5)	0	1 (2.5)
Hypokalaemia	1 (2.5)	1 (2.5)	0
Hyponatraemia	1 (2.5)	0	1 (2.5)
Malnutrition	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	1 (2.5)	0
Back pain	1 (2.5)	1 (2.5)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (5.0)	2 (5.0)	0
Bone giant cell tumour benign	1 (2.5)	1 (2.5)	0
Myelodysplastic syndrome	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	2 (5.0)	2 (5.0)	0
Acute kidney injury	1 (2.5)	1 (2.5)	0
Renal tubular necrosis	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (17.5)	2 (5.0)	2 (5.0)
Acute respiratory failure	1 (2.5)	1 (2.5)	0
Bronchial oedema	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Dyspnoea exertional	1 (2.5)	0	0
Hypoxia	1 (2.5)	1 (2.5)	0
Laryngeal oedema	1 (2.5)	0	1 (2.5)
Pleural effusion	1 (2.5)	0	0
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Venoocclusive disease	1 (2.5)	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213q
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	35 (87.5)	13 (32.5)	20 (50.0)
Blood and lymphatic system disorders			
-Total	16 (40.0)	14 (35.0)	2 (5.0)
Febrile neutropenia	14 (35.0)	14 (35.0)	0
Anaemia	2 (5.0)	0	1 (2.5)
Disseminated intravascular coagulation	2 (5.0)	1 (2.5)	0
Thrombocytopenia	2 (5.0)	1 (2.5)	1 (2.5)
Neutropenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	7 (17.5)	2 (5.0)	4 (10.0)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	2 (5.0)	1 (2.5)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (2.5)	0	0
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Pericardial effusion	1 (2.5)	1 (2.5)	0
Tachycardia	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	7 (17.5)	4 (10.0)	1 (2.5)
Pancreatitis	2 (5.0)	2 (5.0)	0
Abdominal compartment syndrome	1 (2.5)	0	1 (2.5)
Constipation	1 (2.5)	0	0
Diarrhoea	1 (2.5)	1 (2.5)	0
Irritable bowel syndrome	1 (2.5)	0	0
Nausea	1 (2.5)	0	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0
Stomatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	8 (20.0)	1 (2.5)	2 (5.0)
Pyrexia	5 (12.5)	1 (2.5)	0
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (2.5)	0	0
Pain	1 (2.5)	0	0
Systemic inflammatory response syndrome	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			
-Total	2 (5.0)	0	2 (5.0)
Cholestasis	1 (2.5)	0	1 (2.5)
Hepatomegaly	1 (2.5)	0	1 (2.5)
Immune system disorders			
-Total	27 (67.5)	7 (17.5)	11 (27.5)
Cytokine release syndrome	27 (67.5)	7 (17.5)	11 (27.5)
Allergy to immunoglobulin therapy	1 (2.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	16 (40.0)	11 (27.5)	5 (12.5)
Staphylococcal bacteraemia	3 (7.5)	3 (7.5)	0
Pneumonia	2 (5.0)	2 (5.0)	0
Septic shock	2 (5.0)	0	2 (5.0)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchiolitis	1 (2.5)	1 (2.5)	0
Candida infection	1 (2.5)	0	0
Clostridium difficile colitis	1 (2.5)	1 (2.5)	0
Covid-19	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Encephalitis	1 (2.5)	0	1 (2.5)
Escherichia bacteraemia	1 (2.5)	1 (2.5)	0
Gastroenteritis escherichia coli	1 (2.5)	1 (2.5)	0
Gastroenteritis salmonella	1 (2.5)	1 (2.5)	0
Meningitis pneumococcal	1 (2.5)	1 (2.5)	0
Ophthalmic herpes zoster	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0
Pharyngitis	1 (2.5)	1 (2.5)	0
Pharyngitis streptococcal	1 (2.5)	1 (2.5)	0
Pneumocystis jirovecii pneumonia	1 (2.5)	0	1 (2.5)
Pneumonia respiratory syncytial viral	1 (2.5)	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Rhinovirus infection	1 (2.5)	0	0
Sepsis	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (2.5)	1 (2.5)	0
Staphylococcal infection	1 (2.5)	1 (2.5)	0
Staphylococcal sepsis	1 (2.5)	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	4 (10.0)	1 (2.5)	2 (5.0)
Infusion related reaction	1 (2.5)	1 (2.5)	0
Tracheal obstruction	1 (2.5)	0	1 (2.5)
Transfusion reaction	1 (2.5)	0	0
Vasoplegia syndrome	1 (2.5)	0	1 (2.5)
Investigations			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Aspartate aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	1 (2.5)	1 (2.5)	0
Blood uric acid increased	1 (2.5)	0	1 (2.5)
Electrocardiogram qt prolonged	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	6 (15.0)	2 (5.0)	3 (7.5)
Tumour lysis syndrome	2 (5.0)	1 (2.5)	1 (2.5)
Dehydration	1 (2.5)	0	0
Hypercalcaemia	1 (2.5)	1 (2.5)	0
Hyperkalaemia	1 (2.5)	0	1 (2.5)
Hypernatraemia	1 (2.5)	0	1 (2.5)
Hyperphosphataemia	1 (2.5)	0	1 (2.5)
Hypervolaemia	1 (2.5)	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	6 (15.0)	2 (5.0)	1 (2.5)
Back pain	2 (5.0)	1 (2.5)	0
Pain in extremity	2 (5.0)	0	0
Haemarthrosis	1 (2.5)	1 (2.5)	0
Rhabdomyolysis	1 (2.5)	0	1 (2.5)
Nervous system disorders			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (20.0)	5 (12.5)	2 (5.0)
Headache	2 (5.0)	2 (5.0)	0
Seizure	2 (5.0)	1 (2.5)	0
Cerebral haemorrhage	1 (2.5)	0	1 (2.5)
Cognitive disorder	1 (2.5)	0	0
Dysarthria	1 (2.5)	1 (2.5)	0
Encephalopathy	1 (2.5)	1 (2.5)	0
Hydrocephalus	1 (2.5)	0	1 (2.5)
Nervous system disorder	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	2 (5.0)	1 (2.5)	0
Delirium	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	0	0
Renal and urinary disorders			
-Total	5 (12.5)	1 (2.5)	4 (10.0)
Acute kidney injury	4 (10.0)	1 (2.5)	3 (7.5)
Renal failure	1 (2.5)	0	1 (2.5)
Renal tubular necrosis	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.5)	1 (2.5)	0
Endometriosis	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (32.5)	3 (7.5)	10 (25.0)
Respiratory failure	5 (12.5)	0	5 (12.5)
Hypoxia	4 (10.0)	2 (5.0)	2 (5.0)
Acute respiratory distress syndrome	2 (5.0)	0	2 (5.0)
Epistaxis	2 (5.0)	1 (2.5)	0
Pleural effusion	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory distress	2 (5.0)	0	1 (2.5)
Dyspnoea	1 (2.5)	0	1 (2.5)
Pulmonary oedema	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	9 (22.5)	2 (5.0)	7 (17.5)
Hypotension	9 (22.5)	2 (5.0)	7 (17.5)
Flushing	1 (2.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213q
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	13 (72.2)	4 (22.2)	9 (50.0)
Blood and lymphatic system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Febrile neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Pancytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	2 (11.1)	0
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Infections and infestations			
-Total	8 (44.4)	2 (11.1)	6 (33.3)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungaemia	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Investigations			

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.1)	1 (5.6)	1 (5.6)
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	0	1 (5.6)
Nervous system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Renal and urinary disorders			
-Total	1 (5.6)	0	0
Acute kidney injury	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (22.2)	0	4 (22.2)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary haemorrhage	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	7 (87.5)	2 (25.0)	5 (62.5)
Blood and lymphatic system disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Febrile neutropenia	2 (25.0)	1 (12.5)	1 (12.5)
Coagulopathy	1 (12.5)	1 (12.5)	0
Cardiac disorders			
-Total	1 (12.5)	0	1 (12.5)
Tachycardia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	0	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Haemoperitoneum	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (12.5)	0	0
General disorders and administration site conditions			
-Total	3 (37.5)	0	1 (12.5)
Pyrexia	2 (25.0)	0	0
Multiple organ dysfunction syndrome	1 (12.5)	0	1 (12.5)
Systemic inflammatory response syndrome	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Cholestasis	1 (12.5)	0	1 (12.5)
Immune system disorders			
-Total	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	4 (50.0)	0	2 (25.0)
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	6 (75.0)	3 (37.5)	3 (37.5)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Encephalitis	1 (12.5)	0	1 (12.5)
Gastroenteritis escherichia coli	1 (12.5)	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	0	1 (12.5)
Vasoplegia syndrome	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Encephalopathy	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	2 (25.0)	1 (12.5)	1 (12.5)
Renal tubular necrosis	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Respiratory failure	2 (25.0)	0	2 (25.0)
Acute respiratory distress syndrome	1 (12.5)	0	1 (12.5)
Acute respiratory failure	1 (12.5)	1 (12.5)	0
Dyspnoea	1 (12.5)	0	1 (12.5)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (12.5)	0	1 (12.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	22 (73.3)	9 (30.0)	11 (36.7)
Blood and lymphatic system disorders			
-Total	7 (23.3)	6 (20.0)	1 (3.3)
Febrile neutropenia	6 (20.0)	6 (20.0)	0
Disseminated intravascular coagulation	1 (3.3)	0	0
Neutropenia	1 (3.3)	1 (3.3)	0
Pancytopenia	1 (3.3)	1 (3.3)	0
Thrombocytopenia	1 (3.3)	0	1 (3.3)
Cardiac disorders			
-Total	4 (13.3)	2 (6.7)	1 (3.3)
Left ventricular dysfunction	2 (6.7)	2 (6.7)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atrioventricular block first degree	1 (3.3)	0	0
Cardiac failure	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	6 (20.0)	4 (13.3)	1 (3.3)
Abdominal compartment syndrome	1 (3.3)	0	1 (3.3)
Constipation	1 (3.3)	0	0
Gastrointestinal haemorrhage	1 (3.3)	1 (3.3)	0
Ileus	1 (3.3)	1 (3.3)	0
Nausea	1 (3.3)	0	0
Neutropenic colitis	1 (3.3)	1 (3.3)	0
Pancreatitis	1 (3.3)	1 (3.3)	0
Stomatitis	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	9 (30.0)	1 (3.3)	2 (6.7)
Pyrexia	6 (20.0)	1 (3.3)	0
Multiple organ dysfunction syndrome	2 (6.7)	0	2 (6.7)
Oedema peripheral	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (3.3)	0	0
Immune system disorders			
-Total	14 (46.7)	4 (13.3)	7 (23.3)
Cytokine release syndrome	13 (43.3)	4 (13.3)	6 (20.0)
Allergy to immunoglobulin therapy	1 (3.3)	1 (3.3)	0
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	1 (3.3)
Infections and infestations			
-Total	10 (33.3)	6 (20.0)	4 (13.3)
Covid-19 pneumonia	1 (3.3)	0	1 (3.3)
Encephalitis viral	1 (3.3)	0	1 (3.3)
Escherichia bacteraemia	1 (3.3)	1 (3.3)	0
Fungal skin infection	1 (3.3)	1 (3.3)	0
Herpes zoster	1 (3.3)	1 (3.3)	0
Klebsiella bacteraemia	1 (3.3)	1 (3.3)	0
Localised infection	1 (3.3)	1 (3.3)	0
Meningitis bacterial	1 (3.3)	1 (3.3)	0
Pharyngitis streptococcal	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.3)	0	1 (3.3)
Rhinovirus infection	1 (3.3)	0	0
Sepsis	1 (3.3)	0	1 (3.3)
Sialoadenitis	1 (3.3)	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Systemic mycosis	1 (3.3)	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	1 (3.3)	1 (3.3)	0
Infusion related reaction	1 (3.3)	1 (3.3)	0
Investigations			
-Total	5 (16.7)	3 (10.0)	2 (6.7)
Aspartate aminotransferase increased	2 (6.7)	2 (6.7)	0
Amylase increased	1 (3.3)	0	1 (3.3)
Blood bilirubin increased	1 (3.3)	1 (3.3)	0
C-reactive protein increased	1 (3.3)	1 (3.3)	0
Electrocardiogram qt prolonged	1 (3.3)	0	1 (3.3)

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (6.7)	0	1 (3.3)
Dehydration	1 (3.3)	0	0
Hyponatraemia	1 (3.3)	0	1 (3.3)
Musculoskeletal and connective tissue disorders			
-Total	4 (13.3)	1 (3.3)	0
Pain in extremity	2 (6.7)	0	0
Back pain	1 (3.3)	0	0
Haemarthrosis	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	3 (10.0)	1 (3.3)	1 (3.3)
Cerebral haemorrhage	1 (3.3)	0	1 (3.3)
Cognitive disorder	1 (3.3)	0	0
Dysarthria	1 (3.3)	1 (3.3)	0
Psychiatric disorders			
-Total	1 (3.3)	1 (3.3)	0
Delirium	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (6.7)	0	2 (6.7)
Acute kidney injury	1 (3.3)	0	1 (3.3)
Renal failure	1 (3.3)	0	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (23.3)	2 (6.7)	5 (16.7)
Respiratory failure	3 (10.0)	0	3 (10.0)
Epistaxis	2 (6.7)	1 (3.3)	0
Hypoxia	2 (6.7)	1 (3.3)	1 (3.3)
Respiratory distress	2 (6.7)	0	1 (3.3)
Pleural effusion	1 (3.3)	1 (3.3)	0
Pulmonary oedema	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	6 (20.0)	2 (6.7)	4 (13.3)
Hypotension	6 (20.0)	2 (6.7)	4 (13.3)
Flushing	1 (3.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	16 (88.9)	6 (33.3)	9 (50.0)
Blood and lymphatic system disorders			
-Total	8 (44.4)	7 (38.9)	1 (5.6)
Febrile neutropenia	6 (33.3)	6 (33.3)	0
Anaemia	2 (11.1)	0	1 (5.6)
Disseminated intravascular coagulation	1 (5.6)	1 (5.6)	0
Thrombocytopenia	1 (5.6)	1 (5.6)	0
Cardiac disorders			
-Total	2 (11.1)	0	2 (11.1)
Cardiac arrest	2 (11.1)	0	2 (11.1)

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	2 (11.1)	2 (11.1)	0
Anal inflammation	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	0	0
Pancreatitis	1 (5.6)	1 (5.6)	0
Vomiting	1 (5.6)	0	0
General disorders and administration site conditions			
-Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Hepatobiliary disorders			
-Total	1 (5.6)	0	1 (5.6)
Hepatomegaly	1 (5.6)	0	1 (5.6)
Immune system disorders			
-Total	10 (55.6)	4 (22.2)	4 (22.2)
Cytokine release syndrome	10 (55.6)	4 (22.2)	4 (22.2)
Infections and infestations			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (50.0)	8 (44.4)	1 (5.6)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Cytomegalovirus infection reactivation	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Human herpesvirus 6 infection	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Pneumonia respiratory syncytial viral	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Respiratory tract infection	1 (5.6)	1 (5.6)	0
Sinusitis	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	1 (5.6)	0
Staphylococcal infection	1 (5.6)	1 (5.6)	0
Upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	0	0
Transfusion reaction	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypercalcaemia	1 (5.6)	1 (5.6)	0
Hyperkalaemia	1 (5.6)	0	1 (5.6)
Hyperphosphataemia	1 (5.6)	0	1 (5.6)
Metabolic acidosis	1 (5.6)	0	1 (5.6)
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (11.1)	2 (11.1)	0
Back pain	2 (11.1)	2 (11.1)	0
Psychiatric disorders			
-Total	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Renal and urinary disorders			
-Total	1 (5.6)	1 (5.6)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0
Reproductive system and breast disorders			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	1 (5.6)	0
Endometriosis	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypoxia	2 (11.1)	1 (5.6)	1 (5.6)
Pleural effusion	1 (5.6)	0	1 (5.6)
Respiratory failure	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	4 (22.2)	1 (5.6)	3 (16.7)
Hypotension	3 (16.7)	1 (5.6)	2 (11.1)
Venoocclusive disease	1 (5.6)	0	1 (5.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 213r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one SAE	34 (81.0)	12 (28.6)	22 (52.4)
Blood and lymphatic system disorders			
-Total	10 (23.8)	9 (21.4)	1 (2.4)
Febrile neutropenia	9 (21.4)	8 (19.0)	1 (2.4)
Disseminated intravascular coagulation	1 (2.4)	1 (2.4)	0
Pancytopenia	1 (2.4)	1 (2.4)	0
Cardiac disorders			
-Total	3 (7.1)	2 (4.8)	1 (2.4)
Cardiac arrest	1 (2.4)	0	1 (2.4)
Cardiac failure	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (2.4)	1 (2.4)	0
Gastrointestinal disorders			
-Total	1 (2.4)	1 (2.4)	0
Diarrhoea	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions			
-Total	4 (9.5)	0	0
Pyrexia	3 (7.1)	0	0
Non-cardiac chest pain	1 (2.4)	0	0
Hepatobiliary disorders			
-Total	2 (4.8)	2 (4.8)	0
Drug-induced liver injury	1 (2.4)	1 (2.4)	0
Hepatic cytolysis	1 (2.4)	1 (2.4)	0
Immune system disorders			
-Total	23 (54.8)	8 (19.0)	9 (21.4)
Cytokine release syndrome	23 (54.8)	8 (19.0)	9 (21.4)
Drug hypersensitivity	1 (2.4)	1 (2.4)	0
Infections and infestations			

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (54.8)	12 (28.6)	11 (26.2)
Sepsis	3 (7.1)	1 (2.4)	2 (4.8)
Septic shock	3 (7.1)	0	3 (7.1)
Bacteraemia	2 (4.8)	1 (2.4)	1 (2.4)
Candida infection	2 (4.8)	0	1 (2.4)
Device related infection	2 (4.8)	2 (4.8)	0
Gastroenteritis	2 (4.8)	2 (4.8)	0
Parainfluenzae virus infection	2 (4.8)	2 (4.8)	0
Pneumonia	2 (4.8)	1 (2.4)	1 (2.4)
Upper respiratory tract infection	2 (4.8)	2 (4.8)	0
Bronchiolitis	1 (2.4)	1 (2.4)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	1 (2.4)
Covid-19	1 (2.4)	1 (2.4)	0
Encephalitis	1 (2.4)	0	1 (2.4)
Encephalitis viral	1 (2.4)	1 (2.4)	0
Enterobacter infection	1 (2.4)	1 (2.4)	0
Escherichia bacteraemia	1 (2.4)	0	1 (2.4)
Fungaemia	1 (2.4)	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (2.4)	1 (2.4)	0
Klebsiella infection	1 (2.4)	1 (2.4)	0
Mastoiditis	1 (2.4)	1 (2.4)	0
Meningitis pneumococcal	1 (2.4)	1 (2.4)	0
Metapneumovirus infection	1 (2.4)	1 (2.4)	0
Ophthalmic herpes zoster	1 (2.4)	0	0
Otitis externa	1 (2.4)	1 (2.4)	0
Otitis media	1 (2.4)	1 (2.4)	0
Paronychia	1 (2.4)	1 (2.4)	0
Pneumocystis jirovecii pneumonia	1 (2.4)	0	1 (2.4)
Pneumonia fungal	1 (2.4)	1 (2.4)	0
Pneumonia viral	1 (2.4)	1 (2.4)	0
Respiratory syncytial virus infection	1 (2.4)	1 (2.4)	0
Rhinovirus infection	1 (2.4)	1 (2.4)	0
Sinusitis	1 (2.4)	1 (2.4)	0
Soft tissue infection	1 (2.4)	1 (2.4)	0
Staphylococcal abscess	1 (2.4)	1 (2.4)	0
Staphylococcal sepsis	1 (2.4)	0	1 (2.4)

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal skin infection	1 (2.4)	1 (2.4)	0
Urinary tract infection	1 (2.4)	1 (2.4)	0
Varicella zoster virus infection	1 (2.4)	1 (2.4)	0
Vascular device infection	1 (2.4)	1 (2.4)	0
Viral haemorrhagic cystitis	1 (2.4)	1 (2.4)	0
Injury, poisoning and procedural complications			
-Total	1 (2.4)	0	1 (2.4)
Tracheal obstruction	1 (2.4)	0	1 (2.4)
Investigations			
-Total	2 (4.8)	0	2 (4.8)
Neutrophil count decreased	2 (4.8)	0	2 (4.8)
Blood uric acid increased	1 (2.4)	0	1 (2.4)
Metabolism and nutrition disorders			
-Total	6 (14.3)	3 (7.1)	3 (7.1)
Tumour lysis syndrome	2 (4.8)	0	2 (4.8)
Decreased appetite	1 (2.4)	0	1 (2.4)
Hypervolaemia	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	1 (2.4)	1 (2.4)	0
Malnutrition	1 (2.4)	1 (2.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (4.8)	2 (4.8)	0
Bone giant cell tumour benign	1 (2.4)	1 (2.4)	0
Myelodysplastic syndrome	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	6 (14.3)	4 (9.5)	2 (4.8)
Headache	2 (4.8)	2 (4.8)	0
Seizure	2 (4.8)	1 (2.4)	0
Encephalopathy	1 (2.4)	1 (2.4)	0
Haemorrhage intracranial	1 (2.4)	0	1 (2.4)
Hydrocephalus	1 (2.4)	0	1 (2.4)
Nervous system disorder	1 (2.4)	1 (2.4)	0
Psychiatric disorders			
-Total	2 (4.8)	1 (2.4)	0
Mental status changes	2 (4.8)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	3 (7.1)	1 (2.4)	1 (2.4)
Acute kidney injury	2 (4.8)	0	1 (2.4)
Renal tubular necrosis	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (23.8)	1 (2.4)	6 (14.3)
Respiratory failure	3 (7.1)	0	3 (7.1)
Acute respiratory distress syndrome	2 (4.8)	0	2 (4.8)
Bronchial oedema	1 (2.4)	0	0
Dyspnoea exertional	1 (2.4)	0	0
Hypoxia	1 (2.4)	1 (2.4)	0
Laryngeal oedema	1 (2.4)	0	1 (2.4)
Pleural effusion	1 (2.4)	0	0
Pulmonary haemorrhage	1 (2.4)	0	1 (2.4)
Vascular disorders			
-Total	1 (2.4)	0	1 (2.4)
Hypotension	1 (2.4)	0	1 (2.4)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	2 (6.1)	5 (15.2)	6 (18.2)	20 (60.6)
Blood and lymphatic system disorders					
-Total	21 (63.6)	2 (6.1)	3 (9.1)	12 (36.4)	4 (12.1)
Anaemia	13 (39.4)	3 (9.1)	3 (9.1)	7 (21.2)	0
Febrile neutropenia	12 (36.4)	0	0	12 (36.4)	0
Disseminated intravascular coagulation	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Thrombocytopenia	4 (12.1)	0	0	0	4 (12.1)
Neutropenia	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Coagulopathy	1 (3.0)	0	0	1 (3.0)	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (27.3)	4 (12.1)	3 (9.1)	1 (3.0)	1 (3.0)
Tachycardia	9 (27.3)	4 (12.1)	3 (9.1)	1 (3.0)	1 (3.0)
Endocrine disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	22 (66.7)	8 (24.2)	9 (27.3)	5 (15.2)	0
Vomiting	12 (36.4)	7 (21.2)	5 (15.2)	0	0
Nausea	11 (33.3)	5 (15.2)	5 (15.2)	1 (3.0)	0
Diarrhoea	8 (24.2)	3 (9.1)	4 (12.1)	1 (3.0)	0
Abdominal pain	6 (18.2)	1 (3.0)	3 (9.1)	2 (6.1)	0
Constipation	6 (18.2)	4 (12.1)	2 (6.1)	0	0
Mouth haemorrhage	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Stomatitis	1 (3.0)	0	0	1 (3.0)	0
General disorders and administration site conditions					
-Total	14 (42.4)	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)
Fatigue	8 (24.2)	6 (18.2)	2 (6.1)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	8 (24.2)	3 (9.1)	3 (9.1)	1 (3.0)	1 (3.0)
Chills	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Face oedema	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Pain	1 (3.0)	0	0	1 (3.0)	0
Hepatobiliary disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Hepatic function abnormal	1 (3.0)	0	0	1 (3.0)	0
Immune system disorders					
-Total	27 (81.8)	2 (6.1)	12 (36.4)	5 (15.2)	8 (24.2)
Cytokine release syndrome	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)
Hypogammaglobulinaemia	10 (30.3)	1 (3.0)	7 (21.2)	2 (6.1)	0
Infections and infestations					
-Total	7 (21.2)	1 (3.0)	5 (15.2)	1 (3.0)	0
Conjunctivitis	4 (12.1)	1 (3.0)	3 (9.1)	0	0
Staphylococcal infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Candida infection	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	23 (69.7)	2 (6.1)	2 (6.1)	4 (12.1)	15 (45.5)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	16 (48.5)	2 (6.1)	1 (3.0)	2 (6.1)	11 (33.3)
Neutrophil count decreased	13 (39.4)	0	2 (6.1)	1 (3.0)	10 (30.3)
Platelet count decreased	11 (33.3)	2 (6.1)	1 (3.0)	4 (12.1)	4 (12.1)
Alanine aminotransferase increased	9 (27.3)	2 (6.1)	6 (18.2)	1 (3.0)	0
Aspartate aminotransferase increased	8 (24.2)	1 (3.0)	3 (9.1)	2 (6.1)	2 (6.1)
Lymphocyte count decreased	8 (24.2)	0	0	5 (15.2)	3 (9.1)
Blood immunoglobulin m decreased	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Blood bilirubin increased	5 (15.2)	0	1 (3.0)	4 (12.1)	0
Blood immunoglobulin a decreased	4 (12.1)	3 (9.1)	1 (3.0)	0	0
International normalised ratio increased	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Blood fibrinogen decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Serum ferritin increased	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Blood creatinine increased	1 (3.0)	0	0	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (3.0)	0	1 (3.0)	0	0
Metabolism and nutrition disorders					
-Total	19 (57.6)	4 (12.1)	5 (15.2)	6 (18.2)	4 (12.1)
Hypophosphataemia	10 (30.3)	2 (6.1)	4 (12.1)	3 (9.1)	1 (3.0)
Decreased appetite	8 (24.2)	2 (6.1)	1 (3.0)	4 (12.1)	1 (3.0)
Hypocalcaemia	7 (21.2)	1 (3.0)	4 (12.1)	2 (6.1)	0
Hypokalaemia	7 (21.2)	2 (6.1)	1 (3.0)	2 (6.1)	2 (6.1)
Hypoalbuminaemia	4 (12.1)	0	4 (12.1)	0	0
Hyperglycaemia	3 (9.1)	0	0	3 (9.1)	0
Hyperuricaemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Hypervolaemia	1 (3.0)	0	1 (3.0)	0	0
Hypomagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (42.4)	5 (15.2)	8 (24.2)	1 (3.0)	0
Pain in extremity	8 (24.2)	4 (12.1)	4 (12.1)	0	0
Back pain	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	3 (9.1)	0	3 (9.1)	0	0
Myalgia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Nervous system disorders					
-Total	11 (33.3)	5 (15.2)	3 (9.1)	3 (9.1)	0
Headache	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)	0
Encephalopathy	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Tremor	2 (6.1)	2 (6.1)	0	0	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0
Psychiatric disorders					
-Total	7 (21.2)	4 (12.1)	3 (9.1)	0	0
Confusional state	4 (12.1)	4 (12.1)	0	0	0
Anxiety	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Delirium	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Agitation	1 (3.0)	1 (3.0)	0	0	0
Renal and urinary disorders					
-Total	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Acute kidney injury	3 (9.1)	1 (3.0)	0	0	2 (6.1)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	16 (48.5)	8 (24.2)	2 (6.1)	3 (9.1)	3 (9.1)
Cough	6 (18.2)	5 (15.2)	1 (3.0)	0	0
Hypoxia	6 (18.2)	0	2 (6.1)	2 (6.1)	2 (6.1)
Pulmonary oedema	4 (12.1)	0	1 (3.0)	3 (9.1)	0
Tachypnoea	4 (12.1)	2 (6.1)	0	2 (6.1)	0
Dyspnoea	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Pleural effusion	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Nasal congestion	1 (3.0)	0	1 (3.0)	0	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.1)	2 (6.1)	2 (6.1)	0	0
Pruritus	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Dry skin	1 (3.0)	1 (3.0)	0	0	0
Rash	1 (3.0)	0	1 (3.0)	0	0
Vascular disorders					
-Total	13 (39.4)	2 (6.1)	4 (12.1)	4 (12.1)	3 (9.1)

Timing: within 8 weeks post infusion, Age: <10 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	10 (30.3)	1 (3.0)	3 (9.1)	3 (9.1)	3 (9.1)
Hypertension	5 (15.2)	2 (6.1)	1 (3.0)	2 (6.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	2 (6.1)	3 (9.1)	9 (27.3)	19 (57.6)
Blood and lymphatic system disorders					
-Total	18 (54.5)	0	1 (3.0)	9 (27.3)	8 (24.2)
Febrile neutropenia	12 (36.4)	0	0	10 (30.3)	2 (6.1)
Anaemia	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Neutropenia	4 (12.1)	0	0	0	4 (12.1)
Disseminated intravascular coagulation	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Thrombocytopenia	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Coagulopathy	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (18.2)	2 (6.1)	3 (9.1)	1 (3.0)	0
Tachycardia	6 (18.2)	2 (6.1)	3 (9.1)	1 (3.0)	0
Sinus tachycardia	1 (3.0)	1 (3.0)	0	0	0
Endocrine disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	12 (36.4)	6 (18.2)	4 (12.1)	2 (6.1)	0
Diarrhoea	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Nausea	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Vomiting	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Abdominal pain	3 (9.1)	0	3 (9.1)	0	0
Constipation	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	14 (42.4)	8 (24.2)	1 (3.0)	4 (12.1)	1 (3.0)
Pyrexia	10 (30.3)	5 (15.2)	1 (3.0)	3 (9.1)	1 (3.0)
Face oedema	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Oedema peripheral	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	2 (6.1)	2 (6.1)	0	0	0
Chills	1 (3.0)	1 (3.0)	0	0	0
Hepatobiliary disorders					
-Total	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Hepatic function abnormal	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Immune system disorders					
-Total	27 (81.8)	0	6 (18.2)	12 (36.4)	9 (27.3)
Cytokine release syndrome	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Hypogammaglobulinaemia	10 (30.3)	0	5 (15.2)	5 (15.2)	0
Seasonal allergy	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	2 (6.1)	0	2 (6.1)	0	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	18 (54.5)	0	1 (3.0)	7 (21.2)	10 (30.3)
Alanine aminotransferase increased	7 (21.2)	2 (6.1)	1 (3.0)	4 (12.1)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	7 (21.2)	0	3 (9.1)	3 (9.1)	1 (3.0)
Platelet count decreased	7 (21.2)	1 (3.0)	2 (6.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	7 (21.2)	1 (3.0)	2 (6.1)	0	4 (12.1)
Blood bilirubin increased	6 (18.2)	1 (3.0)	1 (3.0)	4 (12.1)	0
Lymphocyte count decreased	6 (18.2)	1 (3.0)	0	3 (9.1)	2 (6.1)
Neutrophil count decreased	6 (18.2)	0	1 (3.0)	1 (3.0)	4 (12.1)
Serum ferritin increased	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Blood fibrinogen decreased	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Electrocardiogram qt prolonged	4 (12.1)	1 (3.0)	1 (3.0)	1 (3.0)	1 (3.0)
Blood creatinine increased	3 (9.1)	1 (3.0)	0	1 (3.0)	1 (3.0)
International normalised ratio increased	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Metabolism and nutrition disorders					
-Total	19 (57.6)	3 (9.1)	4 (12.1)	12 (36.4)	0
Decreased appetite	11 (33.3)	4 (12.1)	3 (9.1)	4 (12.1)	0
Hypocalcaemia	6 (18.2)	1 (3.0)	4 (12.1)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	6 (18.2)	0	1 (3.0)	5 (15.2)	0
Hypoalbuminaemia	5 (15.2)	0	5 (15.2)	0	0
Hypophosphataemia	5 (15.2)	1 (3.0)	1 (3.0)	3 (9.1)	0
Hyperuricaemia	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Hypomagnesaemia	3 (9.1)	3 (9.1)	0	0	0
Tumour lysis syndrome	3 (9.1)	0	0	3 (9.1)	0
Hyperglycaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hypervolaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (24.2)	5 (15.2)	2 (6.1)	1 (3.0)	0
Arthralgia	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Myalgia	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Pain in extremity	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Back pain	1 (3.0)	0	1 (3.0)	0	0
Nervous system disorders					
-Total	15 (45.5)	5 (15.2)	8 (24.2)	2 (6.1)	0
Headache	13 (39.4)	5 (15.2)	7 (21.2)	1 (3.0)	0
Encephalopathy	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Tremor	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Psychiatric disorders					
-Total	8 (24.2)	3 (9.1)	2 (6.1)	3 (9.1)	0
Anxiety	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Confusional state	3 (9.1)	3 (9.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Agitation	2 (6.1)	0	2 (6.1)	0	0
Renal and urinary disorders					
-Total	4 (12.1)	0	0	2 (6.1)	2 (6.1)
Acute kidney injury	4 (12.1)	0	0	2 (6.1)	2 (6.1)
Respiratory, thoracic and mediastinal disorders					
-Total	13 (39.4)	2 (6.1)	1 (3.0)	4 (12.1)	6 (18.2)
Hypoxia	8 (24.2)	0	3 (9.1)	1 (3.0)	4 (12.1)
Pleural effusion	5 (15.2)	3 (9.1)	0	1 (3.0)	1 (3.0)
Cough	4 (12.1)	4 (12.1)	0	0	0
Pulmonary oedema	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Tachypnoea	3 (9.1)	1 (3.0)	0	2 (6.1)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (6.1)	2 (6.1)	0	0	0
Respiratory failure	2 (6.1)	0	0	0	2 (6.1)
Nasal congestion	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (18.2)	3 (9.1)	3 (9.1)	0	0
Rash	4 (12.1)	2 (6.1)	2 (6.1)	0	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0	0	0
Pruritus	1 (3.0)	0	1 (3.0)	0	0
Vascular disorders					
-Total	9 (27.3)	1 (3.0)	2 (6.1)	4 (12.1)	2 (6.1)
Hypotension	7 (21.2)	0	2 (6.1)	3 (9.1)	2 (6.1)
Hypertension	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	1 (7.1)	5 (35.7)	7 (50.0)
Blood and lymphatic system disorders					
-Total	8 (57.1)	1 (7.1)	2 (14.3)	4 (28.6)	1 (7.1)
Anaemia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Coagulopathy	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Neutropenia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	4 (28.6)	2 (14.3)	2 (14.3)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Endocrine disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Adrenal insufficiency	2 (14.3)	0	2 (14.3)	0	0
Gastrointestinal disorders					
-Total	12 (85.7)	7 (50.0)	4 (28.6)	1 (7.1)	0
Vomiting	5 (35.7)	3 (21.4)	2 (14.3)	0	0
Constipation	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Nausea	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Abdominal pain	2 (14.3)	2 (14.3)	0	0	0
Diarrhoea	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Mouth haemorrhage	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Stomatitis	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	8 (57.1)	5 (35.7)	1 (7.1)	2 (14.3)	0
Pyrexia	6 (42.9)	3 (21.4)	1 (7.1)	2 (14.3)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Oedema peripheral	2 (14.3)	2 (14.3)	0	0	0
Face oedema	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Hepatic function abnormal	2 (14.3)	0	2 (14.3)	0	0
Immune system disorders					
-Total	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Cytokine release syndrome	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Hypogammaglobulinaemia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Infections and infestations					
-Total	5 (35.7)	0	3 (21.4)	1 (7.1)	1 (7.1)
Candida infection	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Staphylococcal infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Conjunctivitis	1 (7.1)	0	1 (7.1)	0	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Sinusitis	1 (7.1)	0	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (7.1)	0	0	1 (7.1)	0
Investigations					
-Total	8 (57.1)	2 (14.3)	1 (7.1)	3 (21.4)	2 (14.3)
Aspartate aminotransferase increased	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Platelet count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
International normalised ratio increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Blood bilirubin increased	1 (7.1)	0	0	1 (7.1)	0
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
White blood cell count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	7 (50.0)	2 (14.3)	0	5 (35.7)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	6 (42.9)	1 (7.1)	3 (21.4)	2 (14.3)	0
Decreased appetite	5 (35.7)	3 (21.4)	0	2 (14.3)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)	0	0
Hypervolaemia	3 (21.4)	0	0	3 (21.4)	0
Hypocalcaemia	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Hypoalbuminaemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	0	0	2 (14.3)	0
Hyperuricaemia	1 (7.1)	1 (7.1)	0	0	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (42.9)	3 (21.4)	3 (21.4)	0	0
Arthralgia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Myalgia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Back pain	1 (7.1)	1 (7.1)	0	0	0
Neck pain	1 (7.1)	0	1 (7.1)	0	0
Pain in extremity	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	5 (35.7)	3 (21.4)	1 (7.1)	1 (7.1)	0
Headache	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Somnolence	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Tremor	2 (14.3)	2 (14.3)	0	0	0
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Psychiatric disorders					
-Total	3 (21.4)	1 (7.1)	0	2 (14.3)	0
Agitation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Delirium	2 (14.3)	0	0	2 (14.3)	0
Renal and urinary disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Acute kidney injury	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (57.1)	3 (21.4)	0	3 (21.4)	2 (14.3)
Pulmonary oedema	4 (28.6)	1 (7.1)	0	2 (14.3)	1 (7.1)
Hypoxia	3 (21.4)	0	0	3 (21.4)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (14.3)	2 (14.3)	0	0	0
Respiratory failure	2 (14.3)	0	0	0	2 (14.3)
Dyspnoea	1 (7.1)	0	0	1 (7.1)	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Tachypnoea	1 (7.1)	0	1 (7.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Hyperhidrosis	2 (14.3)	0	2 (14.3)	0	0
Pruritus	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Vascular disorders					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	2 (14.3)	1 (7.1)
Hypertension	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Hypotension	4 (28.6)	0	1 (7.1)	2 (14.3)	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (83.3)	7 (23.3)	6 (20.0)	6 (20.0)	6 (20.0)
Blood and lymphatic system disorders					
-Total	4 (13.3)	1 (3.3)	0	2 (6.7)	1 (3.3)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Anaemia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Thrombocytopenia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Cardiac disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Tachycardia	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (26.7)	7 (23.3)	1 (3.3)	0	0
Vomiting	6 (20.0)	6 (20.0)	0	0	0
Diarrhoea	5 (16.7)	5 (16.7)	0	0	0
Nausea	3 (10.0)	3 (10.0)	0	0	0
Abdominal pain	1 (3.3)	1 (3.3)	0	0	0
Constipation	1 (3.3)	0	1 (3.3)	0	0
General disorders and administration site conditions					
-Total	10 (33.3)	7 (23.3)	2 (6.7)	1 (3.3)	0
Pyrexia	6 (20.0)	3 (10.0)	3 (10.0)	0	0
Fatigue	4 (13.3)	4 (13.3)	0	0	0
Pain	1 (3.3)	0	0	1 (3.3)	0
Immune system disorders					
-Total	3 (10.0)	0	3 (10.0)	0	0
Hypogammaglobulinaemia	3 (10.0)	0	3 (10.0)	0	0
Infections and infestations					
-Total	8 (26.7)	4 (13.3)	3 (10.0)	0	1 (3.3)
Upper respiratory tract infection	4 (13.3)	3 (10.0)	1 (3.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Rhinovirus infection	2 (6.7)	0	2 (6.7)	0	0
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	0	1 (3.3)
Investigations					
-Total	12 (40.0)	4 (13.3)	1 (3.3)	4 (13.3)	3 (10.0)
Neutrophil count decreased	7 (23.3)	1 (3.3)	1 (3.3)	2 (6.7)	3 (10.0)
White blood cell count decreased	7 (23.3)	3 (10.0)	2 (6.7)	1 (3.3)	1 (3.3)
Platelet count decreased	5 (16.7)	3 (10.0)	0	1 (3.3)	1 (3.3)
Lymphocyte count decreased	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Alanine aminotransferase increased	1 (3.3)	0	0	1 (3.3)	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (13.3)	2 (6.7)	0	1 (3.3)	1 (3.3)
Decreased appetite	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Hypokalaemia	2 (6.7)	0	0	1 (3.3)	1 (3.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Pain in extremity	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Arthralgia	1 (3.3)	1 (3.3)	0	0	0
Back pain	1 (3.3)	0	0	1 (3.3)	0
Nervous system disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Headache	1 (3.3)	1 (3.3)	0	0	0
Psychiatric disorders					
-Total	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Anxiety	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Agitation	1 (3.3)	1 (3.3)	0	0	0
Delirium	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (30.0)	6 (20.0)	0	2 (6.7)	1 (3.3)
Cough	6 (20.0)	6 (20.0)	0	0	0
Nasal congestion	3 (10.0)	3 (10.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (6.7)	0	0	2 (6.7)	0
Respiratory failure	1 (3.3)	0	0	0	1 (3.3)
Skin and subcutaneous tissue disorders					
-Total	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Dry skin	1 (3.3)	0	1 (3.3)	0	0
Rash	1 (3.3)	1 (3.3)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (87.1)	5 (16.1)	10 (32.3)	7 (22.6)	5 (16.1)
Blood and lymphatic system disorders					
-Total	5 (16.1)	1 (3.2)	0	2 (6.5)	2 (6.5)
Neutropenia	3 (9.7)	0	0	1 (3.2)	2 (6.5)
Anaemia	1 (3.2)	1 (3.2)	0	0	0
Disseminated intravascular coagulation	1 (3.2)	0	0	1 (3.2)	0
Cardiac disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Tachycardia	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (19.4)	3 (9.7)	3 (9.7)	0	0
Constipation	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Diarrhoea	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Mouth haemorrhage	1 (3.2)	1 (3.2)	0	0	0
Nausea	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					
-Total	9 (29.0)	6 (19.4)	1 (3.2)	2 (6.5)	0
Pyrexia	6 (19.4)	3 (9.7)	1 (3.2)	2 (6.5)	0
Fatigue	2 (6.5)	2 (6.5)	0	0	0
Chills	1 (3.2)	1 (3.2)	0	0	0
Oedema peripheral	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	5 (16.1)	0	5 (16.1)	0	0
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)	0	0
Infections and infestations					
-Total	10 (32.3)	2 (6.5)	6 (19.4)	2 (6.5)	0
Sinusitis	3 (9.7)	0	2 (6.5)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Nasopharyngitis	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Parainfluenzae virus infection	1 (3.2)	1 (3.2)	0	0	0
Rhinovirus infection	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	7 (22.6)	2 (6.5)	1 (3.2)	3 (9.7)	1 (3.2)
Neutrophil count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
White blood cell count decreased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0	0	0
Blood bilirubin increased	1 (3.2)	0	0	1 (3.2)	0
Blood creatinine increased	1 (3.2)	0	1 (3.2)	0	0
Blood immunoglobulin a decreased	1 (3.2)	0	0	1 (3.2)	0
Blood immunoglobulin m decreased	1 (3.2)	0	0	1 (3.2)	0
Lymphocyte count decreased	1 (3.2)	0	1 (3.2)	0	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (22.6)	2 (6.5)	2 (6.5)	2 (6.5)	1 (3.2)
Decreased appetite	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Hyperuricaemia	3 (9.7)	3 (9.7)	0	0	0
Hypervolaemia	1 (3.2)	0	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	1 (3.2)	0	0
Hypophosphataemia	1 (3.2)	0	1 (3.2)	0	0
Tumour lysis syndrome	1 (3.2)	0	0	0	1 (3.2)
Musculoskeletal and connective tissue disorders					
-Total	5 (16.1)	3 (9.7)	1 (3.2)	1 (3.2)	0
Back pain	4 (12.9)	2 (6.5)	1 (3.2)	1 (3.2)	0
Pain in extremity	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Arthralgia	1 (3.2)	1 (3.2)	0	0	0
Myalgia	1 (3.2)	0	1 (3.2)	0	0
Nervous system disorders					
-Total	6 (19.4)	4 (12.9)	2 (6.5)	0	0
Headache	6 (19.4)	4 (12.9)	2 (6.5)	0	0
Psychiatric disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	3 (9.7)	1 (3.2)	1 (3.2)	0	1 (3.2)
Acute kidney injury	3 (9.7)	1 (3.2)	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders					
-Total	7 (22.6)	3 (9.7)	3 (9.7)	1 (3.2)	0
Cough	5 (16.1)	2 (6.5)	3 (9.7)	0	0
Nasal congestion	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Dyspnoea	1 (3.2)	0	1 (3.2)	0	0
Hypoxia	1 (3.2)	0	0	1 (3.2)	0
Pleural effusion	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (19.4)	5 (16.1)	1 (3.2)	0	0
Dry skin	4 (12.9)	3 (9.7)	1 (3.2)	0	0
Rash	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Vascular disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (16.1)	1 (3.2)	1 (3.2)	1 (3.2)	2 (6.5)
Hypotension	4 (12.9)	1 (3.2)	0	1 (3.2)	2 (6.5)
Hypertension	1 (3.2)	0	1 (3.2)	0	0

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	0	7 (50.0)	4 (28.6)	1 (7.1)
Blood and lymphatic system disorders					
-Total	4 (28.6)	1 (7.1)	0	2 (14.3)	1 (7.1)
Anaemia	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Neutropenia	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Gastrointestinal disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
Stomatitis	1 (7.1)	1 (7.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Pyrexia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Non-cardiac chest pain	1 (7.1)	1 (7.1)	0	0	0
Pain	1 (7.1)	0	1 (7.1)	0	0
Immune system disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Infections and infestations					
-Total	6 (42.9)	1 (7.1)	3 (21.4)	2 (14.3)	0
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Parainfluenzae virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Acute sinusitis	1 (7.1)	0	1 (7.1)	0	0
Upper respiratory tract infection	1 (7.1)	0	0	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	1 (7.1)	0	1 (7.1)	0	0
White blood cell count decreased	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Arthralgia	1 (7.1)	0	1 (7.1)	0	0
Back pain	1 (7.1)	0	1 (7.1)	0	0
Neck pain	1 (7.1)	1 (7.1)	0	0	0
Nervous system disorders					
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Headache	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Psychiatric disorders					
-Total	3 (21.4)	0	3 (21.4)	0	0
Anxiety	3 (21.4)	0	3 (21.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Pleural effusion	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Dry skin	1 (7.1)	1 (7.1)	0	0	0
Pruritus	1 (7.1)	0	1 (7.1)	0	0

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Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (40.0)	3 (15.0)	3 (15.0)	1 (5.0)	1 (5.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Diarrhoea	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Constipation	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pyrexia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Immune system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	4 (20.0)	1 (5.0)	2 (10.0)	1 (5.0)	0
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Candida infection	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	2 (10.0)	2 (10.0)	0	0	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0
Platelet count decreased	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hyperglycaemia	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Pain in extremity	2 (10.0)	0	2 (10.0)	0	0
Nervous system disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Headache	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (5.0)	0	0	0	1 (5.0)
Cough	1 (5.0)	1 (5.0)	0	0	0
Dyspnoea	1 (5.0)	0	0	0	1 (5.0)
Pleural effusion	1 (5.0)	0	1 (5.0)	0	0
Tachypnoea	1 (5.0)	0	0	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Dry skin	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hypertension	1 (5.0)	0	0	1 (5.0)	0

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Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (54.5)	1 (4.5)	6 (27.3)	2 (9.1)	3 (13.6)
Blood and lymphatic system disorders					
-Total	1 (4.5)	0	0	0	1 (4.5)
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Gastrointestinal disorders					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Diarrhoea	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Nausea	1 (4.5)	1 (4.5)	0	0	0
Vomiting	1 (4.5)	1 (4.5)	0	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (18.2)	1 (4.5)	3 (13.6)	0	0
Pyrexia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Fatigue	1 (4.5)	0	1 (4.5)	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Immune system disorders					
-Total	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Seasonal allergy	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Hypogammaglobulinaemia	2 (9.1)	0	2 (9.1)	0	0
Infections and infestations					
-Total	7 (31.8)	1 (4.5)	5 (22.7)	1 (4.5)	0
Sinusitis	4 (18.2)	0	4 (18.2)	0	0
Conjunctivitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Rhinovirus infection	2 (9.1)	0	2 (9.1)	0	0
Upper respiratory tract infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Metabolism and nutrition disorders					
-Total	1 (4.5)	0	0	0	1 (4.5)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (4.5)	0	0	0	1 (4.5)
Musculoskeletal and connective tissue disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Arthralgia	1 (4.5)	0	1 (4.5)	0	0
Nervous system disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Headache	1 (4.5)	0	1 (4.5)	0	0
Psychiatric disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Anxiety	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (18.2)	1 (4.5)	1 (4.5)	1 (4.5)	1 (4.5)
Cough	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Dyspnoea	1 (4.5)	0	1 (4.5)	0	0
Hypoxia	1 (4.5)	0	0	1 (4.5)	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0	0	0
Respiratory failure	1 (4.5)	0	0	0	1 (4.5)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Rash	1 (4.5)	0	1 (4.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	0	2 (25.0)	0	1 (12.5)
Gastrointestinal disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Diarrhoea	1 (12.5)	1 (12.5)	0	0	0
General disorders and administration site conditions					
-Total	2 (25.0)	2 (25.0)	0	0	0
Non-cardiac chest pain	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	1 (12.5)	0	0	0
Pyrexia	1 (12.5)	1 (12.5)	0	0	0
Infections and infestations					

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	0	3 (37.5)	0	0
Sinusitis	2 (25.0)	0	2 (25.0)	0	0
Acute sinusitis	1 (12.5)	0	1 (12.5)	0	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0	0	0
Urinary tract infection	1 (12.5)	0	1 (12.5)	0	0
Varicella zoster virus infection	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Neutrophil count decreased	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	1 (12.5)	0	0	0
Platelet count decreased	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Anxiety	1 (12.5)	1 (12.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypertension	1 (12.5)	0	1 (12.5)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	0	5 (15.2)	7 (21.2)	21 (63.6)
Blood and lymphatic system disorders					
-Total	22 (66.7)	2 (6.1)	3 (9.1)	13 (39.4)	4 (12.1)
Anaemia	14 (42.4)	3 (9.1)	4 (12.1)	7 (21.2)	0
Febrile neutropenia	13 (39.4)	0	0	13 (39.4)	0
Thrombocytopenia	5 (15.2)	0	0	1 (3.0)	4 (12.1)
Disseminated intravascular coagulation	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Neutropenia	3 (9.1)	0	1 (3.0)	1 (3.0)	1 (3.0)
Coagulopathy	1 (3.0)	0	0	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	9 (27.3)	4 (12.1)	3 (9.1)	1 (3.0)	1 (3.0)
Tachycardia	9 (27.3)	4 (12.1)	3 (9.1)	1 (3.0)	1 (3.0)
Endocrine disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	27 (81.8)	11 (33.3)	10 (30.3)	6 (18.2)	0
Vomiting	16 (48.5)	11 (33.3)	5 (15.2)	0	0
Diarrhoea	14 (42.4)	8 (24.2)	4 (12.1)	2 (6.1)	0
Nausea	13 (39.4)	7 (21.2)	5 (15.2)	1 (3.0)	0
Constipation	7 (21.2)	4 (12.1)	3 (9.1)	0	0
Abdominal pain	6 (18.2)	1 (3.0)	3 (9.1)	2 (6.1)	0
Mouth haemorrhage	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Stomatitis	1 (3.0)	0	0	1 (3.0)	0
General disorders and administration site conditions					
-Total	19 (57.6)	10 (30.3)	6 (18.2)	2 (6.1)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	13 (39.4)	6 (18.2)	4 (12.1)	2 (6.1)	1 (3.0)
Fatigue	11 (33.3)	9 (27.3)	2 (6.1)	0	0
Chills	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Face oedema	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Pain	2 (6.1)	0	0	2 (6.1)	0
Hepatobiliary disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Hepatic function abnormal	1 (3.0)	0	0	1 (3.0)	0
Immune system disorders					
-Total	29 (87.9)	2 (6.1)	14 (42.4)	5 (15.2)	8 (24.2)
Cytokine release syndrome	24 (72.7)	3 (9.1)	10 (30.3)	3 (9.1)	8 (24.2)
Hypogammaglobulinaemia	13 (39.4)	1 (3.0)	10 (30.3)	2 (6.1)	0
Infections and infestations					
-Total	16 (48.5)	6 (18.2)	7 (21.2)	2 (6.1)	1 (3.0)
Upper respiratory tract infection	6 (18.2)	4 (12.1)	2 (6.1)	0	0
Conjunctivitis	5 (15.2)	1 (3.0)	4 (12.1)	0	0
Nasopharyngitis	3 (9.1)	2 (6.1)	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Candida infection	2 (6.1)	0	2 (6.1)	0	0
Parainfluenzae virus infection	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Staphylococcal infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Investigations					
-Total	23 (69.7)	2 (6.1)	1 (3.0)	5 (15.2)	15 (45.5)
White blood cell count decreased	17 (51.5)	2 (6.1)	2 (6.1)	2 (6.1)	11 (33.3)
Neutrophil count decreased	16 (48.5)	0	1 (3.0)	3 (9.1)	12 (36.4)
Platelet count decreased	14 (42.4)	4 (12.1)	1 (3.0)	5 (15.2)	4 (12.1)
Lymphocyte count decreased	10 (30.3)	0	0	7 (21.2)	3 (9.1)
Alanine aminotransferase increased	9 (27.3)	1 (3.0)	6 (18.2)	2 (6.1)	0
Aspartate aminotransferase increased	8 (24.2)	1 (3.0)	3 (9.1)	2 (6.1)	2 (6.1)
Blood immunoglobulin m decreased	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Blood bilirubin increased	5 (15.2)	0	1 (3.0)	4 (12.1)	0
Blood immunoglobulin a decreased	5 (15.2)	4 (12.1)	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Blood fibrinogen decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Serum ferritin increased	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Blood creatinine increased	1 (3.0)	0	0	1 (3.0)	0
Electrocardiogram qt prolonged	1 (3.0)	0	1 (3.0)	0	0
Metabolism and nutrition disorders					
-Total	21 (63.6)	5 (15.2)	5 (15.2)	7 (21.2)	4 (12.1)
Decreased appetite	11 (33.3)	4 (12.1)	2 (6.1)	4 (12.1)	1 (3.0)
Hypophosphataemia	10 (30.3)	2 (6.1)	4 (12.1)	3 (9.1)	1 (3.0)
Hypocalcaemia	7 (21.2)	1 (3.0)	4 (12.1)	2 (6.1)	0
Hypokalaemia	7 (21.2)	2 (6.1)	1 (3.0)	2 (6.1)	2 (6.1)
Hyperglycaemia	4 (12.1)	0	0	4 (12.1)	0
Hypoalbuminaemia	4 (12.1)	0	4 (12.1)	0	0
Hyperuricaemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Hypervolaemia	1 (3.0)	0	1 (3.0)	0	0
Hypomagnesaemia	1 (3.0)	1 (3.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	16 (48.5)	6 (18.2)	7 (21.2)	3 (9.1)	0
Pain in extremity	12 (36.4)	5 (15.2)	6 (18.2)	1 (3.0)	0
Back pain	5 (15.2)	1 (3.0)	2 (6.1)	2 (6.1)	0
Arthralgia	4 (12.1)	1 (3.0)	3 (9.1)	0	0
Myalgia	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Nervous system disorders					
-Total	12 (36.4)	5 (15.2)	3 (9.1)	4 (12.1)	0
Headache	8 (24.2)	5 (15.2)	1 (3.0)	2 (6.1)	0
Encephalopathy	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Tremor	2 (6.1)	2 (6.1)	0	0	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0
Psychiatric disorders					
-Total	8 (24.2)	4 (12.1)	4 (12.1)	0	0
Anxiety	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Confusional state	4 (12.1)	4 (12.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	2 (6.1)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (6.1)	2 (6.1)	0	0	0
Renal and urinary disorders					
-Total	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Acute kidney injury	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Respiratory, thoracic and mediastinal disorders					
-Total	22 (66.7)	10 (30.3)	2 (6.1)	5 (15.2)	5 (15.2)
Cough	11 (33.3)	10 (30.3)	1 (3.0)	0	0
Hypoxia	8 (24.2)	0	2 (6.1)	4 (12.1)	2 (6.1)
Tachypnoea	5 (15.2)	2 (6.1)	0	2 (6.1)	1 (3.0)
Nasal congestion	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Pulmonary oedema	4 (12.1)	0	1 (3.0)	3 (9.1)	0
Dyspnoea	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Pleural effusion	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Respiratory failure	1 (3.0)	0	0	0	1 (3.0)
Skin and subcutaneous tissue disorders					
-Total	8 (24.2)	5 (15.2)	3 (9.1)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Pruritus	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Rash	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Vascular disorders					
-Total	14 (42.4)	2 (6.1)	4 (12.1)	5 (15.2)	3 (9.1)
Hypotension	10 (30.3)	1 (3.0)	3 (9.1)	3 (9.1)	3 (9.1)
Hypertension	6 (18.2)	2 (6.1)	1 (3.0)	3 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (100)	1 (3.0)	3 (9.1)	7 (21.2)	22 (66.7)
Blood and lymphatic system disorders					
-Total	20 (60.6)	0	1 (3.0)	10 (30.3)	9 (27.3)
Febrile neutropenia	12 (36.4)	0	0	10 (30.3)	2 (6.1)
Anaemia	6 (18.2)	3 (9.1)	3 (9.1)	0	0
Neutropenia	5 (15.2)	0	0	0	5 (15.2)
Disseminated intravascular coagulation	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Thrombocytopenia	3 (9.1)	0	0	1 (3.0)	2 (6.1)
Coagulopathy	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (18.2)	2 (6.1)	3 (9.1)	1 (3.0)	0
Tachycardia	6 (18.2)	2 (6.1)	3 (9.1)	1 (3.0)	0
Sinus tachycardia	1 (3.0)	1 (3.0)	0	0	0
Endocrine disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Adrenal insufficiency	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	18 (54.5)	8 (24.2)	8 (24.2)	2 (6.1)	0
Diarrhoea	9 (27.3)	6 (18.2)	3 (9.1)	0	0
Nausea	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Vomiting	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Abdominal pain	3 (9.1)	0	3 (9.1)	0	0
Constipation	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Mouth haemorrhage	1 (3.0)	1 (3.0)	0	0	0
General disorders and administration site conditions					
-Total	20 (60.6)	9 (27.3)	4 (12.1)	6 (18.2)	1 (3.0)
Pyrexia	15 (45.5)	6 (18.2)	3 (9.1)	5 (15.2)	1 (3.0)
Fatigue	5 (15.2)	4 (12.1)	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Face oedema	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Chills	2 (6.1)	2 (6.1)	0	0	0
Pain	1 (3.0)	0	1 (3.0)	0	0
Hepatobiliary disorders					
-Total	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Hepatic function abnormal	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Immune system disorders					
-Total	28 (84.8)	0	7 (21.2)	12 (36.4)	9 (27.3)
Cytokine release syndrome	25 (75.8)	1 (3.0)	5 (15.2)	10 (30.3)	9 (27.3)
Hypogammaglobulinaemia	15 (45.5)	0	10 (30.3)	5 (15.2)	0
Seasonal allergy	4 (12.1)	2 (6.1)	2 (6.1)	0	0
Infections and infestations					
-Total	13 (39.4)	2 (6.1)	8 (24.2)	3 (9.1)	0
Upper respiratory tract infection	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Rhinovirus infection	4 (12.1)	0	4 (12.1)	0	0
Sinusitis	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Conjunctivitis	2 (6.1)	1 (3.0)	1 (3.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Parainfluenzae virus infection	1 (3.0)	1 (3.0)	0	0	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	18 (54.5)	0	1 (3.0)	7 (21.2)	10 (30.3)
Alanine aminotransferase increased	7 (21.2)	2 (6.1)	1 (3.0)	4 (12.1)	0
Aspartate aminotransferase increased	7 (21.2)	0	3 (9.1)	3 (9.1)	1 (3.0)
Platelet count decreased	7 (21.2)	1 (3.0)	2 (6.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	7 (21.2)	1 (3.0)	2 (6.1)	0	4 (12.1)
Blood bilirubin increased	6 (18.2)	1 (3.0)	1 (3.0)	4 (12.1)	0
Lymphocyte count decreased	6 (18.2)	0	1 (3.0)	3 (9.1)	2 (6.1)
Neutrophil count decreased	6 (18.2)	0	1 (3.0)	1 (3.0)	4 (12.1)
Serum ferritin increased	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Blood creatinine increased	4 (12.1)	1 (3.0)	1 (3.0)	1 (3.0)	1 (3.0)
Blood fibrinogen decreased	4 (12.1)	0	3 (9.1)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	4 (12.1)	1 (3.0)	1 (3.0)	1 (3.0)	1 (3.0)
International normalised ratio increased	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Blood immunoglobulin a decreased	1 (3.0)	0	0	1 (3.0)	0
Blood immunoglobulin m decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	21 (63.6)	3 (9.1)	5 (15.2)	11 (33.3)	2 (6.1)
Decreased appetite	14 (42.4)	4 (12.1)	5 (15.2)	4 (12.1)	1 (3.0)
Hypokalaemia	7 (21.2)	0	2 (6.1)	5 (15.2)	0
Hyperuricaemia	6 (18.2)	5 (15.2)	0	1 (3.0)	0
Hypocalcaemia	6 (18.2)	1 (3.0)	4 (12.1)	1 (3.0)	0
Hypophosphataemia	6 (18.2)	1 (3.0)	2 (6.1)	3 (9.1)	0
Hypoalbuminaemia	5 (15.2)	0	5 (15.2)	0	0
Tumour lysis syndrome	4 (12.1)	0	0	3 (9.1)	1 (3.0)
Hypervolaemia	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Hypomagnesaemia	3 (9.1)	3 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Musculoskeletal and connective tissue disorders					
-Total	13 (39.4)	7 (21.2)	4 (12.1)	2 (6.1)	0
Arthralgia	5 (15.2)	3 (9.1)	1 (3.0)	1 (3.0)	0
Myalgia	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Back pain	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Pain in extremity	4 (12.1)	2 (6.1)	2 (6.1)	0	0
Nervous system disorders					
-Total	17 (51.5)	6 (18.2)	9 (27.3)	2 (6.1)	0
Headache	15 (45.5)	6 (18.2)	8 (24.2)	1 (3.0)	0
Encephalopathy	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Somnolence	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Tremor	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Psychiatric disorders					
-Total	10 (30.3)	3 (9.1)	4 (12.1)	3 (9.1)	0
Anxiety	5 (15.2)	0	3 (9.1)	2 (6.1)	0
Confusional state	3 (9.1)	3 (9.1)	0	0	0
Delirium	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	2 (6.1)	0	2 (6.1)	0	0
Renal and urinary disorders					
-Total	7 (21.2)	1 (3.0)	1 (3.0)	2 (6.1)	3 (9.1)
Acute kidney injury	7 (21.2)	1 (3.0)	1 (3.0)	2 (6.1)	3 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	17 (51.5)	4 (12.1)	2 (6.1)	4 (12.1)	7 (21.2)
Cough	11 (33.3)	7 (21.2)	4 (12.1)	0	0
Hypoxia	9 (27.3)	0	2 (6.1)	3 (9.1)	4 (12.1)
Oropharyngeal pain	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Pleural effusion	5 (15.2)	3 (9.1)	0	1 (3.0)	1 (3.0)
Nasal congestion	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Pulmonary oedema	4 (12.1)	1 (3.0)	2 (6.1)	1 (3.0)	0
Respiratory failure	3 (9.1)	0	0	0	3 (9.1)
Tachypnoea	3 (9.1)	1 (3.0)	0	2 (6.1)	0
Dyspnoea	2 (6.1)	0	2 (6.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (27.3)	5 (15.2)	4 (12.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Dry skin	4 (12.1)	3 (9.1)	1 (3.0)	0	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0	0	0
Pruritus	1 (3.0)	0	1 (3.0)	0	0
Vascular disorders					
-Total	12 (36.4)	2 (6.1)	2 (6.1)	4 (12.1)	4 (12.1)
Hypotension	10 (30.3)	1 (3.0)	2 (6.1)	3 (9.1)	4 (12.1)
Hypertension	5 (15.2)	1 (3.0)	3 (9.1)	1 (3.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	2 (14.3)	5 (35.7)	7 (50.0)
Blood and lymphatic system disorders					
-Total	9 (64.3)	0	2 (14.3)	6 (42.9)	1 (7.1)
Anaemia	5 (35.7)	1 (7.1)	2 (14.3)	2 (14.3)	0
Neutropenia	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Coagulopathy	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	4 (28.6)	2 (14.3)	2 (14.3)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Tachycardia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Endocrine disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Adrenal insufficiency	2 (14.3)	0	2 (14.3)	0	0
Gastrointestinal disorders					
-Total	12 (85.7)	7 (50.0)	4 (28.6)	1 (7.1)	0
Vomiting	5 (35.7)	3 (21.4)	2 (14.3)	0	0
Constipation	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Nausea	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Diarrhoea	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Abdominal pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Mouth haemorrhage	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Stomatitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	10 (71.4)	5 (35.7)	3 (21.4)	2 (14.3)	0
Pyrexia	7 (50.0)	2 (14.3)	3 (21.4)	2 (14.3)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Non-cardiac chest pain	2 (14.3)	2 (14.3)	0	0	0
Oedema peripheral	2 (14.3)	2 (14.3)	0	0	0
Pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Face oedema	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Hepatic function abnormal	2 (14.3)	0	2 (14.3)	0	0
Immune system disorders					
-Total	12 (85.7)	0	4 (28.6)	4 (28.6)	4 (28.6)
Cytokine release syndrome	12 (85.7)	1 (7.1)	3 (21.4)	4 (28.6)	4 (28.6)
Hypogammaglobulinaemia	5 (35.7)	1 (7.1)	4 (28.6)	0	0
Infections and infestations					
-Total	10 (71.4)	1 (7.1)	5 (35.7)	3 (21.4)	1 (7.1)
Sinusitis	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Acute sinusitis	2 (14.3)	0	2 (14.3)	0	0
Candida infection	2 (14.3)	0	1 (7.1)	0	1 (7.1)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Parainfluenzae virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Rhinovirus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Staphylococcal infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Urinary tract infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Varicella zoster virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Conjunctivitis	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	8 (57.1)	1 (7.1)	2 (14.3)	3 (21.4)	2 (14.3)
Aspartate aminotransferase increased	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Platelet count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
International normalised ratio increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (14.3)	1 (7.1)	0	0	1 (7.1)
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
White blood cell count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	7 (50.0)	2 (14.3)	0	5 (35.7)	0
Hypokalaemia	6 (42.9)	1 (7.1)	3 (21.4)	2 (14.3)	0
Decreased appetite	5 (35.7)	3 (21.4)	0	2 (14.3)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)	0	0
Hypervolaemia	3 (21.4)	0	0	3 (21.4)	0
Hypocalcaemia	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Hypoalbuminaemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	0	0	2 (14.3)	0
Hyperuricaemia	1 (7.1)	1 (7.1)	0	0	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	6 (42.9)	2 (14.3)	4 (28.6)	0	0
Arthralgia	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Myalgia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Neck pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Back pain	1 (7.1)	0	1 (7.1)	0	0
Pain in extremity	1 (7.1)	1 (7.1)	0	0	0
Nervous system disorders					
-Total	6 (42.9)	3 (21.4)	2 (14.3)	1 (7.1)	0
Headache	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Somnolence	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Tremor	2 (14.3)	2 (14.3)	0	0	0
Encephalopathy	1 (7.1)	0	0	1 (7.1)	0
Psychiatric disorders					
-Total	7 (50.0)	2 (14.3)	3 (21.4)	2 (14.3)	0
Anxiety	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Agitation	2 (14.3)	1 (7.1)	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	2 (14.3)	0	0	2 (14.3)	0
Renal and urinary disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Acute kidney injury	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (64.3)	3 (21.4)	1 (7.1)	3 (21.4)	2 (14.3)
Pulmonary oedema	4 (28.6)	1 (7.1)	0	2 (14.3)	1 (7.1)
Hypoxia	3 (21.4)	0	0	3 (21.4)	0
Dyspnoea	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Oropharyngeal pain	2 (14.3)	2 (14.3)	0	0	0
Respiratory failure	2 (14.3)	0	0	0	2 (14.3)
Cough	1 (7.1)	1 (7.1)	0	0	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Pleural effusion	1 (7.1)	0	1 (7.1)	0	0
Tachypnoea	1 (7.1)	0	1 (7.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (35.7)	1 (7.1)	4 (28.6)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Hyperhidrosis	2 (14.3)	0	2 (14.3)	0	0
Dry skin	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	2 (14.3)	1 (7.1)
Hypertension	5 (35.7)	1 (7.1)	3 (21.4)	1 (7.1)	0
Hypotension	4 (28.6)	0	1 (7.1)	2 (14.3)	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (97.8)	4 (8.7)	7 (15.2)	10 (21.7)	24 (52.2)
Blood and lymphatic system disorders					
-Total	21 (45.7)	1 (2.2)	4 (8.7)	9 (19.6)	7 (15.2)
Febrile neutropenia	11 (23.9)	0	0	11 (23.9)	0
Anaemia	7 (15.2)	1 (2.2)	3 (6.5)	3 (6.5)	0
Disseminated intravascular coagulation	5 (10.9)	0	5 (10.9)	0	0
Thrombocytopenia	5 (10.9)	0	0	0	5 (10.9)
Neutropenia	4 (8.7)	0	1 (2.2)	0	3 (6.5)
Cardiac disorders					
-Total	9 (19.6)	3 (6.5)	4 (8.7)	2 (4.3)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	9 (19.6)	3 (6.5)	4 (8.7)	2 (4.3)	0
Gastrointestinal disorders					
-Total	23 (50.0)	11 (23.9)	8 (17.4)	4 (8.7)	0
Nausea	12 (26.1)	7 (15.2)	4 (8.7)	1 (2.2)	0
Vomiting	12 (26.1)	9 (19.6)	3 (6.5)	0	0
Diarrhoea	7 (15.2)	4 (8.7)	2 (4.3)	1 (2.2)	0
Abdominal pain	6 (13.0)	0	4 (8.7)	2 (4.3)	0
Constipation	5 (10.9)	2 (4.3)	3 (6.5)	0	0
General disorders and administration site conditions					
-Total	18 (39.1)	10 (21.7)	4 (8.7)	2 (4.3)	2 (4.3)
Pyrexia	11 (23.9)	6 (13.0)	2 (4.3)	1 (2.2)	2 (4.3)
Fatigue	7 (15.2)	5 (10.9)	2 (4.3)	0	0
Face oedema	4 (8.7)	3 (6.5)	0	1 (2.2)	0
Chills	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Oedema peripheral	3 (6.5)	2 (4.3)	0	1 (2.2)	0
Generalised oedema	1 (2.2)	0	1 (2.2)	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	35 (76.1)	1 (2.2)	12 (26.1)	11 (23.9)	11 (23.9)
Cytokine release syndrome	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Hypogammaglobulinaemia	12 (26.1)	1 (2.2)	8 (17.4)	3 (6.5)	0
Infections and infestations					
-Total	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Conjunctivitis	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Investigations					
-Total	25 (54.3)	2 (4.3)	3 (6.5)	7 (15.2)	13 (28.3)
Alanine aminotransferase increased	13 (28.3)	4 (8.7)	6 (13.0)	3 (6.5)	0
Aspartate aminotransferase increased	12 (26.1)	1 (2.2)	5 (10.9)	4 (8.7)	2 (4.3)
White blood cell count decreased	12 (26.1)	2 (4.3)	1 (2.2)	1 (2.2)	8 (17.4)
Platelet count decreased	11 (23.9)	2 (4.3)	2 (4.3)	4 (8.7)	3 (6.5)
Blood bilirubin increased	8 (17.4)	0	1 (2.2)	7 (15.2)	0
Neutrophil count decreased	8 (17.4)	0	0	0	8 (17.4)
Serum ferritin increased	6 (13.0)	1 (2.2)	4 (8.7)	1 (2.2)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	5 (10.9)	0	0	2 (4.3)	3 (6.5)
International normalised ratio increased	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Blood immunoglobulin m decreased	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Metabolism and nutrition disorders					
-Total	23 (50.0)	4 (8.7)	7 (15.2)	9 (19.6)	3 (6.5)
Decreased appetite	10 (21.7)	3 (6.5)	3 (6.5)	3 (6.5)	1 (2.2)
Hypocalcaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Hypokalaemia	9 (19.6)	1 (2.2)	3 (6.5)	4 (8.7)	1 (2.2)
Hypophosphataemia	7 (15.2)	3 (6.5)	1 (2.2)	2 (4.3)	1 (2.2)
Hyperuricaemia	4 (8.7)	3 (6.5)	1 (2.2)	0	0
Hypoalbuminaemia	4 (8.7)	0	4 (8.7)	0	0
Hyperglycaemia	3 (6.5)	0	0	3 (6.5)	0
Hypervolaemia	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	13 (28.3)	5 (10.9)	8 (17.4)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Pain in extremity	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Back pain	2 (4.3)	0	2 (4.3)	0	0
Myalgia	2 (4.3)	2 (4.3)	0	0	0
Nervous system disorders					
-Total	15 (32.6)	8 (17.4)	4 (8.7)	3 (6.5)	0
Headache	11 (23.9)	7 (15.2)	2 (4.3)	2 (4.3)	0
Encephalopathy	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Psychiatric disorders					
-Total	8 (17.4)	2 (4.3)	4 (8.7)	2 (4.3)	0
Delirium	5 (10.9)	2 (4.3)	1 (2.2)	2 (4.3)	0
Anxiety	3 (6.5)	0	3 (6.5)	0	0
Mental status changes	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	3 (6.5)	1 (2.2)	0	0	2 (4.3)
Acute kidney injury	3 (6.5)	1 (2.2)	0	0	2 (4.3)
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (41.3)	7 (15.2)	4 (8.7)	2 (4.3)	6 (13.0)
Hypoxia	9 (19.6)	0	3 (6.5)	2 (4.3)	4 (8.7)
Pleural effusion	6 (13.0)	3 (6.5)	0	2 (4.3)	1 (2.2)
Pulmonary oedema	6 (13.0)	1 (2.2)	2 (4.3)	2 (4.3)	1 (2.2)
Cough	4 (8.7)	4 (8.7)	0	0	0
Oropharyngeal pain	3 (6.5)	3 (6.5)	0	0	0
Tachypnoea	3 (6.5)	2 (4.3)	0	1 (2.2)	0
Nasal congestion	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Dyspnoea	1 (2.2)	0	0	1 (2.2)	0
Epistaxis	1 (2.2)	1 (2.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Rash	3 (6.5)	1 (2.2)	2 (4.3)	0	0
Vascular disorders					
-Total	15 (32.6)	2 (4.3)	6 (13.0)	5 (10.9)	2 (4.3)
Hypotension	10 (21.7)	0	5 (10.9)	3 (6.5)	2 (4.3)
Hypertension	7 (15.2)	3 (6.5)	2 (4.3)	2 (4.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	1 (2.9)	11 (32.4)	21 (61.8)
Blood and lymphatic system disorders					
-Total	24 (70.6)	1 (2.9)	1 (2.9)	16 (47.1)	6 (17.6)
Febrile neutropenia	15 (44.1)	0	0	13 (38.2)	2 (5.9)
Anaemia	14 (41.2)	4 (11.8)	5 (14.7)	5 (14.7)	0
Neutropenia	5 (14.7)	0	1 (2.9)	1 (2.9)	3 (8.8)
Thrombocytopenia	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Disseminated intravascular coagulation	2 (5.9)	0	0	2 (5.9)	0
Cardiac disorders					
-Total	8 (23.5)	4 (11.8)	3 (8.8)	0	1 (2.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	8 (23.5)	4 (11.8)	3 (8.8)	0	1 (2.9)
Gastrointestinal disorders					
-Total	23 (67.6)	11 (32.4)	10 (29.4)	2 (5.9)	0
Vomiting	9 (26.5)	3 (8.8)	5 (14.7)	1 (2.9)	0
Diarrhoea	8 (23.5)	4 (11.8)	4 (11.8)	0	0
Constipation	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Nausea	6 (17.6)	3 (8.8)	2 (5.9)	1 (2.9)	0
Abdominal pain	5 (14.7)	3 (8.8)	2 (5.9)	0	0
General disorders and administration site conditions					
-Total	18 (52.9)	9 (26.5)	4 (11.8)	5 (14.7)	0
Pyrexia	13 (38.2)	5 (14.7)	3 (8.8)	5 (14.7)	0
Face oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Fatigue	4 (11.8)	4 (11.8)	0	0	0
Generalised oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Chills	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Oedema peripheral	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (91.2)	2 (5.9)	9 (26.5)	10 (29.4)	10 (29.4)
Cytokine release syndrome	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Hypogammaglobulinaemia	11 (32.4)	1 (2.9)	6 (17.6)	4 (11.8)	0
Infections and infestations					
-Total	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Conjunctivitis	2 (5.9)	0	2 (5.9)	0	0
Rhinovirus infection	2 (5.9)	0	2 (5.9)	0	0
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Investigations					
-Total	23 (67.6)	2 (5.9)	1 (2.9)	8 (23.5)	12 (35.3)
Neutrophil count decreased	12 (35.3)	0	3 (8.8)	2 (5.9)	7 (20.6)
White blood cell count decreased	12 (35.3)	1 (2.9)	2 (5.9)	1 (2.9)	8 (23.5)
Lymphocyte count decreased	10 (29.4)	2 (5.9)	0	6 (17.6)	2 (5.9)
Platelet count decreased	10 (29.4)	2 (5.9)	1 (2.9)	2 (5.9)	5 (14.7)
Aspartate aminotransferase increased	7 (20.6)	1 (2.9)	1 (2.9)	4 (11.8)	1 (2.9)
International normalised ratio increased	6 (17.6)	4 (11.8)	2 (5.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (14.7)	0	2 (5.9)	3 (8.8)	0
Blood bilirubin increased	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Serum ferritin increased	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	20 (58.8)	4 (11.8)	3 (8.8)	12 (35.3)	1 (2.9)
Decreased appetite	14 (41.2)	6 (17.6)	1 (2.9)	7 (20.6)	0
Hypokalaemia	10 (29.4)	2 (5.9)	2 (5.9)	5 (14.7)	1 (2.9)
Hypophosphataemia	10 (29.4)	0	4 (11.8)	6 (17.6)	0
Hypoalbuminaemia	7 (20.6)	0	6 (17.6)	1 (2.9)	0
Hypocalcaemia	7 (20.6)	0	5 (14.7)	2 (5.9)	0
Hyperglycaemia	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Hypervolaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Hyperuricaemia	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (44.1)	8 (23.5)	5 (14.7)	2 (5.9)	0
Myalgia	7 (20.6)	4 (11.8)	3 (8.8)	0	0
Back pain	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Pain in extremity	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Arthralgia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Nervous system disorders					
-Total	16 (47.1)	6 (17.6)	7 (20.6)	3 (8.8)	0
Headache	12 (35.3)	5 (14.7)	7 (20.6)	0	0
Tremor	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Encephalopathy	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Psychiatric disorders					
-Total	6 (17.6)	2 (5.9)	0	4 (11.8)	0
Anxiety	3 (8.8)	1 (2.9)	0	2 (5.9)	0
Delirium	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Mental status changes	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Renal and urinary disorders					
-Total	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)
Acute kidney injury	6 (17.6)	0	1 (2.9)	3 (8.8)	2 (5.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	19 (55.9)	7 (20.6)	0	9 (26.5)	3 (8.8)
Hypoxia	8 (23.5)	0	2 (5.9)	4 (11.8)	2 (5.9)
Cough	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Pulmonary oedema	6 (17.6)	1 (2.9)	1 (2.9)	4 (11.8)	0
Tachypnoea	5 (14.7)	1 (2.9)	1 (2.9)	3 (8.8)	0
Epistaxis	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Dyspnoea	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	2 (5.9)	0	0	0
Rhinorrhoea	2 (5.9)	2 (5.9)	0	0	0
Nasal congestion	1 (2.9)	1 (2.9)	0	0	0
Pleural effusion	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Rash	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Dry skin	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (35.3)	2 (5.9)	1 (2.9)	5 (14.7)	4 (11.8)
Hypotension	11 (32.4)	1 (2.9)	1 (2.9)	5 (14.7)	4 (11.8)
Hypertension	6 (17.6)	1 (2.9)	3 (8.8)	2 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (81.4)	7 (16.3)	12 (27.9)	11 (25.6)	5 (11.6)
Blood and lymphatic system disorders					
-Total	6 (14.0)	1 (2.3)	0	3 (7.0)	2 (4.7)
Febrile neutropenia	3 (7.0)	0	0	3 (7.0)	0
Anaemia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Thrombocytopenia	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Disseminated intravascular coagulation	1 (2.3)	0	0	1 (2.3)	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Cardiac disorders					
-Total	2 (4.7)	2 (4.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (4.7)	2 (4.7)	0	0	0
Gastrointestinal disorders					
-Total	9 (20.9)	6 (14.0)	3 (7.0)	0	0
Diarrhoea	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Vomiting	3 (7.0)	3 (7.0)	0	0	0
Constipation	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Nausea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Abdominal pain	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					
-Total	13 (30.2)	7 (16.3)	4 (9.3)	2 (4.7)	0
Pyrexia	10 (23.3)	4 (9.3)	4 (9.3)	2 (4.7)	0
Fatigue	3 (7.0)	3 (7.0)	0	0	0
Immune system disorders					
-Total	5 (11.6)	0	5 (11.6)	0	0
Hypogammaglobulinaemia	5 (11.6)	0	5 (11.6)	0	0
Infections and infestations					
-Total	15 (34.9)	5 (11.6)	8 (18.6)	1 (2.3)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	6 (14.0)	3 (7.0)	2 (4.7)	1 (2.3)	0
Nasopharyngitis	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Pneumonia	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)
Gastroenteritis	2 (4.7)	2 (4.7)	0	0	0
Rhinovirus infection	2 (4.7)	0	2 (4.7)	0	0
Conjunctivitis	1 (2.3)	0	1 (2.3)	0	0
Sinusitis	1 (2.3)	0	1 (2.3)	0	0
Investigations					
-Total	11 (25.6)	2 (4.7)	1 (2.3)	6 (14.0)	2 (4.7)
White blood cell count decreased	5 (11.6)	2 (4.7)	2 (4.7)	0	1 (2.3)
Neutrophil count decreased	4 (9.3)	0	0	2 (4.7)	2 (4.7)
Platelet count decreased	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Alanine aminotransferase increased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Blood bilirubin increased	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Lymphocyte count decreased	2 (4.7)	0	0	2 (4.7)	0
Blood immunoglobulin m decreased	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	7 (16.3)	2 (4.7)	2 (4.7)	2 (4.7)	1 (2.3)
Decreased appetite	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Hyperuricaemia	1 (2.3)	1 (2.3)	0	0	0
Hypervolaemia	1 (2.3)	0	0	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	0	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	1 (2.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (16.3)	3 (7.0)	2 (4.7)	2 (4.7)	0
Back pain	4 (9.3)	2 (4.7)	0	2 (4.7)	0
Arthralgia	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Pain in extremity	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Myalgia	1 (2.3)	0	1 (2.3)	0	0
Nervous system disorders					
-Total	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Headache	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Psychiatric disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (9.3)	1 (2.3)	3 (7.0)	0	0
Anxiety	4 (9.3)	1 (2.3)	3 (7.0)	0	0
Delirium	1 (2.3)	0	1 (2.3)	0	0
Renal and urinary disorders					
-Total	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Acute kidney injury	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (20.9)	5 (11.6)	2 (4.7)	2 (4.7)	0
Cough	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Nasal congestion	3 (7.0)	3 (7.0)	0	0	0
Hypoxia	2 (4.7)	0	0	2 (4.7)	0
Pleural effusion	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Epistaxis	1 (2.3)	0	1 (2.3)	0	0
Oropharyngeal pain	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Rash	3 (7.0)	2 (4.7)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Vascular disorders					
-Total	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Hypotension	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Hypertension	1 (2.3)	0	1 (2.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (84.4)	4 (12.5)	11 (34.4)	6 (18.8)	6 (18.8)
Blood and lymphatic system disorders					
-Total	7 (21.9)	2 (6.3)	0	3 (9.4)	2 (6.3)
Anaemia	4 (12.5)	3 (9.4)	0	1 (3.1)	0
Neutropenia	4 (12.5)	0	0	2 (6.3)	2 (6.3)
Gastrointestinal disorders					
-Total	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Nausea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Vomiting	3 (9.4)	3 (9.4)	0	0	0
Diarrhoea	2 (6.3)	2 (6.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (3.1)	0	1 (3.1)	0	0
Constipation	1 (3.1)	0	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	9 (28.1)	7 (21.9)	2 (6.3)	0	0
Pyrexia	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Fatigue	3 (9.4)	3 (9.4)	0	0	0
Chills	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	5 (15.6)	0	5 (15.6)	0	0
Hypogammaglobulinaemia	5 (15.6)	0	5 (15.6)	0	0
Infections and infestations					
-Total	9 (28.1)	1 (3.1)	4 (12.5)	4 (12.5)	0
Gastroenteritis	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Rhinovirus infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sinusitis	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Investigations					
-Total	9 (28.1)	3 (9.4)	2 (6.3)	2 (6.3)	2 (6.3)
Neutrophil count decreased	6 (18.8)	2 (6.3)	1 (3.1)	1 (3.1)	2 (6.3)
White blood cell count decreased	5 (15.6)	2 (6.3)	0	3 (9.4)	0
Lymphocyte count decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Platelet count decreased	2 (6.3)	2 (6.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Hyperuricaemia	2 (6.3)	2 (6.3)	0	0	0
Hypokalaemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Decreased appetite	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Back pain	2 (6.3)	0	2 (6.3)	0	0
Pain in extremity	2 (6.3)	1 (3.1)	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Headache	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Psychiatric disorders					
-Total	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Anxiety	2 (6.3)	0	2 (6.3)	0	0
Mental status changes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Renal and urinary disorders					
-Total	1 (3.1)	0	0	0	1 (3.1)
Acute kidney injury	1 (3.1)	0	0	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders					
-Total	8 (25.0)	5 (15.6)	2 (6.3)	1 (3.1)	0
Cough	6 (18.8)	4 (12.5)	2 (6.3)	0	0
Nasal congestion	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rhinorrhoea	3 (9.4)	3 (9.4)	0	0	0
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Dyspnoea	1 (3.1)	0	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0	1 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Dry skin	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	2 (6.3)	0	0	0	2 (6.3)
Hypotension	2 (6.3)	0	0	0	2 (6.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (37.9)	2 (6.9)	4 (13.8)	3 (10.3)	2 (6.9)
Blood and lymphatic system disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Anaemia	1 (3.4)	0	1 (3.4)	0	0
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Gastrointestinal disorders					
-Total	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Diarrhoea	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Nausea	1 (3.4)	1 (3.4)	0	0	0
Vomiting	1 (3.4)	1 (3.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (13.8)	0	3 (10.3)	1 (3.4)	0
Pyrexia	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Fatigue	1 (3.4)	0	1 (3.4)	0	0
Infections and infestations					
-Total	7 (24.1)	2 (6.9)	2 (6.9)	2 (6.9)	1 (3.4)
Conjunctivitis	4 (13.8)	2 (6.9)	2 (6.9)	0	0
Pneumonia	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Rhinovirus infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Upper respiratory tract infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Investigations					
-Total	1 (3.4)	1 (3.4)	0	0	0
Blood bilirubin increased	1 (3.4)	1 (3.4)	0	0	0
Neutrophil count decreased	1 (3.4)	1 (3.4)	0	0	0
Platelet count decreased	1 (3.4)	1 (3.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Decreased appetite	1 (3.4)	0	0	0	1 (3.4)
Hyperglycaemia	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (6.9)	0	2 (6.9)	0	0
Arthralgia	1 (3.4)	0	1 (3.4)	0	0
Pain in extremity	1 (3.4)	0	1 (3.4)	0	0
Nervous system disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Headache	1 (3.4)	0	0	1 (3.4)	0
Psychiatric disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Anxiety	1 (3.4)	0	1 (3.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (13.8)	2 (6.9)	1 (3.4)	0	1 (3.4)

Timing: >1 year post-CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	4 (13.8)	3 (10.3)	1 (3.4)	0	0
Dyspnoea	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Rhinorrhoea	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Oropharyngeal pain	1 (3.4)	1 (3.4)	0	0	0
Pleural effusion	1 (3.4)	0	1 (3.4)	0	0
Tachypnoea	1 (3.4)	0	0	0	1 (3.4)
Vascular disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Hypertension	1 (3.4)	0	0	1 (3.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (57.1)	3 (14.3)	6 (28.6)	1 (4.8)	2 (9.5)
Blood and lymphatic system disorders					
-Total	1 (4.8)	0	0	0	1 (4.8)
Neutropenia	1 (4.8)	0	0	0	1 (4.8)
Gastrointestinal disorders					
-Total	3 (14.3)	3 (14.3)	0	0	0
Diarrhoea	2 (9.5)	2 (9.5)	0	0	0
Constipation	1 (4.8)	1 (4.8)	0	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (9.5)	2 (9.5)	0	0	0
Pyrexia	2 (9.5)	2 (9.5)	0	0	0
Immune system disorders					
-Total	3 (14.3)	0	3 (14.3)	0	0
Hypogammaglobulinaemia	3 (14.3)	0	3 (14.3)	0	0
Infections and infestations					
-Total	7 (33.3)	2 (9.5)	5 (23.8)	0	0
Sinusitis	4 (19.0)	0	4 (19.0)	0	0
Upper respiratory tract infection	3 (14.3)	1 (4.8)	2 (9.5)	0	0
Rhinovirus infection	2 (9.5)	0	2 (9.5)	0	0
Gastroenteritis	1 (4.8)	1 (4.8)	0	0	0
Investigations					
-Total	3 (14.3)	2 (9.5)	0	0	1 (4.8)
Neutrophil count decreased	2 (9.5)	1 (4.8)	0	0	1 (4.8)
Platelet count decreased	1 (4.8)	1 (4.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (4.8)	0	1 (4.8)	0	0
Nervous system disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Headache	1 (4.8)	0	1 (4.8)	0	0
Psychiatric disorders					
-Total	1 (4.8)	1 (4.8)	0	0	0
Anxiety	1 (4.8)	1 (4.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Dyspnoea	1 (4.8)	0	1 (4.8)	0	0
Epistaxis	1 (4.8)	1 (4.8)	0	0	0
Hypoxia	1 (4.8)	0	0	1 (4.8)	0
Rhinorrhoea	1 (4.8)	0	1 (4.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Rash	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Dry skin	1 (4.8)	1 (4.8)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Hypertension	1 (4.8)	0	1 (4.8)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (100)	2 (4.3)	6 (13.0)	12 (26.1)	26 (56.5)
Blood and lymphatic system disorders					
-Total	23 (50.0)	1 (2.2)	4 (8.7)	11 (23.9)	7 (15.2)
Febrile neutropenia	12 (26.1)	0	0	12 (26.1)	0
Anaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Disseminated intravascular coagulation	6 (13.0)	0	5 (10.9)	1 (2.2)	0
Thrombocytopenia	6 (13.0)	0	0	1 (2.2)	5 (10.9)
Neutropenia	4 (8.7)	0	1 (2.2)	0	3 (6.5)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (19.6)	3 (6.5)	4 (8.7)	2 (4.3)	0
Tachycardia	9 (19.6)	3 (6.5)	4 (8.7)	2 (4.3)	0
Gastrointestinal disorders					
-Total	32 (69.6)	15 (32.6)	12 (26.1)	5 (10.9)	0
Vomiting	15 (32.6)	12 (26.1)	3 (6.5)	0	0
Diarrhoea	14 (30.4)	8 (17.4)	4 (8.7)	2 (4.3)	0
Nausea	14 (30.4)	8 (17.4)	5 (10.9)	1 (2.2)	0
Constipation	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Abdominal pain	6 (13.0)	0	4 (8.7)	2 (4.3)	0
General disorders and administration site conditions					
-Total	25 (54.3)	9 (19.6)	9 (19.6)	5 (10.9)	2 (4.3)
Pyrexia	19 (41.3)	6 (13.0)	7 (15.2)	4 (8.7)	2 (4.3)
Fatigue	11 (23.9)	8 (17.4)	3 (6.5)	0	0
Face oedema	4 (8.7)	3 (6.5)	0	1 (2.2)	0
Chills	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Oedema peripheral	3 (6.5)	2 (4.3)	0	1 (2.2)	0
Generalised oedema	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	37 (80.4)	1 (2.2)	14 (30.4)	11 (23.9)	11 (23.9)
Cytokine release syndrome	31 (67.4)	3 (6.5)	9 (19.6)	8 (17.4)	11 (23.9)
Hypogammaglobulinaemia	17 (37.0)	1 (2.2)	13 (28.3)	3 (6.5)	0
Infections and infestations					
-Total	22 (47.8)	7 (15.2)	9 (19.6)	4 (8.7)	2 (4.3)
Upper respiratory tract infection	8 (17.4)	4 (8.7)	2 (4.3)	2 (4.3)	0
Conjunctivitis	6 (13.0)	2 (4.3)	4 (8.7)	0	0
Pneumonia	6 (13.0)	1 (2.2)	1 (2.2)	2 (4.3)	2 (4.3)
Nasopharyngitis	5 (10.9)	3 (6.5)	2 (4.3)	0	0
Rhinovirus infection	4 (8.7)	0	3 (6.5)	1 (2.2)	0
Gastroenteritis	2 (4.3)	2 (4.3)	0	0	0
Sinusitis	2 (4.3)	0	2 (4.3)	0	0
Investigations					
-Total	25 (54.3)	1 (2.2)	3 (6.5)	8 (17.4)	13 (28.3)
Alanine aminotransferase increased	13 (28.3)	3 (6.5)	6 (13.0)	4 (8.7)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	12 (26.1)	1 (2.2)	5 (10.9)	4 (8.7)	2 (4.3)
Neutrophil count decreased	12 (26.1)	1 (2.2)	0	2 (4.3)	9 (19.6)
Platelet count decreased	12 (26.1)	2 (4.3)	2 (4.3)	5 (10.9)	3 (6.5)
White blood cell count decreased	12 (26.1)	1 (2.2)	2 (4.3)	1 (2.2)	8 (17.4)
Blood bilirubin increased	9 (19.6)	0	2 (4.3)	7 (15.2)	0
Lymphocyte count decreased	7 (15.2)	0	0	4 (8.7)	3 (6.5)
Serum ferritin increased	6 (13.0)	1 (2.2)	4 (8.7)	1 (2.2)	0
Blood immunoglobulin m decreased	3 (6.5)	1 (2.2)	0	2 (4.3)	0
International normalised ratio increased	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Metabolism and nutrition disorders					
-Total	27 (58.7)	5 (10.9)	8 (17.4)	10 (21.7)	4 (8.7)
Decreased appetite	15 (32.6)	4 (8.7)	6 (13.0)	3 (6.5)	2 (4.3)
Hypocalcaemia	9 (19.6)	2 (4.3)	4 (8.7)	3 (6.5)	0
Hypokalaemia	9 (19.6)	1 (2.2)	3 (6.5)	4 (8.7)	1 (2.2)
Hypophosphataemia	8 (17.4)	3 (6.5)	2 (4.3)	2 (4.3)	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Hyperglycaemia	4 (8.7)	0	0	4 (8.7)	0
Hypoalbuminaemia	4 (8.7)	0	4 (8.7)	0	0
Hypervolaemia	3 (6.5)	0	1 (2.2)	2 (4.3)	0
Musculoskeletal and connective tissue disorders					
-Total	18 (39.1)	7 (15.2)	9 (19.6)	2 (4.3)	0
Pain in extremity	10 (21.7)	4 (8.7)	6 (13.0)	0	0
Arthralgia	9 (19.6)	4 (8.7)	5 (10.9)	0	0
Back pain	5 (10.9)	1 (2.2)	2 (4.3)	2 (4.3)	0
Myalgia	3 (6.5)	2 (4.3)	1 (2.2)	0	0
Nervous system disorders					
-Total	16 (34.8)	8 (17.4)	4 (8.7)	4 (8.7)	0
Headache	12 (26.1)	7 (15.2)	2 (4.3)	3 (6.5)	0
Encephalopathy	4 (8.7)	1 (2.2)	2 (4.3)	1 (2.2)	0
Psychiatric disorders					
-Total	12 (26.1)	2 (4.3)	8 (17.4)	2 (4.3)	0
Anxiety	8 (17.4)	1 (2.2)	7 (15.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	6 (13.0)	2 (4.3)	2 (4.3)	2 (4.3)	0
Mental status changes	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	5 (10.9)	2 (4.3)	1 (2.2)	0	2 (4.3)
Acute kidney injury	5 (10.9)	2 (4.3)	1 (2.2)	0	2 (4.3)
Respiratory, thoracic and mediastinal disorders					
-Total	27 (58.7)	11 (23.9)	6 (13.0)	3 (6.5)	7 (15.2)
Cough	13 (28.3)	11 (23.9)	2 (4.3)	0	0
Hypoxia	11 (23.9)	0	3 (6.5)	4 (8.7)	4 (8.7)
Pleural effusion	8 (17.4)	3 (6.5)	2 (4.3)	2 (4.3)	1 (2.2)
Pulmonary oedema	6 (13.0)	1 (2.2)	2 (4.3)	2 (4.3)	1 (2.2)
Nasal congestion	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Oropharyngeal pain	5 (10.9)	4 (8.7)	1 (2.2)	0	0
Tachypnoea	4 (8.7)	2 (4.3)	0	1 (2.2)	1 (2.2)
Dyspnoea	3 (6.5)	1 (2.2)	0	1 (2.2)	1 (2.2)
Epistaxis	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Rhinorrhoea	2 (4.3)	1 (2.2)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	5 (10.9)	3 (6.5)	2 (4.3)	0	0
Rash	4 (8.7)	2 (4.3)	2 (4.3)	0	0
Dry skin	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Vascular disorders					
-Total	18 (39.1)	3 (6.5)	6 (13.0)	7 (15.2)	2 (4.3)
Hypotension	12 (26.1)	1 (2.2)	5 (10.9)	4 (8.7)	2 (4.3)
Hypertension	9 (19.6)	3 (6.5)	3 (6.5)	3 (6.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	2 (5.9)	10 (29.4)	22 (64.7)
Blood and lymphatic system disorders					
-Total	27 (79.4)	1 (2.9)	1 (2.9)	18 (52.9)	7 (20.6)
Anaemia	16 (47.1)	5 (14.7)	5 (14.7)	6 (17.6)	0
Febrile neutropenia	15 (44.1)	0	0	13 (38.2)	2 (5.9)
Neutropenia	7 (20.6)	0	1 (2.9)	2 (5.9)	4 (11.8)
Thrombocytopenia	3 (8.8)	0	0	2 (5.9)	1 (2.9)
Disseminated intravascular coagulation	2 (5.9)	0	0	2 (5.9)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (23.5)	4 (11.8)	3 (8.8)	0	1 (2.9)
Tachycardia	8 (23.5)	4 (11.8)	3 (8.8)	0	1 (2.9)
Gastrointestinal disorders					
-Total	24 (70.6)	11 (32.4)	11 (32.4)	2 (5.9)	0
Diarrhoea	12 (35.3)	8 (23.5)	4 (11.8)	0	0
Vomiting	11 (32.4)	5 (14.7)	5 (14.7)	1 (2.9)	0
Nausea	8 (23.5)	4 (11.8)	3 (8.8)	1 (2.9)	0
Constipation	7 (20.6)	4 (11.8)	3 (8.8)	0	0
Abdominal pain	5 (14.7)	2 (5.9)	3 (8.8)	0	0
General disorders and administration site conditions					
-Total	22 (64.7)	13 (38.2)	4 (11.8)	5 (14.7)	0
Pyrexia	16 (47.1)	8 (23.5)	3 (8.8)	5 (14.7)	0
Fatigue	6 (17.6)	6 (17.6)	0	0	0
Chills	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Face oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Generalised oedema	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Oedema peripheral	4 (11.8)	3 (8.8)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	32 (94.1)	1 (2.9)	11 (32.4)	10 (29.4)	10 (29.4)
Cytokine release syndrome	30 (88.2)	2 (5.9)	9 (26.5)	9 (26.5)	10 (29.4)
Hypogammaglobulinaemia	16 (47.1)	1 (2.9)	11 (32.4)	4 (11.8)	0
Infections and infestations					
-Total	14 (41.2)	1 (2.9)	8 (23.5)	5 (14.7)	0
Rhinovirus infection	5 (14.7)	0	4 (11.8)	1 (2.9)	0
Sinusitis	5 (14.7)	0	3 (8.8)	2 (5.9)	0
Upper respiratory tract infection	5 (14.7)	1 (2.9)	3 (8.8)	1 (2.9)	0
Gastroenteritis	4 (11.8)	2 (5.9)	0	2 (5.9)	0
Conjunctivitis	2 (5.9)	0	2 (5.9)	0	0
Nasopharyngitis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Investigations					
-Total	23 (67.6)	2 (5.9)	1 (2.9)	8 (23.5)	12 (35.3)
White blood cell count decreased	13 (38.2)	2 (5.9)	2 (5.9)	1 (2.9)	8 (23.5)
Neutrophil count decreased	12 (35.3)	0	2 (5.9)	2 (5.9)	8 (23.5)
Platelet count decreased	12 (35.3)	4 (11.8)	1 (2.9)	2 (5.9)	5 (14.7)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	10 (29.4)	1 (2.9)	1 (2.9)	6 (17.6)	2 (5.9)
Aspartate aminotransferase increased	7 (20.6)	1 (2.9)	1 (2.9)	4 (11.8)	1 (2.9)
International normalised ratio increased	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Alanine aminotransferase increased	5 (14.7)	0	2 (5.9)	3 (8.8)	0
Blood bilirubin increased	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Blood immunoglobulin m decreased	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Serum ferritin increased	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	21 (61.8)	5 (14.7)	3 (8.8)	12 (35.3)	1 (2.9)
Decreased appetite	15 (44.1)	7 (20.6)	1 (2.9)	7 (20.6)	0
Hypokalaemia	11 (32.4)	2 (5.9)	3 (8.8)	5 (14.7)	1 (2.9)
Hypophosphataemia	10 (29.4)	0	4 (11.8)	6 (17.6)	0
Hypoalbuminaemia	7 (20.6)	0	6 (17.6)	1 (2.9)	0
Hypocalcaemia	7 (20.6)	0	5 (14.7)	2 (5.9)	0
Hyperglycaemia	5 (14.7)	0	4 (11.8)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Hypervolaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Musculoskeletal and connective tissue disorders					
-Total	17 (50.0)	8 (23.5)	6 (17.6)	3 (8.8)	0
Myalgia	7 (20.6)	4 (11.8)	3 (8.8)	0	0
Pain in extremity	7 (20.6)	4 (11.8)	2 (5.9)	1 (2.9)	0
Back pain	5 (14.7)	1 (2.9)	3 (8.8)	1 (2.9)	0
Arthralgia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Nervous system disorders					
-Total	19 (55.9)	7 (20.6)	9 (26.5)	3 (8.8)	0
Headache	15 (44.1)	6 (17.6)	9 (26.5)	0	0
Tremor	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Encephalopathy	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Psychiatric disorders					
-Total	11 (32.4)	3 (8.8)	3 (8.8)	5 (14.7)	0
Anxiety	6 (17.6)	2 (5.9)	2 (5.9)	2 (5.9)	0
Mental status changes	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Renal and urinary disorders					
-Total	7 (20.6)	0	1 (2.9)	3 (8.8)	3 (8.8)
Acute kidney injury	7 (20.6)	0	1 (2.9)	3 (8.8)	3 (8.8)
Respiratory, thoracic and mediastinal disorders					
-Total	22 (64.7)	9 (26.5)	1 (2.9)	9 (26.5)	3 (8.8)
Cough	10 (29.4)	7 (20.6)	3 (8.8)	0	0
Hypoxia	9 (26.5)	0	1 (2.9)	6 (17.6)	2 (5.9)
Pulmonary oedema	6 (17.6)	1 (2.9)	1 (2.9)	4 (11.8)	0
Epistaxis	5 (14.7)	3 (8.8)	1 (2.9)	1 (2.9)	0
Tachypnoea	5 (14.7)	1 (2.9)	1 (2.9)	3 (8.8)	0
Dyspnoea	4 (11.8)	0	2 (5.9)	1 (2.9)	1 (2.9)
Nasal congestion	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Rhinorrhoea	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Oropharyngeal pain	3 (8.8)	3 (8.8)	0	0	0
Pleural effusion	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (29.4)	7 (20.6)	3 (8.8)	0	0
Dry skin	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Rash	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Vascular disorders					
-Total	14 (41.2)	2 (5.9)	2 (5.9)	4 (11.8)	6 (17.6)
Hypotension	12 (35.3)	1 (2.9)	1 (2.9)	4 (11.8)	6 (17.6)
Hypertension	7 (20.6)	1 (2.9)	4 (11.8)	2 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	4 (6.8)	7 (11.9)	20 (33.9)	28 (47.5)
Blood and lymphatic system disorders					
-Total	31 (52.5)	1 (1.7)	6 (10.2)	17 (28.8)	7 (11.9)
Febrile neutropenia	18 (30.5)	0	0	17 (28.8)	1 (1.7)
Anaemia	16 (27.1)	4 (6.8)	7 (11.9)	5 (8.5)	0
Neutropenia	6 (10.2)	0	2 (3.4)	1 (1.7)	3 (5.1)
Thrombocytopenia	5 (8.5)	0	0	1 (1.7)	4 (6.8)
Disseminated intravascular coagulation	4 (6.8)	0	3 (5.1)	1 (1.7)	0
Splenomegaly	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Leukopenia	2 (3.4)	0	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					
-Total	15 (25.4)	6 (10.2)	5 (8.5)	2 (3.4)	2 (3.4)
Tachycardia	15 (25.4)	6 (10.2)	6 (10.2)	2 (3.4)	1 (1.7)
Cardiac failure	1 (1.7)	0	0	0	1 (1.7)
Endocrine disorders					
-Total	2 (3.4)	0	2 (3.4)	0	0
Adrenal insufficiency	2 (3.4)	0	2 (3.4)	0	0
Gastrointestinal disorders					
-Total	36 (61.0)	17 (28.8)	13 (22.0)	6 (10.2)	0
Vomiting	18 (30.5)	11 (18.6)	7 (11.9)	0	0
Nausea	14 (23.7)	7 (11.9)	6 (10.2)	1 (1.7)	0
Diarrhoea	12 (20.3)	7 (11.9)	4 (6.8)	1 (1.7)	0
Abdominal pain	10 (16.9)	2 (3.4)	6 (10.2)	2 (3.4)	0
Constipation	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Stomatitis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	0	0	1 (1.7)	0
Trichoglossia	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	29 (49.2)	17 (28.8)	5 (8.5)	4 (6.8)	3 (5.1)
Pyrexia	20 (33.9)	11 (18.6)	4 (6.8)	3 (5.1)	2 (3.4)
Fatigue	9 (15.3)	7 (11.9)	2 (3.4)	0	0
Face oedema	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Chills	5 (8.5)	3 (5.1)	2 (3.4)	0	0
Oedema peripheral	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Hepatobiliary disorders					
-Total	6 (10.2)	2 (3.4)	4 (6.8)	0	0
Hyperbilirubinaemia	3 (5.1)	0	3 (5.1)	0	0
Hepatomegaly	2 (3.4)	2 (3.4)	0	0	0
Hepatic function abnormal	1 (1.7)	0	1 (1.7)	0	0
Immune system disorders					
-Total	47 (79.7)	2 (3.4)	15 (25.4)	18 (30.5)	12 (20.3)
Cytokine release syndrome	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Hypogammaglobulinaemia	18 (30.5)	1 (1.7)	10 (16.9)	7 (11.9)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	7 (11.9)	0	4 (6.8)	3 (5.1)	0
Conjunctivitis	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Rhinovirus infection	1 (1.7)	0	1 (1.7)	0	0
Sinusitis	1 (1.7)	0	0	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Investigations					
-Total	33 (55.9)	4 (6.8)	2 (3.4)	12 (20.3)	15 (25.4)
Platelet count decreased	15 (25.4)	3 (5.1)	3 (5.1)	4 (6.8)	5 (8.5)
White blood cell count decreased	15 (25.4)	3 (5.1)	3 (5.1)	2 (3.4)	7 (11.9)
Alanine aminotransferase increased	13 (22.0)	4 (6.8)	6 (10.2)	3 (5.1)	0
Aspartate aminotransferase increased	13 (22.0)	1 (1.7)	5 (8.5)	6 (10.2)	1 (1.7)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	13 (22.0)	0	3 (5.1)	1 (1.7)	9 (15.3)
Lymphocyte count decreased	12 (20.3)	2 (3.4)	0	6 (10.2)	4 (6.8)
Blood bilirubin increased	8 (13.6)	1 (1.7)	1 (1.7)	6 (10.2)	0
International normalised ratio increased	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Blood immunoglobulin m decreased	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Activated partial thromboplastin time prolonged	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Blood immunoglobulin a decreased	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Blood fibrinogen decreased	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Serum ferritin increased	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Blood creatine phosphokinase increased	1 (1.7)	0	0	0	1 (1.7)
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Gamma-glutamyltransferase increased	1 (1.7)	0	0	1 (1.7)	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (54.2)	7 (11.9)	7 (11.9)	13 (22.0)	5 (8.5)
Decreased appetite	18 (30.5)	9 (15.3)	3 (5.1)	5 (8.5)	1 (1.7)
Hypokalaemia	14 (23.7)	2 (3.4)	4 (6.8)	6 (10.2)	2 (3.4)
Hypophosphataemia	12 (20.3)	3 (5.1)	3 (5.1)	6 (10.2)	0
Hypocalcaemia	11 (18.6)	2 (3.4)	6 (10.2)	3 (5.1)	0
Hypoalbuminaemia	6 (10.2)	0	6 (10.2)	0	0
Hyperglycaemia	5 (8.5)	0	2 (3.4)	3 (5.1)	0
Hyperphosphataemia	4 (6.8)	4 (6.8)	0	0	0
Hyperuricaemia	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0
Hypervolaemia	4 (6.8)	0	2 (3.4)	2 (3.4)	0
Hypomagnesaemia	3 (5.1)	3 (5.1)	0	0	0
Hypertriglyceridaemia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Metabolic acidosis	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Hypercalcaemia	1 (1.7)	0	0	1 (1.7)	0
Hyperkalaemia	1 (1.7)	0	0	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (39.0)	12 (20.3)	10 (16.9)	1 (1.7)	0
Pain in extremity	10 (16.9)	6 (10.2)	4 (6.8)	0	0
Arthralgia	8 (13.6)	4 (6.8)	4 (6.8)	0	0
Myalgia	7 (11.9)	4 (6.8)	3 (5.1)	0	0
Back pain	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Muscular weakness	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Nervous system disorders					
-Total	27 (45.8)	11 (18.6)	9 (15.3)	7 (11.9)	0
Headache	20 (33.9)	11 (18.6)	7 (11.9)	2 (3.4)	0
Encephalopathy	8 (13.6)	1 (1.7)	3 (5.1)	4 (6.8)	0
Seizure	1 (1.7)	0	0	1 (1.7)	0
Psychiatric disorders					
-Total	13 (22.0)	5 (8.5)	4 (6.8)	4 (6.8)	0
Delirium	7 (11.9)	2 (3.4)	2 (3.4)	3 (5.1)	0
Confusional state	5 (8.5)	5 (8.5)	0	0	0
Anxiety	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Renal and urinary disorders					

Timing: within 8 weeks post infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (11.9)	1 (1.7)	1 (1.7)	3 (5.1)	2 (3.4)
Acute kidney injury	7 (11.9)	1 (1.7)	1 (1.7)	3 (5.1)	2 (3.4)
Haematuria	1 (1.7)	1 (1.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (47.5)	11 (18.6)	3 (5.1)	8 (13.6)	6 (10.2)
Hypoxia	12 (20.3)	0	5 (8.5)	5 (8.5)	2 (3.4)
Pulmonary oedema	10 (16.9)	2 (3.4)	3 (5.1)	4 (6.8)	1 (1.7)
Cough	8 (13.6)	7 (11.9)	1 (1.7)	0	0
Tachypnoea	7 (11.9)	2 (3.4)	1 (1.7)	4 (6.8)	0
Pleural effusion	5 (8.5)	3 (5.1)	0	2 (3.4)	0
Oropharyngeal pain	4 (6.8)	4 (6.8)	0	0	0
Dyspnoea	3 (5.1)	0	0	2 (3.4)	1 (1.7)
Epistaxis	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Respiratory failure	3 (5.1)	0	0	0	3 (5.1)
Nasal congestion	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Rhinorrhoea	2 (3.4)	2 (3.4)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Race: White

Group term Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (18.6)	4 (6.8)	7 (11.9)	0	0
Pruritus	5 (8.5)	1 (1.7)	4 (6.8)	0	0
Rash	5 (8.5)	2 (3.4)	3 (5.1)	0	0
Dry skin	1 (1.7)	1 (1.7)	0	0	0
Rash maculo-papular	1 (1.7)	0	1 (1.7)	0	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	21 (35.6)	3 (5.1)	6 (10.2)	8 (13.6)	4 (6.8)
Hypotension	19 (32.2)	1 (1.7)	6 (10.2)	8 (13.6)	4 (6.8)
Hypertension	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	2 (20.0)	7 (70.0)
Blood and lymphatic system disorders					
-Total	8 (80.0)	0	1 (10.0)	2 (20.0)	5 (50.0)
Disseminated intravascular coagulation	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Neutropenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Thrombocytopenia	2 (20.0)	0	0	0	2 (20.0)
Hypofibrinogenaemia	1 (10.0)	0	1 (10.0)	0	0
Leukopenia	1 (10.0)	0	0	0	1 (10.0)
Splenomegaly	1 (10.0)	1 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (30.0)	2 (20.0)	0	0	1 (10.0)
Cardiac dysfunction	2 (20.0)	2 (20.0)	0	0	0
Cardiac arrest	1 (10.0)	0	0	0	1 (10.0)
Tachycardia	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	3 (30.0)	3 (30.0)	0	0
Constipation	2 (20.0)	2 (20.0)	0	0	0
Nausea	2 (20.0)	2 (20.0)	0	0	0
Pancreatitis	2 (20.0)	0	2 (20.0)	0	0
Diarrhoea	1 (10.0)	0	1 (10.0)	0	0
Enterocolitis	1 (10.0)	0	1 (10.0)	0	0
General disorders and administration site conditions					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Pyrexia	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Fatigue	1 (10.0)	1 (10.0)	0	0	0
Hepatobiliary disorders					

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (50.0)	0	1 (10.0)	2 (20.0)	2 (20.0)
Hepatic function abnormal	4 (40.0)	0	1 (10.0)	2 (20.0)	1 (10.0)
Hepatomegaly	1 (10.0)	0	0	0	1 (10.0)
Immune system disorders					
-Total	9 (90.0)	0	4 (40.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Infections and infestations					
-Total	7 (70.0)	2 (20.0)	1 (10.0)	3 (30.0)	1 (10.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bk virus infection	1 (10.0)	1 (10.0)	0	0	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Urinary tract infection viral	1 (10.0)	1 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	7 (70.0)	0	1 (10.0)	2 (20.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	0	0	4 (40.0)
Blood fibrinogen decreased	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Serum ferritin increased	3 (30.0)	0	3 (30.0)	0	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)	0	0
Blood bilirubin increased	1 (10.0)	0	0	1 (10.0)	0
Blood creatine phosphokinase increased	1 (10.0)	0	0	1 (10.0)	0
Fibrin d dimer increased	1 (10.0)	1 (10.0)	0	0	0
Gamma-glutamyltransferase increased	1 (10.0)	0	0	1 (10.0)	0
Haptoglobin decreased	1 (10.0)	1 (10.0)	0	0	0
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	4 (40.0)	1 (10.0)	0	2 (20.0)	1 (10.0)
Tumour lysis syndrome	2 (20.0)	0	0	2 (20.0)	0
Hypercalcaemia	1 (10.0)	0	0	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	0	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	0	0	1 (10.0)
Hyperuricaemia	1 (10.0)	1 (10.0)	0	0	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)	0	0
Metabolic acidosis	1 (10.0)	0	0	0	1 (10.0)
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Arthralgia	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	0	1 (10.0)	0
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Headache	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	3 (30.0)	1 (10.0)	0	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Haematuria	1 (10.0)	1 (10.0)	0	0	0
Proteinuria	1 (10.0)	1 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (70.0)	3 (30.0)	0	0	4 (40.0)
Hypoxia	4 (40.0)	0	0	0	4 (40.0)
Cough	1 (10.0)	1 (10.0)	0	0	0
Haemoptysis	1 (10.0)	0	1 (10.0)	0	0
Nasal congestion	1 (10.0)	1 (10.0)	0	0	0
Nasal dryness	1 (10.0)	1 (10.0)	0	0	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0	0	0
Pleural effusion	1 (10.0)	1 (10.0)	0	0	0
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Erythema nodosum	1 (10.0)	1 (10.0)	0	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Skin ulcer	1 (10.0)	0	1 (10.0)	0	0
Vascular disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hypertension	1 (10.0)	0	1 (10.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	0	0	10 (90.9)
Blood and lymphatic system disorders					
-Total	8 (72.7)	1 (9.1)	0	6 (54.5)	1 (9.1)
Febrile neutropenia	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Anaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0
Thrombocytopenia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Tachycardia	1 (9.1)	1 (9.1)	0	0	0
Endocrine disorders					

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	0	2 (18.2)	0	0
Adrenal insufficiency	2 (18.2)	0	2 (18.2)	0	0
Gastrointestinal disorders					
-Total	7 (63.6)	1 (9.1)	4 (36.4)	2 (18.2)	0
Constipation	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Vomiting	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Diarrhoea	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Nausea	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Pancreatitis	1 (9.1)	0	1 (9.1)	0	0
General disorders and administration site conditions					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Pyrexia	2 (18.2)	0	0	2 (18.2)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Fatigue	1 (9.1)	1 (9.1)	0	0	0
Multiple organ dysfunction syndrome	1 (9.1)	0	0	0	1 (9.1)
Oedema peripheral	1 (9.1)	1 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hyperbilirubinaemia	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Immune system disorders					
-Total	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Cytokine release syndrome	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Hypogammaglobulinaemia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Infections and infestations					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	9 (81.8)	0	0	3 (27.3)	6 (54.5)
Neutrophil count decreased	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Platelet count decreased	5 (45.5)	1 (9.1)	0	1 (9.1)	3 (27.3)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	5 (45.5)	0	0	0	5 (45.5)
Alanine aminotransferase increased	4 (36.4)	0	1 (9.1)	3 (27.3)	0
Aspartate aminotransferase increased	4 (36.4)	0	0	2 (18.2)	2 (18.2)
Blood bilirubin increased	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Lymphocyte count decreased	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Activated partial thromboplastin time prolonged	2 (18.2)	0	1 (9.1)	1 (9.1)	0
International normalised ratio increased	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Serum ferritin increased	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)
Blood immunoglobulin a decreased	1 (9.1)	1 (9.1)	0	0	0
Blood immunoglobulin m decreased	1 (9.1)	1 (9.1)	0	0	0
Fibrin d dimer increased	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (90.9)	1 (9.1)	2 (18.2)	6 (54.5)	1 (9.1)
Decreased appetite	6 (54.5)	0	1 (9.1)	5 (45.5)	0
Hypocalcaemia	5 (45.5)	0	3 (27.3)	2 (18.2)	0
Hypokalaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0
Hypophosphataemia	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Hypoalbuminaemia	4 (36.4)	0	3 (27.3)	1 (9.1)	0
Hyperglycaemia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Hypomagnesaemia	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hyperuricaemia	2 (18.2)	2 (18.2)	0	0	0
Hypervolaemia	2 (18.2)	0	0	2 (18.2)	0
Hypercalcaemia	1 (9.1)	0	1 (9.1)	0	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Myalgia	2 (18.2)	2 (18.2)	0	0	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Cognitive disorder	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Headache	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Psychiatric disorders					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Anxiety	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Confusional state	2 (18.2)	2 (18.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	1 (9.1)	0	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	0	2 (18.2)	0
Cough	1 (9.1)	1 (9.1)	0	0	0
Epistaxis	1 (9.1)	0	0	1 (9.1)	0
Hypoxia	1 (9.1)	0	0	1 (9.1)	0
Pleural effusion	1 (9.1)	0	0	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (9.1)	0	0	1 (9.1)	0
Rash maculo-papular	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	5 (45.5)	1 (9.1)	0	2 (18.2)	2 (18.2)
Hypertension	4 (36.4)	1 (9.1)	0	3 (27.3)	0
Hypotension	2 (18.2)	0	0	0	2 (18.2)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (85.5)	10 (18.2)	16 (29.1)	13 (23.6)	8 (14.5)
Blood and lymphatic system disorders					
-Total	9 (16.4)	3 (5.5)	1 (1.8)	4 (7.3)	1 (1.8)
Anaemia	5 (9.1)	4 (7.3)	0	1 (1.8)	0
Febrile neutropenia	2 (3.6)	0	0	2 (3.6)	0
Neutropenia	2 (3.6)	0	0	1 (1.8)	1 (1.8)
Disseminated intravascular coagulation	1 (1.8)	0	0	1 (1.8)	0
Leukopenia	1 (1.8)	0	1 (1.8)	0	0
Thrombocytopenia	1 (1.8)	0	0	1 (1.8)	0
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.5)	2 (3.6)	0	0	1 (1.8)
Tachycardia	2 (3.6)	2 (3.6)	0	0	0
Cardiac arrest	1 (1.8)	0	0	0	1 (1.8)
Cardiac failure	1 (1.8)	0	0	1 (1.8)	0
Gastrointestinal disorders					
-Total	9 (16.4)	6 (10.9)	3 (5.5)	0	0
Diarrhoea	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Nausea	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Vomiting	3 (5.5)	3 (5.5)	0	0	0
Abdominal pain	1 (1.8)	1 (1.8)	0	0	0
Constipation	1 (1.8)	0	1 (1.8)	0	0
Pancreatitis	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	17 (30.9)	12 (21.8)	4 (7.3)	1 (1.8)	0
Pyrexia	10 (18.2)	5 (9.1)	4 (7.3)	1 (1.8)	0
Fatigue	6 (10.9)	6 (10.9)	0	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	6 (10.9)	0	6 (10.9)	0	0
Hypogammaglobulinaemia	6 (10.9)	0	6 (10.9)	0	0
Infections and infestations					
-Total	23 (41.8)	5 (9.1)	11 (20.0)	5 (9.1)	2 (3.6)
Upper respiratory tract infection	6 (10.9)	2 (3.6)	3 (5.5)	1 (1.8)	0
Gastroenteritis	5 (9.1)	3 (5.5)	0	2 (3.6)	0
Nasopharyngitis	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Rhinovirus infection	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Parainfluenzae virus infection	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Pneumonia	3 (5.5)	1 (1.8)	1 (1.8)	0	1 (1.8)
Sinusitis	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Bk virus infection	1 (1.8)	0	0	1 (1.8)	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Viral infection	1 (1.8)	0	1 (1.8)	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (30.9)	4 (7.3)	3 (5.5)	7 (12.7)	3 (5.5)
Neutrophil count decreased	8 (14.5)	1 (1.8)	1 (1.8)	3 (5.5)	3 (5.5)
White blood cell count decreased	8 (14.5)	3 (5.5)	2 (3.6)	2 (3.6)	1 (1.8)
Lymphocyte count decreased	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Platelet count decreased	4 (7.3)	2 (3.6)	0	1 (1.8)	1 (1.8)
Alanine aminotransferase increased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Blood bilirubin increased	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Blood immunoglobulin a decreased	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Blood immunoglobulin m decreased	1 (1.8)	0	0	1 (1.8)	0
Metabolism and nutrition disorders					
-Total	10 (18.2)	3 (5.5)	3 (5.5)	2 (3.6)	2 (3.6)
Decreased appetite	5 (9.1)	1 (1.8)	3 (5.5)	1 (1.8)	0
Hyperuricaemia	3 (5.5)	3 (5.5)	0	0	0
Hypokalaemia	2 (3.6)	0	1 (1.8)	0	1 (1.8)
Hyperkalaemia	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (1.8)	0	0	1 (1.8)	0
Hypophosphataemia	1 (1.8)	0	1 (1.8)	0	0
Iron overload	1 (1.8)	0	1 (1.8)	0	0
Tumour lysis syndrome	1 (1.8)	0	0	0	1 (1.8)
Musculoskeletal and connective tissue disorders					
-Total	8 (14.5)	4 (7.3)	3 (5.5)	1 (1.8)	0
Back pain	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Pain in extremity	4 (7.3)	2 (3.6)	2 (3.6)	0	0
Arthralgia	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Myalgia	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	10 (18.2)	6 (10.9)	3 (5.5)	1 (1.8)	0
Headache	9 (16.4)	6 (10.9)	3 (5.5)	0	0
Seizure	1 (1.8)	0	0	1 (1.8)	0
Psychiatric disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Anxiety	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Renal and urinary disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Acute kidney injury	3 (5.5)	1 (1.8)	1 (1.8)	0	1 (1.8)
Haematuria	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	15 (27.3)	9 (16.4)	3 (5.5)	2 (3.6)	1 (1.8)
Cough	11 (20.0)	8 (14.5)	3 (5.5)	0	0
Nasal congestion	6 (10.9)	5 (9.1)	1 (1.8)	0	0
Epistaxis	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hypoxia	2 (3.6)	0	0	2 (3.6)	0
Oropharyngeal pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Rhinorrhoea	2 (3.6)	2 (3.6)	0	0	0
Dyspnoea	1 (1.8)	0	1 (1.8)	0	0
Pleural effusion	1 (1.8)	1 (1.8)	0	0	0
Respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Skin and subcutaneous tissue disorders					
-Total	8 (14.5)	6 (10.9)	2 (3.6)	0	0
Dry skin	5 (9.1)	3 (5.5)	2 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Vascular disorders					
-Total	4 (7.3)	1 (1.8)	1 (1.8)	1 (1.8)	1 (1.8)
Hypotension	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Hypertension	1 (1.8)	0	1 (1.8)	0	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	2 (22.2)	0	5 (55.6)
Blood and lymphatic system disorders					
-Total	4 (44.4)	0	0	1 (11.1)	3 (33.3)
Neutropenia	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Lymphopenia	1 (11.1)	0	0	1 (11.1)	0
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Cardiac failure	1 (11.1)	0	0	0	1 (11.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	4 (44.4)	3 (33.3)	1 (11.1)	0	0
Constipation	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	1 (11.1)	0	0	0
Enteritis	1 (11.1)	0	1 (11.1)	0	0
Nausea	1 (11.1)	1 (11.1)	0	0	0
Stomatitis	1 (11.1)	1 (11.1)	0	0	0
Trichoglossia	1 (11.1)	1 (11.1)	0	0	0
Vomiting	1 (11.1)	1 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	1 (11.1)	1 (11.1)	0	0	0
Pyrexia	1 (11.1)	1 (11.1)	0	0	0
Immune system disorders					
-Total	2 (22.2)	0	2 (22.2)	0	0
Hypogammaglobulinaemia	2 (22.2)	0	2 (22.2)	0	0
Infections and infestations					
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection reactivation	1 (11.1)	0	0	1 (11.1)	0
Human herpesvirus 6 infection	1 (11.1)	0	0	1 (11.1)	0
Nasopharyngitis	1 (11.1)	1 (11.1)	0	0	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Viral infection	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
White blood cell count decreased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (22.2)	1 (11.1)	0	0	1 (11.1)
Decreased appetite	1 (11.1)	1 (11.1)	0	0	0
Metabolic acidosis	1 (11.1)	0	0	0	1 (11.1)
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Arthralgia	1 (11.1)	1 (11.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal chest pain	1 (11.1)	1 (11.1)	0	0	0
Psychiatric disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Anxiety	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	1 (11.1)	0	0
Renal and urinary disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Cystitis haemorrhagic	1 (11.1)	0	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (22.2)	0	2 (22.2)	0	0
Pleural effusion	1 (11.1)	0	1 (11.1)	0	0
Upper respiratory tract inflammation	1 (11.1)	0	1 (11.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (22.2)	2 (22.2)	0	0	0
Dry skin	1 (11.1)	1 (11.1)	0	0	0
Skin swelling	1 (11.1)	1 (11.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Hypotension	1 (11.1)	0	0	0	1 (11.1)

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Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	2 (18.2)	2 (18.2)	4 (36.4)	2 (18.2)
Blood and lymphatic system disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Cardiac arrest	1 (9.1)	0	0	0	1 (9.1)
Gastrointestinal disorders					
-Total	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Diarrhoea	2 (18.2)	2 (18.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (18.2)	2 (18.2)	0	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Constipation	1 (9.1)	0	1 (9.1)	0	0
Nausea	1 (9.1)	0	1 (9.1)	0	0
Pancreatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Pyrexia	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Immune system disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Hypogammaglobulinaemia	2 (18.2)	0	2 (18.2)	0	0
Infections and infestations					
-Total	6 (54.5)	1 (9.1)	1 (9.1)	3 (27.3)	1 (9.1)
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Parainfluenzae virus infection	1 (9.1)	0	1 (9.1)	0	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	2 (18.2)	2 (18.2)	0	0	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0	0	0
Platelet count decreased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Hypokalaemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	0	1 (9.1)	0	0
Pain in extremity	1 (9.1)	0	0	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	3 (27.3)	0	0
Anxiety	3 (27.3)	0	3 (27.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Hypoxia	1 (9.1)	0	0	1 (9.1)	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Pruritus	1 (9.1)	0	1 (9.1)	0	0

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Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (43.6)	4 (10.3)	5 (12.8)	4 (10.3)	4 (10.3)
Blood and lymphatic system disorders					
-Total	2 (5.1)	0	1 (2.6)	0	1 (2.6)
Anaemia	1 (2.6)	0	1 (2.6)	0	0
Neutropenia	1 (2.6)	0	0	0	1 (2.6)
Thrombocytopenia	1 (2.6)	0	1 (2.6)	0	0
Gastrointestinal disorders					
-Total	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Diarrhoea	2 (5.1)	1 (2.6)	0	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (10.3)	2 (5.1)	1 (2.6)	1 (2.6)	0
Pyrexia	4 (10.3)	2 (5.1)	1 (2.6)	1 (2.6)	0
Immune system disorders					
-Total	4 (10.3)	0	4 (10.3)	0	0
Hypogammaglobulinaemia	3 (7.7)	0	3 (7.7)	0	0
Seasonal allergy	1 (2.6)	0	1 (2.6)	0	0
Infections and infestations					
-Total	11 (28.2)	4 (10.3)	5 (12.8)	2 (5.1)	0
Sinusitis	5 (12.8)	0	5 (12.8)	0	0
Conjunctivitis	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Rhinovirus infection	3 (7.7)	0	3 (7.7)	0	0
Upper respiratory tract infection	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Oral herpes	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	1 (2.6)	0	0	0
Otitis media	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	0	1 (2.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Investigations					
-Total	3 (7.7)	2 (5.1)	0	0	1 (2.6)
Neutrophil count decreased	2 (5.1)	1 (2.6)	0	0	1 (2.6)
Platelet count decreased	2 (5.1)	2 (5.1)	0	0	0
Blood bilirubin increased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (2.6)	0	0	0	1 (2.6)
Decreased appetite	1 (2.6)	0	0	0	1 (2.6)
Musculoskeletal and connective tissue disorders					
-Total	2 (5.1)	0	2 (5.1)	0	0
Pain in extremity	2 (5.1)	0	2 (5.1)	0	0
Nervous system disorders					
-Total	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Headache	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Seizure	1 (2.6)	0	0	1 (2.6)	0
Psychiatric disorders					

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Anxiety	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (12.8)	3 (7.7)	0	1 (2.6)	1 (2.6)
Cough	2 (5.1)	2 (5.1)	0	0	0
Dyspnoea	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Rhinorrhoea	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Epistaxis	1 (2.6)	1 (2.6)	0	0	0
Hypoxia	1 (2.6)	0	0	1 (2.6)	0
Oropharyngeal pain	1 (2.6)	1 (2.6)	0	0	0
Respiratory failure	1 (2.6)	0	0	0	1 (2.6)
Skin and subcutaneous tissue disorders					
-Total	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Dry skin	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	0	1 (2.6)	0	0

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Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Mydriasis	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Diarrhoea	1 (16.7)	1 (16.7)	0	0	0
Infections and infestations					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Fungal skin infection	1 (16.7)	0	1 (16.7)	0	0

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	0	1 (16.7)	0
Varicella zoster virus infection	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypercholesterolaemia	1 (16.7)	0	1 (16.7)	0	0
Hypertriglyceridaemia	1 (16.7)	0	1 (16.7)	0	0
Iron overload	1 (16.7)	0	1 (16.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Joint effusion	1 (16.7)	0	1 (16.7)	0	0
Synovitis	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0

Timing: >1 year post-CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Endometriosis	1 (16.7)	0	0	1 (16.7)	0
Vascular disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypertension	1 (16.7)	0	1 (16.7)	0	0

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Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	1 (20.0)	3 (60.0)	0	1 (20.0)
Gastrointestinal disorders					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Diarrhoea	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Constipation	1 (20.0)	1 (20.0)	0	0	0
Nausea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Fatigue	1 (20.0)	0	1 (20.0)	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (20.0)	0	0	0	1 (20.0)
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Immune system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Seasonal allergy	2 (40.0)	2 (40.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Conjunctivitis	1 (20.0)	1 (20.0)	0	0	0
Parainfluenzae virus infection	1 (20.0)	0	0	1 (20.0)	0
Pneumonia	1 (20.0)	0	0	0	1 (20.0)
Rhinovirus infection	1 (20.0)	0	0	1 (20.0)	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	1 (20.0)	0	0	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0	0	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperglycaemia	1 (20.0)	0	0	1 (20.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthralgia	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Cough	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Dyspnoea	1 (20.0)	0	0	0	1 (20.0)
Pleural effusion	1 (20.0)	0	1 (20.0)	0	0
Rhinorrhoea	1 (20.0)	0	1 (20.0)	0	0
Tachypnoea	1 (20.0)	0	0	0	1 (20.0)
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	1 (20.0)	0	0	0
Rash maculo-papular	1 (20.0)	1 (20.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hypertension	1 (20.0)	0	0	1 (20.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	1 (1.7)	6 (10.2)	19 (32.2)	33 (55.9)
Blood and lymphatic system disorders					
-Total	35 (59.3)	1 (1.7)	6 (10.2)	20 (33.9)	8 (13.6)
Anaemia	19 (32.2)	6 (10.2)	8 (13.6)	5 (8.5)	0
Febrile neutropenia	19 (32.2)	0	0	18 (30.5)	1 (1.7)
Neutropenia	8 (13.6)	0	2 (3.4)	2 (3.4)	4 (6.8)
Thrombocytopenia	6 (10.2)	0	0	2 (3.4)	4 (6.8)
Disseminated intravascular coagulation	5 (8.5)	0	3 (5.1)	2 (3.4)	0
Splenomegaly	3 (5.1)	2 (3.4)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Lymphopenia	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					
-Total	16 (27.1)	6 (10.2)	5 (8.5)	2 (3.4)	3 (5.1)
Tachycardia	15 (25.4)	6 (10.2)	6 (10.2)	2 (3.4)	1 (1.7)
Cardiac failure	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Cardiac arrest	1 (1.7)	0	0	0	1 (1.7)
Endocrine disorders					
-Total	2 (3.4)	0	2 (3.4)	0	0
Adrenal insufficiency	2 (3.4)	0	2 (3.4)	0	0
Gastrointestinal disorders					
-Total	41 (69.5)	18 (30.5)	16 (27.1)	7 (11.9)	0
Vomiting	19 (32.2)	12 (20.3)	7 (11.9)	0	0
Diarrhoea	18 (30.5)	11 (18.6)	5 (8.5)	2 (3.4)	0
Nausea	15 (25.4)	7 (11.9)	7 (11.9)	1 (1.7)	0
Abdominal pain	10 (16.9)	2 (3.4)	6 (10.2)	2 (3.4)	0
Constipation	7 (11.9)	3 (5.1)	4 (6.8)	0	0
Pancreatitis	2 (3.4)	1 (1.7)	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Trichoglossia	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	36 (61.0)	19 (32.2)	8 (13.6)	6 (10.2)	3 (5.1)
Pyrexia	26 (44.1)	12 (20.3)	7 (11.9)	5 (8.5)	2 (3.4)
Fatigue	14 (23.7)	12 (20.3)	2 (3.4)	0	0
Face oedema	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Chills	6 (10.2)	4 (6.8)	2 (3.4)	0	0
Oedema peripheral	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Hepatobiliary disorders					
-Total	6 (10.2)	2 (3.4)	4 (6.8)	0	0
Hyperbilirubinaemia	3 (5.1)	0	3 (5.1)	0	0
Hepatomegaly	2 (3.4)	2 (3.4)	0	0	0
Hepatic function abnormal	1 (1.7)	0	1 (1.7)	0	0
Immune system disorders					
-Total	50 (84.7)	1 (1.7)	19 (32.2)	18 (30.5)	12 (20.3)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	43 (72.9)	3 (5.1)	14 (23.7)	14 (23.7)	12 (20.3)
Hypogammaglobulinaemia	24 (40.7)	1 (1.7)	16 (27.1)	7 (11.9)	0
Seasonal allergy	2 (3.4)	0	2 (3.4)	0	0
Infections and infestations					
-Total	30 (50.8)	6 (10.2)	12 (20.3)	10 (16.9)	2 (3.4)
Upper respiratory tract infection	9 (15.3)	4 (6.8)	4 (6.8)	1 (1.7)	0
Conjunctivitis	7 (11.9)	2 (3.4)	5 (8.5)	0	0
Rhinovirus infection	7 (11.9)	0	6 (10.2)	1 (1.7)	0
Gastroenteritis	6 (10.2)	4 (6.8)	0	2 (3.4)	0
Sinusitis	6 (10.2)	0	4 (6.8)	2 (3.4)	0
Nasopharyngitis	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Pneumonia	4 (6.8)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Oral herpes	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Parainfluenzae virus infection	3 (5.1)	1 (1.7)	0	1 (1.7)	1 (1.7)
Otitis media	2 (3.4)	0	2 (3.4)	0	0
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Bacteraemia	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bk virus infection	1 (1.7)	0	0	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	0	0	1 (1.7)	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Varicella zoster virus infection	1 (1.7)	0	0	1 (1.7)	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Investigations					
-Total	33 (55.9)	3 (5.1)	2 (3.4)	13 (22.0)	15 (25.4)
Platelet count decreased	18 (30.5)	5 (8.5)	3 (5.1)	5 (8.5)	5 (8.5)
Neutrophil count decreased	17 (28.8)	1 (1.7)	2 (3.4)	3 (5.1)	11 (18.6)
White blood cell count decreased	16 (27.1)	3 (5.1)	4 (6.8)	2 (3.4)	7 (11.9)
Lymphocyte count decreased	14 (23.7)	1 (1.7)	1 (1.7)	8 (13.6)	4 (6.8)
Alanine aminotransferase increased	13 (22.0)	3 (5.1)	6 (10.2)	4 (6.8)	0
Aspartate aminotransferase increased	13 (22.0)	1 (1.7)	5 (8.5)	6 (10.2)	1 (1.7)
Blood bilirubin increased	9 (15.3)	1 (1.7)	2 (3.4)	6 (10.2)	0
International normalised ratio increased	7 (11.9)	5 (8.5)	2 (3.4)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Blood immunoglobulin m decreased	6 (10.2)	3 (5.1)	1 (1.7)	2 (3.4)	0
Activated partial thromboplastin time prolonged	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Blood fibrinogen decreased	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Serum ferritin increased	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Blood creatine phosphokinase increased	1 (1.7)	0	0	0	1 (1.7)
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Gamma-glutamyltransferase increased	1 (1.7)	0	0	1 (1.7)	0
Metabolism and nutrition disorders					
-Total	35 (59.3)	8 (13.6)	8 (13.6)	12 (20.3)	7 (11.9)
Decreased appetite	23 (39.0)	10 (16.9)	6 (10.2)	5 (8.5)	2 (3.4)
Hypokalaemia	15 (25.4)	2 (3.4)	5 (8.5)	6 (10.2)	2 (3.4)
Hypophosphataemia	13 (22.0)	3 (5.1)	4 (6.8)	6 (10.2)	0
Hypocalcaemia	11 (18.6)	2 (3.4)	6 (10.2)	3 (5.1)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	6 (10.2)	4 (6.8)	1 (1.7)	1 (1.7)	0
Hypoalbuminaemia	6 (10.2)	0	6 (10.2)	0	0
Hyperglycaemia	5 (8.5)	0	2 (3.4)	3 (5.1)	0
Hypervolaemia	5 (8.5)	0	2 (3.4)	3 (5.1)	0
Hyperphosphataemia	4 (6.8)	4 (6.8)	0	0	0
Hypomagnesaemia	3 (5.1)	3 (5.1)	0	0	0
Hyperkalaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Hypertriglyceridaemia	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Metabolic acidosis	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Tumour lysis syndrome	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Hypercalcaemia	1 (1.7)	0	0	1 (1.7)	0
Iron overload	1 (1.7)	0	1 (1.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	28 (47.5)	15 (25.4)	11 (18.6)	2 (3.4)	0
Pain in extremity	15 (25.4)	8 (13.6)	7 (11.9)	0	0
Arthralgia	8 (13.6)	4 (6.8)	4 (6.8)	0	0
Myalgia	8 (13.6)	4 (6.8)	4 (6.8)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	7 (11.9)	2 (3.4)	3 (5.1)	2 (3.4)	0
Muscular weakness	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Nervous system disorders					
-Total	32 (54.2)	12 (20.3)	10 (16.9)	10 (16.9)	0
Headache	24 (40.7)	12 (20.3)	9 (15.3)	3 (5.1)	0
Encephalopathy	8 (13.6)	1 (1.7)	3 (5.1)	4 (6.8)	0
Seizure	3 (5.1)	0	0	3 (5.1)	0
Psychiatric disorders					
-Total	16 (27.1)	6 (10.2)	6 (10.2)	4 (6.8)	0
Anxiety	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0
Delirium	7 (11.9)	2 (3.4)	2 (3.4)	3 (5.1)	0
Confusional state	5 (8.5)	5 (8.5)	0	0	0
Renal and urinary disorders					
-Total	10 (16.9)	2 (3.4)	1 (1.7)	4 (6.8)	3 (5.1)
Acute kidney injury	10 (16.9)	2 (3.4)	2 (3.4)	3 (5.1)	3 (5.1)
Haematuria	2 (3.4)	1 (1.7)	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	37 (62.7)	16 (27.1)	4 (6.8)	9 (15.3)	8 (13.6)
Cough	19 (32.2)	15 (25.4)	4 (6.8)	0	0
Hypoxia	14 (23.7)	0	4 (6.8)	8 (13.6)	2 (3.4)
Pulmonary oedema	10 (16.9)	2 (3.4)	3 (5.1)	4 (6.8)	1 (1.7)
Nasal congestion	8 (13.6)	6 (10.2)	2 (3.4)	0	0
Oropharyngeal pain	7 (11.9)	6 (10.2)	1 (1.7)	0	0
Tachypnoea	7 (11.9)	2 (3.4)	1 (1.7)	4 (6.8)	0
Dyspnoea	6 (10.2)	1 (1.7)	2 (3.4)	2 (3.4)	1 (1.7)
Epistaxis	6 (10.2)	4 (6.8)	2 (3.4)	0	0
Pleural effusion	5 (8.5)	3 (5.1)	0	2 (3.4)	0
Respiratory failure	5 (8.5)	0	0	0	5 (8.5)
Rhinorrhoea	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (28.8)	8 (13.6)	9 (15.3)	0	0
Dry skin	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Rash	7 (11.9)	3 (5.1)	4 (6.8)	0	0

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=59 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	5 (8.5)	1 (1.7)	4 (6.8)	0	0
Rash maculo-papular	1 (1.7)	0	1 (1.7)	0	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	23 (39.0)	4 (6.8)	6 (10.2)	8 (13.6)	5 (8.5)
Hypotension	21 (35.6)	2 (3.4)	6 (10.2)	8 (13.6)	5 (8.5)
Hypertension	9 (15.3)	3 (5.1)	5 (8.5)	1 (1.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	2 (20.0)	7 (70.0)
Blood and lymphatic system disorders					
-Total	8 (80.0)	0	1 (10.0)	2 (20.0)	5 (50.0)
Disseminated intravascular coagulation	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Neutropenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Thrombocytopenia	2 (20.0)	0	0	0	2 (20.0)
Hypofibrinogenaemia	1 (10.0)	0	1 (10.0)	0	0
Leukopenia	1 (10.0)	0	0	0	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (10.0)	0	0	1 (10.0)	0
Splenomegaly	1 (10.0)	1 (10.0)	0	0	0
Cardiac disorders					
-Total	4 (40.0)	2 (20.0)	0	0	2 (20.0)
Cardiac dysfunction	2 (20.0)	2 (20.0)	0	0	0
Cardiac arrest	1 (10.0)	0	0	0	1 (10.0)
Cardiac failure	1 (10.0)	0	0	0	1 (10.0)
Tachycardia	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Mydriasis	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	7 (70.0)	3 (30.0)	4 (40.0)	0	0
Constipation	3 (30.0)	3 (30.0)	0	0	0
Diarrhoea	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Nausea	3 (30.0)	3 (30.0)	0	0	0
Pancreatitis	2 (20.0)	0	2 (20.0)	0	0
Enteritis	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (10.0)	0	1 (10.0)	0	0
Stomatitis	1 (10.0)	1 (10.0)	0	0	0
Trichoglossia	1 (10.0)	1 (10.0)	0	0	0
Vomiting	1 (10.0)	1 (10.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Pyrexia	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Fatigue	1 (10.0)	1 (10.0)	0	0	0
Hepatobiliary disorders					
-Total	5 (50.0)	0	1 (10.0)	2 (20.0)	2 (20.0)
Hepatic function abnormal	4 (40.0)	0	1 (10.0)	2 (20.0)	1 (10.0)
Hepatomegaly	1 (10.0)	0	0	0	1 (10.0)
Immune system disorders					
-Total	9 (90.0)	0	4 (40.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	8 (80.0)	1 (10.0)	2 (20.0)	2 (20.0)	3 (30.0)
Hypogammaglobulinaemia	5 (50.0)	0	5 (50.0)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (80.0)	2 (20.0)	1 (10.0)	4 (40.0)	1 (10.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bk virus infection	1 (10.0)	1 (10.0)	0	0	0
Cytomegalovirus infection reactivation	1 (10.0)	0	0	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	0	0	1 (10.0)
Fungal skin infection	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	0	1 (10.0)	0
Meningitis bacterial	1 (10.0)	0	0	1 (10.0)	0
Nasopharyngitis	1 (10.0)	1 (10.0)	0	0	0
Oral herpes	1 (10.0)	0	0	1 (10.0)	0
Otitis externa	1 (10.0)	0	1 (10.0)	0	0
Otitis media	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	1 (10.0)	0
Sinusitis	1 (10.0)	0	1 (10.0)	0	0
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Upper respiratory tract infection	1 (10.0)	0	0	1 (10.0)	0
Urinary tract infection viral	1 (10.0)	1 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Varicella zoster virus infection	1 (10.0)	0	1 (10.0)	0	0
Viral infection	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	7 (70.0)	0	1 (10.0)	2 (20.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	0	0	4 (40.0)
Blood fibrinogen decreased	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Serum ferritin increased	3 (30.0)	0	3 (30.0)	0	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)	0	0
Blood bilirubin increased	1 (10.0)	0	0	1 (10.0)	0
Blood creatine phosphokinase increased	1 (10.0)	0	0	1 (10.0)	0
Fibrin d dimer increased	1 (10.0)	1 (10.0)	0	0	0
Gamma-glutamyltransferase increased	1 (10.0)	0	0	1 (10.0)	0
Haptoglobin decreased	1 (10.0)	1 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0
Metabolism and nutrition disorders					
-Total	6 (60.0)	2 (20.0)	1 (10.0)	1 (10.0)	2 (20.0)
Metabolic acidosis	2 (20.0)	0	0	0	2 (20.0)
Tumour lysis syndrome	2 (20.0)	0	0	2 (20.0)	0
Decreased appetite	1 (10.0)	1 (10.0)	0	0	0
Hypercalcaemia	1 (10.0)	0	0	1 (10.0)	0
Hypercholesterolaemia	1 (10.0)	0	1 (10.0)	0	0
Hyperkalaemia	1 (10.0)	0	0	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	0	0	1 (10.0)
Hypertriglyceridaemia	1 (10.0)	0	1 (10.0)	0	0
Hyperuricaemia	1 (10.0)	1 (10.0)	0	0	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)	0	0
Iron overload	1 (10.0)	0	1 (10.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (40.0)	0	2 (20.0)	2 (20.0)	0
Arthralgia	2 (20.0)	1 (10.0)	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (10.0)	0	0	1 (10.0)	0
Joint effusion	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	0	1 (10.0)	0
Musculoskeletal chest pain	1 (10.0)	1 (10.0)	0	0	0
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Synovitis	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Headache	1 (10.0)	0	1 (10.0)	0	0
Seizure	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Anxiety	1 (10.0)	0	1 (10.0)	0	0
Delirium	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	4 (40.0)	1 (10.0)	1 (10.0)	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Cystitis haemorrhagic	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (10.0)	1 (10.0)	0	0	0
Proteinuria	1 (10.0)	1 (10.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Endometriosis	1 (10.0)	0	0	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (80.0)	2 (20.0)	2 (20.0)	0	4 (40.0)
Hypoxia	4 (40.0)	0	0	0	4 (40.0)
Pleural effusion	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Cough	1 (10.0)	1 (10.0)	0	0	0
Haemoptysis	1 (10.0)	0	1 (10.0)	0	0
Nasal congestion	1 (10.0)	1 (10.0)	0	0	0
Nasal dryness	1 (10.0)	1 (10.0)	0	0	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0	0	0
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Upper respiratory tract inflammation	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Dry skin	1 (10.0)	1 (10.0)	0	0	0
Erythema nodosum	1 (10.0)	1 (10.0)	0	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Skin swelling	1 (10.0)	1 (10.0)	0	0	0
Skin ulcer	1 (10.0)	0	1 (10.0)	0	0
Vascular disorders					
-Total	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Hypertension	2 (20.0)	0	2 (20.0)	0	0
Hypotension	1 (10.0)	0	0	0	1 (10.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	1 (9.1)	0	10 (90.9)
Blood and lymphatic system disorders					
-Total	9 (81.8)	1 (9.1)	0	7 (63.6)	1 (9.1)
Anaemia	6 (54.5)	1 (9.1)	1 (9.1)	4 (36.4)	0
Febrile neutropenia	6 (54.5)	0	0	5 (45.5)	1 (9.1)
Thrombocytopenia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Cardiac arrest	1 (9.1)	0	0	0	1 (9.1)
Tachycardia	1 (9.1)	1 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Adrenal insufficiency	2 (18.2)	0	2 (18.2)	0	0
Gastrointestinal disorders					
-Total	10 (90.9)	2 (18.2)	5 (45.5)	3 (27.3)	0
Vomiting	6 (54.5)	4 (36.4)	1 (9.1)	1 (9.1)	0
Diarrhoea	5 (45.5)	3 (27.3)	2 (18.2)	0	0
Constipation	4 (36.4)	1 (9.1)	3 (27.3)	0	0
Nausea	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Pancreatitis	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
General disorders and administration site conditions					
-Total	8 (72.7)	2 (18.2)	1 (9.1)	3 (27.3)	2 (18.2)
Pyrexia	6 (54.5)	1 (9.1)	2 (18.2)	3 (27.3)	0
Fatigue	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Multiple organ dysfunction syndrome	2 (18.2)	0	0	0	2 (18.2)
Chills	1 (9.1)	1 (9.1)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (9.1)	1 (9.1)	0	0	0
Hepatobiliary disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hyperbilirubinaemia	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Immune system disorders					
-Total	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Cytokine release syndrome	10 (90.9)	1 (9.1)	2 (18.2)	1 (9.1)	6 (54.5)
Hypogammaglobulinaemia	4 (36.4)	1 (9.1)	3 (27.3)	0	0
Seasonal allergy	2 (18.2)	2 (18.2)	0	0	0
Infections and infestations					
-Total	7 (63.6)	1 (9.1)	1 (9.1)	3 (27.3)	2 (18.2)
Upper respiratory tract infection	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Nasopharyngitis	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Parainfluenzae virus infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Rhinovirus infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Staphylococcal bacteraemia	2 (18.2)	0	0	2 (18.2)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (9.1)	0	0	0	1 (9.1)
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Encephalitis viral	1 (9.1)	0	0	1 (9.1)	0
Otitis externa	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Investigations					
-Total	9 (81.8)	0	0	3 (27.3)	6 (54.5)
Neutrophil count decreased	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Platelet count decreased	5 (45.5)	1 (9.1)	0	1 (9.1)	3 (27.3)
White blood cell count decreased	5 (45.5)	0	0	0	5 (45.5)
Alanine aminotransferase increased	4 (36.4)	0	1 (9.1)	3 (27.3)	0
Aspartate aminotransferase increased	4 (36.4)	0	0	2 (18.2)	2 (18.2)
Blood bilirubin increased	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Lymphocyte count decreased	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Activated partial thromboplastin time prolonged	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Serum ferritin increased	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	0	0	1 (9.1)
Blood immunoglobulin a decreased	1 (9.1)	1 (9.1)	0	0	0
Blood immunoglobulin m decreased	1 (9.1)	1 (9.1)	0	0	0
Fibrin d dimer increased	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	10 (90.9)	0	2 (18.2)	7 (63.6)	1 (9.1)
Decreased appetite	6 (54.5)	0	1 (9.1)	5 (45.5)	0
Hypocalcaemia	5 (45.5)	0	3 (27.3)	2 (18.2)	0
Hypokalaemia	5 (45.5)	1 (9.1)	1 (9.1)	3 (27.3)	0
Hypophosphataemia	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Hyperglycaemia	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Hypoalbuminaemia	4 (36.4)	0	3 (27.3)	1 (9.1)	0
Hypomagnesaemia	3 (27.3)	2 (18.2)	1 (9.1)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (18.2)	2 (18.2)	0	0	0
Hypervolaemia	2 (18.2)	0	0	2 (18.2)	0
Hypercalcaemia	1 (9.1)	0	1 (9.1)	0	0
Tumour lysis syndrome	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (45.5)	1 (9.1)	2 (18.2)	2 (18.2)	0
Arthralgia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Back pain	2 (18.2)	0	2 (18.2)	0	0
Myalgia	2 (18.2)	2 (18.2)	0	0	0
Pain in extremity	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Cognitive disorder	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Headache	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Psychiatric disorders					
-Total	7 (63.6)	2 (18.2)	4 (36.4)	1 (9.1)	0
Anxiety	5 (45.5)	0	4 (36.4)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	2 (18.2)	2 (18.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (54.5)	1 (9.1)	0	3 (27.3)	2 (18.2)
Cough	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hypoxia	2 (18.2)	0	0	2 (18.2)	0
Pleural effusion	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Pulmonary oedema	2 (18.2)	0	0	2 (18.2)	0
Rhinorrhoea	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Tachypnoea	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Dyspnoea	1 (9.1)	0	0	0	1 (9.1)
Epistaxis	1 (9.1)	0	0	1 (9.1)	0
Skin and subcutaneous tissue disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Rash maculo-papular	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Pruritus	1 (9.1)	0	1 (9.1)	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (54.5)	1 (9.1)	0	3 (27.3)	2 (18.2)
Hypertension	5 (45.5)	1 (9.1)	0	4 (36.4)	0
Hypotension	2 (18.2)	0	0	0	2 (18.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	3 (20.0)	1 (6.7)	11 (73.3)
Blood and lymphatic system disorders					
-Total	10 (66.7)	0	1 (6.7)	7 (46.7)	2 (13.3)
Febrile neutropenia	8 (53.3)	0	0	6 (40.0)	2 (13.3)
Anaemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Coagulopathy	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	0	1 (6.7)	0	0
Thrombocytopenia	1 (6.7)	0	0	1 (6.7)	0
Cardiac disorders					
-Total	4 (26.7)	1 (6.7)	3 (20.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (20.0)	0	3 (20.0)	0	0
Sinus tachycardia	2 (13.3)	2 (13.3)	0	0	0
Endocrine disorders					
-Total	3 (20.0)	0	3 (20.0)	0	0
Adrenal insufficiency	3 (20.0)	0	3 (20.0)	0	0
Gastrointestinal disorders					
-Total	9 (60.0)	3 (20.0)	5 (33.3)	1 (6.7)	0
Constipation	4 (26.7)	1 (6.7)	3 (20.0)	0	0
Diarrhoea	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Vomiting	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Abdominal pain	1 (6.7)	1 (6.7)	0	0	0
Nausea	1 (6.7)	0	1 (6.7)	0	0
General disorders and administration site conditions					
-Total	5 (33.3)	2 (13.3)	1 (6.7)	2 (13.3)	0
Oedema peripheral	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Pyrexia	3 (20.0)	1 (6.7)	0	2 (13.3)	0
Chills	2 (13.3)	2 (13.3)	0	0	0
Generalised oedema	2 (13.3)	0	2 (13.3)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	1 (6.7)	1 (6.7)	0	0	0
Fatigue	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					
-Total	14 (93.3)	0	5 (33.3)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Hypogammaglobulinaemia	4 (26.7)	1 (6.7)	2 (13.3)	1 (6.7)	0
Seasonal allergy	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	3 (20.0)	0	0	3 (20.0)	0
Staphylococcal bacteraemia	2 (13.3)	0	0	2 (13.3)	0
Adenovirus infection	1 (6.7)	0	0	1 (6.7)	0
Conjunctivitis	1 (6.7)	1 (6.7)	0	0	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Investigations					
-Total	9 (60.0)	0	0	4 (26.7)	5 (33.3)
Aspartate aminotransferase increased	7 (46.7)	0	1 (6.7)	4 (26.7)	2 (13.3)
Alanine aminotransferase increased	5 (33.3)	0	2 (13.3)	3 (20.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (26.7)	0	0	4 (26.7)	0
Blood creatinine increased	3 (20.0)	1 (6.7)	0	2 (13.3)	0
Platelet count decreased	3 (20.0)	0	0	0	3 (20.0)
White blood cell count decreased	3 (20.0)	0	0	0	3 (20.0)
Activated partial thromboplastin time prolonged	2 (13.3)	0	1 (6.7)	1 (6.7)	0
International normalised ratio increased	2 (13.3)	0	2 (13.3)	0	0
Neutrophil count decreased	2 (13.3)	0	0	0	2 (13.3)
Blood uric acid increased	1 (6.7)	1 (6.7)	0	0	0
Serum ferritin increased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	12 (80.0)	0	3 (20.0)	7 (46.7)	2 (13.3)
Hypocalcaemia	8 (53.3)	0	5 (33.3)	3 (20.0)	0
Decreased appetite	7 (46.7)	0	2 (13.3)	5 (33.3)	0
Hypokalaemia	6 (40.0)	1 (6.7)	2 (13.3)	2 (13.3)	1 (6.7)
Hyperglycaemia	5 (33.3)	0	3 (20.0)	2 (13.3)	0
Hypoalbuminaemia	5 (33.3)	0	4 (26.7)	1 (6.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Hyperuricaemia	3 (20.0)	2 (13.3)	0	1 (6.7)	0
Hypervolaemia	3 (20.0)	0	0	3 (20.0)	0
Hypomagnesaemia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Acidosis	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypercalcaemia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Tumour lysis syndrome	2 (13.3)	0	0	2 (13.3)	0
Hyperkalaemia	1 (6.7)	0	0	1 (6.7)	0
Malnutrition	1 (6.7)	0	0	1 (6.7)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (33.3)	3 (20.0)	1 (6.7)	1 (6.7)	0
Arthralgia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Myalgia	2 (13.3)	2 (13.3)	0	0	0
Back pain	1 (6.7)	1 (6.7)	0	0	0
Nervous system disorders					
-Total	7 (46.7)	1 (6.7)	4 (26.7)	2 (13.3)	0
Headache	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Cognitive disorder	3 (20.0)	0	2 (13.3)	1 (6.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0
Psychiatric disorders					
-Total	3 (20.0)	0	1 (6.7)	2 (13.3)	0
Anxiety	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Delirium	1 (6.7)	0	0	1 (6.7)	0
Mental status changes	1 (6.7)	0	1 (6.7)	0	0
Renal and urinary disorders					
-Total	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Acute kidney injury	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Respiratory, thoracic and mediastinal disorders					
-Total	8 (53.3)	0	1 (6.7)	3 (20.0)	4 (26.7)
Pulmonary oedema	4 (26.7)	0	1 (6.7)	2 (13.3)	1 (6.7)
Hypoxia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Pleural effusion	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Acute respiratory distress syndrome	1 (6.7)	0	0	0	1 (6.7)
Nasal congestion	1 (6.7)	0	1 (6.7)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (6.7)	0	0	1 (6.7)	0
Skin and subcutaneous tissue disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Pruritus	1 (6.7)	0	1 (6.7)	0	0
Vascular disorders					
-Total	8 (53.3)	1 (6.7)	1 (6.7)	4 (26.7)	2 (13.3)
Hypotension	6 (40.0)	0	1 (6.7)	3 (20.0)	2 (13.3)
Hypertension	4 (26.7)	2 (13.3)	0	2 (13.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (98.5)	5 (7.7)	5 (7.7)	20 (30.8)	34 (52.3)
Blood and lymphatic system disorders					
-Total	37 (56.9)	3 (4.6)	5 (7.7)	18 (27.7)	11 (16.9)
Febrile neutropenia	18 (27.7)	0	0	18 (27.7)	0
Anaemia	17 (26.2)	5 (7.7)	7 (10.8)	5 (7.7)	0
Neutropenia	9 (13.8)	0	2 (3.1)	1 (1.5)	6 (9.2)
Thrombocytopenia	7 (10.8)	0	0	1 (1.5)	6 (9.2)
Disseminated intravascular coagulation	6 (9.2)	0	4 (6.2)	2 (3.1)	0
Coagulopathy	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (23.1)	7 (10.8)	5 (7.7)	2 (3.1)	1 (1.5)
Tachycardia	14 (21.5)	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)
Sinus tachycardia	1 (1.5)	0	1 (1.5)	0	0
Endocrine disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	37 (56.9)	19 (29.2)	13 (20.0)	5 (7.7)	0
Vomiting	19 (29.2)	11 (16.9)	8 (12.3)	0	0
Nausea	17 (26.2)	10 (15.4)	5 (7.7)	2 (3.1)	0
Diarrhoea	13 (20.0)	7 (10.8)	5 (7.7)	1 (1.5)	0
Abdominal pain	10 (15.4)	2 (3.1)	6 (9.2)	2 (3.1)	0
Constipation	7 (10.8)	5 (7.7)	2 (3.1)	0	0
General disorders and administration site conditions					
-Total	31 (47.7)	17 (26.2)	7 (10.8)	5 (7.7)	2 (3.1)
Pyrexia	21 (32.3)	10 (15.4)	5 (7.7)	4 (6.2)	2 (3.1)
Fatigue	10 (15.4)	8 (12.3)	2 (3.1)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Chills	4 (6.2)	2 (3.1)	2 (3.1)	0	0
Generalised oedema	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Oedema peripheral	3 (4.6)	2 (3.1)	0	1 (1.5)	0
Immune system disorders					
-Total	52 (80.0)	3 (4.6)	16 (24.6)	20 (30.8)	13 (20.0)
Cytokine release syndrome	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Hypogammaglobulinaemia	19 (29.2)	1 (1.5)	12 (18.5)	6 (9.2)	0
Infections and infestations					
-Total	8 (12.3)	0	5 (7.7)	3 (4.6)	0
Conjunctivitis	4 (6.2)	0	4 (6.2)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sinusitis	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Investigations					
-Total	40 (61.5)	4 (6.2)	4 (6.2)	11 (16.9)	21 (32.3)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	21 (32.3)	3 (4.6)	3 (4.6)	2 (3.1)	13 (20.0)
Neutrophil count decreased	18 (27.7)	0	3 (4.6)	2 (3.1)	13 (20.0)
Platelet count decreased	18 (27.7)	4 (6.2)	3 (4.6)	6 (9.2)	5 (7.7)
Lymphocyte count decreased	15 (23.1)	2 (3.1)	0	8 (12.3)	5 (7.7)
Alanine aminotransferase increased	13 (20.0)	4 (6.2)	6 (9.2)	3 (4.6)	0
Aspartate aminotransferase increased	12 (18.5)	2 (3.1)	5 (7.7)	4 (6.2)	1 (1.5)
Blood bilirubin increased	8 (12.3)	1 (1.5)	2 (3.1)	5 (7.7)	0
Blood fibrinogen decreased	7 (10.8)	2 (3.1)	3 (4.6)	1 (1.5)	1 (1.5)
International normalised ratio increased	7 (10.8)	6 (9.2)	1 (1.5)	0	0
Serum ferritin increased	7 (10.8)	1 (1.5)	5 (7.7)	1 (1.5)	0
Blood immunoglobulin m decreased	6 (9.2)	4 (6.2)	1 (1.5)	1 (1.5)	0
Blood immunoglobulin a decreased	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Activated partial thromboplastin time prolonged	4 (6.2)	3 (4.6)	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (1.5)	0	0	0	1 (1.5)
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Metabolism and nutrition disorders					
-Total	34 (52.3)	9 (13.8)	6 (9.2)	15 (23.1)	4 (6.2)
Decreased appetite	17 (26.2)	9 (13.8)	2 (3.1)	5 (7.7)	1 (1.5)
Hypokalaemia	13 (20.0)	2 (3.1)	3 (4.6)	7 (10.8)	1 (1.5)
Hypophosphataemia	13 (20.0)	3 (4.6)	4 (6.2)	5 (7.7)	1 (1.5)
Hypocalcaemia	8 (12.3)	2 (3.1)	4 (6.2)	2 (3.1)	0
Hypoalbuminaemia	6 (9.2)	0	6 (9.2)	0	0
Hyperuricaemia	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Hyperglycaemia	3 (4.6)	0	1 (1.5)	2 (3.1)	0
Hypervolaemia	3 (4.6)	0	2 (3.1)	1 (1.5)	0
Hypomagnesaemia	3 (4.6)	3 (4.6)	0	0	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0
Hypercalcaemia	1 (1.5)	0	0	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	0	0	1 (1.5)
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (35.4)	10 (15.4)	12 (18.5)	1 (1.5)	0
Pain in extremity	11 (16.9)	6 (9.2)	5 (7.7)	0	0
Arthralgia	8 (12.3)	4 (6.2)	4 (6.2)	0	0
Myalgia	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Back pain	5 (7.7)	1 (1.5)	3 (4.6)	1 (1.5)	0
Nervous system disorders					
-Total	26 (40.0)	12 (18.5)	9 (13.8)	5 (7.7)	0
Headache	19 (29.2)	10 (15.4)	7 (10.8)	2 (3.1)	0
Encephalopathy	7 (10.8)	1 (1.5)	3 (4.6)	3 (4.6)	0
Somnolence	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Psychiatric disorders					
-Total	15 (23.1)	8 (12.3)	3 (4.6)	4 (6.2)	0
Confusional state	7 (10.8)	7 (10.8)	0	0	0
Delirium	6 (9.2)	2 (3.1)	2 (3.1)	2 (3.1)	0
Anxiety	4 (6.2)	1 (1.5)	2 (3.1)	1 (1.5)	0
Mental status changes	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Renal and urinary disorders					
-Total	7 (10.8)	1 (1.5)	1 (1.5)	2 (3.1)	3 (4.6)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	7 (10.8)	1 (1.5)	1 (1.5)	2 (3.1)	3 (4.6)
Respiratory, thoracic and mediastinal disorders					
-Total	31 (47.7)	14 (21.5)	3 (4.6)	8 (12.3)	6 (9.2)
Hypoxia	14 (21.5)	0	5 (7.7)	4 (6.2)	5 (7.7)
Cough	10 (15.4)	9 (13.8)	1 (1.5)	0	0
Pulmonary oedema	8 (12.3)	2 (3.1)	2 (3.1)	4 (6.2)	0
Tachypnoea	7 (10.8)	3 (4.6)	1 (1.5)	3 (4.6)	0
Oropharyngeal pain	5 (7.7)	5 (7.7)	0	0	0
Pleural effusion	5 (7.7)	4 (6.2)	0	1 (1.5)	0
Epistaxis	4 (6.2)	2 (3.1)	1 (1.5)	1 (1.5)	0
Dyspnoea	3 (4.6)	0	0	2 (3.1)	1 (1.5)
Nasal congestion	2 (3.1)	2 (3.1)	0	0	0
Acute respiratory distress syndrome	1 (1.5)	0	0	0	1 (1.5)
Skin and subcutaneous tissue disorders					
-Total	10 (15.4)	5 (7.7)	5 (7.7)	0	0
Pruritus	5 (7.7)	2 (3.1)	3 (4.6)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

Group term Preferred term	All patients N=65 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	5 (7.7)	2 (3.1)	3 (4.6)	0	0
Dry skin	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	19 (29.2)	3 (4.6)	6 (9.2)	6 (9.2)	4 (6.2)
Hypotension	15 (23.1)	1 (1.5)	5 (7.7)	5 (7.7)	4 (6.2)
Hypertension	9 (13.8)	2 (3.1)	5 (7.7)	2 (3.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	1 (7.1)	4 (28.6)	4 (28.6)	3 (21.4)
Blood and lymphatic system disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Anaemia	2 (14.3)	0	0	2 (14.3)	0
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Tachycardia	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	4 (28.6)	2 (14.3)	2 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
Vomiting	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	6 (42.9)	3 (21.4)	2 (14.3)	1 (7.1)	0
Pyrexia	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Fatigue	2 (14.3)	2 (14.3)	0	0	0
Immune system disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Infections and infestations					
-Total	6 (42.9)	0	3 (21.4)	2 (14.3)	1 (7.1)
Upper respiratory tract infection	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Bacteraemia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Respiratory syncytial virus infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Adenovirus infection	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Neutrophil count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
White blood cell count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Blood uric acid increased	1 (7.1)	0	0	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	1 (7.1)	2 (14.3)
Decreased appetite	2 (14.3)	0	2 (14.3)	0	0
Hyperuricaemia	2 (14.3)	2 (14.3)	0	0	0
Hypokalaemia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Hyperkalaemia	1 (7.1)	0	1 (7.1)	0	0
Malnutrition	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	0	1 (7.1)
Musculoskeletal and connective tissue disorders					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Pain in extremity	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Arthralgia	1 (7.1)	0	1 (7.1)	0	0
Myalgia	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Headache	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Psychiatric disorders					
-Total	4 (28.6)	0	4 (28.6)	0	0
Anxiety	3 (21.4)	0	3 (21.4)	0	0
Mental status changes	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Acute kidney injury	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	2 (14.3)	1 (7.1)	0	1 (7.1)
Nasal congestion	2 (14.3)	2 (14.3)	0	0	0
Rhinitis allergic	2 (14.3)	1 (7.1)	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	1 (7.1)	0	0	0	1 (7.1)
Cough	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Dry skin	2 (14.3)	2 (14.3)	0	0	0
Pruritus	1 (7.1)	0	1 (7.1)	0	0
Vascular disorders					
-Total	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Hypotension	2 (14.3)	0	0	1 (7.1)	1 (7.1)

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Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (80.3)	9 (14.8)	18 (29.5)	14 (23.0)	8 (13.1)
Blood and lymphatic system disorders					
-Total	11 (18.0)	3 (4.9)	0	4 (6.6)	4 (6.6)
Neutropenia	5 (8.2)	0	0	2 (3.3)	3 (4.9)
Anaemia	4 (6.6)	4 (6.6)	0	0	0
Febrile neutropenia	2 (3.3)	0	0	2 (3.3)	0
Thrombocytopenia	2 (3.3)	0	0	1 (1.6)	1 (1.6)
Disseminated intravascular coagulation	1 (1.6)	0	0	1 (1.6)	0
Cardiac disorders					
-Total	1 (1.6)	1 (1.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal disorders					
-Total	10 (16.4)	7 (11.5)	3 (4.9)	0	0
Vomiting	5 (8.2)	5 (8.2)	0	0	0
Diarrhoea	4 (6.6)	4 (6.6)	0	0	0
Nausea	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Constipation	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Abdominal pain	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	16 (26.2)	11 (18.0)	4 (6.6)	1 (1.6)	0
Pyrexia	11 (18.0)	6 (9.8)	4 (6.6)	1 (1.6)	0
Fatigue	4 (6.6)	4 (6.6)	0	0	0
Chills	1 (1.6)	1 (1.6)	0	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	8 (13.1)	0	8 (13.1)	0	0
Hypogammaglobulinaemia	8 (13.1)	0	8 (13.1)	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (27.9)	6 (9.8)	8 (13.1)	3 (4.9)	0
Nasopharyngitis	7 (11.5)	4 (6.6)	3 (4.9)	0	0
Upper respiratory tract infection	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Rhinovirus infection	4 (6.6)	0	3 (4.9)	1 (1.6)	0
Sinusitis	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Investigations					
-Total	20 (32.8)	6 (9.8)	3 (4.9)	8 (13.1)	3 (4.9)
Neutrophil count decreased	8 (13.1)	2 (3.3)	1 (1.6)	2 (3.3)	3 (4.9)
White blood cell count decreased	8 (13.1)	4 (6.6)	2 (3.3)	2 (3.3)	0
Lymphocyte count decreased	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Platelet count decreased	4 (6.6)	3 (4.9)	0	1 (1.6)	0
Alanine aminotransferase increased	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Blood bilirubin increased	2 (3.3)	0	1 (1.6)	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Blood creatinine increased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin m decreased	1 (1.6)	0	0	1 (1.6)	0
Blood uric acid increased	1 (1.6)	0	0	1 (1.6)	0
Metabolism and nutrition disorders					
-Total	7 (11.5)	3 (4.9)	1 (1.6)	3 (4.9)	0
Decreased appetite	4 (6.6)	2 (3.3)	1 (1.6)	1 (1.6)	0
Hyperuricaemia	1 (1.6)	1 (1.6)	0	0	0
Hypervolaemia	1 (1.6)	0	0	1 (1.6)	0
Hypokalaemia	1 (1.6)	0	0	1 (1.6)	0
Hypophosphataemia	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (11.5)	3 (4.9)	2 (3.3)	2 (3.3)	0
Back pain	4 (6.6)	2 (3.3)	1 (1.6)	1 (1.6)	0
Pain in extremity	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Arthralgia	2 (3.3)	2 (3.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Headache	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Psychiatric disorders					
-Total	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Anxiety	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Mental status changes	1 (1.6)	0	0	1 (1.6)	0
Renal and urinary disorders					
-Total	1 (1.6)	1 (1.6)	0	0	0
Acute kidney injury	1 (1.6)	1 (1.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (23.0)	7 (11.5)	4 (6.6)	3 (4.9)	0
Cough	10 (16.4)	7 (11.5)	3 (4.9)	0	0
Nasal congestion	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Epistaxis	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Hypoxia	3 (4.9)	0	0	3 (4.9)	0
Pleural effusion	2 (3.3)	1 (1.6)	1 (1.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (1.6)	0	1 (1.6)	0	0
Oropharyngeal pain	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (11.5)	5 (8.2)	2 (3.3)	0	0
Dry skin	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Rash	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Vascular disorders					
-Total	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Hypotension	2 (3.3)	1 (1.6)	0	0	1 (1.6)
Hypertension	1 (1.6)	0	1 (1.6)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (42.9)	0	3 (42.9)	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Nausea	1 (14.3)	1 (14.3)	0	0	0
Vomiting	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Fatigue	1 (14.3)	0	1 (14.3)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Seasonal allergy	2 (28.6)	2 (28.6)	0	0	0
Infections and infestations					
-Total	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract infection	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthralgia	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Cough	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Rash	1 (14.3)	1 (14.3)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (48.8)	5 (11.6)	8 (18.6)	4 (9.3)	4 (9.3)
Blood and lymphatic system disorders					
-Total	2 (4.7)	0	1 (2.3)	0	1 (2.3)
Anaemia	1 (2.3)	0	1 (2.3)	0	0
Neutropenia	1 (2.3)	0	0	0	1 (2.3)
Thrombocytopenia	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	4 (9.3)	3 (7.0)	0	1 (2.3)	0
Diarrhoea	4 (9.3)	3 (7.0)	0	1 (2.3)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0
Pyrexia	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0
Immune system disorders					
-Total	4 (9.3)	0	4 (9.3)	0	0
Hypogammaglobulinaemia	3 (7.0)	0	3 (7.0)	0	0
Seasonal allergy	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	13 (30.2)	3 (7.0)	7 (16.3)	3 (7.0)	0
Sinusitis	6 (14.0)	0	6 (14.0)	0	0
Conjunctivitis	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Rhinovirus infection	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Upper respiratory tract infection	4 (9.3)	2 (4.7)	1 (2.3)	1 (2.3)	0
Staphylococcal bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Investigations					
-Total	4 (9.3)	3 (7.0)	0	0	1 (2.3)
Neutrophil count decreased	3 (7.0)	2 (4.7)	0	0	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (4.7)	2 (4.7)	0	0	0
Blood bilirubin increased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Decreased appetite	1 (2.3)	0	0	0	1 (2.3)
Hyperglycaemia	1 (2.3)	0	0	1 (2.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (4.7)	0	2 (4.7)	0	0
Pain in extremity	2 (4.7)	0	2 (4.7)	0	0
Nervous system disorders					
-Total	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Headache	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Psychiatric disorders					
-Total	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Anxiety	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (11.6)	3 (7.0)	0	1 (2.3)	1 (2.3)
Cough	3 (7.0)	3 (7.0)	0	0	0
Dyspnoea	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)
Epistaxis	1 (2.3)	1 (2.3)	0	0	0
Hypoxia	1 (2.3)	0	0	1 (2.3)	0
Oropharyngeal pain	1 (2.3)	1 (2.3)	0	0	0
Pleural effusion	1 (2.3)	0	1 (2.3)	0	0
Tachypnoea	1 (2.3)	0	0	0	1 (2.3)
Skin and subcutaneous tissue disorders					
-Total	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Dry skin	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	0	1 (2.3)	0	0
Vascular disorders					
-Total	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hypertension	2 (4.7)	0	1 (2.3)	1 (2.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (100)	0	2 (13.3)	1 (6.7)	12 (80.0)
Blood and lymphatic system disorders					
-Total	11 (73.3)	0	1 (6.7)	8 (53.3)	2 (13.3)
Febrile neutropenia	8 (53.3)	0	0	6 (40.0)	2 (13.3)
Anaemia	5 (33.3)	0	1 (6.7)	4 (26.7)	0
Coagulopathy	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Disseminated intravascular coagulation	1 (6.7)	0	1 (6.7)	0	0
Thrombocytopenia	1 (6.7)	0	0	1 (6.7)	0
Cardiac disorders					
-Total	4 (26.7)	1 (6.7)	3 (20.0)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (20.0)	0	3 (20.0)	0	0
Sinus tachycardia	2 (13.3)	2 (13.3)	0	0	0
Endocrine disorders					
-Total	3 (20.0)	0	3 (20.0)	0	0
Adrenal insufficiency	3 (20.0)	0	3 (20.0)	0	0
Gastrointestinal disorders					
-Total	12 (80.0)	4 (26.7)	7 (46.7)	1 (6.7)	0
Diarrhoea	6 (40.0)	3 (20.0)	3 (20.0)	0	0
Constipation	4 (26.7)	1 (6.7)	3 (20.0)	0	0
Vomiting	4 (26.7)	3 (20.0)	0	1 (6.7)	0
Nausea	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Abdominal pain	1 (6.7)	0	1 (6.7)	0	0
General disorders and administration site conditions					
-Total	9 (60.0)	3 (20.0)	3 (20.0)	3 (20.0)	0
Pyrexia	6 (40.0)	1 (6.7)	2 (13.3)	3 (20.0)	0
Fatigue	4 (26.7)	3 (20.0)	1 (6.7)	0	0
Oedema peripheral	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Chills	2 (13.3)	2 (13.3)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	2 (13.3)	0	2 (13.3)	0	0
Face oedema	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					
-Total	14 (93.3)	0	5 (33.3)	1 (6.7)	8 (53.3)
Cytokine release syndrome	13 (86.7)	0	4 (26.7)	1 (6.7)	8 (53.3)
Hypogammaglobulinaemia	6 (40.0)	1 (6.7)	4 (26.7)	1 (6.7)	0
Seasonal allergy	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Infections and infestations					
-Total	7 (46.7)	0	2 (13.3)	4 (26.7)	1 (6.7)
Upper respiratory tract infection	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Adenovirus infection	2 (13.3)	0	0	2 (13.3)	0
Bacteraemia	2 (13.3)	0	1 (6.7)	0	1 (6.7)
Respiratory syncytial virus infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Staphylococcal bacteraemia	2 (13.3)	0	0	2 (13.3)	0
Conjunctivitis	1 (6.7)	1 (6.7)	0	0	0
Rhinovirus infection	1 (6.7)	0	1 (6.7)	0	0
Investigations					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (66.7)	0	0	4 (26.7)	6 (40.0)
Aspartate aminotransferase increased	7 (46.7)	0	1 (6.7)	4 (26.7)	2 (13.3)
Alanine aminotransferase increased	5 (33.3)	0	2 (13.3)	3 (20.0)	0
Blood bilirubin increased	4 (26.7)	0	0	4 (26.7)	0
Blood creatinine increased	3 (20.0)	1 (6.7)	0	2 (13.3)	0
Neutrophil count decreased	3 (20.0)	0	0	0	3 (20.0)
Platelet count decreased	3 (20.0)	0	0	0	3 (20.0)
White blood cell count decreased	3 (20.0)	0	0	0	3 (20.0)
Activated partial thromboplastin time prolonged	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Blood uric acid increased	2 (13.3)	1 (6.7)	0	0	1 (6.7)
International normalised ratio increased	2 (13.3)	0	2 (13.3)	0	0
Serum ferritin increased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	13 (86.7)	0	4 (26.7)	6 (40.0)	3 (20.0)
Decreased appetite	9 (60.0)	0	4 (26.7)	5 (33.3)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	8 (53.3)	0	5 (33.3)	3 (20.0)	0
Hypokalaemia	7 (46.7)	1 (6.7)	3 (20.0)	2 (13.3)	1 (6.7)
Hyperglycaemia	5 (33.3)	0	3 (20.0)	2 (13.3)	0
Hypoalbuminaemia	5 (33.3)	0	4 (26.7)	1 (6.7)	0
Hyperuricaemia	4 (26.7)	3 (20.0)	0	1 (6.7)	0
Hypophosphataemia	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Hypervolaemia	3 (20.0)	0	0	3 (20.0)	0
Hypomagnesaemia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Tumour lysis syndrome	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Acidosis	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypercalcaemia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Hyperkalaemia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Malnutrition	2 (13.3)	0	0	2 (13.3)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (53.3)	3 (20.0)	3 (20.0)	2 (13.3)	0
Arthralgia	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Myalgia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Back pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Nervous system disorders					
-Total	7 (46.7)	1 (6.7)	4 (26.7)	2 (13.3)	0
Headache	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Cognitive disorder	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Somnolence	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Encephalopathy	1 (6.7)	0	0	1 (6.7)	0
Psychiatric disorders					
-Total	7 (46.7)	0	5 (33.3)	2 (13.3)	0
Anxiety	5 (33.3)	0	4 (26.7)	1 (6.7)	0
Mental status changes	2 (13.3)	0	2 (13.3)	0	0
Delirium	1 (6.7)	0	0	1 (6.7)	0
Renal and urinary disorders					
-Total	4 (26.7)	0	1 (6.7)	1 (6.7)	2 (13.3)
Acute kidney injury	4 (26.7)	0	1 (6.7)	1 (6.7)	2 (13.3)
Respiratory, thoracic and mediastinal disorders					
-Total	11 (73.3)	1 (6.7)	2 (13.3)	3 (20.0)	5 (33.3)
Pulmonary oedema	4 (26.7)	0	1 (6.7)	2 (13.3)	1 (6.7)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Nasal congestion	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Acute respiratory distress syndrome	2 (13.3)	0	0	0	2 (13.3)
Cough	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pleural effusion	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Rhinitis allergic	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Oropharyngeal pain	1 (6.7)	1 (6.7)	0	0	0
Tachypnoea	1 (6.7)	0	0	1 (6.7)	0
Skin and subcutaneous tissue disorders					
-Total	5 (33.3)	3 (20.0)	2 (13.3)	0	0
Dry skin	2 (13.3)	2 (13.3)	0	0	0
Pruritus	2 (13.3)	0	2 (13.3)	0	0
Rash	1 (6.7)	1 (6.7)	0	0	0
Vascular disorders					
-Total	9 (60.0)	1 (6.7)	1 (6.7)	4 (26.7)	3 (20.0)
Hypotension	7 (46.7)	0	1 (6.7)	3 (20.0)	3 (20.0)
Hypertension	4 (26.7)	2 (13.3)	0	2 (13.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (100)	3 (4.6)	7 (10.8)	20 (30.8)	35 (53.8)
Blood and lymphatic system disorders					
-Total	40 (61.5)	2 (3.1)	5 (7.7)	21 (32.3)	12 (18.5)
Anaemia	20 (30.8)	7 (10.8)	8 (12.3)	5 (7.7)	0
Febrile neutropenia	19 (29.2)	0	0	19 (29.2)	0
Neutropenia	11 (16.9)	0	2 (3.1)	2 (3.1)	7 (10.8)
Thrombocytopenia	8 (12.3)	0	0	2 (3.1)	6 (9.2)
Disseminated intravascular coagulation	7 (10.8)	0	4 (6.2)	3 (4.6)	0
Coagulopathy	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	15 (23.1)	7 (10.8)	5 (7.7)	2 (3.1)	1 (1.5)
Tachycardia	14 (21.5)	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)
Sinus tachycardia	1 (1.5)	0	1 (1.5)	0	0
Endocrine disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	44 (67.7)	22 (33.8)	16 (24.6)	6 (9.2)	0
Vomiting	22 (33.8)	14 (21.5)	8 (12.3)	0	0
Diarrhoea	20 (30.8)	13 (20.0)	5 (7.7)	2 (3.1)	0
Nausea	19 (29.2)	11 (16.9)	6 (9.2)	2 (3.1)	0
Abdominal pain	10 (15.4)	2 (3.1)	6 (9.2)	2 (3.1)	0
Constipation	10 (15.4)	6 (9.2)	4 (6.2)	0	0
General disorders and administration site conditions					
-Total	38 (58.5)	19 (29.2)	10 (15.4)	7 (10.8)	2 (3.1)
Pyrexia	29 (44.6)	13 (20.0)	8 (12.3)	6 (9.2)	2 (3.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	13 (20.0)	11 (16.9)	2 (3.1)	0	0
Face oedema	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Chills	5 (7.7)	3 (4.6)	2 (3.1)	0	0
Oedema peripheral	4 (6.2)	3 (4.6)	0	1 (1.5)	0
Generalised oedema	3 (4.6)	2 (3.1)	1 (1.5)	0	0
Immune system disorders					
-Total	55 (84.6)	2 (3.1)	20 (30.8)	20 (30.8)	13 (20.0)
Cytokine release syndrome	48 (73.8)	5 (7.7)	14 (21.5)	16 (24.6)	13 (20.0)
Hypogammaglobulinaemia	27 (41.5)	1 (1.5)	20 (30.8)	6 (9.2)	0
Seasonal allergy	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	30 (46.2)	8 (12.3)	14 (21.5)	8 (12.3)	0
Upper respiratory tract infection	9 (13.8)	5 (7.7)	2 (3.1)	2 (3.1)	0
Rhinovirus infection	8 (12.3)	0	6 (9.2)	2 (3.1)	0
Conjunctivitis	7 (10.8)	1 (1.5)	6 (9.2)	0	0
Nasopharyngitis	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Sinusitis	7 (10.8)	0	5 (7.7)	2 (3.1)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	3 (4.6)	0	0	3 (4.6)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	0	1 (1.5)	0
Investigations					
-Total	40 (61.5)	3 (4.6)	4 (6.2)	12 (18.5)	21 (32.3)
White blood cell count decreased	22 (33.8)	3 (4.6)	4 (6.2)	2 (3.1)	13 (20.0)
Neutrophil count decreased	21 (32.3)	1 (1.5)	2 (3.1)	4 (6.2)	14 (21.5)
Platelet count decreased	21 (32.3)	6 (9.2)	3 (4.6)	7 (10.8)	5 (7.7)
Lymphocyte count decreased	17 (26.2)	1 (1.5)	1 (1.5)	10 (15.4)	5 (7.7)
Alanine aminotransferase increased	13 (20.0)	3 (4.6)	6 (9.2)	4 (6.2)	0
Aspartate aminotransferase increased	12 (18.5)	2 (3.1)	5 (7.7)	4 (6.2)	1 (1.5)
Blood bilirubin increased	9 (13.8)	1 (1.5)	3 (4.6)	5 (7.7)	0
Blood fibrinogen decreased	7 (10.8)	2 (3.1)	3 (4.6)	1 (1.5)	1 (1.5)
Blood immunoglobulin a decreased	7 (10.8)	5 (7.7)	1 (1.5)	1 (1.5)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	7 (10.8)	4 (6.2)	1 (1.5)	2 (3.1)	0
International normalised ratio increased	7 (10.8)	6 (9.2)	1 (1.5)	0	0
Serum ferritin increased	7 (10.8)	1 (1.5)	5 (7.7)	1 (1.5)	0
Activated partial thromboplastin time prolonged	4 (6.2)	3 (4.6)	1 (1.5)	0	0
Blood creatinine increased	2 (3.1)	0	1 (1.5)	0	1 (1.5)
Blood uric acid increased	2 (3.1)	1 (1.5)	0	1 (1.5)	0
Metabolism and nutrition disorders					
-Total	37 (56.9)	10 (15.4)	6 (9.2)	16 (24.6)	5 (7.7)
Decreased appetite	21 (32.3)	11 (16.9)	3 (4.6)	5 (7.7)	2 (3.1)
Hypophosphataemia	14 (21.5)	3 (4.6)	5 (7.7)	5 (7.7)	1 (1.5)
Hypokalaemia	13 (20.0)	2 (3.1)	3 (4.6)	7 (10.8)	1 (1.5)
Hypocalcaemia	8 (12.3)	2 (3.1)	4 (6.2)	2 (3.1)	0
Hypoalbuminaemia	6 (9.2)	0	6 (9.2)	0	0
Hyperuricaemia	5 (7.7)	4 (6.2)	1 (1.5)	0	0
Hyperglycaemia	4 (6.2)	0	1 (1.5)	3 (4.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	4 (6.2)	0	2 (3.1)	2 (3.1)	0
Hypomagnesaemia	3 (4.6)	3 (4.6)	0	0	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0
Hypercalcaemia	1 (1.5)	0	0	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	0	0	1 (1.5)
Musculoskeletal and connective tissue disorders					
-Total	27 (41.5)	12 (18.5)	12 (18.5)	3 (4.6)	0
Pain in extremity	15 (23.1)	7 (10.8)	7 (10.8)	1 (1.5)	0
Arthralgia	9 (13.8)	5 (7.7)	4 (6.2)	0	0
Back pain	8 (12.3)	2 (3.1)	4 (6.2)	2 (3.1)	0
Myalgia	7 (10.8)	4 (6.2)	3 (4.6)	0	0
Nervous system disorders					
-Total	30 (46.2)	13 (20.0)	11 (16.9)	6 (9.2)	0
Headache	23 (35.4)	11 (16.9)	9 (13.8)	3 (4.6)	0
Encephalopathy	7 (10.8)	1 (1.5)	3 (4.6)	3 (4.6)	0
Somnolence	3 (4.6)	1 (1.5)	1 (1.5)	1 (1.5)	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (30.8)	9 (13.8)	6 (9.2)	5 (7.7)	0
Anxiety	9 (13.8)	3 (4.6)	5 (7.7)	1 (1.5)	0
Confusional state	7 (10.8)	7 (10.8)	0	0	0
Delirium	7 (10.8)	2 (3.1)	3 (4.6)	2 (3.1)	0
Mental status changes	3 (4.6)	1 (1.5)	0	2 (3.1)	0
Renal and urinary disorders					
-Total	8 (12.3)	2 (3.1)	1 (1.5)	2 (3.1)	3 (4.6)
Acute kidney injury	8 (12.3)	2 (3.1)	1 (1.5)	2 (3.1)	3 (4.6)
Respiratory, thoracic and mediastinal disorders					
-Total	41 (63.1)	19 (29.2)	6 (9.2)	9 (13.8)	7 (10.8)
Cough	21 (32.3)	17 (26.2)	4 (6.2)	0	0
Hypoxia	17 (26.2)	0	4 (6.2)	8 (12.3)	5 (7.7)
Pulmonary oedema	8 (12.3)	2 (3.1)	2 (3.1)	4 (6.2)	0
Tachypnoea	8 (12.3)	3 (4.6)	1 (1.5)	3 (4.6)	1 (1.5)
Dyspnoea	7 (10.8)	1 (1.5)	2 (3.1)	2 (3.1)	2 (3.1)
Epistaxis	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Oropharyngeal pain	7 (10.8)	6 (9.2)	1 (1.5)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	7 (10.8)	4 (6.2)	2 (3.1)	1 (1.5)	0
Nasal congestion	6 (9.2)	5 (7.7)	1 (1.5)	0	0
Acute respiratory distress syndrome	1 (1.5)	0	0	0	1 (1.5)
Skin and subcutaneous tissue disorders					
-Total	15 (23.1)	8 (12.3)	7 (10.8)	0	0
Rash	7 (10.8)	3 (4.6)	4 (6.2)	0	0
Dry skin	6 (9.2)	4 (6.2)	2 (3.1)	0	0
Pruritus	5 (7.7)	2 (3.1)	3 (4.6)	0	0
Vascular disorders					
-Total	23 (35.4)	4 (6.2)	7 (10.8)	7 (10.8)	5 (7.7)
Hypotension	17 (26.2)	2 (3.1)	5 (7.7)	5 (7.7)	5 (7.7)
Hypertension	12 (18.5)	2 (3.1)	7 (10.8)	3 (4.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	2 (33.3)	0	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	1 (16.7)	0	1 (16.7)	0	0
Fatigue	1 (16.7)	1 (16.7)	0	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (16.7)	0	0	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Nasal congestion	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	73 (98.6)	4 (5.4)	7 (9.5)	20 (27.0)	42 (56.8)
Blood and lymphatic system disorders					
-Total	43 (58.1)	3 (4.1)	6 (8.1)	23 (31.1)	11 (14.9)
Febrile neutropenia	23 (31.1)	0	0	22 (29.7)	1 (1.4)
Anaemia	19 (25.7)	4 (5.4)	7 (9.5)	8 (10.8)	0
Neutropenia	9 (12.2)	0	2 (2.7)	1 (1.4)	6 (8.1)
Thrombocytopenia	7 (9.5)	0	0	2 (2.7)	5 (6.8)
Disseminated intravascular coagulation	6 (8.1)	0	5 (6.8)	1 (1.4)	0
Coagulopathy	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (21.6)	7 (9.5)	7 (9.5)	2 (2.7)	0
Tachycardia	14 (18.9)	6 (8.1)	6 (8.1)	2 (2.7)	0
Sinus tachycardia	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Eye disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Eyelid oedema	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	44 (59.5)	20 (27.0)	17 (23.0)	7 (9.5)	0
Vomiting	21 (28.4)	12 (16.2)	8 (10.8)	1 (1.4)	0
Nausea	17 (23.0)	9 (12.2)	6 (8.1)	2 (2.7)	0
Diarrhoea	15 (20.3)	8 (10.8)	6 (8.1)	1 (1.4)	0
Abdominal pain	11 (14.9)	3 (4.1)	6 (8.1)	2 (2.7)	0
Constipation	10 (13.5)	5 (6.8)	5 (6.8)	0	0
Mouth haemorrhage	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Abdominal distension	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.7)	1 (1.4)	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	32 (43.2)	16 (21.6)	7 (9.5)	6 (8.1)	3 (4.1)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	21 (28.4)	10 (13.5)	4 (5.4)	5 (6.8)	2 (2.7)
Fatigue	10 (13.5)	8 (10.8)	2 (2.7)	0	0
Face oedema	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Chills	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Oedema peripheral	5 (6.8)	4 (5.4)	0	1 (1.4)	0
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Catheter site pain	1 (1.4)	0	0	1 (1.4)	0
Multiple organ dysfunction syndrome	1 (1.4)	0	0	0	1 (1.4)
Hepatobiliary disorders					
-Total	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Cholelithiasis	1 (1.4)	0	1 (1.4)	0	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	61 (82.4)	3 (4.1)	18 (24.3)	21 (28.4)	19 (25.7)
Cytokine release syndrome	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Hypogammaglobulinaemia	21 (28.4)	2 (2.7)	13 (17.6)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	9 (12.2)	1 (1.4)	6 (8.1)	2 (2.7)	0
Conjunctivitis	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Rhinovirus infection	2 (2.7)	0	2 (2.7)	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Pneumonia	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	2 (2.7)	0	2 (2.7)	0	0
Infusion related reaction	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	46 (62.2)	4 (5.4)	4 (5.4)	13 (17.6)	25 (33.8)
White blood cell count decreased	22 (29.7)	3 (4.1)	2 (2.7)	2 (2.7)	15 (20.3)
Platelet count decreased	20 (27.0)	4 (5.4)	3 (4.1)	6 (8.1)	7 (9.5)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	7 (9.5)	3 (4.1)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	17 (23.0)	4 (5.4)	8 (10.8)	5 (6.8)	0
Neutrophil count decreased	17 (23.0)	0	3 (4.1)	1 (1.4)	13 (17.6)
Lymphocyte count decreased	14 (18.9)	2 (2.7)	0	7 (9.5)	5 (6.8)
Blood bilirubin increased	11 (14.9)	1 (1.4)	2 (2.7)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Serum ferritin increased	8 (10.8)	1 (1.4)	5 (6.8)	2 (2.7)	0
Blood immunoglobulin m decreased	5 (6.8)	4 (5.4)	0	1 (1.4)	0
Electrocardiogram qt prolonged	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Blood creatinine increased	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Weight increased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	1 (1.4)	0
Blood immunoglobulin g decreased	1 (1.4)	1 (1.4)	0	0	0
Lipase increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	39 (52.7)	8 (10.8)	9 (12.2)	18 (24.3)	4 (5.4)
Decreased appetite	22 (29.7)	8 (10.8)	3 (4.1)	10 (13.5)	1 (1.4)
Hypokalaemia	18 (24.3)	3 (4.1)	5 (6.8)	9 (12.2)	1 (1.4)
Hypocalcaemia	14 (18.9)	2 (2.7)	8 (10.8)	4 (5.4)	0
Hypophosphataemia	14 (18.9)	3 (4.1)	4 (5.4)	6 (8.1)	1 (1.4)
Hypoalbuminaemia	10 (13.5)	0	9 (12.2)	1 (1.4)	0
Hyperglycaemia	7 (9.5)	0	3 (4.1)	4 (5.4)	0
Hyperuricaemia	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Hypomagnesaemia	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Acidosis	1 (1.4)	0	0	0	1 (1.4)
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Hypernatraemia	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	27 (36.5)	12 (16.2)	13 (17.6)	2 (2.7)	0
Pain in extremity	11 (14.9)	6 (8.1)	5 (6.8)	0	0
Arthralgia	10 (13.5)	4 (5.4)	5 (6.8)	1 (1.4)	0
Myalgia	8 (10.8)	5 (6.8)	3 (4.1)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Nervous system disorders					
-Total	27 (36.5)	12 (16.2)	10 (13.5)	5 (6.8)	0
Headache	20 (27.0)	10 (13.5)	8 (10.8)	2 (2.7)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Somnolence	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Psychiatric disorders					
-Total	17 (23.0)	6 (8.1)	6 (8.1)	5 (6.8)	0
Delirium	7 (9.5)	2 (2.7)	2 (2.7)	3 (4.1)	0
Anxiety	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	8 (10.8)	1 (1.4)	2 (2.7)	2 (2.7)	3 (4.1)
Acute kidney injury	7 (9.5)	1 (1.4)	1 (1.4)	2 (2.7)	3 (4.1)
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	34 (45.9)	12 (16.2)	4 (5.4)	9 (12.2)	9 (12.2)
Hypoxia	16 (21.6)	0	5 (6.8)	5 (6.8)	6 (8.1)
Pulmonary oedema	12 (16.2)	2 (2.7)	3 (4.1)	6 (8.1)	1 (1.4)
Cough	10 (13.5)	9 (12.2)	1 (1.4)	0	0
Pleural effusion	7 (9.5)	4 (5.4)	0	2 (2.7)	1 (1.4)
Tachypnoea	6 (8.1)	3 (4.1)	1 (1.4)	2 (2.7)	0
Oropharyngeal pain	5 (6.8)	5 (6.8)	0	0	0
Atelectasis	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Dyspnoea	2 (2.7)	0	0	2 (2.7)	0
Nasal congestion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Skin and subcutaneous tissue disorders					
-Total	14 (18.9)	5 (6.8)	9 (12.2)	0	0
Pruritus	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Erythema	3 (4.1)	3 (4.1)	0	0	0
Rash	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Hyperhidrosis	2 (2.7)	0	2 (2.7)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	1 (1.4)	0	0
Skin ulcer	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	25 (33.8)	4 (5.4)	7 (9.5)	9 (12.2)	5 (6.8)
Hypotension	19 (25.7)	1 (1.4)	6 (8.1)	7 (9.5)	5 (6.8)
Hypertension	12 (16.2)	4 (5.4)	5 (6.8)	3 (4.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Lymphocytosis	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	2 (40.0)	0	0
Gastroenteritis	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal infection	1 (20.0)	1 (20.0)	0	0	0
Otitis externa	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Fibula fracture	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	1 (20.0)	0
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Persistent depressive disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Dry skin	2 (40.0)	2 (40.0)	0	0	0
Skin hypopigmentation	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (84.3)	11 (15.7)	19 (27.1)	17 (24.3)	12 (17.1)
Blood and lymphatic system disorders					
-Total	13 (18.6)	3 (4.3)	0	6 (8.6)	4 (5.7)
Anaemia	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Neutropenia	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	2 (2.9)	2 (2.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.9)	2 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	15 (21.4)	10 (14.3)	5 (7.1)	0	0
Diarrhoea	7 (10.0)	6 (8.6)	1 (1.4)	0	0
Vomiting	6 (8.6)	6 (8.6)	0	0	0
Nausea	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Constipation	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Abdominal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	21 (30.0)	13 (18.6)	6 (8.6)	2 (2.9)	0
Pyrexia	15 (21.4)	7 (10.0)	6 (8.6)	2 (2.9)	0
Fatigue	5 (7.1)	5 (7.1)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Oedema peripheral	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	10 (14.3)	0	10 (14.3)	0	0
Hypogammaglobulinaemia	10 (14.3)	0	10 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	21 (30.0)	3 (4.3)	10 (14.3)	6 (8.6)	2 (2.9)
Upper respiratory tract infection	7 (10.0)	3 (4.3)	2 (2.9)	2 (2.9)	0
Rhinovirus infection	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Gastroenteritis	4 (5.7)	2 (2.9)	0	2 (2.9)	0
Pneumonia	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Sinusitis	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Otitis externa	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Infusion related reaction	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Investigations					
-Total	20 (28.6)	4 (5.7)	4 (5.7)	8 (11.4)	4 (5.7)
White blood cell count decreased	9 (12.9)	4 (5.7)	2 (2.9)	2 (2.9)	1 (1.4)
Neutrophil count decreased	8 (11.4)	1 (1.4)	1 (1.4)	2 (2.9)	4 (5.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (7.1)	3 (4.3)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Alanine aminotransferase increased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Weight increased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	9 (12.9)	3 (4.3)	3 (4.3)	2 (2.9)	1 (1.4)
Decreased appetite	6 (8.6)	2 (2.9)	3 (4.3)	1 (1.4)	0
Hypokalaemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hyperuricaemia	2 (2.9)	2 (2.9)	0	0	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (15.7)	4 (5.7)	4 (5.7)	3 (4.3)	0
Back pain	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Pain in extremity	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
Arthralgia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	9 (12.9)	5 (7.1)	4 (5.7)	0	0
Headache	9 (12.9)	5 (7.1)	4 (5.7)	0	0
Psychiatric disorders					
-Total	7 (10.0)	1 (1.4)	6 (8.6)	0	0
Anxiety	6 (8.6)	1 (1.4)	5 (7.1)	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Acute kidney injury	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	16 (22.9)	8 (11.4)	4 (5.7)	3 (4.3)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	10 (14.3)	7 (10.0)	3 (4.3)	0	0
Nasal congestion	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Hypoxia	3 (4.3)	0	0	3 (4.3)	0
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Acute respiratory distress syndrome	1 (1.4)	0	0	0	1 (1.4)
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Oropharyngeal pain	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (14.3)	5 (7.1)	4 (5.7)	1 (1.4)	0
Dry skin	4 (5.7)	2 (2.9)	2 (2.9)	0	0
Rash	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Pruritus	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	5 (7.1)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.9)
Hypotension	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Irritable bowel syndrome	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Rhinovirus infection	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (51.1)	5 (10.6)	10 (21.3)	5 (10.6)	4 (8.5)
Blood and lymphatic system disorders					
-Total	2 (4.3)	0	1 (2.1)	0	1 (2.1)
Anaemia	1 (2.1)	0	1 (2.1)	0	0
Neutropenia	1 (2.1)	0	0	0	1 (2.1)
Thrombocytopenia	1 (2.1)	0	1 (2.1)	0	0
Eye disorders					
-Total	1 (2.1)	1 (2.1)	0	0	0
Eyelid oedema	1 (2.1)	1 (2.1)	0	0	0
Gastrointestinal disorders					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (12.8)	4 (8.5)	1 (2.1)	1 (2.1)	0
Diarrhoea	5 (10.6)	3 (6.4)	1 (2.1)	1 (2.1)	0
Constipation	1 (2.1)	1 (2.1)	0	0	0
Nausea	1 (2.1)	1 (2.1)	0	0	0
Vomiting	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	5 (10.6)	2 (4.3)	1 (2.1)	1 (2.1)	1 (2.1)
Pyrexia	4 (8.5)	2 (4.3)	1 (2.1)	1 (2.1)	0
Fatigue	1 (2.1)	0	1 (2.1)	0	0
Multiple organ dysfunction syndrome	1 (2.1)	0	0	0	1 (2.1)
Immune system disorders					
-Total	7 (14.9)	2 (4.3)	4 (8.5)	0	1 (2.1)
Hypogammaglobulinaemia	3 (6.4)	0	3 (6.4)	0	0
Seasonal allergy	3 (6.4)	2 (4.3)	1 (2.1)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	0	0	1 (2.1)
Infections and infestations					
-Total	13 (27.7)	4 (8.5)	7 (14.9)	1 (2.1)	1 (2.1)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	5 (10.6)	0	5 (10.6)	0	0
Upper respiratory tract infection	5 (10.6)	2 (4.3)	2 (4.3)	1 (2.1)	0
Conjunctivitis	4 (8.5)	2 (4.3)	2 (4.3)	0	0
Rhinovirus infection	3 (6.4)	0	2 (4.3)	1 (2.1)	0
Gastroenteritis	1 (2.1)	1 (2.1)	0	0	0
Pneumonia	1 (2.1)	0	0	0	1 (2.1)
Injury, poisoning and procedural complications					
-Total	1 (2.1)	0	0	1 (2.1)	0
Infusion related reaction	1 (2.1)	0	0	1 (2.1)	0
Investigations					
-Total	5 (10.6)	3 (6.4)	1 (2.1)	0	1 (2.1)
Neutrophil count decreased	3 (6.4)	2 (4.3)	0	0	1 (2.1)
Platelet count decreased	2 (4.3)	2 (4.3)	0	0	0
Blood bilirubin increased	1 (2.1)	1 (2.1)	0	0	0
Blood immunoglobulin g decreased	1 (2.1)	0	1 (2.1)	0	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (6.4)	0	0	2 (4.3)	1 (2.1)
Decreased appetite	1 (2.1)	0	0	0	1 (2.1)
Hyperglycaemia	1 (2.1)	0	0	1 (2.1)	0
Hypernatraemia	1 (2.1)	0	0	1 (2.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (6.4)	0	3 (6.4)	0	0
Pain in extremity	2 (4.3)	0	2 (4.3)	0	0
Arthralgia	1 (2.1)	0	1 (2.1)	0	0
Nervous system disorders					
-Total	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Headache	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Psychiatric disorders					
-Total	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Anxiety	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (10.6)	2 (4.3)	1 (2.1)	1 (2.1)	1 (2.1)
Cough	4 (8.5)	3 (6.4)	1 (2.1)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	3 (6.4)	1 (2.1)	1 (2.1)	0	1 (2.1)
Hypoxia	1 (2.1)	0	0	1 (2.1)	0
Oropharyngeal pain	1 (2.1)	1 (2.1)	0	0	0
Pleural effusion	1 (2.1)	0	1 (2.1)	0	0
Tachypnoea	1 (2.1)	0	0	0	1 (2.1)
Skin and subcutaneous tissue disorders					
-Total	3 (6.4)	2 (4.3)	1 (2.1)	0	0
Rash	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Dry skin	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					
-Total	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Hypertension	2 (4.3)	0	1 (2.1)	1 (2.1)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders					
-Total	5 (83.3)	0	1 (16.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Lymphocytosis	1 (16.7)	0	1 (16.7)	0	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Irritable bowel syndrome	1 (16.7)	0	1 (16.7)	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	0	2 (33.3)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	2 (33.3)	2 (33.3)	0	0	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Face oedema	1 (16.7)	0	1 (16.7)	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0	0	0
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0	0	0
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (50.0)	0	2 (33.3)	0	1 (16.7)
Fibula fracture	1 (16.7)	0	1 (16.7)	0	0
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Persistent depressive disorder	1 (16.7)	0	1 (16.7)	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Nasal congestion	2 (33.3)	2 (33.3)	0	0	0
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Cough	1 (16.7)	1 (16.7)	0	0	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	4 (66.7)	3 (50.0)	0	1 (16.7)	0
Dry skin	2 (33.3)	2 (33.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin hypopigmentation	1 (16.7)	1 (16.7)	0	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (100)	2 (2.7)	7 (9.5)	20 (27.0)	45 (60.8)
Blood and lymphatic system disorders					
-Total	47 (63.5)	2 (2.7)	6 (8.1)	27 (36.5)	12 (16.2)
Febrile neutropenia	24 (32.4)	0	0	23 (31.1)	1 (1.4)
Anaemia	23 (31.1)	6 (8.1)	8 (10.8)	9 (12.2)	0
Neutropenia	11 (14.9)	0	2 (2.7)	2 (2.7)	7 (9.5)
Thrombocytopenia	8 (10.8)	0	0	3 (4.1)	5 (6.8)
Disseminated intravascular coagulation	7 (9.5)	0	5 (6.8)	2 (2.7)	0
Coagulopathy	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (21.6)	7 (9.5)	7 (9.5)	2 (2.7)	0
Tachycardia	14 (18.9)	6 (8.1)	6 (8.1)	2 (2.7)	0
Sinus tachycardia	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Eyelid oedema	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	55 (74.3)	25 (33.8)	22 (29.7)	8 (10.8)	0
Diarrhoea	26 (35.1)	16 (21.6)	8 (10.8)	2 (2.7)	0
Vomiting	26 (35.1)	17 (23.0)	8 (10.8)	1 (1.4)	0
Nausea	21 (28.4)	11 (14.9)	8 (10.8)	2 (2.7)	0
Constipation	13 (17.6)	6 (8.1)	7 (9.5)	0	0
Abdominal pain	11 (14.9)	2 (2.7)	7 (9.5)	2 (2.7)	0
Mouth haemorrhage	4 (5.4)	2 (2.7)	0	2 (2.7)	0
Abdominal distension	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.7)	1 (1.4)	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	43 (58.1)	20 (27.0)	10 (13.5)	9 (12.2)	4 (5.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	32 (43.2)	14 (18.9)	8 (10.8)	8 (10.8)	2 (2.7)
Fatigue	15 (20.3)	12 (16.2)	3 (4.1)	0	0
Face oedema	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Chills	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Oedema peripheral	6 (8.1)	5 (6.8)	0	1 (1.4)	0
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	0	0	2 (2.7)
Catheter site pain	1 (1.4)	0	0	1 (1.4)	0
Hepatobiliary disorders					
-Total	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Cholelithiasis	1 (1.4)	0	1 (1.4)	0	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	64 (86.5)	2 (2.7)	21 (28.4)	21 (28.4)	20 (27.0)
Cytokine release syndrome	56 (75.7)	4 (5.4)	16 (21.6)	17 (23.0)	19 (25.7)
Hypogammaglobulinaemia	31 (41.9)	2 (2.7)	23 (31.1)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Infections and infestations					
-Total	33 (44.6)	7 (9.5)	14 (18.9)	9 (12.2)	3 (4.1)
Upper respiratory tract infection	12 (16.2)	5 (6.8)	4 (5.4)	3 (4.1)	0
Rhinovirus infection	8 (10.8)	0	6 (8.1)	2 (2.7)	0
Conjunctivitis	7 (9.5)	2 (2.7)	5 (6.8)	0	0
Sinusitis	6 (8.1)	0	4 (5.4)	2 (2.7)	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Pneumonia	5 (6.8)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.7)
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Encephalitis	1 (1.4)	0	0	0	1 (1.4)
Injury, poisoning and procedural complications					
-Total	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Infusion related reaction	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Wound	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	47 (63.5)	3 (4.1)	5 (6.8)	14 (18.9)	25 (33.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	23 (31.1)	6 (8.1)	3 (4.1)	7 (9.5)	7 (9.5)
White blood cell count decreased	23 (31.1)	3 (4.1)	3 (4.1)	2 (2.7)	15 (20.3)
Neutrophil count decreased	21 (28.4)	1 (1.4)	2 (2.7)	3 (4.1)	15 (20.3)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	7 (9.5)	3 (4.1)
Alanine aminotransferase increased	17 (23.0)	3 (4.1)	8 (10.8)	6 (8.1)	0
Lymphocyte count decreased	16 (21.6)	1 (1.4)	1 (1.4)	9 (12.2)	5 (6.8)
Blood bilirubin increased	12 (16.2)	1 (1.4)	3 (4.1)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Serum ferritin increased	8 (10.8)	1 (1.4)	5 (6.8)	2 (2.7)	0
Blood immunoglobulin m decreased	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Blood creatinine increased	4 (5.4)	0	1 (1.4)	2 (2.7)	1 (1.4)
Electrocardiogram qt prolonged	4 (5.4)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Blood immunoglobulin g decreased	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Weight increased	3 (4.1)	1 (1.4)	0	2 (2.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (1.4)	0	0	1 (1.4)	0
Lipase increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	44 (59.5)	9 (12.2)	10 (13.5)	20 (27.0)	5 (6.8)
Decreased appetite	28 (37.8)	10 (13.5)	6 (8.1)	10 (13.5)	2 (2.7)
Hypokalaemia	19 (25.7)	3 (4.1)	6 (8.1)	9 (12.2)	1 (1.4)
Hypophosphataemia	15 (20.3)	3 (4.1)	5 (6.8)	6 (8.1)	1 (1.4)
Hypocalcaemia	14 (18.9)	2 (2.7)	8 (10.8)	4 (5.4)	0
Hypoalbuminaemia	10 (13.5)	0	9 (12.2)	1 (1.4)	0
Hyperglycaemia	8 (10.8)	0	3 (4.1)	5 (6.8)	0
Hyperuricaemia	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Hypomagnesaemia	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Hypernatraemia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Acidosis	1 (1.4)	0	0	0	1 (1.4)
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	34 (45.9)	14 (18.9)	15 (20.3)	5 (6.8)	0
Pain in extremity	17 (23.0)	8 (10.8)	8 (10.8)	1 (1.4)	0
Arthralgia	12 (16.2)	5 (6.8)	6 (8.1)	1 (1.4)	0
Back pain	10 (13.5)	2 (2.7)	5 (6.8)	3 (4.1)	0
Myalgia	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Nervous system disorders					
-Total	31 (41.9)	13 (17.6)	12 (16.2)	6 (8.1)	0
Headache	24 (32.4)	11 (14.9)	10 (13.5)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Somnolence	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Psychiatric disorders					
-Total	25 (33.8)	7 (9.5)	13 (17.6)	5 (6.8)	0
Anxiety	14 (18.9)	3 (4.1)	9 (12.2)	2 (2.7)	0
Delirium	8 (10.8)	2 (2.7)	3 (4.1)	3 (4.1)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Sleep disorder	2 (2.7)	0	2 (2.7)	0	0
Renal and urinary disorders					
-Total	11 (14.9)	2 (2.7)	3 (4.1)	2 (2.7)	4 (5.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	10 (13.5)	2 (2.7)	2 (2.7)	2 (2.7)	4 (5.4)
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	46 (62.2)	17 (23.0)	7 (9.5)	11 (14.9)	11 (14.9)
Cough	22 (29.7)	17 (23.0)	5 (6.8)	0	0
Hypoxia	19 (25.7)	0	4 (5.4)	9 (12.2)	6 (8.1)
Pulmonary oedema	12 (16.2)	2 (2.7)	3 (4.1)	6 (8.1)	1 (1.4)
Pleural effusion	9 (12.2)	4 (5.4)	2 (2.7)	2 (2.7)	1 (1.4)
Nasal congestion	7 (9.5)	5 (6.8)	2 (2.7)	0	0
Oropharyngeal pain	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Tachypnoea	7 (9.5)	3 (4.1)	1 (1.4)	2 (2.7)	1 (1.4)
Dyspnoea	6 (8.1)	1 (1.4)	2 (2.7)	2 (2.7)	1 (1.4)
Acute respiratory distress syndrome	2 (2.7)	0	0	0	2 (2.7)
Atelectasis	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Skin and subcutaneous tissue disorders					
-Total	22 (29.7)	9 (12.2)	12 (16.2)	1 (1.4)	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	6 (8.1)	2 (2.7)	4 (5.4)	0	0
Rash	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Erythema	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Hyperhidrosis	2 (2.7)	0	2 (2.7)	0	0
Decubitus ulcer	1 (1.4)	0	0	1 (1.4)	0
Petechiae	1 (1.4)	0	1 (1.4)	0	0
Skin ulcer	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	30 (40.5)	5 (6.8)	8 (10.8)	10 (13.5)	7 (9.5)
Hypotension	22 (29.7)	2 (2.7)	6 (8.1)	7 (9.5)	7 (9.5)
Hypertension	15 (20.3)	4 (5.4)	7 (9.5)	4 (5.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Immune system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (50.0)	0	0	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	1 (50.0)	0
Blood creatinine increased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypocalcaemia	1 (50.0)	0	0	1 (50.0)	0
Hypokalaemia	1 (50.0)	0	0	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Psychiatric disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Anxiety	1 (50.0)	0	1 (50.0)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Pleural effusion	1 (50.0)	0	0	0	1 (50.0)
Wheezing	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	0	0	1 (50.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	77 (98.7)	5 (6.4)	8 (10.3)	20 (25.6)	44 (56.4)
Blood and lymphatic system disorders					
-Total	44 (56.4)	2 (2.6)	5 (6.4)	24 (30.8)	13 (16.7)
Febrile neutropenia	25 (32.1)	0	0	23 (29.5)	2 (2.6)
Anaemia	21 (26.9)	5 (6.4)	8 (10.3)	8 (10.3)	0
Neutropenia	9 (11.5)	0	2 (2.6)	1 (1.3)	6 (7.7)
Thrombocytopenia	8 (10.3)	0	0	2 (2.6)	6 (7.7)
Disseminated intravascular coagulation	7 (9.0)	0	5 (6.4)	2 (2.6)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (23.1)	6 (7.7)	6 (7.7)	5 (6.4)	1 (1.3)
Tachycardia	17 (21.8)	7 (9.0)	7 (9.0)	2 (2.6)	1 (1.3)
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Endocrine disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Hypothyroidism	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					
-Total	46 (59.0)	22 (28.2)	18 (23.1)	6 (7.7)	0
Vomiting	21 (26.9)	12 (15.4)	8 (10.3)	1 (1.3)	0
Nausea	18 (23.1)	10 (12.8)	6 (7.7)	2 (2.6)	0
Diarrhoea	15 (19.2)	8 (10.3)	6 (7.7)	1 (1.3)	0
Abdominal pain	11 (14.1)	3 (3.8)	6 (7.7)	2 (2.6)	0
Constipation	11 (14.1)	6 (7.7)	5 (6.4)	0	0
General disorders and administration site conditions					
-Total	34 (43.6)	18 (23.1)	7 (9.0)	7 (9.0)	2 (2.6)
Pyrexia	24 (30.8)	11 (14.1)	5 (6.4)	6 (7.7)	2 (2.6)
Fatigue	11 (14.1)	9 (11.5)	2 (2.6)	0	0
Face oedema	8 (10.3)	5 (6.4)	2 (2.6)	1 (1.3)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	64 (82.1)	3 (3.8)	21 (26.9)	20 (25.6)	20 (25.6)
Cytokine release syndrome	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Hypogammaglobulinaemia	23 (29.5)	2 (2.6)	14 (17.9)	7 (9.0)	0
Seasonal allergy	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	8 (10.3)	1 (1.3)	6 (7.7)	0	1 (1.3)
Conjunctivitis	5 (6.4)	1 (1.3)	4 (5.1)	0	0
Rhinovirus infection	2 (2.6)	0	2 (2.6)	0	0
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	48 (61.5)	3 (3.8)	5 (6.4)	15 (19.2)	25 (32.1)
White blood cell count decreased	24 (30.8)	3 (3.8)	3 (3.8)	2 (2.6)	16 (20.5)
Platelet count decreased	21 (26.9)	4 (5.1)	3 (3.8)	6 (7.7)	8 (10.3)
Neutrophil count decreased	20 (25.6)	0	3 (3.8)	2 (2.6)	15 (19.2)
Aspartate aminotransferase increased	18 (23.1)	2 (2.6)	6 (7.7)	8 (10.3)	2 (2.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	17 (21.8)	4 (5.1)	8 (10.3)	5 (6.4)	0
Lymphocyte count decreased	15 (19.2)	2 (2.6)	0	8 (10.3)	5 (6.4)
Blood bilirubin increased	11 (14.1)	1 (1.3)	2 (2.6)	8 (10.3)	0
International normalised ratio increased	9 (11.5)	6 (7.7)	3 (3.8)	0	0
Serum ferritin increased	8 (10.3)	1 (1.3)	5 (6.4)	2 (2.6)	0
Activated partial thromboplastin time prolonged	5 (6.4)	3 (3.8)	2 (2.6)	0	0
Blood creatinine increased	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Weight decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	43 (55.1)	8 (10.3)	9 (11.5)	22 (28.2)	4 (5.1)
Decreased appetite	24 (30.8)	9 (11.5)	4 (5.1)	10 (12.8)	1 (1.3)
Hypokalaemia	18 (23.1)	3 (3.8)	5 (6.4)	8 (10.3)	2 (2.6)
Hypophosphataemia	17 (21.8)	3 (3.8)	5 (6.4)	8 (10.3)	1 (1.3)
Hypocalcaemia	15 (19.2)	2 (2.6)	9 (11.5)	4 (5.1)	0
Hypoalbuminaemia	11 (14.1)	0	10 (12.8)	1 (1.3)	0
Hyperglycaemia	8 (10.3)	0	4 (5.1)	4 (5.1)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	7 (9.0)	5 (6.4)	1 (1.3)	1 (1.3)	0
Tumour lysis syndrome	3 (3.8)	0	0	3 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	28 (35.9)	13 (16.7)	13 (16.7)	2 (2.6)	0
Pain in extremity	11 (14.1)	6 (7.7)	5 (6.4)	0	0
Arthralgia	10 (12.8)	4 (5.1)	5 (6.4)	1 (1.3)	0
Myalgia	9 (11.5)	6 (7.7)	3 (3.8)	0	0
Back pain	6 (7.7)	2 (2.6)	3 (3.8)	1 (1.3)	0
Nervous system disorders					
-Total	33 (42.3)	12 (15.4)	11 (14.1)	9 (11.5)	1 (1.3)
Headache	23 (29.5)	12 (15.4)	9 (11.5)	2 (2.6)	0
Encephalopathy	8 (10.3)	1 (1.3)	3 (3.8)	4 (5.1)	0
Cognitive disorder	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Seizure	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Psychiatric disorders					
-Total	14 (17.9)	3 (3.8)	6 (7.7)	5 (6.4)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	7 (9.0)	2 (2.6)	2 (2.6)	3 (3.8)	0
Anxiety	5 (6.4)	1 (1.3)	2 (2.6)	2 (2.6)	0
Sleep disorder	2 (2.6)	0	2 (2.6)	0	0
Renal and urinary disorders					
-Total	9 (11.5)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Acute kidney injury	9 (11.5)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders					
-Total	35 (44.9)	13 (16.7)	4 (5.1)	11 (14.1)	7 (9.0)
Hypoxia	17 (21.8)	0	5 (6.4)	6 (7.7)	6 (7.7)
Pulmonary oedema	12 (15.4)	2 (2.6)	3 (3.8)	6 (7.7)	1 (1.3)
Cough	10 (12.8)	9 (11.5)	1 (1.3)	0	0
Tachypnoea	8 (10.3)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	6 (7.7)	4 (5.1)	0	2 (2.6)	0
Oropharyngeal pain	5 (6.4)	5 (6.4)	0	0	0
Nasal congestion	3 (3.8)	2 (2.6)	1 (1.3)	0	0
Rhinorrhoea	2 (2.6)	2 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (7.7)	3 (3.8)	3 (3.8)	0	0
Rash	5 (6.4)	2 (2.6)	3 (3.8)	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	27 (34.6)	4 (5.1)	7 (9.0)	10 (12.8)	6 (7.7)
Hypotension	21 (26.9)	1 (1.3)	6 (7.7)	8 (10.3)	6 (7.7)
Hypertension	13 (16.7)	4 (5.1)	5 (6.4)	4 (5.1)	0
Capillary leak syndrome	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Pyrexia	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	1 (50.0)	0
Weight decreased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Decreased appetite	1 (50.0)	0	0	1 (50.0)	0
Haemochromatosis	1 (50.0)	0	0	1 (50.0)	0
Hypophosphataemia	1 (50.0)	0	1 (50.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Growth retardation	1 (50.0)	0	1 (50.0)	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	0	0	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Psychiatric disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Sleep disorder	1 (50.0)	0	1 (50.0)	0	0
Renal and urinary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Renal tubular disorder	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Lung disorder	1 (50.0)	1 (50.0)	0	0	0
Vascular disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hypotension	1 (50.0)	1 (50.0)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 214f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (80.8)	13 (17.8)	23 (31.5)	13 (17.8)	10 (13.7)
Blood and lymphatic system disorders					
-Total	12 (16.4)	3 (4.1)	0	5 (6.8)	4 (5.5)
Anaemia	6 (8.2)	4 (5.5)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Cardiac disorders					
-Total	2 (2.7)	2 (2.7)	0	0	0
Tachycardia	2 (2.7)	2 (2.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	14 (19.2)	9 (12.3)	5 (6.8)	0	0
Diarrhoea	7 (9.6)	6 (8.2)	1 (1.4)	0	0
Vomiting	6 (8.2)	6 (8.2)	0	0	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	20 (27.4)	13 (17.8)	6 (8.2)	1 (1.4)	0
Pyrexia	14 (19.2)	7 (9.6)	6 (8.2)	1 (1.4)	0
Fatigue	6 (8.2)	6 (8.2)	0	0	0
Immune system disorders					
-Total	9 (12.3)	0	9 (12.3)	0	0
Hypogammaglobulinaemia	9 (12.3)	0	9 (12.3)	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (16.4)	2 (2.7)	9 (12.3)	1 (1.4)	0
Upper respiratory tract infection	7 (9.6)	3 (4.1)	3 (4.1)	1 (1.4)	0
Rhinovirus infection	5 (6.8)	0	4 (5.5)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	20 (27.4)	6 (8.2)	3 (4.1)	7 (9.6)	4 (5.5)
Neutrophil count decreased	10 (13.7)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.5)
White blood cell count decreased	10 (13.7)	4 (5.5)	2 (2.7)	3 (4.1)	1 (1.4)
Platelet count decreased	5 (6.8)	3 (4.1)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.5)	1 (1.4)	1 (1.4)	2 (2.7)	0
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (12.3)	4 (5.5)	2 (2.7)	1 (1.4)	2 (2.7)
Decreased appetite	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	11 (15.1)	4 (5.5)	4 (5.5)	3 (4.1)	0
Back pain	6 (8.2)	2 (2.7)	2 (2.7)	2 (2.7)	0
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	10 (13.7)	6 (8.2)	4 (5.5)	0	0
Headache	10 (13.7)	6 (8.2)	4 (5.5)	0	0
Psychiatric disorders					
-Total	6 (8.2)	1 (1.4)	5 (6.8)	0	0
Anxiety	6 (8.2)	1 (1.4)	5 (6.8)	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	17 (23.3)	10 (13.7)	4 (5.5)	3 (4.1)	0
Cough	11 (15.1)	8 (11.0)	3 (4.1)	0	0
Nasal congestion	6 (8.2)	5 (6.8)	1 (1.4)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0
Rhinorrhoea	3 (4.1)	3 (4.1)	0	0	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (12.3)	7 (9.6)	2 (2.7)	0	0
Dry skin	6 (8.2)	4 (5.5)	2 (2.7)	0	0
Rash	4 (5.5)	3 (4.1)	1 (1.4)	0	0
Vascular disorders					
-Total	4 (5.5)	0	1 (1.4)	1 (1.4)	2 (2.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	3 (4.1)	0	0	1 (1.4)	2 (2.7)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Endocrine disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Delayed puberty	1 (50.0)	0	1 (50.0)	0	0
Hypothyroidism	1 (50.0)	0	1 (50.0)	0	0
Eye disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Dry eye	1 (50.0)	1 (50.0)	0	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (50.0)	1 (50.0)	0	0	0
Vomiting	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Fatigue	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Seasonal allergy	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Decreased appetite	1 (50.0)	0	0	0	1 (50.0)
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Osteopenia	1 (50.0)	1 (50.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Cough	1 (50.0)	0	1 (50.0)	0	0
Rhinorrhoea	1 (50.0)	0	1 (50.0)	0	0

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Table 214f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (43.8)	4 (8.3)	10 (20.8)	3 (6.3)	4 (8.3)
Blood and lymphatic system disorders					
-Total	2 (4.2)	0	1 (2.1)	0	1 (2.1)
Anaemia	1 (2.1)	0	1 (2.1)	0	0
Neutropenia	1 (2.1)	0	0	0	1 (2.1)
Thrombocytopenia	1 (2.1)	0	1 (2.1)	0	0
Gastrointestinal disorders					
-Total	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Diarrhoea	4 (8.3)	3 (6.3)	0	1 (2.1)	0
Constipation	1 (2.1)	1 (2.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (10.4)	2 (4.2)	2 (4.2)	1 (2.1)	0
Pyrexia	5 (10.4)	2 (4.2)	2 (4.2)	1 (2.1)	0
Immune system disorders					
-Total	5 (10.4)	1 (2.1)	4 (8.3)	0	0
Hypogammaglobulinaemia	3 (6.3)	0	3 (6.3)	0	0
Seasonal allergy	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Infections and infestations					
-Total	12 (25.0)	3 (6.3)	5 (10.4)	2 (4.2)	2 (4.2)
Upper respiratory tract infection	5 (10.4)	2 (4.2)	2 (4.2)	1 (2.1)	0
Conjunctivitis	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Rhinovirus infection	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Sepsis	2 (4.2)	0	0	0	2 (4.2)
Investigations					
-Total	4 (8.3)	3 (6.3)	0	0	1 (2.1)
Neutrophil count decreased	3 (6.3)	2 (4.2)	0	0	1 (2.1)
Platelet count decreased	2 (4.2)	2 (4.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (2.1)	1 (2.1)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (2.1)	0	0	1 (2.1)	0
Hyperglycaemia	1 (2.1)	0	0	1 (2.1)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (8.3)	0	4 (8.3)	0	0
Pain in extremity	2 (4.2)	0	2 (4.2)	0	0
Arthralgia	1 (2.1)	0	1 (2.1)	0	0
Growth retardation	1 (2.1)	0	1 (2.1)	0	0
Nervous system disorders					
-Total	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Headache	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	0	0	1 (2.1)	0
Psychiatric disorders					
-Total	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Anxiety	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.3)	2 (4.2)	0	1 (2.1)	1 (2.1)
Cough	3 (6.3)	3 (6.3)	0	0	0
Rhinorrhoea	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Hypoxia	1 (2.1)	0	0	1 (2.1)	0
Oropharyngeal pain	1 (2.1)	1 (2.1)	0	0	0
Pleural effusion	1 (2.1)	0	1 (2.1)	0	0
Tachypnoea	1 (2.1)	0	0	0	1 (2.1)
Wheezing	1 (2.1)	0	1 (2.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Rash	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Dry skin	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					
-Total	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Hypertension	2 (4.2)	0	1 (2.1)	1 (2.1)	0

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Table 214f
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Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Delayed puberty	1 (50.0)	0	1 (50.0)	0	0
Hypothyroidism	1 (50.0)	0	1 (50.0)	0	0
Eye disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Dry eye	1 (50.0)	1 (50.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Nausea	1 (50.0)	1 (50.0)	0	0	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0	0	0
Vomiting	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Fatigue	1 (50.0)	0	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Seasonal allergy	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	0	0	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	1 (50.0)	0
Blood creatinine increased	1 (50.0)	0	0	1 (50.0)	0
Weight decreased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	0	0	1 (50.0)
Haemochromatosis	1 (50.0)	0	0	1 (50.0)	0
Hypocalcaemia	1 (50.0)	0	0	1 (50.0)	0
Hypokalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypophosphataemia	1 (50.0)	0	1 (50.0)	0	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Growth retardation	1 (50.0)	0	1 (50.0)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteopenia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	0	0	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0
Psychiatric disorders					
-Total	2 (100)	0	2 (100)	0	0
Anxiety	1 (50.0)	0	1 (50.0)	0	0
Sleep disorder	1 (50.0)	0	1 (50.0)	0	0
Renal and urinary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Renal tubular disorder	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (50.0)	0	1 (50.0)	0	0
Lung disorder	1 (50.0)	1 (50.0)	0	0	0
Pleural effusion	1 (50.0)	0	0	0	1 (50.0)
Rhinorrhoea	1 (50.0)	0	1 (50.0)	0	0
Wheezing	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	2 (100)	1 (50.0)	0	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0	0	0

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Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (100)	3 (3.8)	9 (11.5)	20 (25.6)	46 (59.0)
Blood and lymphatic system disorders					
-Total	48 (61.5)	2 (2.6)	5 (6.4)	27 (34.6)	14 (17.9)
Febrile neutropenia	26 (33.3)	0	0	24 (30.8)	2 (2.6)
Anaemia	25 (32.1)	7 (9.0)	9 (11.5)	9 (11.5)	0
Neutropenia	11 (14.1)	0	2 (2.6)	2 (2.6)	7 (9.0)
Thrombocytopenia	9 (11.5)	0	0	3 (3.8)	6 (7.7)
Disseminated intravascular coagulation	7 (9.0)	0	5 (6.4)	2 (2.6)	0
Pancytopenia	1 (1.3)	0	0	1 (1.3)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (23.1)	6 (7.7)	6 (7.7)	5 (6.4)	1 (1.3)
Tachycardia	17 (21.8)	7 (9.0)	7 (9.0)	2 (2.6)	1 (1.3)
Left ventricular dysfunction	3 (3.8)	0	0	3 (3.8)	0
Endocrine disorders					
-Total	2 (2.6)	0	2 (2.6)	0	0
Hypothyroidism	2 (2.6)	0	2 (2.6)	0	0
Gastrointestinal disorders					
-Total	55 (70.5)	26 (33.3)	22 (28.2)	7 (9.0)	0
Diarrhoea	25 (32.1)	16 (20.5)	7 (9.0)	2 (2.6)	0
Vomiting	25 (32.1)	16 (20.5)	8 (10.3)	1 (1.3)	0
Nausea	21 (26.9)	11 (14.1)	8 (10.3)	2 (2.6)	0
Constipation	14 (17.9)	7 (9.0)	7 (9.0)	0	0
Abdominal pain	11 (14.1)	2 (2.6)	7 (9.0)	2 (2.6)	0
General disorders and administration site conditions					
-Total	43 (55.1)	20 (25.6)	12 (15.4)	9 (11.5)	2 (2.6)
Pyrexia	34 (43.6)	14 (17.9)	10 (12.8)	8 (10.3)	2 (2.6)
Fatigue	16 (20.5)	14 (17.9)	2 (2.6)	0	0
Face oedema	8 (10.3)	5 (6.4)	2 (2.6)	1 (1.3)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	67 (85.9)	2 (2.6)	25 (32.1)	20 (25.6)	20 (25.6)
Cytokine release syndrome	59 (75.6)	5 (6.4)	18 (23.1)	16 (20.5)	20 (25.6)
Hypogammaglobulinaemia	32 (41.0)	2 (2.6)	23 (29.5)	7 (9.0)	0
Seasonal allergy	3 (3.8)	1 (1.3)	2 (2.6)	0	0
Infections and infestations					
-Total	26 (33.3)	5 (6.4)	15 (19.2)	3 (3.8)	3 (3.8)
Upper respiratory tract infection	12 (15.4)	5 (6.4)	5 (6.4)	2 (2.6)	0
Rhinovirus infection	9 (11.5)	0	7 (9.0)	2 (2.6)	0
Conjunctivitis	8 (10.3)	2 (2.6)	6 (7.7)	0	0
Respiratory syncytial virus infection	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Sepsis	2 (2.6)	0	0	0	2 (2.6)
Encephalitis	1 (1.3)	0	0	0	1 (1.3)
Paronychia	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	49 (62.8)	3 (3.8)	5 (6.4)	16 (20.5)	25 (32.1)
White blood cell count decreased	25 (32.1)	3 (3.8)	4 (5.1)	2 (2.6)	16 (20.5)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	24 (30.8)	1 (1.3)	2 (2.6)	4 (5.1)	17 (21.8)
Platelet count decreased	24 (30.8)	6 (7.7)	3 (3.8)	7 (9.0)	8 (10.3)
Aspartate aminotransferase increased	18 (23.1)	2 (2.6)	6 (7.7)	8 (10.3)	2 (2.6)
Alanine aminotransferase increased	17 (21.8)	3 (3.8)	8 (10.3)	6 (7.7)	0
Lymphocyte count decreased	17 (21.8)	1 (1.3)	1 (1.3)	10 (12.8)	5 (6.4)
Blood bilirubin increased	12 (15.4)	1 (1.3)	3 (3.8)	8 (10.3)	0
International normalised ratio increased	9 (11.5)	6 (7.7)	3 (3.8)	0	0
Serum ferritin increased	8 (10.3)	1 (1.3)	5 (6.4)	2 (2.6)	0
Activated partial thromboplastin time prolonged	5 (6.4)	3 (3.8)	2 (2.6)	0	0
Blood creatinine increased	4 (5.1)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)
Weight decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	47 (60.3)	10 (12.8)	10 (12.8)	22 (28.2)	5 (6.4)
Decreased appetite	29 (37.2)	11 (14.1)	7 (9.0)	10 (12.8)	1 (1.3)
Hypokalaemia	19 (24.4)	3 (3.8)	6 (7.7)	8 (10.3)	2 (2.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	17 (21.8)	3 (3.8)	5 (6.4)	8 (10.3)	1 (1.3)
Hypocalcaemia	15 (19.2)	2 (2.6)	9 (11.5)	4 (5.1)	0
Hypoalbuminaemia	11 (14.1)	0	10 (12.8)	1 (1.3)	0
Hyperglycaemia	9 (11.5)	0	4 (5.1)	5 (6.4)	0
Hyperuricaemia	9 (11.5)	7 (9.0)	1 (1.3)	1 (1.3)	0
Tumour lysis syndrome	4 (5.1)	0	0	3 (3.8)	1 (1.3)
Musculoskeletal and connective tissue disorders					
-Total	35 (44.9)	14 (17.9)	16 (20.5)	5 (6.4)	0
Pain in extremity	17 (21.8)	8 (10.3)	8 (10.3)	1 (1.3)	0
Arthralgia	12 (15.4)	5 (6.4)	6 (7.7)	1 (1.3)	0
Back pain	10 (12.8)	2 (2.6)	5 (6.4)	3 (3.8)	0
Myalgia	10 (12.8)	6 (7.7)	4 (5.1)	0	0
Growth retardation	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorders					
-Total	37 (47.4)	13 (16.7)	12 (15.4)	11 (14.1)	1 (1.3)
Headache	27 (34.6)	13 (16.7)	11 (14.1)	3 (3.8)	0
Encephalopathy	8 (10.3)	1 (1.3)	3 (3.8)	4 (5.1)	0
Seizure	3 (3.8)	0	1 (1.3)	2 (2.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	2 (2.6)	0	1 (1.3)	1 (1.3)	0
Cerebral haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Dysarthria	1 (1.3)	0	0	1 (1.3)	0
Psychiatric disorders					
-Total	21 (26.9)	4 (5.1)	12 (15.4)	5 (6.4)	0
Anxiety	13 (16.7)	3 (3.8)	8 (10.3)	2 (2.6)	0
Delirium	8 (10.3)	2 (2.6)	3 (3.8)	3 (3.8)	0
Sleep disorder	2 (2.6)	0	2 (2.6)	0	0
Renal and urinary disorders					
-Total	12 (15.4)	2 (2.6)	2 (2.6)	3 (3.8)	5 (6.4)
Acute kidney injury	12 (15.4)	2 (2.6)	2 (2.6)	3 (3.8)	5 (6.4)
Respiratory, thoracic and mediastinal disorders					
-Total	46 (59.0)	18 (23.1)	7 (9.0)	13 (16.7)	8 (10.3)
Cough	22 (28.2)	18 (23.1)	4 (5.1)	0	0
Hypoxia	20 (25.6)	0	4 (5.1)	10 (12.8)	6 (7.7)
Pulmonary oedema	12 (15.4)	2 (2.6)	3 (3.8)	6 (7.7)	1 (1.3)
Nasal congestion	9 (11.5)	7 (9.0)	2 (2.6)	0	0
Tachypnoea	9 (11.5)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

			All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	8 (10.3)	7 (9.0)	1 (1.3)	0	0
Pleural effusion	8 (10.3)	4 (5.1)	2 (2.6)	2 (2.6)	0
Rhinorrhoea	5 (6.4)	4 (5.1)	1 (1.3)	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (19.2)	10 (12.8)	5 (6.4)	0	0
Dry skin	8 (10.3)	6 (7.7)	2 (2.6)	0	0
Rash	8 (10.3)	4 (5.1)	4 (5.1)	0	0
Vascular disorders					
-Total	31 (39.7)	4 (5.1)	8 (10.3)	11 (14.1)	8 (10.3)
Hypotension	23 (29.5)	1 (1.3)	6 (7.7)	8 (10.3)	8 (10.3)
Hypertension	16 (20.5)	4 (5.1)	7 (9.0)	5 (6.4)	0
Capillary leak syndrome	1 (1.3)	0	1 (1.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Anal haemorrhage	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0
Blood fibrinogen decreased	1 (100)	1 (100)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Blood uric acid increased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	1 (100)	0	0	0
Decreased appetite	1 (100)	1 (100)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Pain in extremity	1 (100)	1 (100)	0	0	0
Psychiatric disorders					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dry skin	1 (100)	1 (100)	0	0	0
Rash papular	1 (100)	1 (100)	0	0	0
Rash pruritic	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (98.7)	4 (5.1)	8 (10.1)	21 (26.6)	45 (57.0)
Blood and lymphatic system disorders					
-Total	44 (55.7)	1 (1.3)	5 (6.3)	25 (31.6)	13 (16.5)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
Anaemia	20 (25.3)	4 (5.1)	8 (10.1)	8 (10.1)	0
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Disseminated intravascular coagulation	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Cardiac disorders					
-Total	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Gastrointestinal disorders					
-Total	45 (57.0)	21 (26.6)	17 (21.5)	7 (8.9)	0
Vomiting	21 (26.6)	12 (15.2)	8 (10.1)	1 (1.3)	0
Nausea	18 (22.8)	10 (12.7)	6 (7.6)	2 (2.5)	0
Diarrhoea	15 (19.0)	8 (10.1)	6 (7.6)	1 (1.3)	0
Constipation	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Abdominal pain	10 (12.7)	2 (2.5)	6 (7.6)	2 (2.5)	0
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
General disorders and administration site conditions					
-Total	34 (43.0)	18 (22.8)	7 (8.9)	7 (8.9)	2 (2.5)
Pyrexia	24 (30.4)	11 (13.9)	5 (6.3)	6 (7.6)	2 (2.5)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Immune system disorders					
-Total	66 (83.5)	3 (3.8)	21 (26.6)	21 (26.6)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	23 (29.1)	2 (2.5)	14 (17.7)	7 (8.9)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	7 (8.9)	1 (1.3)	6 (7.6)	0	0
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Investigations					
-Total	47 (59.5)	3 (3.8)	4 (5.1)	15 (19.0)	25 (31.6)
White blood cell count decreased	24 (30.4)	3 (3.8)	3 (3.8)	2 (2.5)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Neutrophil count decreased	20 (25.3)	0	3 (3.8)	2 (2.5)	15 (19.0)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	4 (5.1)	8 (10.1)	6 (7.6)	0
Lymphocyte count decreased	15 (19.0)	2 (2.5)	0	8 (10.1)	5 (6.3)
Blood bilirubin increased	12 (15.2)	1 (1.3)	2 (2.5)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Blood fibrinogen decreased	6 (7.6)	1 (1.3)	3 (3.8)	1 (1.3)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin a decreased	4 (5.1)	3 (3.8)	1 (1.3)	0	0
Blood uric acid increased	1 (1.3)	1 (1.3)	0	0	0
Metabolism and nutrition disorders					
-Total	42 (53.2)	7 (8.9)	10 (12.7)	21 (26.6)	4 (5.1)
Decreased appetite	23 (29.1)	8 (10.1)	4 (5.1)	10 (12.7)	1 (1.3)
Hypokalaemia	19 (24.1)	3 (3.8)	5 (6.3)	9 (11.4)	2 (2.5)
Hypophosphataemia	17 (21.5)	3 (3.8)	5 (6.3)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	8 (10.1)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	27 (34.2)	12 (15.2)	13 (16.5)	2 (2.5)	0
Arthralgia	10 (12.7)	4 (5.1)	5 (6.3)	1 (1.3)	0
Pain in extremity	10 (12.7)	5 (6.3)	5 (6.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Back pain	6 (7.6)	2 (2.5)	3 (3.8)	1 (1.3)	0
Nervous system disorders					
-Total	30 (38.0)	13 (16.5)	11 (13.9)	6 (7.6)	0
Headache	23 (29.1)	12 (15.2)	9 (11.4)	2 (2.5)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Psychiatric disorders					
-Total	15 (19.0)	5 (6.3)	5 (6.3)	5 (6.3)	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Anxiety	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Irritability	2 (2.5)	2 (2.5)	0	0	0
Renal and urinary disorders					
-Total	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Acute kidney injury	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders					
-Total	35 (44.3)	12 (15.2)	4 (5.1)	11 (13.9)	8 (10.1)
Hypoxia	17 (21.5)	0	5 (6.3)	6 (7.6)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	9 (11.4)	8 (10.1)	1 (1.3)	0	0
Tachypnoea	8 (10.1)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	7 (8.9)	4 (5.1)	0	2 (2.5)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0	0	0
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Rhinorrhoea	1 (1.3)	1 (1.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (8.9)	3 (3.8)	4 (5.1)	0	0
Rash	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Rash papular	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Vascular disorders					
-Total	27 (34.2)	4 (5.1)	7 (8.9)	10 (12.7)	6 (7.6)
Hypotension	21 (26.6)	1 (1.3)	6 (7.6)	8 (10.1)	6 (7.6)
Hypertension	13 (16.5)	4 (5.1)	5 (6.3)	4 (5.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

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Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Diarrhoea	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0
Proctalgia	1 (100)	1 (100)	0	0	0
Vomiting	1 (100)	1 (100)	0	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Rhinorrhoea	1 (100)	1 (100)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (81.1)	12 (16.2)	21 (28.4)	17 (23.0)	10 (13.5)
Blood and lymphatic system disorders					
-Total	13 (17.6)	3 (4.1)	0	6 (8.1)	4 (5.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	2 (2.7)	2 (2.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Gastrointestinal disorders					
-Total	13 (17.6)	8 (10.8)	5 (6.8)	0	0
Diarrhoea	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Vomiting	5 (6.8)	5 (6.8)	0	0	0
Nausea	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	21 (28.4)	13 (17.6)	6 (8.1)	2 (2.7)	0
Pyrexia	15 (20.3)	7 (9.5)	6 (8.1)	2 (2.7)	0
Fatigue	6 (8.1)	6 (8.1)	0	0	0
Immune system disorders					
-Total	9 (12.2)	0	9 (12.2)	0	0
Hypogammaglobulinaemia	9 (12.2)	0	9 (12.2)	0	0
Infections and infestations					
-Total	12 (16.2)	2 (2.7)	8 (10.8)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	22 (29.7)	5 (6.8)	3 (4.1)	9 (12.2)	5 (6.8)
Neutrophil count decreased	10 (13.5)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.4)
White blood cell count decreased	9 (12.2)	3 (4.1)	2 (2.7)	3 (4.1)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Platelet count decreased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (13.5)	4 (5.4)	3 (4.1)	2 (2.7)	1 (1.4)
Decreased appetite	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (14.9)	4 (5.4)	4 (5.4)	3 (4.1)	0
Back pain	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Headache	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Psychiatric disorders					
-Total	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	16 (21.6)	9 (12.2)	4 (5.4)	3 (4.1)	0
Cough	10 (13.5)	7 (9.5)	3 (4.1)	0	0
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rhinorrhoea	2 (2.7)	2 (2.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (12.2)	7 (9.5)	2 (2.7)	0	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Rash	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Vascular disorders					
-Total	5 (6.8)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (5.4)	1 (1.4)	0	1 (1.4)	2 (2.7)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (46.0)	5 (10.0)	11 (22.0)	3 (6.0)	4 (8.0)
Blood and lymphatic system disorders					
-Total	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	6 (12.0)	4 (8.0)	1 (2.0)	1 (2.0)	0
Diarrhoea	5 (10.0)	3 (6.0)	1 (2.0)	1 (2.0)	0
Constipation	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.0)	1 (2.0)	0	0	0
Vomiting	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	6 (12.0)	2 (4.0)	3 (6.0)	1 (2.0)	0
Pyrexia	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Fatigue	1 (2.0)	0	1 (2.0)	0	0
Immune system disorders					
-Total	3 (6.0)	0	3 (6.0)	0	0
Hypogammaglobulinaemia	3 (6.0)	0	3 (6.0)	0	0
Infections and infestations					
-Total	11 (22.0)	3 (6.0)	6 (12.0)	2 (4.0)	0
Upper respiratory tract infection	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Conjunctivitis	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Rhinovirus infection	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Investigations					
-Total	4 (8.0)	3 (6.0)	0	0	1 (2.0)
Neutrophil count decreased	3 (6.0)	2 (4.0)	0	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (4.0)	2 (4.0)	0	0	0
Blood bilirubin increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	0	0	1 (2.0)
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (6.0)	0	3 (6.0)	0	0
Pain in extremity	2 (4.0)	0	2 (4.0)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Headache	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Psychiatric disorders					
-Total	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Anxiety	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.0)	2 (4.0)	1 (2.0)	1 (2.0)	1 (2.0)
Cough	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Rhinorrhoea	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Hypoxia	1 (2.0)	0	0	1 (2.0)	0
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Tachypnoea	1 (2.0)	0	0	0	1 (2.0)
Skin and subcutaneous tissue disorders					
-Total	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Rash	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hypertension	2 (4.0)	0	1 (2.0)	1 (2.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

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Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Anal haemorrhage	1 (100)	1 (100)	0	0	0
Diarrhoea	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (100)	1 (100)	0	0	0
Vomiting	1 (100)	1 (100)	0	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0
Blood fibrinogen decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Blood uric acid increased	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	1 (100)	0	0	0
Decreased appetite	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Pain in extremity	1 (100)	1 (100)	0	0	0
Psychiatric disorders					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Rhinorrhoea	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dry skin	1 (100)	1 (100)	0	0	0
Rash papular	1 (100)	1 (100)	0	0	0
Rash pruritic	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	3 (3.8)	8 (10.1)	21 (26.6)	47 (59.5)
Blood and lymphatic system disorders					
-Total	49 (62.0)	1 (1.3)	5 (6.3)	29 (36.7)	14 (17.7)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	24 (30.4)	6 (7.6)	9 (11.4)	9 (11.4)	0
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Disseminated intravascular coagulation	8 (10.1)	0	5 (6.3)	3 (3.8)	0
Cardiac disorders					
-Total	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Gastrointestinal disorders					
-Total	55 (69.6)	25 (31.6)	22 (27.8)	8 (10.1)	0
Diarrhoea	25 (31.6)	15 (19.0)	8 (10.1)	2 (2.5)	0
Vomiting	25 (31.6)	16 (20.3)	8 (10.1)	1 (1.3)	0
Nausea	21 (26.6)	11 (13.9)	8 (10.1)	2 (2.5)	0
Constipation	14 (17.7)	7 (8.9)	7 (8.9)	0	0
Abdominal pain	10 (12.7)	1 (1.3)	7 (8.9)	2 (2.5)	0
Proctalgia	1 (1.3)	0	0	1 (1.3)	0
General disorders and administration site conditions					
-Total	44 (55.7)	20 (25.3)	12 (15.2)	10 (12.7)	2 (2.5)
Pyrexia	35 (44.3)	14 (17.7)	10 (12.7)	9 (11.4)	2 (2.5)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Immune system disorders					
-Total	68 (86.1)	2 (2.5)	24 (30.4)	21 (26.6)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	32 (40.5)	2 (2.5)	23 (29.1)	7 (8.9)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	26 (32.9)	6 (7.6)	16 (20.3)	4 (5.1)	0
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Investigations					
-Total	48 (60.8)	2 (2.5)	4 (5.1)	16 (20.3)	26 (32.9)
Neutrophil count decreased	24 (30.4)	1 (1.3)	2 (2.5)	4 (5.1)	17 (21.5)
White blood cell count decreased	24 (30.4)	2 (2.5)	4 (5.1)	2 (2.5)	16 (20.3)
Platelet count decreased	23 (29.1)	5 (6.3)	3 (3.8)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	3 (3.8)	8 (10.1)	7 (8.9)	0
Lymphocyte count decreased	17 (21.5)	1 (1.3)	1 (1.3)	10 (12.7)	5 (6.3)
Blood bilirubin increased	13 (16.5)	1 (1.3)	3 (3.8)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Blood fibrinogen decreased	6 (7.6)	1 (1.3)	3 (3.8)	1 (1.3)	1 (1.3)
Blood immunoglobulin a decreased	6 (7.6)	4 (5.1)	1 (1.3)	1 (1.3)	0
Blood immunoglobulin m decreased	6 (7.6)	3 (3.8)	1 (1.3)	2 (2.5)	0
Blood uric acid increased	3 (3.8)	1 (1.3)	0	1 (1.3)	1 (1.3)
Metabolism and nutrition disorders					
-Total	47 (59.5)	9 (11.4)	11 (13.9)	22 (27.8)	5 (6.3)
Decreased appetite	29 (36.7)	10 (12.7)	7 (8.9)	10 (12.7)	2 (2.5)
Hypokalaemia	20 (25.3)	3 (3.8)	6 (7.6)	9 (11.4)	2 (2.5)
Hypophosphataemia	18 (22.8)	3 (3.8)	6 (7.6)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	9 (11.4)	0	4 (5.1)	5 (6.3)	0
Hyperuricaemia	9 (11.4)	7 (8.9)	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	34 (43.0)	14 (17.7)	15 (19.0)	5 (6.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	16 (20.3)	7 (8.9)	8 (10.1)	1 (1.3)	0
Arthralgia	12 (15.2)	5 (6.3)	6 (7.6)	1 (1.3)	0
Back pain	10 (12.7)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)	0	0
Nervous system disorders					
-Total	34 (43.0)	14 (17.7)	13 (16.5)	7 (8.9)	0
Headache	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Psychiatric disorders					
-Total	22 (27.8)	6 (7.6)	11 (13.9)	5 (6.3)	0
Anxiety	14 (17.7)	3 (3.8)	9 (11.4)	2 (2.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Irritability	2 (2.5)	2 (2.5)	0	0	0
Renal and urinary disorders					
-Total	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Acute kidney injury	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Respiratory, thoracic and mediastinal disorders					
-Total	46 (58.2)	17 (21.5)	7 (8.9)	13 (16.5)	9 (11.4)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	22 (27.8)	17 (21.5)	5 (6.3)	0	0
Hypoxia	20 (25.3)	0	4 (5.1)	10 (12.7)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)	0	0
Pleural effusion	9 (11.4)	4 (5.1)	2 (2.5)	2 (2.5)	1 (1.3)
Tachypnoea	9 (11.4)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)	0	0
Rhinorrhoea	5 (6.3)	3 (3.8)	2 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (19.0)	9 (11.4)	6 (7.6)	0	0
Rash	8 (10.1)	4 (5.1)	4 (5.1)	0	0
Dry skin	7 (8.9)	5 (6.3)	2 (2.5)	0	0
Rash papular	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Vascular disorders					
-Total	32 (40.5)	5 (6.3)	8 (10.1)	11 (13.9)	8 (10.1)
Hypotension	24 (30.4)	2 (2.5)	6 (7.6)	8 (10.1)	8 (10.1)
Hypertension	16 (20.3)	4 (5.1)	7 (8.9)	5 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Constipation	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	1 (100)	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dermatitis atopic	1 (100)	1 (100)	0	0	0
Rash vesicular	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (98.7)	5 (6.3)	8 (10.1)	21 (26.6)	44 (55.7)
Blood and lymphatic system disorders					
-Total	45 (57.0)	2 (2.5)	5 (6.3)	25 (31.6)	13 (16.5)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
Anaemia	21 (26.6)	5 (6.3)	8 (10.1)	8 (10.1)	0
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Disseminated intravascular coagulation	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Cardiac disorders					
-Total	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Gastrointestinal disorders					
-Total	45 (57.0)	22 (27.8)	17 (21.5)	6 (7.6)	0
Vomiting	21 (26.6)	12 (15.2)	8 (10.1)	1 (1.3)	0
Nausea	18 (22.8)	10 (12.7)	6 (7.6)	2 (2.5)	0
Diarrhoea	15 (19.0)	8 (10.1)	6 (7.6)	1 (1.3)	0
Abdominal pain	11 (13.9)	3 (3.8)	6 (7.6)	2 (2.5)	0
Constipation	10 (12.7)	6 (7.6)	4 (5.1)	0	0
General disorders and administration site conditions					
-Total	34 (43.0)	18 (22.8)	7 (8.9)	7 (8.9)	2 (2.5)
Pyrexia	24 (30.4)	11 (13.9)	5 (6.3)	6 (7.6)	2 (2.5)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Immune system disorders					
-Total	65 (82.3)	3 (3.8)	20 (25.3)	21 (26.6)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	22 (27.8)	2 (2.5)	13 (16.5)	7 (8.9)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	7 (8.9)	1 (1.3)	6 (7.6)	0	0
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Investigations					
-Total	46 (58.2)	3 (3.8)	4 (5.1)	15 (19.0)	24 (30.4)
White blood cell count decreased	23 (29.1)	3 (3.8)	3 (3.8)	1 (1.3)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Neutrophil count decreased	19 (24.1)	0	3 (3.8)	2 (2.5)	14 (17.7)
Alanine aminotransferase increased	18 (22.8)	4 (5.1)	8 (10.1)	6 (7.6)	0
Lymphocyte count decreased	14 (17.7)	2 (2.5)	0	7 (8.9)	5 (6.3)
Blood bilirubin increased	12 (15.2)	1 (1.3)	2 (2.5)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	43 (54.4)	8 (10.1)	10 (12.7)	21 (26.6)	4 (5.1)
Decreased appetite	24 (30.4)	9 (11.4)	4 (5.1)	10 (12.7)	1 (1.3)
Hypokalaemia	19 (24.1)	3 (3.8)	5 (6.3)	9 (11.4)	2 (2.5)
Hypophosphataemia	17 (21.5)	3 (3.8)	5 (6.3)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	8 (10.1)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	28 (35.4)	13 (16.5)	13 (16.5)	2 (2.5)	0
Pain in extremity	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Arthralgia	10 (12.7)	4 (5.1)	5 (6.3)	1 (1.3)	0
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Back pain	6 (7.6)	2 (2.5)	3 (3.8)	1 (1.3)	0
Nervous system disorders					
-Total	30 (38.0)	13 (16.5)	11 (13.9)	6 (7.6)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	23 (29.1)	12 (15.2)	9 (11.4)	2 (2.5)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Psychiatric disorders					
-Total	13 (16.5)	3 (3.8)	5 (6.3)	5 (6.3)	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Anxiety	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Renal and urinary disorders					
-Total	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Acute kidney injury	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders					
-Total	36 (45.6)	13 (16.5)	4 (5.1)	11 (13.9)	8 (10.1)
Hypoxia	17 (21.5)	0	5 (6.3)	6 (7.6)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Cough	10 (12.7)	9 (11.4)	1 (1.3)	0	0
Tachypnoea	8 (10.1)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	7 (8.9)	4 (5.1)	0	2 (2.5)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (8.9)	4 (5.1)	3 (3.8)	0	0
Rash	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Dermatitis atopic	1 (1.3)	1 (1.3)	0	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	27 (34.2)	4 (5.1)	7 (8.9)	10 (12.7)	6 (7.6)
Hypotension	21 (26.6)	1 (1.3)	6 (7.6)	8 (10.1)	6 (7.6)
Hypertension	13 (16.5)	4 (5.1)	5 (6.3)	4 (5.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

			All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Cystitis	1 (100)	0	1 (100)	0	0
Nasopharyngitis	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	0	0	1 (100)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dermatitis atopic	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (81.1)	12 (16.2)	23 (31.1)	16 (21.6)	9 (12.2)
Blood and lymphatic system disorders					
-Total	14 (18.9)	4 (5.4)	0	6 (8.1)	4 (5.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Lymphadenopathy	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.7)	2 (2.7)	0	0	0
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Gastrointestinal disorders					
-Total	14 (18.9)	9 (12.2)	5 (6.8)	0	0
Diarrhoea	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Vomiting	6 (8.1)	6 (8.1)	0	0	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	21 (28.4)	13 (17.6)	6 (8.1)	2 (2.7)	0
Pyrexia	15 (20.3)	7 (9.5)	6 (8.1)	2 (2.7)	0
Fatigue	6 (8.1)	6 (8.1)	0	0	0
Immune system disorders					
-Total	10 (13.5)	0	10 (13.5)	0	0
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)	0	0
Infections and infestations					
-Total	19 (25.7)	6 (8.1)	9 (12.2)	4 (5.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Gastroenteritis	5 (6.8)	3 (4.1)	0	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	19 (25.7)	6 (8.1)	3 (4.1)	7 (9.5)	3 (4.1)
Neutrophil count decreased	9 (12.2)	2 (2.7)	1 (1.4)	3 (4.1)	3 (4.1)
White blood cell count decreased	9 (12.2)	4 (5.4)	2 (2.7)	2 (2.7)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Platelet count decreased	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	10 (13.5)	4 (5.4)	3 (4.1)	2 (2.7)	1 (1.4)
Decreased appetite	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (14.9)	4 (5.4)	4 (5.4)	3 (4.1)	0
Back pain	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Headache	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Psychiatric disorders					
-Total	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	15 (20.3)	8 (10.8)	4 (5.4)	3 (4.1)	0
Cough	10 (13.5)	7 (9.5)	3 (4.1)	0	0
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (12.2)	7 (9.5)	2 (2.7)	0	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Rash	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Vascular disorders					
-Total	5 (6.8)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.7)
Hypotension	4 (5.4)	1 (1.4)	0	1 (1.4)	2 (2.7)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	1 (100)	0	0
Lymphadenopathy	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Bronchitis	1 (100)	0	1 (100)	0	0
Gastroenteritis	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (100)	1 (100)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (46.9)	4 (8.2)	11 (22.4)	4 (8.2)	4 (8.2)
Blood and lymphatic system disorders					
-Total	2 (4.1)	0	1 (2.0)	0	1 (2.0)
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	6 (12.2)	4 (8.2)	1 (2.0)	1 (2.0)	0
Diarrhoea	5 (10.2)	3 (6.1)	1 (2.0)	1 (2.0)	0
Constipation	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.0)	1 (2.0)	0	0	0
Vomiting	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	6 (12.2)	2 (4.1)	3 (6.1)	1 (2.0)	0
Pyrexia	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Fatigue	1 (2.0)	0	1 (2.0)	0	0
Immune system disorders					
-Total	3 (6.1)	0	3 (6.1)	0	0
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)	0	0
Infections and infestations					
-Total	11 (22.4)	3 (6.1)	6 (12.2)	2 (4.1)	0
Upper respiratory tract infection	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)	0	0
Rhinovirus infection	4 (8.2)	0	3 (6.1)	1 (2.0)	0
Bronchitis	1 (2.0)	0	1 (2.0)	0	0
Investigations					
-Total	3 (6.1)	2 (4.1)	0	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (6.1)	2 (4.1)	0	0	1 (2.0)
Blood bilirubin increased	1 (2.0)	1 (2.0)	0	0	0
Platelet count decreased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (4.1)	0	0	1 (2.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	0	0	1 (2.0)
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (6.1)	0	3 (6.1)	0	0
Pain in extremity	2 (4.1)	0	2 (4.1)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Headache	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Psychiatric disorders					
-Total	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Anxiety	2 (4.1)	1 (2.0)	1 (2.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	5 (10.2)	2 (4.1)	1 (2.0)	1 (2.0)	1 (2.0)
Cough	4 (8.2)	3 (6.1)	1 (2.0)	0	0
Hypoxia	1 (2.0)	0	0	1 (2.0)	0
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Tachypnoea	1 (2.0)	0	0	0	1 (2.0)
Skin and subcutaneous tissue disorders					
-Total	4 (8.2)	2 (4.1)	1 (2.0)	1 (2.0)	0
Rash	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Dermatitis atopic	1 (2.0)	0	0	1 (2.0)	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Hypertension	2 (4.1)	0	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Blood and lymphatic system disorders					
-Total	1 (100)	0	1 (100)	0	0
Lymphadenopathy	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Constipation	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Bronchitis	1 (100)	0	1 (100)	0	0
Cystitis	1 (100)	0	1 (100)	0	0
Gastroenteritis	1 (100)	1 (100)	0	0	0
Nasopharyngitis	1 (100)	1 (100)	0	0	0
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	1 (100)	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	0	0	1 (100)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis atopic	1 (100)	1 (100)	0	0	0
Rash vesicular	1 (100)	1 (100)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	3 (3.8)	9 (11.4)	21 (26.6)	46 (58.2)
Blood and lymphatic system disorders					
-Total	50 (63.3)	2 (2.5)	5 (6.3)	29 (36.7)	14 (17.7)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	25 (31.6)	7 (8.9)	9 (11.4)	9 (11.4)	0
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Disseminated intravascular coagulation	8 (10.1)	0	5 (6.3)	3 (3.8)	0
Lymphadenopathy	1 (1.3)	1 (1.3)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Gastrointestinal disorders					
-Total	55 (69.6)	26 (32.9)	22 (27.8)	7 (8.9)	0
Diarrhoea	26 (32.9)	16 (20.3)	8 (10.1)	2 (2.5)	0
Vomiting	26 (32.9)	17 (21.5)	8 (10.1)	1 (1.3)	0
Nausea	22 (27.8)	12 (15.2)	8 (10.1)	2 (2.5)	0
Constipation	13 (16.5)	7 (8.9)	6 (7.6)	0	0
Abdominal pain	11 (13.9)	2 (2.5)	7 (8.9)	2 (2.5)	0
General disorders and administration site conditions					
-Total	44 (55.7)	20 (25.3)	12 (15.2)	10 (12.7)	2 (2.5)
Pyrexia	35 (44.3)	14 (17.7)	10 (12.7)	9 (11.4)	2 (2.5)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Immune system disorders					
-Total	68 (86.1)	2 (2.5)	24 (30.4)	21 (26.6)	21 (26.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	32 (40.5)	2 (2.5)	23 (29.1)	7 (8.9)	0
Infections and infestations					
-Total	29 (36.7)	7 (8.9)	16 (20.3)	6 (7.6)	0
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Nasopharyngitis	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Gastroenteritis	5 (6.3)	3 (3.8)	0	2 (2.5)	0
Bronchitis	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	47 (59.5)	3 (3.8)	4 (5.1)	16 (20.3)	24 (30.4)
White blood cell count decreased	24 (30.4)	3 (3.8)	4 (5.1)	1 (1.3)	16 (20.3)
Neutrophil count decreased	23 (29.1)	1 (1.3)	2 (2.5)	4 (5.1)	16 (20.3)
Platelet count decreased	23 (29.1)	5 (6.3)	3 (3.8)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	18 (22.8)	3 (3.8)	8 (10.1)	7 (8.9)	0
Lymphocyte count decreased	16 (20.3)	1 (1.3)	1 (1.3)	9 (11.4)	5 (6.3)
Blood bilirubin increased	13 (16.5)	1 (1.3)	3 (3.8)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Metabolism and nutrition disorders					
-Total	48 (60.8)	10 (12.7)	11 (13.9)	22 (27.8)	5 (6.3)
Decreased appetite	30 (38.0)	11 (13.9)	7 (8.9)	10 (12.7)	2 (2.5)
Hypokalaemia	20 (25.3)	3 (3.8)	6 (7.6)	9 (11.4)	2 (2.5)
Hypophosphataemia	18 (22.8)	3 (3.8)	6 (7.6)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	9 (11.4)	0	4 (5.1)	5 (6.3)	0
Hyperuricaemia	9 (11.4)	7 (8.9)	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	35 (44.3)	15 (19.0)	15 (19.0)	5 (6.3)	0
Pain in extremity	17 (21.5)	8 (10.1)	8 (10.1)	1 (1.3)	0
Arthralgia	12 (15.2)	5 (6.3)	6 (7.6)	1 (1.3)	0
Back pain	10 (12.7)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)	0	0
Nervous system disorders					
-Total	34 (43.0)	14 (17.7)	13 (16.5)	7 (8.9)	0
Headache	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Psychiatric disorders					
-Total	20 (25.3)	4 (5.1)	11 (13.9)	5 (6.3)	0
Anxiety	14 (17.7)	3 (3.8)	9 (11.4)	2 (2.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Renal and urinary disorders					
-Total	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Acute kidney injury	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	46 (58.2)	17 (21.5)	7 (8.9)	13 (16.5)	9 (11.4)
Cough	22 (27.8)	17 (21.5)	5 (6.3)	0	0
Hypoxia	20 (25.3)	0	4 (5.1)	10 (12.7)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)	0	0
Pleural effusion	9 (11.4)	4 (5.1)	2 (2.5)	2 (2.5)	1 (1.3)
Tachypnoea	9 (11.4)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (20.3)	11 (13.9)	4 (5.1)	1 (1.3)	0
Dry skin	8 (10.1)	6 (7.6)	2 (2.5)	0	0
Rash	8 (10.1)	4 (5.1)	4 (5.1)	0	0
Dermatitis atopic	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Vascular disorders					
-Total	32 (40.5)	5 (6.3)	8 (10.1)	11 (13.9)	8 (10.1)
Hypotension	24 (30.4)	2 (2.5)	6 (7.6)	8 (10.1)	8 (10.1)
Hypertension	16 (20.3)	4 (5.1)	7 (8.9)	5 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
General disorders and administration site conditions					
-Total	1 (100)	1 (100)	0	0	0
Pyrexia	1 (100)	1 (100)	0	0	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Gamma-glutamyltransferase increased	1 (100)	0	0	1 (100)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	78 (98.7)	4 (5.1)	8 (10.1)	21 (26.6)	45 (57.0)
Blood and lymphatic system disorders					
-Total	45 (57.0)	2 (2.5)	5 (6.3)	25 (31.6)	13 (16.5)
Febrile neutropenia	26 (32.9)	0	0	24 (30.4)	2 (2.5)
Anaemia	21 (26.6)	5 (6.3)	8 (10.1)	8 (10.1)	0
Neutropenia	9 (11.4)	0	2 (2.5)	1 (1.3)	6 (7.6)
Thrombocytopenia	8 (10.1)	0	0	2 (2.5)	6 (7.6)
Disseminated intravascular coagulation	7 (8.9)	0	5 (6.3)	2 (2.5)	0
Cardiac disorders					
-Total	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Gastrointestinal disorders					
-Total	46 (58.2)	22 (27.8)	18 (22.8)	6 (7.6)	0
Vomiting	21 (26.6)	12 (15.2)	8 (10.1)	1 (1.3)	0
Nausea	18 (22.8)	10 (12.7)	6 (7.6)	2 (2.5)	0
Diarrhoea	15 (19.0)	8 (10.1)	6 (7.6)	1 (1.3)	0
Abdominal pain	11 (13.9)	3 (3.8)	6 (7.6)	2 (2.5)	0
Constipation	11 (13.9)	6 (7.6)	5 (6.3)	0	0
General disorders and administration site conditions					
-Total	33 (41.8)	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)
Pyrexia	23 (29.1)	10 (12.7)	5 (6.3)	6 (7.6)	2 (2.5)
Fatigue	11 (13.9)	9 (11.4)	2 (2.5)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Immune system disorders					
-Total	66 (83.5)	3 (3.8)	21 (26.6)	21 (26.6)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	23 (29.1)	2 (2.5)	14 (17.7)	7 (8.9)	0
Infections and infestations					

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (13.9)	1 (1.3)	8 (10.1)	2 (2.5)	0
Conjunctivitis	5 (6.3)	1 (1.3)	4 (5.1)	0	0
Staphylococcal infection	4 (5.1)	0	2 (2.5)	2 (2.5)	0
Rhinovirus infection	2 (2.5)	0	2 (2.5)	0	0
Investigations					
-Total	47 (59.5)	3 (3.8)	3 (3.8)	16 (20.3)	25 (31.6)
White blood cell count decreased	24 (30.4)	3 (3.8)	3 (3.8)	2 (2.5)	16 (20.3)
Platelet count decreased	21 (26.6)	4 (5.1)	3 (3.8)	6 (7.6)	8 (10.1)
Neutrophil count decreased	20 (25.3)	0	3 (3.8)	2 (2.5)	15 (19.0)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	4 (5.1)	8 (10.1)	6 (7.6)	0
Lymphocyte count decreased	15 (19.0)	2 (2.5)	0	8 (10.1)	5 (6.3)
Blood bilirubin increased	12 (15.2)	1 (1.3)	2 (2.5)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gamma-glutamyltransferase increased	1 (1.3)	0	0	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	43 (54.4)	8 (10.1)	10 (12.7)	21 (26.6)	4 (5.1)
Decreased appetite	24 (30.4)	9 (11.4)	4 (5.1)	10 (12.7)	1 (1.3)
Hypokalaemia	19 (24.1)	3 (3.8)	5 (6.3)	9 (11.4)	2 (2.5)
Hypophosphataemia	17 (21.5)	3 (3.8)	5 (6.3)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	8 (10.1)	0	4 (5.1)	4 (5.1)	0
Hyperuricaemia	7 (8.9)	5 (6.3)	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	28 (35.4)	13 (16.5)	13 (16.5)	2 (2.5)	0
Pain in extremity	11 (13.9)	6 (7.6)	5 (6.3)	0	0
Arthralgia	10 (12.7)	4 (5.1)	5 (6.3)	1 (1.3)	0
Myalgia	9 (11.4)	6 (7.6)	3 (3.8)	0	0
Back pain	6 (7.6)	2 (2.5)	3 (3.8)	1 (1.3)	0
Nervous system disorders					

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	30 (38.0)	13 (16.5)	11 (13.9)	6 (7.6)	0
Headache	23 (29.1)	12 (15.2)	9 (11.4)	2 (2.5)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Psychiatric disorders					
-Total	13 (16.5)	3 (3.8)	5 (6.3)	5 (6.3)	0
Delirium	7 (8.9)	2 (2.5)	2 (2.5)	3 (3.8)	0
Anxiety	6 (7.6)	1 (1.3)	3 (3.8)	2 (2.5)	0
Renal and urinary disorders					
-Total	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Acute kidney injury	9 (11.4)	1 (1.3)	1 (1.3)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders					
-Total	36 (45.6)	13 (16.5)	4 (5.1)	11 (13.9)	8 (10.1)
Hypoxia	17 (21.5)	0	5 (6.3)	6 (7.6)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Cough	10 (12.7)	9 (11.4)	1 (1.3)	0	0
Tachypnoea	8 (10.1)	3 (3.8)	1 (1.3)	4 (5.1)	0
Pleural effusion	7 (8.9)	4 (5.1)	0	2 (2.5)	1 (1.3)
Oropharyngeal pain	5 (6.3)	5 (6.3)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasal congestion	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (7.6)	3 (3.8)	3 (3.8)	0	0
Rash	5 (6.3)	2 (2.5)	3 (3.8)	0	0
Dry skin	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	27 (34.2)	4 (5.1)	7 (8.9)	10 (12.7)	6 (7.6)
Hypotension	21 (26.6)	1 (1.3)	6 (7.6)	8 (10.1)	6 (7.6)
Hypertension	13 (16.5)	4 (5.1)	5 (6.3)	4 (5.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Photosensitivity reaction	1 (100)	0	1 (100)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (82.4)	13 (17.6)	23 (31.1)	15 (20.3)	10 (13.5)
Blood and lymphatic system disorders					
-Total	13 (17.6)	3 (4.1)	0	6 (8.1)	4 (5.4)
Anaemia	6 (8.1)	4 (5.4)	0	2 (2.7)	0
Neutropenia	5 (6.8)	0	0	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	0	0	3 (4.1)	0
Thrombocytopenia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	2 (2.7)	2 (2.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.7)	2 (2.7)	0	0	0
Gastrointestinal disorders					
-Total	14 (18.9)	9 (12.2)	5 (6.8)	0	0
Diarrhoea	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Vomiting	6 (8.1)	6 (8.1)	0	0	0
Nausea	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Constipation	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Abdominal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	21 (28.4)	13 (17.6)	6 (8.1)	2 (2.7)	0
Pyrexia	15 (20.3)	7 (9.5)	6 (8.1)	2 (2.7)	0
Fatigue	6 (8.1)	6 (8.1)	0	0	0
Immune system disorders					
-Total	10 (13.5)	0	10 (13.5)	0	0
Hypogammaglobulinaemia	10 (13.5)	0	10 (13.5)	0	0
Infections and infestations					
-Total	12 (16.2)	2 (2.7)	8 (10.8)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	8 (10.8)	3 (4.1)	3 (4.1)	2 (2.7)	0
Rhinovirus infection	5 (6.8)	0	4 (5.4)	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	20 (27.0)	6 (8.1)	3 (4.1)	7 (9.5)	4 (5.4)
Neutrophil count decreased	10 (13.5)	2 (2.7)	1 (1.4)	3 (4.1)	4 (5.4)
White blood cell count decreased	10 (13.5)	4 (5.4)	2 (2.7)	3 (4.1)	1 (1.4)
Platelet count decreased	5 (6.8)	3 (4.1)	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	4 (5.4)	1 (1.4)	1 (1.4)	2 (2.7)	0
Alanine aminotransferase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood bilirubin increased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	10 (13.5)	4 (5.4)	3 (4.1)	2 (2.7)	1 (1.4)
Decreased appetite	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Hyperuricaemia	3 (4.1)	3 (4.1)	0	0	0
Hypokalaemia	3 (4.1)	0	1 (1.4)	1 (1.4)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (14.9)	4 (5.4)	4 (5.4)	3 (4.1)	0
Back pain	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0
Pain in extremity	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Arthralgia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Headache	10 (13.5)	6 (8.1)	4 (5.4)	0	0
Psychiatric disorders					
-Total	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Anxiety	6 (8.1)	1 (1.4)	5 (6.8)	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Acute kidney injury	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	16 (21.6)	9 (12.2)	4 (5.4)	3 (4.1)	0
Cough	11 (14.9)	8 (10.8)	3 (4.1)	0	0
Nasal congestion	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Hypoxia	3 (4.1)	0	0	3 (4.1)	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (12.2)	7 (9.5)	2 (2.7)	0	0
Dry skin	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Rash	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Vascular disorders					
-Total	5 (6.8)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.7)
Hypotension	4 (5.4)	1 (1.4)	0	1 (1.4)	2 (2.7)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (46.9)	5 (10.2)	11 (22.4)	3 (6.1)	4 (8.2)
Blood and lymphatic system disorders					
-Total	2 (4.1)	0	1 (2.0)	0	1 (2.0)
Anaemia	1 (2.0)	0	1 (2.0)	0	0
Neutropenia	1 (2.0)	0	0	0	1 (2.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	6 (12.2)	4 (8.2)	1 (2.0)	1 (2.0)	0
Diarrhoea	5 (10.2)	3 (6.1)	1 (2.0)	1 (2.0)	0
Constipation	1 (2.0)	1 (2.0)	0	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.0)	1 (2.0)	0	0	0
Vomiting	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	6 (12.2)	2 (4.1)	3 (6.1)	1 (2.0)	0
Pyrexia	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Fatigue	1 (2.0)	0	1 (2.0)	0	0
Immune system disorders					
-Total	3 (6.1)	0	3 (6.1)	0	0
Hypogammaglobulinaemia	3 (6.1)	0	3 (6.1)	0	0
Infections and infestations					
-Total	11 (22.4)	3 (6.1)	6 (12.2)	2 (4.1)	0
Upper respiratory tract infection	5 (10.2)	2 (4.1)	2 (4.1)	1 (2.0)	0
Conjunctivitis	4 (8.2)	2 (4.1)	2 (4.1)	0	0
Rhinovirus infection	4 (8.2)	0	3 (6.1)	1 (2.0)	0
Investigations					
-Total	4 (8.2)	3 (6.1)	0	0	1 (2.0)
Neutrophil count decreased	3 (6.1)	2 (4.1)	0	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (4.1)	2 (4.1)	0	0	0
Blood bilirubin increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (4.1)	0	0	1 (2.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	0	0	1 (2.0)
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (6.1)	0	3 (6.1)	0	0
Pain in extremity	2 (4.1)	0	2 (4.1)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Headache	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Psychiatric disorders					
-Total	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Anxiety	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.2)	2 (4.1)	1 (2.0)	1 (2.0)	1 (2.0)
Cough	4 (8.2)	3 (6.1)	1 (2.0)	0	0
Hypoxia	1 (2.0)	0	0	1 (2.0)	0
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	1 (2.0)	0	0
Tachypnoea	1 (2.0)	0	0	0	1 (2.0)
Skin and subcutaneous tissue disorders					
-Total	3 (6.1)	2 (4.1)	1 (2.0)	0	0
Rash	2 (4.1)	1 (2.0)	1 (2.0)	0	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (4.1)	0	1 (2.0)	1 (2.0)	0
Hypertension	2 (4.1)	0	1 (2.0)	1 (2.0)	0

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Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
General disorders and administration site conditions					
-Total	1 (100)	1 (100)	0	0	0
Pyrexia	1 (100)	1 (100)	0	0	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Gamma-glutamyltransferase increased	1 (100)	0	0	1 (100)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Photosensitivity reaction	1 (100)	0	1 (100)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 214i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	79 (100)	2 (2.5)	9 (11.4)	21 (26.6)	47 (59.5)
Blood and lymphatic system disorders					
-Total	50 (63.3)	2 (2.5)	5 (6.3)	29 (36.7)	14 (17.7)
Febrile neutropenia	27 (34.2)	0	0	25 (31.6)	2 (2.5)
Anaemia	25 (31.6)	7 (8.9)	9 (11.4)	9 (11.4)	0
Neutropenia	11 (13.9)	0	2 (2.5)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	0	0	3 (3.8)	6 (7.6)
Disseminated intravascular coagulation	8 (10.1)	0	5 (6.3)	3 (3.8)	0
Cardiac disorders					
-Total	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (21.5)	7 (8.9)	7 (8.9)	2 (2.5)	1 (1.3)
Gastrointestinal disorders					
-Total	56 (70.9)	26 (32.9)	23 (29.1)	7 (8.9)	0
Diarrhoea	26 (32.9)	16 (20.3)	8 (10.1)	2 (2.5)	0
Vomiting	26 (32.9)	17 (21.5)	8 (10.1)	1 (1.3)	0
Nausea	22 (27.8)	12 (15.2)	8 (10.1)	2 (2.5)	0
Constipation	14 (17.7)	7 (8.9)	7 (8.9)	0	0
Abdominal pain	11 (13.9)	2 (2.5)	7 (8.9)	2 (2.5)	0
General disorders and administration site conditions					
-Total	43 (54.4)	19 (24.1)	12 (15.2)	10 (12.7)	2 (2.5)
Pyrexia	34 (43.0)	13 (16.5)	10 (12.7)	9 (11.4)	2 (2.5)
Fatigue	17 (21.5)	14 (17.7)	3 (3.8)	0	0
Face oedema	8 (10.1)	5 (6.3)	2 (2.5)	1 (1.3)	0
Immune system disorders					
-Total	69 (87.3)	2 (2.5)	25 (31.6)	21 (26.6)	21 (26.6)
Cytokine release syndrome	61 (77.2)	5 (6.3)	18 (22.8)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	33 (41.8)	2 (2.5)	24 (30.4)	7 (8.9)	0
Infections and infestations					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (36.7)	6 (7.6)	17 (21.5)	6 (7.6)	0
Upper respiratory tract infection	13 (16.5)	5 (6.3)	5 (6.3)	3 (3.8)	0
Rhinovirus infection	9 (11.4)	0	7 (8.9)	2 (2.5)	0
Conjunctivitis	8 (10.1)	2 (2.5)	6 (7.6)	0	0
Staphylococcal infection	4 (5.1)	0	2 (2.5)	2 (2.5)	0
Investigations					
-Total	48 (60.8)	3 (3.8)	3 (3.8)	17 (21.5)	25 (31.6)
White blood cell count decreased	25 (31.6)	3 (3.8)	4 (5.1)	2 (2.5)	16 (20.3)
Neutrophil count decreased	24 (30.4)	1 (1.3)	2 (2.5)	4 (5.1)	17 (21.5)
Platelet count decreased	24 (30.4)	6 (7.6)	3 (3.8)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	19 (24.1)	2 (2.5)	6 (7.6)	8 (10.1)	3 (3.8)
Alanine aminotransferase increased	18 (22.8)	3 (3.8)	8 (10.1)	7 (8.9)	0
Lymphocyte count decreased	17 (21.5)	1 (1.3)	1 (1.3)	10 (12.7)	5 (6.3)
Blood bilirubin increased	13 (16.5)	1 (1.3)	3 (3.8)	9 (11.4)	0
International normalised ratio increased	9 (11.4)	6 (7.6)	3 (3.8)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	8 (10.1)	1 (1.3)	5 (6.3)	2 (2.5)	0
Gamma-glutamyltransferase increased	1 (1.3)	0	0	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	48 (60.8)	10 (12.7)	11 (13.9)	22 (27.8)	5 (6.3)
Decreased appetite	30 (38.0)	11 (13.9)	7 (8.9)	10 (12.7)	2 (2.5)
Hypokalaemia	20 (25.3)	3 (3.8)	6 (7.6)	9 (11.4)	2 (2.5)
Hypophosphataemia	18 (22.8)	3 (3.8)	6 (7.6)	8 (10.1)	1 (1.3)
Hypocalcaemia	16 (20.3)	2 (2.5)	9 (11.4)	5 (6.3)	0
Hypoalbuminaemia	11 (13.9)	0	10 (12.7)	1 (1.3)	0
Hyperglycaemia	9 (11.4)	0	4 (5.1)	5 (6.3)	0
Hyperuricaemia	9 (11.4)	7 (8.9)	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders					
-Total	35 (44.3)	15 (19.0)	15 (19.0)	5 (6.3)	0
Pain in extremity	17 (21.5)	8 (10.1)	8 (10.1)	1 (1.3)	0
Arthralgia	12 (15.2)	5 (6.3)	6 (7.6)	1 (1.3)	0
Back pain	10 (12.7)	2 (2.5)	5 (6.3)	3 (3.8)	0
Myalgia	10 (12.7)	6 (7.6)	4 (5.1)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	34 (43.0)	14 (17.7)	13 (16.5)	7 (8.9)	0
Headache	27 (34.2)	13 (16.5)	11 (13.9)	3 (3.8)	0
Encephalopathy	8 (10.1)	1 (1.3)	3 (3.8)	4 (5.1)	0
Psychiatric disorders					
-Total	20 (25.3)	4 (5.1)	11 (13.9)	5 (6.3)	0
Anxiety	14 (17.7)	3 (3.8)	9 (11.4)	2 (2.5)	0
Delirium	8 (10.1)	2 (2.5)	3 (3.8)	3 (3.8)	0
Renal and urinary disorders					
-Total	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Acute kidney injury	12 (15.2)	2 (2.5)	2 (2.5)	3 (3.8)	5 (6.3)
Respiratory, thoracic and mediastinal disorders					
-Total	47 (59.5)	18 (22.8)	7 (8.9)	13 (16.5)	9 (11.4)
Cough	23 (29.1)	18 (22.8)	5 (6.3)	0	0
Hypoxia	20 (25.3)	0	4 (5.1)	10 (12.7)	6 (7.6)
Pulmonary oedema	12 (15.2)	2 (2.5)	3 (3.8)	6 (7.6)	1 (1.3)
Nasal congestion	9 (11.4)	7 (8.9)	2 (2.5)	0	0
Pleural effusion	9 (11.4)	4 (5.1)	2 (2.5)	2 (2.5)	1 (1.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	9 (11.4)	3 (3.8)	1 (1.3)	4 (5.1)	1 (1.3)
Oropharyngeal pain	8 (10.1)	7 (8.9)	1 (1.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (19.0)	10 (12.7)	5 (6.3)	0	0
Dry skin	8 (10.1)	6 (7.6)	2 (2.5)	0	0
Rash	8 (10.1)	4 (5.1)	4 (5.1)	0	0
Vascular disorders					
-Total	32 (40.5)	5 (6.3)	8 (10.1)	11 (13.9)	8 (10.1)
Hypotension	24 (30.4)	2 (2.5)	6 (7.6)	8 (10.1)	8 (10.1)
Hypertension	16 (20.3)	4 (5.1)	7 (8.9)	5 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (96.3)	2 (7.4)	4 (14.8)	7 (25.9)	13 (48.1)
Blood and lymphatic system disorders					
-Total	11 (40.7)	1 (3.7)	3 (11.1)	3 (11.1)	4 (14.8)
Anaemia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Disseminated intravascular coagulation	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Febrile neutropenia	3 (11.1)	0	0	3 (11.1)	0
Neutropenia	3 (11.1)	0	1 (3.7)	0	2 (7.4)
Thrombocytopenia	2 (7.4)	0	0	0	2 (7.4)
Cardiac disorders					
-Total	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
Eye disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Eyelid oedema	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Gastrointestinal disorders					
-Total	19 (70.4)	10 (37.0)	7 (25.9)	2 (7.4)	0
Vomiting	7 (25.9)	6 (22.2)	1 (3.7)	0	0
Diarrhoea	6 (22.2)	3 (11.1)	2 (7.4)	1 (3.7)	0
Abdominal pain	5 (18.5)	1 (3.7)	4 (14.8)	0	0
Nausea	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Abdominal pain upper	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Pancreatitis	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Constipation	2 (7.4)	2 (7.4)	0	0	0
General disorders and administration site conditions					
-Total	10 (37.0)	7 (25.9)	2 (7.4)	0	1 (3.7)
Pyrexia	6 (22.2)	4 (14.8)	1 (3.7)	0	1 (3.7)
Fatigue	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Face oedema	3 (11.1)	2 (7.4)	1 (3.7)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	2 (7.4)	2 (7.4)	0	0	0
Hepatobiliary disorders					
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hepatic function abnormal	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Immune system disorders					
-Total	21 (77.8)	0	3 (11.1)	9 (33.3)	9 (33.3)
Cytokine release syndrome	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Hypogammaglobulinaemia	7 (25.9)	1 (3.7)	3 (11.1)	3 (11.1)	0
Haemophagocytic lymphohistiocytosis	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Infections and infestations					
-Total	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Conjunctivitis	2 (7.4)	0	2 (7.4)	0	0
Nail infection	1 (3.7)	1 (3.7)	0	0	0
Investigations					
-Total	15 (55.6)	2 (7.4)	1 (3.7)	4 (14.8)	8 (29.6)
Neutrophil count decreased	7 (25.9)	0	1 (3.7)	0	6 (22.2)
White blood cell count decreased	7 (25.9)	0	1 (3.7)	1 (3.7)	5 (18.5)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (22.2)	1 (3.7)	2 (7.4)	3 (11.1)	0
Lymphocyte count decreased	6 (22.2)	2 (7.4)	0	2 (7.4)	2 (7.4)
Aspartate aminotransferase increased	5 (18.5)	0	4 (14.8)	1 (3.7)	0
Blood fibrinogen decreased	5 (18.5)	1 (3.7)	3 (11.1)	0	1 (3.7)
Platelet count decreased	5 (18.5)	1 (3.7)	1 (3.7)	1 (3.7)	2 (7.4)
Blood bilirubin increased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Serum ferritin increased	4 (14.8)	0	4 (14.8)	0	0
Electrocardiogram qt prolonged	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Blood immunoglobulin m decreased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
International normalised ratio increased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Blood uric acid increased	1 (3.7)	1 (3.7)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (63.0)	4 (14.8)	2 (7.4)	9 (33.3)	2 (7.4)
Hypokalaemia	9 (33.3)	1 (3.7)	2 (7.4)	5 (18.5)	1 (3.7)
Decreased appetite	7 (25.9)	4 (14.8)	0	3 (11.1)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	7 (25.9)	2 (7.4)	2 (7.4)	2 (7.4)	1 (3.7)
Hypocalcaemia	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Hypoalbuminaemia	3 (11.1)	0	3 (11.1)	0	0
Tumour lysis syndrome	2 (7.4)	0	0	2 (7.4)	0
Hyperuricaemia	1 (3.7)	0	1 (3.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (37.0)	5 (18.5)	5 (18.5)	0	0
Pain in extremity	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Arthralgia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Myalgia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Back pain	1 (3.7)	0	1 (3.7)	0	0
Nervous system disorders					
-Total	9 (33.3)	4 (14.8)	3 (11.1)	2 (7.4)	0
Headache	7 (25.9)	3 (11.1)	4 (14.8)	0	0
Encephalopathy	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Tremor	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Psychiatric disorders					
-Total	7 (25.9)	4 (14.8)	1 (3.7)	2 (7.4)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Insomnia	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Anxiety	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Mental status changes	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Renal and urinary disorders					
-Total	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Acute kidney injury	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Respiratory, thoracic and mediastinal disorders					
-Total	13 (48.1)	4 (14.8)	1 (3.7)	4 (14.8)	4 (14.8)
Hypoxia	8 (29.6)	0	2 (7.4)	2 (7.4)	4 (14.8)
Pleural effusion	4 (14.8)	3 (11.1)	0	1 (3.7)	0
Pulmonary oedema	4 (14.8)	2 (7.4)	1 (3.7)	1 (3.7)	0
Cough	3 (11.1)	3 (11.1)	0	0	0
Tachypnoea	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Oropharyngeal pain	2 (7.4)	2 (7.4)	0	0	0
Epistaxis	1 (3.7)	0	1 (3.7)	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Rash	2 (7.4)	0	2 (7.4)	0	0
Dry skin	1 (3.7)	1 (3.7)	0	0	0
Vascular disorders					
-Total	10 (37.0)	1 (3.7)	3 (11.1)	3 (11.1)	3 (11.1)
Hypotension	7 (25.9)	0	2 (7.4)	2 (7.4)	3 (11.1)
Hypertension	5 (18.5)	1 (3.7)	2 (7.4)	2 (7.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (100)	3 (5.7)	4 (7.5)	14 (26.4)	32 (60.4)
Blood and lymphatic system disorders					
-Total	34 (64.2)	1 (1.9)	2 (3.8)	22 (41.5)	9 (17.0)
Febrile neutropenia	23 (43.4)	0	0	21 (39.6)	2 (3.8)
Anaemia	17 (32.1)	3 (5.7)	6 (11.3)	8 (15.1)	0
Neutropenia	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Disseminated intravascular coagulation	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Cardiac disorders					
-Total	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0
Gastrointestinal disorders					
-Total	29 (54.7)	11 (20.8)	13 (24.5)	5 (9.4)	0
Nausea	14 (26.4)	7 (13.2)	5 (9.4)	2 (3.8)	0
Vomiting	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0
Constipation	9 (17.0)	4 (7.5)	5 (9.4)	0	0
Diarrhoea	9 (17.0)	5 (9.4)	4 (7.5)	0	0
Abdominal pain	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
Pancreatitis	1 (1.9)	0	1 (1.9)	0	0
General disorders and administration site conditions					
-Total	26 (49.1)	13 (24.5)	5 (9.4)	7 (13.2)	1 (1.9)
Pyrexia	18 (34.0)	7 (13.2)	4 (7.5)	6 (11.3)	1 (1.9)
Fatigue	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Chills	6 (11.3)	4 (7.5)	2 (3.8)	0	0
Face oedema	5 (9.4)	3 (5.7)	1 (1.9)	1 (1.9)	0
Oedema peripheral	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Hepatobiliary disorders					
-Total	2 (3.8)	0	2 (3.8)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	2 (3.8)	0	2 (3.8)	0	0
Immune system disorders					
-Total	45 (84.9)	3 (5.7)	18 (34.0)	12 (22.6)	12 (22.6)
Cytokine release syndrome	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Hypogammaglobulinaemia	16 (30.2)	1 (1.9)	11 (20.8)	4 (7.5)	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	0	1 (1.9)	0
Infections and infestations					
-Total	7 (13.2)	2 (3.8)	4 (7.5)	1 (1.9)	0
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Rhinovirus infection	2 (3.8)	0	2 (3.8)	0	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Sinusitis	1 (1.9)	0	0	1 (1.9)	0
Investigations					
-Total	33 (62.3)	2 (3.8)	3 (5.7)	10 (18.9)	18 (34.0)
White blood cell count decreased	17 (32.1)	3 (5.7)	2 (3.8)	1 (1.9)	11 (20.8)
Platelet count decreased	16 (30.2)	3 (5.7)	2 (3.8)	5 (9.4)	6 (11.3)
Aspartate aminotransferase increased	14 (26.4)	2 (3.8)	2 (3.8)	7 (13.2)	3 (5.7)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	13 (24.5)	0	2 (3.8)	2 (3.8)	9 (17.0)
Alanine aminotransferase increased	12 (22.6)	3 (5.7)	6 (11.3)	3 (5.7)	0
Lymphocyte count decreased	9 (17.0)	0	0	6 (11.3)	3 (5.7)
Blood bilirubin increased	8 (15.1)	0	1 (1.9)	7 (13.2)	0
International normalised ratio increased	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Blood immunoglobulin m decreased	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Serum ferritin increased	4 (7.5)	1 (1.9)	1 (1.9)	2 (3.8)	0
Blood fibrinogen decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Electrocardiogram qt prolonged	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	27 (50.9)	4 (7.5)	7 (13.2)	14 (26.4)	2 (3.8)
Decreased appetite	17 (32.1)	5 (9.4)	4 (7.5)	7 (13.2)	1 (1.9)
Hypocalcaemia	12 (22.6)	1 (1.9)	8 (15.1)	3 (5.7)	0
Hypokalaemia	10 (18.9)	2 (3.8)	3 (5.7)	4 (7.5)	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	10 (18.9)	1 (1.9)	3 (5.7)	6 (11.3)	0
Hyperglycaemia	8 (15.1)	0	4 (7.5)	4 (7.5)	0
Hypoalbuminaemia	8 (15.1)	0	7 (13.2)	1 (1.9)	0
Hyperuricaemia	6 (11.3)	5 (9.4)	0	1 (1.9)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	18 (34.0)	8 (15.1)	8 (15.1)	2 (3.8)	0
Myalgia	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Arthralgia	6 (11.3)	2 (3.8)	3 (5.7)	1 (1.9)	0
Pain in extremity	6 (11.3)	4 (7.5)	2 (3.8)	0	0
Back pain	5 (9.4)	2 (3.8)	2 (3.8)	1 (1.9)	0
Nervous system disorders					
-Total	22 (41.5)	10 (18.9)	8 (15.1)	4 (7.5)	0
Headache	16 (30.2)	9 (17.0)	5 (9.4)	2 (3.8)	0
Encephalopathy	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Tremor	3 (5.7)	3 (5.7)	0	0	0
Psychiatric disorders					
-Total	9 (17.0)	2 (3.8)	3 (5.7)	4 (7.5)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Delirium	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Insomnia	1 (1.9)	1 (1.9)	0	0	0
Mental status changes	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Acute kidney injury	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders					
-Total	26 (49.1)	10 (18.9)	2 (3.8)	8 (15.1)	6 (11.3)
Hypoxia	9 (17.0)	0	3 (5.7)	4 (7.5)	2 (3.8)
Pulmonary oedema	8 (15.1)	0	2 (3.8)	5 (9.4)	1 (1.9)
Cough	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Tachypnoea	5 (9.4)	2 (3.8)	1 (1.9)	2 (3.8)	0
Respiratory failure	4 (7.5)	0	0	0	4 (7.5)
Epistaxis	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Nasal congestion	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Oropharyngeal pain	3 (5.7)	3 (5.7)	0	0	0
Pleural effusion	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Rash	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Vascular disorders					
-Total	17 (32.1)	3 (5.7)	4 (7.5)	7 (13.2)	3 (5.7)
Hypotension	14 (26.4)	1 (1.9)	4 (7.5)	6 (11.3)	3 (5.7)
Hypertension	8 (15.1)	3 (5.7)	3 (5.7)	2 (3.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (80.0)	3 (12.0)	6 (24.0)	7 (28.0)	4 (16.0)
Blood and lymphatic system disorders					
-Total	4 (16.0)	0	0	3 (12.0)	1 (4.0)
Neutropenia	3 (12.0)	0	0	2 (8.0)	1 (4.0)
Anaemia	1 (4.0)	1 (4.0)	0	0	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Thrombocytopenia	1 (4.0)	0	0	1 (4.0)	0
Cardiac disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Tachycardia	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	5 (20.0)	3 (12.0)	1 (4.0)	1 (4.0)	0
Constipation	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Diarrhoea	2 (8.0)	2 (8.0)	0	0	0
Nausea	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Pancreatitis	1 (4.0)	0	0	1 (4.0)	0
Vomiting	1 (4.0)	1 (4.0)	0	0	0
General disorders and administration site conditions					
-Total	7 (28.0)	4 (16.0)	2 (8.0)	1 (4.0)	0
Pyrexia	5 (20.0)	2 (8.0)	2 (8.0)	1 (4.0)	0
Fatigue	1 (4.0)	1 (4.0)	0	0	0
Oedema peripheral	1 (4.0)	1 (4.0)	0	0	0
Immune system disorders					
-Total	3 (12.0)	0	3 (12.0)	0	0
Hypogammaglobulinaemia	3 (12.0)	0	3 (12.0)	0	0
Infections and infestations					
-Total	8 (32.0)	2 (8.0)	5 (20.0)	1 (4.0)	0
Nasopharyngitis	3 (12.0)	2 (8.0)	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Rhinovirus infection	2 (8.0)	0	2 (8.0)	0	0
Nail infection	1 (4.0)	1 (4.0)	0	0	0
Investigations					
-Total	8 (32.0)	1 (4.0)	1 (4.0)	4 (16.0)	2 (8.0)
Blood uric acid increased	2 (8.0)	0	0	1 (4.0)	1 (4.0)
Platelet count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Alanine aminotransferase increased	1 (4.0)	1 (4.0)	0	0	0
Blood bilirubin increased	1 (4.0)	0	0	1 (4.0)	0
Blood immunoglobulin m decreased	1 (4.0)	0	0	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	0	1 (4.0)	0	0
Neutrophil count decreased	1 (4.0)	0	0	0	1 (4.0)
White blood cell count decreased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (12.0)	1 (4.0)	1 (4.0)	0	1 (4.0)
Hyperuricaemia	2 (8.0)	2 (8.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (4.0)	0	1 (4.0)	0	0
Hypokalaemia	1 (4.0)	0	1 (4.0)	0	0
Tumour lysis syndrome	1 (4.0)	0	0	0	1 (4.0)
Musculoskeletal and connective tissue disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Pain in extremity	1 (4.0)	1 (4.0)	0	0	0
Nervous system disorders					
-Total	3 (12.0)	3 (12.0)	0	0	0
Headache	3 (12.0)	3 (12.0)	0	0	0
Psychiatric disorders					
-Total	2 (8.0)	0	2 (8.0)	0	0
Anxiety	1 (4.0)	0	1 (4.0)	0	0
Mental status changes	1 (4.0)	0	1 (4.0)	0	0
Renal and urinary disorders					
-Total	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Acute kidney injury	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Respiratory, thoracic and mediastinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (28.0)	4 (16.0)	2 (8.0)	1 (4.0)	0
Cough	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Nasal congestion	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Pleural effusion	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Epistaxis	1 (4.0)	0	1 (4.0)	0	0
Hypoxia	1 (4.0)	0	0	1 (4.0)	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Dry skin	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Vascular disorders					
-Total	3 (12.0)	0	1 (4.0)	0	2 (8.0)
Hypotension	2 (8.0)	0	0	0	2 (8.0)
Hypertension	1 (4.0)	0	1 (4.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (84.0)	8 (16.0)	17 (34.0)	10 (20.0)	7 (14.0)
Blood and lymphatic system disorders					
-Total	9 (18.0)	3 (6.0)	0	3 (6.0)	3 (6.0)
Anaemia	5 (10.0)	3 (6.0)	0	2 (4.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Neutropenia	2 (4.0)	0	0	0	2 (4.0)
Disseminated intravascular coagulation	1 (2.0)	0	0	1 (2.0)	0
Thrombocytopenia	1 (2.0)	0	0	0	1 (2.0)
Cardiac disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					
-Total	10 (20.0)	7 (14.0)	3 (6.0)	0	0
Diarrhoea	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Vomiting	5 (10.0)	5 (10.0)	0	0	0
Nausea	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Abdominal pain upper	1 (2.0)	1 (2.0)	0	0	0
Constipation	1 (2.0)	0	1 (2.0)	0	0
Pancreatitis	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	15 (30.0)	10 (20.0)	4 (8.0)	1 (2.0)	0
Pyrexia	10 (20.0)	5 (10.0)	4 (8.0)	1 (2.0)	0
Fatigue	5 (10.0)	5 (10.0)	0	0	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	7 (14.0)	0	7 (14.0)	0	0
Hypogammaglobulinaemia	7 (14.0)	0	7 (14.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	13 (26.0)	4 (8.0)	7 (14.0)	2 (4.0)	0
Upper respiratory tract infection	8 (16.0)	3 (6.0)	3 (6.0)	2 (4.0)	0
Nasopharyngitis	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Rhinovirus infection	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Conjunctivitis	1 (2.0)	0	1 (2.0)	0	0
Investigations					
-Total	14 (28.0)	4 (8.0)	2 (4.0)	5 (10.0)	3 (6.0)
Neutrophil count decreased	9 (18.0)	2 (4.0)	1 (2.0)	3 (6.0)	3 (6.0)
White blood cell count decreased	9 (18.0)	3 (6.0)	2 (4.0)	3 (6.0)	1 (2.0)
Lymphocyte count decreased	3 (6.0)	1 (2.0)	0	2 (4.0)	0
Platelet count decreased	3 (6.0)	2 (4.0)	0	0	1 (2.0)
Alanine aminotransferase increased	1 (2.0)	0	0	1 (2.0)	0
Blood bilirubin increased	1 (2.0)	0	1 (2.0)	0	0
Metabolism and nutrition disorders					
-Total	7 (14.0)	3 (6.0)	1 (2.0)	2 (4.0)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)	0
Hypokalaemia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Hyperuricaemia	1 (2.0)	1 (2.0)	0	0	0
Hypophosphataemia	1 (2.0)	0	1 (2.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (20.0)	3 (6.0)	4 (8.0)	3 (6.0)	0
Back pain	6 (12.0)	2 (4.0)	2 (4.0)	2 (4.0)	0
Pain in extremity	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Arthralgia	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Myalgia	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	7 (14.0)	3 (6.0)	4 (8.0)	0	0
Headache	7 (14.0)	3 (6.0)	4 (8.0)	0	0
Psychiatric disorders					
-Total	6 (12.0)	1 (2.0)	4 (8.0)	1 (2.0)	0
Anxiety	5 (10.0)	1 (2.0)	4 (8.0)	0	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Mental status changes	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Acute kidney injury	1 (2.0)	0	1 (2.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (20.0)	5 (10.0)	2 (4.0)	2 (4.0)	1 (2.0)
Cough	7 (14.0)	5 (10.0)	2 (4.0)	0	0
Nasal congestion	4 (8.0)	4 (8.0)	0	0	0
Epistaxis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Hypoxia	2 (4.0)	0	0	2 (4.0)	0
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Skin and subcutaneous tissue disorders					
-Total	6 (12.0)	5 (10.0)	1 (2.0)	0	0
Dry skin	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Rash	2 (4.0)	2 (4.0)	0	0	0
Vascular disorders					
-Total	2 (4.0)	1 (2.0)	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (4.0)	1 (2.0)	0	1 (2.0)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=16			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (43.8)	1 (6.3)	2 (12.5)	3 (18.8)	1 (6.3)
Blood and lymphatic system disorders					
-Total	2 (12.5)	0	1 (6.3)	0	1 (6.3)
Anaemia	1 (6.3)	0	1 (6.3)	0	0
Neutropenia	1 (6.3)	0	0	0	1 (6.3)
Thrombocytopenia	1 (6.3)	0	1 (6.3)	0	0
Eye disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Eyelid oedema	1 (6.3)	1 (6.3)	0	0	0
Gastrointestinal disorders					

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Diarrhoea	2 (12.5)	1 (6.3)	0	1 (6.3)	0
General disorders and administration site conditions					
-Total	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Pyrexia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Immune system disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Hypogammaglobulinaemia	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					
-Total	6 (37.5)	1 (6.3)	4 (25.0)	1 (6.3)	0
Conjunctivitis	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Sinusitis	3 (18.8)	0	3 (18.8)	0	0
Upper respiratory tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Nail infection	1 (6.3)	0	1 (6.3)	0	0
Rhinovirus infection	1 (6.3)	0	1 (6.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (6.3)	0	1 (6.3)	0	0
Nervous system disorders					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Headache	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (18.8)	2 (12.5)	0	1 (6.3)	0
Cough	1 (6.3)	1 (6.3)	0	0	0
Epistaxis	1 (6.3)	1 (6.3)	0	0	0
Hypoxia	1 (6.3)	0	0	1 (6.3)	0
Oropharyngeal pain	1 (6.3)	1 (6.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Rash	1 (6.3)	0	1 (6.3)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (47.1)	4 (11.8)	8 (23.5)	0	4 (11.8)
Gastrointestinal disorders					
-Total	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Diarrhoea	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Constipation	1 (2.9)	1 (2.9)	0	0	0
Nausea	1 (2.9)	1 (2.9)	0	0	0
Vomiting	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	4 (11.8)	1 (2.9)	3 (8.8)	0	0
Pyrexia	3 (8.8)	1 (2.9)	2 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	3 (8.8)	0	2 (5.9)	0	1 (2.9)
Hypogammaglobulinaemia	2 (5.9)	0	2 (5.9)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	0	0	1 (2.9)
Infections and infestations					
-Total	7 (20.6)	2 (5.9)	4 (11.8)	1 (2.9)	0
Rhinovirus infection	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Sinusitis	3 (8.8)	0	3 (8.8)	0	0
Upper respiratory tract infection	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Conjunctivitis	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	4 (11.8)	3 (8.8)	0	0	1 (2.9)
Neutrophil count decreased	3 (8.8)	2 (5.9)	0	0	1 (2.9)
Platelet count decreased	2 (5.9)	2 (5.9)	0	0	0
Blood bilirubin increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Decreased appetite	1 (2.9)	0	0	0	1 (2.9)
Hyperglycaemia	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (5.9)	0	2 (5.9)	0	0
Arthralgia	1 (2.9)	0	1 (2.9)	0	0
Pain in extremity	1 (2.9)	0	1 (2.9)	0	0
Psychiatric disorders					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Anxiety	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (11.8)	1 (2.9)	1 (2.9)	0	2 (5.9)
Cough	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Pleural effusion	1 (2.9)	0	1 (2.9)	0	0
Respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Tachypnoea	1 (2.9)	0	0	0	1 (2.9)
Skin and subcutaneous tissue disorders					

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.9)	2 (5.9)	0	0	0
Dry skin	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hypertension	2 (5.9)	0	1 (2.9)	1 (2.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (100)	1 (3.7)	5 (18.5)	7 (25.9)	14 (51.9)
Blood and lymphatic system disorders					
-Total	14 (51.9)	1 (3.7)	3 (11.1)	5 (18.5)	5 (18.5)
Anaemia	6 (22.2)	3 (11.1)	3 (11.1)	0	0
Neutropenia	5 (18.5)	0	1 (3.7)	1 (3.7)	3 (11.1)
Disseminated intravascular coagulation	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Febrile neutropenia	4 (14.8)	0	0	4 (14.8)	0
Thrombocytopenia	3 (11.1)	0	0	1 (3.7)	2 (7.4)
Cardiac disorders					
-Total	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
Eye disorders					
-Total	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Eyelid oedema	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Gastrointestinal disorders					
-Total	21 (77.8)	10 (37.0)	7 (25.9)	4 (14.8)	0
Diarrhoea	10 (37.0)	6 (22.2)	2 (7.4)	2 (7.4)	0
Vomiting	8 (29.6)	7 (25.9)	1 (3.7)	0	0
Abdominal pain	5 (18.5)	1 (3.7)	4 (14.8)	0	0
Nausea	5 (18.5)	3 (11.1)	2 (7.4)	0	0
Constipation	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Pancreatitis	4 (14.8)	0	2 (7.4)	2 (7.4)	0
Abdominal pain upper	3 (11.1)	2 (7.4)	1 (3.7)	0	0
General disorders and administration site conditions					
-Total	13 (48.1)	7 (25.9)	3 (11.1)	2 (7.4)	1 (3.7)
Pyrexia	10 (37.0)	5 (18.5)	2 (7.4)	2 (7.4)	1 (3.7)
Fatigue	5 (18.5)	4 (14.8)	1 (3.7)	0	0
Face oedema	3 (11.1)	2 (7.4)	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	3 (11.1)	3 (11.1)	0	0	0
Hepatobiliary disorders					
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Hepatic function abnormal	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Immune system disorders					
-Total	23 (85.2)	0	5 (18.5)	9 (33.3)	9 (33.3)
Cytokine release syndrome	20 (74.1)	0	3 (11.1)	8 (29.6)	9 (33.3)
Hypogammaglobulinaemia	11 (40.7)	1 (3.7)	7 (25.9)	3 (11.1)	0
Haemophagocytic lymphohistiocytosis	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Infections and infestations					
-Total	11 (40.7)	2 (7.4)	7 (25.9)	2 (7.4)	0
Conjunctivitis	5 (18.5)	1 (3.7)	4 (14.8)	0	0
Nail infection	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Nasopharyngitis	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Rhinovirus infection	3 (11.1)	0	3 (11.1)	0	0
Sinusitis	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Upper respiratory tract infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	16 (59.3)	2 (7.4)	0	5 (18.5)	9 (33.3)
White blood cell count decreased	8 (29.6)	1 (3.7)	1 (3.7)	1 (3.7)	5 (18.5)
Neutrophil count decreased	7 (25.9)	0	1 (3.7)	0	6 (22.2)
Platelet count decreased	7 (25.9)	2 (7.4)	1 (3.7)	2 (7.4)	2 (7.4)
Alanine aminotransferase increased	6 (22.2)	1 (3.7)	2 (7.4)	3 (11.1)	0
Lymphocyte count decreased	6 (22.2)	1 (3.7)	1 (3.7)	2 (7.4)	2 (7.4)
Aspartate aminotransferase increased	5 (18.5)	0	4 (14.8)	1 (3.7)	0
Blood fibrinogen decreased	5 (18.5)	1 (3.7)	3 (11.1)	0	1 (3.7)
Blood bilirubin increased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Serum ferritin increased	4 (14.8)	0	4 (14.8)	0	0
Blood immunoglobulin m decreased	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Blood uric acid increased	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
Electrocardiogram qt prolonged	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
International normalised ratio increased	2 (7.4)	1 (3.7)	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	17 (63.0)	4 (14.8)	2 (7.4)	8 (29.6)	3 (11.1)
Hypokalaemia	10 (37.0)	1 (3.7)	3 (11.1)	5 (18.5)	1 (3.7)
Decreased appetite	8 (29.6)	4 (14.8)	1 (3.7)	3 (11.1)	0
Hypophosphataemia	7 (25.9)	2 (7.4)	2 (7.4)	2 (7.4)	1 (3.7)
Hypocalcaemia	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Hyperuricaemia	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Hypoalbuminaemia	3 (11.1)	0	3 (11.1)	0	0
Tumour lysis syndrome	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Musculoskeletal and connective tissue disorders					
-Total	11 (40.7)	6 (22.2)	5 (18.5)	0	0
Pain in extremity	7 (25.9)	3 (11.1)	4 (14.8)	0	0
Arthralgia	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Myalgia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Back pain	1 (3.7)	0	1 (3.7)	0	0
Nervous system disorders					
-Total	10 (37.0)	4 (14.8)	3 (11.1)	3 (11.1)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	8 (29.6)	3 (11.1)	4 (14.8)	1 (3.7)	0
Encephalopathy	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Tremor	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Psychiatric disorders					
-Total	9 (33.3)	4 (14.8)	3 (11.1)	2 (7.4)	0
Anxiety	3 (11.1)	0	2 (7.4)	1 (3.7)	0
Delirium	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Insomnia	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Mental status changes	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Renal and urinary disorders					
-Total	6 (22.2)	1 (3.7)	0	1 (3.7)	4 (14.8)
Acute kidney injury	6 (22.2)	1 (3.7)	0	1 (3.7)	4 (14.8)
Respiratory, thoracic and mediastinal disorders					
-Total	18 (66.7)	8 (29.6)	2 (7.4)	4 (14.8)	4 (14.8)
Hypoxia	9 (33.3)	0	1 (3.7)	4 (14.8)	4 (14.8)
Cough	7 (25.9)	6 (22.2)	1 (3.7)	0	0
Pleural effusion	5 (18.5)	3 (11.1)	1 (3.7)	1 (3.7)	0
Oropharyngeal pain	4 (14.8)	3 (11.1)	1 (3.7)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	4 (14.8)	2 (7.4)	1 (3.7)	1 (3.7)	0
Epistaxis	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Tachypnoea	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Nasal congestion	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Dry skin	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Rash	3 (11.1)	0	3 (11.1)	0	0
Vascular disorders					
-Total	11 (40.7)	1 (3.7)	3 (11.1)	2 (7.4)	5 (18.5)
Hypotension	8 (29.6)	0	2 (7.4)	1 (3.7)	5 (18.5)
Hypertension	6 (22.2)	1 (3.7)	3 (11.1)	2 (7.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (100)	1 (1.9)	4 (7.5)	13 (24.5)	35 (66.0)
Blood and lymphatic system disorders					
-Total	36 (67.9)	1 (1.9)	2 (3.8)	24 (45.3)	9 (17.0)
Febrile neutropenia	23 (43.4)	0	0	21 (39.6)	2 (3.8)
Anaemia	19 (35.8)	4 (7.5)	6 (11.3)	9 (17.0)	0
Neutropenia	6 (11.3)	0	1 (1.9)	1 (1.9)	4 (7.5)
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Disseminated intravascular coagulation	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Cardiac disorders					
-Total	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (26.4)	6 (11.3)	7 (13.2)	1 (1.9)	0
Gastrointestinal disorders					
-Total	36 (67.9)	15 (28.3)	16 (30.2)	5 (9.4)	0
Vomiting	18 (34.0)	10 (18.9)	7 (13.2)	1 (1.9)	0
Nausea	17 (32.1)	9 (17.0)	6 (11.3)	2 (3.8)	0
Diarrhoea	16 (30.2)	10 (18.9)	6 (11.3)	0	0
Constipation	10 (18.9)	4 (7.5)	6 (11.3)	0	0
Abdominal pain	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Pancreatitis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal pain upper	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	34 (64.2)	16 (30.2)	9 (17.0)	8 (15.1)	1 (1.9)
Pyrexia	25 (47.2)	9 (17.0)	8 (15.1)	7 (13.2)	1 (1.9)
Fatigue	12 (22.6)	10 (18.9)	2 (3.8)	0	0
Chills	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Face oedema	5 (9.4)	3 (5.7)	1 (1.9)	1 (1.9)	0
Oedema peripheral	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.8)	0	2 (3.8)	0	0
Hepatic function abnormal	2 (3.8)	0	2 (3.8)	0	0
Immune system disorders					
-Total	46 (86.8)	2 (3.8)	19 (35.8)	12 (22.6)	13 (24.5)
Cytokine release syndrome	41 (77.4)	5 (9.4)	15 (28.3)	9 (17.0)	12 (22.6)
Hypogammaglobulinaemia	22 (41.5)	1 (1.9)	17 (32.1)	4 (7.5)	0
Haemophagocytic lymphohistiocytosis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Infections and infestations					
-Total	22 (41.5)	7 (13.2)	11 (20.8)	4 (7.5)	0
Upper respiratory tract infection	11 (20.8)	5 (9.4)	4 (7.5)	2 (3.8)	0
Rhinovirus infection	6 (11.3)	0	4 (7.5)	2 (3.8)	0
Nasopharyngitis	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Sinusitis	4 (7.5)	0	3 (5.7)	1 (1.9)	0
Conjunctivitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Nail infection	1 (1.9)	1 (1.9)	0	0	0
Investigations					
-Total	33 (62.3)	1 (1.9)	4 (7.5)	10 (18.9)	18 (34.0)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	17 (32.1)	1 (1.9)	1 (1.9)	4 (7.5)	11 (20.8)
Platelet count decreased	17 (32.1)	4 (7.5)	2 (3.8)	5 (9.4)	6 (11.3)
White blood cell count decreased	17 (32.1)	2 (3.8)	3 (5.7)	1 (1.9)	11 (20.8)
Aspartate aminotransferase increased	14 (26.4)	2 (3.8)	2 (3.8)	7 (13.2)	3 (5.7)
Alanine aminotransferase increased	12 (22.6)	2 (3.8)	6 (11.3)	4 (7.5)	0
Lymphocyte count decreased	11 (20.8)	0	0	8 (15.1)	3 (5.7)
Blood bilirubin increased	9 (17.0)	0	2 (3.8)	7 (13.2)	0
International normalised ratio increased	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Blood immunoglobulin m decreased	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Serum ferritin increased	4 (7.5)	1 (1.9)	1 (1.9)	2 (3.8)	0
Blood fibrinogen decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Electrocardiogram qt prolonged	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (60.4)	6 (11.3)	8 (15.1)	15 (28.3)	3 (5.7)
Decreased appetite	22 (41.5)	7 (13.2)	6 (11.3)	7 (13.2)	2 (3.8)
Hypocalcaemia	12 (22.6)	1 (1.9)	8 (15.1)	3 (5.7)	0
Hypophosphataemia	11 (20.8)	1 (1.9)	4 (7.5)	6 (11.3)	0
Hypokalaemia	10 (18.9)	2 (3.8)	3 (5.7)	4 (7.5)	1 (1.9)
Hyperglycaemia	9 (17.0)	0	4 (7.5)	5 (9.4)	0
Hypoalbuminaemia	8 (15.1)	0	7 (13.2)	1 (1.9)	0
Hyperuricaemia	6 (11.3)	5 (9.4)	0	1 (1.9)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	24 (45.3)	9 (17.0)	10 (18.9)	5 (9.4)	0
Pain in extremity	10 (18.9)	5 (9.4)	4 (7.5)	1 (1.9)	0
Back pain	9 (17.0)	2 (3.8)	4 (7.5)	3 (5.7)	0
Arthralgia	8 (15.1)	3 (5.7)	4 (7.5)	1 (1.9)	0
Myalgia	8 (15.1)	5 (9.4)	3 (5.7)	0	0
Nervous system disorders					
-Total	25 (47.2)	11 (20.8)	10 (18.9)	4 (7.5)	0
Headache	19 (35.8)	10 (18.9)	7 (13.2)	2 (3.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Tremor	3 (5.7)	3 (5.7)	0	0	0
Psychiatric disorders					
-Total	16 (30.2)	3 (5.7)	8 (15.1)	5 (9.4)	0
Anxiety	11 (20.8)	3 (5.7)	7 (13.2)	1 (1.9)	0
Delirium	5 (9.4)	0	2 (3.8)	3 (5.7)	0
Mental status changes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Insomnia	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	6 (11.3)	1 (1.9)	2 (3.8)	2 (3.8)	1 (1.9)
Acute kidney injury	6 (11.3)	1 (1.9)	2 (3.8)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders					
-Total	32 (60.4)	11 (20.8)	3 (5.7)	9 (17.0)	9 (17.0)
Cough	16 (30.2)	12 (22.6)	4 (7.5)	0	0
Hypoxia	11 (20.8)	0	3 (5.7)	6 (11.3)	2 (3.8)
Pulmonary oedema	8 (15.1)	0	2 (3.8)	5 (9.4)	1 (1.9)
Nasal congestion	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Respiratory failure	6 (11.3)	0	0	0	6 (11.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	6 (11.3)	2 (3.8)	1 (1.9)	2 (3.8)	1 (1.9)
Epistaxis	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Oropharyngeal pain	4 (7.5)	4 (7.5)	0	0	0
Pleural effusion	4 (7.5)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Skin and subcutaneous tissue disorders					
-Total	10 (18.9)	8 (15.1)	2 (3.8)	0	0
Dry skin	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Rash	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Vascular disorders					
-Total	21 (39.6)	4 (7.5)	5 (9.4)	9 (17.0)	3 (5.7)
Hypotension	16 (30.2)	2 (3.8)	4 (7.5)	7 (13.2)	3 (5.7)
Hypertension	10 (18.9)	3 (5.7)	4 (7.5)	3 (5.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	3 (10.7)	3 (10.7)	7 (25.0)	14 (50.0)
Blood and lymphatic system disorders					
-Total	12 (42.9)	1 (3.6)	1 (3.6)	8 (28.6)	2 (7.1)
Febrile neutropenia	6 (21.4)	0	0	6 (21.4)	0
Anaemia	5 (17.9)	1 (3.6)	0	4 (14.3)	0
Neutropenia	3 (10.7)	0	1 (3.6)	1 (3.6)	1 (3.6)
Disseminated intravascular coagulation	2 (7.1)	0	2 (7.1)	0	0
Thrombocytopenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Leukopenia	1 (3.6)	0	0	1 (3.6)	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (53.6)	5 (17.9)	8 (28.6)	2 (7.1)	0
Vomiting	7 (25.0)	5 (17.9)	2 (7.1)	0	0
Abdominal pain	5 (17.9)	0	5 (17.9)	0	0
Diarrhoea	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Nausea	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Constipation	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Abdominal pain upper	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Stomatitis	1 (3.6)	0	0	1 (3.6)	0
General disorders and administration site conditions					
-Total	11 (39.3)	7 (25.0)	3 (10.7)	1 (3.6)	0
Pyrexia	5 (17.9)	3 (10.7)	2 (7.1)	0	0
Face oedema	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Asthenia	2 (7.1)	2 (7.1)	0	0	0
Oedema peripheral	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Fatigue	1 (3.6)	1 (3.6)	0	0	0
Influenza like illness	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (75.0)	0	5 (17.9)	8 (28.6)	8 (28.6)
Cytokine release syndrome	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Hypogammaglobulinaemia	10 (35.7)	1 (3.6)	5 (17.9)	4 (14.3)	0
Immunodeficiency	3 (10.7)	0	0	3 (10.7)	0
Infections and infestations					
-Total	6 (21.4)	2 (7.1)	3 (10.7)	1 (3.6)	0
Conjunctivitis	3 (10.7)	0	3 (10.7)	0	0
Nail infection	2 (7.1)	2 (7.1)	0	0	0
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Investigations					
-Total	11 (39.3)	1 (3.6)	1 (3.6)	2 (7.1)	7 (25.0)
Lymphocyte count decreased	7 (25.0)	1 (3.6)	0	3 (10.7)	3 (10.7)
Neutrophil count decreased	6 (21.4)	0	1 (3.6)	0	5 (17.9)
White blood cell count decreased	6 (21.4)	1 (3.6)	0	1 (3.6)	4 (14.3)
Platelet count decreased	5 (17.9)	1 (3.6)	1 (3.6)	1 (3.6)	2 (7.1)
Alanine aminotransferase increased	2 (7.1)	0	0	2 (7.1)	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.6)	0	0	1 (3.6)	0
Blood bilirubin increased	1 (3.6)	0	0	1 (3.6)	0
Blood fibrinogen decreased	1 (3.6)	0	0	0	1 (3.6)
Serum ferritin increased	1 (3.6)	1 (3.6)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (35.7)	3 (10.7)	2 (7.1)	4 (14.3)	1 (3.6)
Hypokalaemia	5 (17.9)	1 (3.6)	1 (3.6)	3 (10.7)	0
Decreased appetite	4 (14.3)	2 (7.1)	1 (3.6)	1 (3.6)	0
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Hypophosphataemia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Hyperglycaemia	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Hyperuricaemia	1 (3.6)	0	1 (3.6)	0	0
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)	0	0
Hypocalcaemia	1 (3.6)	0	0	1 (3.6)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (35.7)	4 (14.3)	5 (17.9)	1 (3.6)	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Back pain	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Pain in extremity	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Myalgia	1 (3.6)	1 (3.6)	0	0	0
Nervous system disorders					
-Total	12 (42.9)	6 (21.4)	4 (14.3)	2 (7.1)	0
Headache	9 (32.1)	7 (25.0)	2 (7.1)	0	0
Encephalopathy	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Psychiatric disorders					
-Total	4 (14.3)	2 (7.1)	1 (3.6)	1 (3.6)	0
Anxiety	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (32.1)	4 (14.3)	2 (7.1)	3 (10.7)	0
Cough	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Pulmonary oedema	4 (14.3)	1 (3.6)	0	3 (10.7)	0

Timing: within 8 weeks post infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	3 (10.7)	0	3 (10.7)	0	0
Oropharyngeal pain	2 (7.1)	2 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (21.4)	2 (7.1)	4 (14.3)	0	0
Dermatitis atopic	2 (7.1)	2 (7.1)	0	0	0
Pruritus	2 (7.1)	0	2 (7.1)	0	0
Rash	2 (7.1)	0	2 (7.1)	0	0
Vascular disorders					
-Total	5 (17.9)	1 (3.6)	2 (7.1)	2 (7.1)	0
Hypotension	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Hypertension	2 (7.1)	1 (3.6)	0	1 (3.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (100)	2 (4.4)	5 (11.1)	13 (28.9)	25 (55.6)
Blood and lymphatic system disorders					
-Total	28 (62.2)	1 (2.2)	3 (6.7)	17 (37.8)	7 (15.6)
Febrile neutropenia	20 (44.4)	0	0	18 (40.0)	2 (4.4)
Anaemia	15 (33.3)	4 (8.9)	7 (15.6)	4 (8.9)	0
Thrombocytopenia	5 (11.1)	0	0	1 (2.2)	4 (8.9)
Disseminated intravascular coagulation	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Neutropenia	3 (6.7)	0	1 (2.2)	0	2 (4.4)
Leukopenia	1 (2.2)	0	1 (2.2)	0	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (37.8)	7 (15.6)	6 (13.3)	2 (4.4)	2 (4.4)
Tachycardia	17 (37.8)	7 (15.6)	7 (15.6)	2 (4.4)	1 (2.2)
Cardiac failure	1 (2.2)	0	0	0	1 (2.2)
Gastrointestinal disorders					
-Total	29 (64.4)	13 (28.9)	10 (22.2)	6 (13.3)	0
Vomiting	14 (31.1)	7 (15.6)	6 (13.3)	1 (2.2)	0
Nausea	12 (26.7)	7 (15.6)	4 (8.9)	1 (2.2)	0
Diarrhoea	9 (20.0)	7 (15.6)	1 (2.2)	1 (2.2)	0
Constipation	7 (15.6)	4 (8.9)	3 (6.7)	0	0
Abdominal pain	5 (11.1)	2 (4.4)	1 (2.2)	2 (4.4)	0
Pancreatitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Abdominal pain upper	1 (2.2)	1 (2.2)	0	0	0
Stomatitis	1 (2.2)	0	1 (2.2)	0	0
Trichoglossia	1 (2.2)	0	1 (2.2)	0	0
General disorders and administration site conditions					
-Total	26 (57.8)	14 (31.1)	4 (8.9)	6 (13.3)	2 (4.4)
Pyrexia	18 (40.0)	7 (15.6)	3 (6.7)	6 (13.3)	2 (4.4)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	10 (22.2)	8 (17.8)	2 (4.4)	0	0
Chills	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Face oedema	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Oedema peripheral	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Pain	1 (2.2)	0	0	1 (2.2)	0
Hepatobiliary disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Hepatic function abnormal	1 (2.2)	0	1 (2.2)	0	0
Immune system disorders					
-Total	38 (84.4)	2 (4.4)	14 (31.1)	12 (26.7)	10 (22.2)
Cytokine release syndrome	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Hypogammaglobulinaemia	11 (24.4)	1 (2.2)	7 (15.6)	3 (6.7)	0
Infections and infestations					
-Total	5 (11.1)	1 (2.2)	3 (6.7)	1 (2.2)	0
Conjunctivitis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Rhinovirus infection	2 (4.4)	0	2 (4.4)	0	0
Sinusitis	1 (2.2)	0	0	1 (2.2)	0
Investigations					

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (73.3)	3 (6.7)	3 (6.7)	12 (26.7)	15 (33.3)
Aspartate aminotransferase increased	18 (40.0)	2 (4.4)	6 (13.3)	7 (15.6)	3 (6.7)
Alanine aminotransferase increased	16 (35.6)	4 (8.9)	8 (17.8)	4 (8.9)	0
Platelet count decreased	14 (31.1)	3 (6.7)	2 (4.4)	4 (8.9)	5 (11.1)
White blood cell count decreased	14 (31.1)	2 (4.4)	3 (6.7)	1 (2.2)	8 (17.8)
Blood bilirubin increased	11 (24.4)	1 (2.2)	2 (4.4)	8 (17.8)	0
Neutrophil count decreased	11 (24.4)	0	2 (4.4)	2 (4.4)	7 (15.6)
International normalised ratio increased	9 (20.0)	6 (13.3)	3 (6.7)	0	0
Lymphocyte count decreased	8 (17.8)	1 (2.2)	0	5 (11.1)	2 (4.4)
Activated partial thromboplastin time prolonged	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Blood immunoglobulin m decreased	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin a decreased	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Electrocardiogram qt prolonged	5 (11.1)	1 (2.2)	2 (4.4)	1 (2.2)	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	4 (8.9)	1 (2.2)	0	2 (4.4)	1 (2.2)
Blood fibrinogen decreased	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Serum ferritin increased	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Blood creatine phosphokinase increased	1 (2.2)	0	0	0	1 (2.2)
Metabolism and nutrition disorders					
-Total	34 (75.6)	6 (13.3)	7 (15.6)	16 (35.6)	5 (11.1)
Decreased appetite	20 (44.4)	7 (15.6)	3 (6.7)	9 (20.0)	1 (2.2)
Hypocalcaemia	15 (33.3)	2 (4.4)	9 (20.0)	4 (8.9)	0
Hypokalaemia	14 (31.1)	2 (4.4)	4 (8.9)	6 (13.3)	2 (4.4)
Hypophosphataemia	14 (31.1)	3 (6.7)	5 (11.1)	6 (13.3)	0
Hypoalbuminaemia	9 (20.0)	0	8 (17.8)	1 (2.2)	0
Hyperglycaemia	6 (13.3)	0	3 (6.7)	3 (6.7)	0
Hyperuricaemia	6 (13.3)	5 (11.1)	0	1 (2.2)	0
Hypervolaemia	6 (13.3)	0	2 (4.4)	4 (8.9)	0
Hyperphosphataemia	5 (11.1)	4 (8.9)	0	0	1 (2.2)
Hypomagnesaemia	3 (6.7)	3 (6.7)	0	0	0
Metabolic acidosis	3 (6.7)	1 (2.2)	0	0	2 (4.4)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (4.4)	0	0	2 (4.4)	0
Musculoskeletal and connective tissue disorders					
-Total	17 (37.8)	9 (20.0)	7 (15.6)	1 (2.2)	0
Myalgia	8 (17.8)	5 (11.1)	3 (6.7)	0	0
Arthralgia	6 (13.3)	2 (4.4)	3 (6.7)	1 (2.2)	0
Pain in extremity	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Back pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Nervous system disorders					
-Total	18 (40.0)	5 (11.1)	8 (17.8)	5 (11.1)	0
Headache	13 (28.9)	4 (8.9)	7 (15.6)	2 (4.4)	0
Encephalopathy	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0
Somnolence	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Psychiatric disorders					
-Total	15 (33.3)	7 (15.6)	3 (6.7)	5 (11.1)	0
Delirium	7 (15.6)	2 (4.4)	2 (4.4)	3 (6.7)	0
Agitation	5 (11.1)	2 (4.4)	3 (6.7)	0	0
Confusional state	5 (11.1)	5 (11.1)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Mental status changes	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Renal and urinary disorders					
-Total	7 (15.6)	1 (2.2)	1 (2.2)	3 (6.7)	2 (4.4)
Acute kidney injury	7 (15.6)	1 (2.2)	1 (2.2)	3 (6.7)	2 (4.4)
Haematuria	1 (2.2)	1 (2.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	25 (55.6)	8 (17.8)	1 (2.2)	8 (17.8)	8 (17.8)
Hypoxia	11 (24.4)	0	2 (4.4)	6 (13.3)	3 (6.7)
Pulmonary oedema	8 (17.8)	1 (2.2)	3 (6.7)	3 (6.7)	1 (2.2)
Tachypnoea	8 (17.8)	3 (6.7)	1 (2.2)	4 (8.9)	0
Cough	6 (13.3)	6 (13.3)	0	0	0
Pleural effusion	6 (13.3)	3 (6.7)	0	2 (4.4)	1 (2.2)
Respiratory failure	4 (8.9)	0	0	0	4 (8.9)
Dyspnoea	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Epistaxis	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Nasal congestion	3 (6.7)	2 (4.4)	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (4.4)	2 (4.4)	0	0	0
Rhinorrhoea	2 (4.4)	2 (4.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Pruritus	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Rash	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Dry skin	1 (2.2)	1 (2.2)	0	0	0
Skin ulcer	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	21 (46.7)	3 (6.7)	4 (8.9)	8 (17.8)	6 (13.3)
Hypotension	18 (40.0)	1 (2.2)	4 (8.9)	7 (15.6)	6 (13.3)
Hypertension	10 (22.2)	3 (6.7)	4 (8.9)	3 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders					
-Total	6 (85.7)	0	2 (28.6)	0	4 (57.1)
Neutropenia	3 (42.9)	0	0	0	3 (42.9)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)	0	0
Anaemia	1 (14.3)	0	1 (14.3)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Hypofibrinogenaemia	1 (14.3)	0	1 (14.3)	0	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Cardiac dysfunction	2 (28.6)	2 (28.6)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	3 (42.9)	3 (42.9)	0	0
Nausea	2 (28.6)	2 (28.6)	0	0	0
Pancreatitis	2 (28.6)	0	2 (28.6)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Enterocolitis	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Face oedema	1 (14.3)	1 (14.3)	0	0	0
Influenza like illness	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)
Immune system disorders					
-Total	7 (100)	1 (14.3)	1 (14.3)	2 (28.6)	3 (42.9)
Cytokine release syndrome	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)	0	0
Infections and infestations					
-Total	5 (71.4)	2 (28.6)	1 (14.3)	1 (14.3)	1 (14.3)
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bk virus infection	1 (14.3)	1 (14.3)	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Pneumonia	1 (14.3)	0	0	1 (14.3)	0
Urinary tract infection viral	1 (14.3)	1 (14.3)	0	0	0
Investigations					
-Total	5 (71.4)	0	0	0	5 (71.4)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	3 (42.9)	0	3 (42.9)	0	0
Blood fibrinogen decreased	2 (28.6)	0	2 (28.6)	0	0
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Blood creatine phosphokinase increased	1 (14.3)	0	0	1 (14.3)	0
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	3 (42.9)	1 (14.3)	0	0	2 (28.6)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (28.6)	0	0	0	2 (28.6)
Haematuria	1 (14.3)	1 (14.3)	0	0	0
Proteinuria	1 (14.3)	1 (14.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Heavy menstrual bleeding	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (71.4)	2 (28.6)	0	0	3 (42.9)
Hypoxia	3 (42.9)	0	0	0	3 (42.9)
Epistaxis	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0	0	0
Pleural effusion	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Erythema nodosum	1 (14.3)	1 (14.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Skin ulcer	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

			All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (89.3)	6 (21.4)	8 (28.6)	6 (21.4)	5 (17.9)
Blood and lymphatic system disorders					
-Total	5 (17.9)	1 (3.6)	0	3 (10.7)	1 (3.6)
Anaemia	2 (7.1)	2 (7.1)	0	0	0
Neutropenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Disseminated intravascular coagulation	1 (3.6)	0	0	1 (3.6)	0
Febrile neutropenia	1 (3.6)	0	0	1 (3.6)	0
Thrombocytopenia	1 (3.6)	0	0	1 (3.6)	0
Gastrointestinal disorders					
-Total	5 (17.9)	3 (10.7)	1 (3.6)	1 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	2 (7.1)	0	2 (7.1)	0	0
Pancreatitis	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Vomiting	2 (7.1)	2 (7.1)	0	0	0
Abdominal pain upper	1 (3.6)	1 (3.6)	0	0	0
Diarrhoea	1 (3.6)	1 (3.6)	0	0	0
Nausea	1 (3.6)	1 (3.6)	0	0	0
General disorders and administration site conditions					
-Total	4 (14.3)	1 (3.6)	3 (10.7)	0	0
Pyrexia	4 (14.3)	1 (3.6)	3 (10.7)	0	0
Asthenia	1 (3.6)	1 (3.6)	0	0	0
Immune system disorders					
-Total	1 (3.6)	0	0	1 (3.6)	0
Immunodeficiency	1 (3.6)	0	0	1 (3.6)	0
Infections and infestations					
-Total	15 (53.6)	5 (17.9)	5 (17.9)	3 (10.7)	2 (7.1)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)	0	0
Gastroenteritis	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Rhinitis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Upper respiratory tract infection	2 (7.1)	2 (7.1)	0	0	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Conjunctivitis	1 (3.6)	0	1 (3.6)	0	0
Nail infection	1 (3.6)	1 (3.6)	0	0	0
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0
Rhinovirus infection	1 (3.6)	0	1 (3.6)	0	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Investigations					
-Total	4 (14.3)	2 (7.1)	0	0	2 (7.1)
White blood cell count decreased	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Neutrophil count decreased	2 (7.1)	0	0	0	2 (7.1)
Platelet count decreased	2 (7.1)	2 (7.1)	0	0	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.6)	0	0	1 (3.6)	0
Decreased appetite	1 (3.6)	0	0	1 (3.6)	0
Hypophosphataemia	1 (3.6)	0	1 (3.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Back pain	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Arthralgia	1 (3.6)	1 (3.6)	0	0	0
Nervous system disorders					
-Total	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Headache	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Psychiatric disorders					
-Total	2 (7.1)	0	2 (7.1)	0	0
Anxiety	2 (7.1)	0	2 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (17.9)	3 (10.7)	1 (3.6)	0	1 (3.6)
Cough	4 (14.3)	3 (10.7)	1 (3.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (3.6)	0	0	0	1 (3.6)
Skin and subcutaneous tissue disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Dermatitis atopic	1 (3.6)	1 (3.6)	0	0	0
Dry skin	1 (3.6)	0	1 (3.6)	0	0
Rash	1 (3.6)	0	1 (3.6)	0	0
Vascular disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Hypotension	1 (3.6)	1 (3.6)	0	0	0

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Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	6 (15.0)	13 (32.5)	12 (30.0)	4 (10.0)
Blood and lymphatic system disorders					
-Total	5 (12.5)	1 (2.5)	1 (2.5)	2 (5.0)	1 (2.5)
Anaemia	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Febrile neutropenia	2 (5.0)	0	0	2 (5.0)	0
Leukopenia	1 (2.5)	0	1 (2.5)	0	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					
-Total	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Tachycardia	2 (5.0)	2 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (2.5)	0	0	1 (2.5)	0
Gastrointestinal disorders					
-Total	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Diarrhoea	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Nausea	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Vomiting	4 (10.0)	4 (10.0)	0	0	0
Abdominal pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	18 (45.0)	12 (30.0)	3 (7.5)	3 (7.5)	0
Pyrexia	10 (25.0)	5 (12.5)	3 (7.5)	2 (5.0)	0
Fatigue	6 (15.0)	6 (15.0)	0	0	0
Pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Chills	1 (2.5)	1 (2.5)	0	0	0
Oedema peripheral	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	8 (20.0)	0	8 (20.0)	0	0
Hypogammaglobulinaemia	8 (20.0)	0	8 (20.0)	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (32.5)	1 (2.5)	8 (20.0)	3 (7.5)	1 (2.5)
Upper respiratory tract infection	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Rhinovirus infection	3 (7.5)	0	3 (7.5)	0	0
Gastroenteritis	2 (5.0)	2 (5.0)	0	0	0
Otitis externa	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Otitis media	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Parainfluenzae virus infection	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinusitis	2 (5.0)	0	2 (5.0)	0	0
Bacteraemia	1 (2.5)	0	1 (2.5)	0	0
Bk virus infection	1 (2.5)	0	0	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0	0	0
Investigations					
-Total	15 (37.5)	4 (10.0)	3 (7.5)	7 (17.5)	1 (2.5)
Neutrophil count decreased	7 (17.5)	2 (5.0)	1 (2.5)	3 (7.5)	1 (2.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	2 (5.0)	1 (2.5)	1 (2.5)
Lymphocyte count decreased	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Alanine aminotransferase increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood bilirubin increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	10 (25.0)	4 (10.0)	2 (5.0)	2 (5.0)	2 (5.0)
Decreased appetite	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Hyperuricaemia	3 (7.5)	3 (7.5)	0	0	0
Hypokalaemia	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hypervolaemia	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	0	1 (2.5)
Musculoskeletal and connective tissue disorders					
-Total	9 (22.5)	3 (7.5)	3 (7.5)	3 (7.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	5 (12.5)	2 (5.0)	2 (5.0)	1 (2.5)	0
Back pain	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Arthralgia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Myalgia	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Headache	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Psychiatric disorders					
-Total	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Mental status changes	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Agitation	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Acute kidney injury	3 (7.5)	1 (2.5)	1 (2.5)	0	1 (2.5)
Haematuria	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (30.0)	7 (17.5)	2 (5.0)	3 (7.5)	0
Cough	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Nasal congestion	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Hypoxia	3 (7.5)	0	0	3 (7.5)	0
Rhinorrhoea	3 (7.5)	3 (7.5)	0	0	0
Oropharyngeal pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Dyspnoea	1 (2.5)	0	1 (2.5)	0	0
Pleural effusion	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (20.0)	6 (15.0)	2 (5.0)	0	0
Dry skin	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Rash	3 (7.5)	3 (7.5)	0	0	0
Pruritus	1 (2.5)	0	1 (2.5)	0	0
Vascular disorders					
-Total	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Hypotension	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Hypertension	1 (2.5)	0	1 (2.5)	0	0

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Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	1 (14.3)	1 (14.3)	4 (57.1)
Blood and lymphatic system disorders					
-Total	4 (57.1)	0	1 (14.3)	1 (14.3)	2 (28.6)
Neutropenia	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Anaemia	1 (14.3)	1 (14.3)	0	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Cardiac disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Cardiac failure	1 (14.3)	0	0	0	1 (14.3)
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Enteritis	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	1 (14.3)	0	0	0
Trichoglossia	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Hypogammaglobulinaemia	2 (28.6)	0	2 (28.6)	0	0
Infections and infestations					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	0	1 (14.3)	0
Metabolism and nutrition disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Metabolic acidosis	1 (14.3)	0	0	0	1 (14.3)
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Cystitis haemorrhagic	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract inflammation	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Skin swelling	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Hypotension	1 (14.3)	0	0	0	1 (14.3)

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Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (45.5)	4 (18.2)	1 (4.5)	1 (4.5)	4 (18.2)
Blood and lymphatic system disorders					
-Total	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Anaemia	1 (4.5)	0	1 (4.5)	0	0
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Thrombocytopenia	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Diarrhoea	3 (13.6)	2 (9.1)	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Pyrexia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Infections and infestations					
-Total	8 (36.4)	4 (18.2)	0	1 (4.5)	3 (13.6)
Conjunctivitis	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Sepsis	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Gastroenteritis	1 (4.5)	1 (4.5)	0	0	0
Parainfluenzae virus infection	1 (4.5)	0	0	1 (4.5)	0
Pneumonia	1 (4.5)	0	0	0	1 (4.5)
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Rhinovirus infection	1 (4.5)	0	0	1 (4.5)	0
Sinusitis	1 (4.5)	0	1 (4.5)	0	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	1 (4.5)	1 (4.5)	0	0	0
Platelet count decreased	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Decreased appetite	1 (4.5)	0	0	0	1 (4.5)
Hyperglycaemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (9.1)	0	2 (9.1)	0	0
Pain in extremity	2 (9.1)	0	2 (9.1)	0	0
Nervous system disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Headache	1 (4.5)	0	0	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (13.6)	2 (9.1)	0	0	1 (4.5)
Cough	2 (9.1)	2 (9.1)	0	0	0
Dyspnoea	1 (4.5)	0	0	0	1 (4.5)
Epistaxis	1 (4.5)	1 (4.5)	0	0	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (4.5)	0	1 (4.5)	0	0
Tachypnoea	1 (4.5)	0	0	0	1 (4.5)
Skin and subcutaneous tissue disorders					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Dermatitis atopic	1 (4.5)	0	0	1 (4.5)	0
Dry skin	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Hypertension	1 (4.5)	0	0	1 (4.5)	0

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Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (56.5)	2 (8.7)	8 (34.8)	2 (8.7)	1 (4.3)
Gastrointestinal disorders					
-Total	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Diarrhoea	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Constipation	1 (4.3)	1 (4.3)	0	0	0
Nausea	1 (4.3)	1 (4.3)	0	0	0
Vomiting	1 (4.3)	1 (4.3)	0	0	0
General disorders and administration site conditions					
-Total	3 (13.0)	0	3 (13.0)	0	0
Fatigue	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (4.3)	0	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	1 (4.3)	0	0
Immune system disorders					
-Total	3 (13.0)	0	3 (13.0)	0	0
Hypogammaglobulinaemia	3 (13.0)	0	3 (13.0)	0	0
Infections and infestations					
-Total	7 (30.4)	1 (4.3)	5 (21.7)	1 (4.3)	0
Sinusitis	4 (17.4)	0	4 (17.4)	0	0
Upper respiratory tract infection	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Rhinovirus infection	2 (8.7)	0	2 (8.7)	0	0
Conjunctivitis	1 (4.3)	0	1 (4.3)	0	0
Nail infection	1 (4.3)	0	1 (4.3)	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	0	1 (4.3)	0
Urinary tract infection	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	2 (8.7)	2 (8.7)	0	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (8.7)	2 (8.7)	0	0	0
Blood bilirubin increased	1 (4.3)	1 (4.3)	0	0	0
Platelet count decreased	1 (4.3)	1 (4.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Arthralgia	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Headache	1 (4.3)	0	1 (4.3)	0	0
Seizure	1 (4.3)	0	0	1 (4.3)	0
Psychiatric disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Anxiety	1 (4.3)	0	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (17.4)	1 (4.3)	1 (4.3)	1 (4.3)	1 (4.3)
Rhinorrhoea	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Cough	2 (8.7)	1 (4.3)	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Hypoxia	1 (4.3)	0	0	1 (4.3)	0
Respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Skin and subcutaneous tissue disorders					
-Total	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Rash	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Vascular disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Hypertension	1 (4.3)	0	1 (4.3)	0	0

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Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	0	1 (20.0)	1 (20.0)
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Pain	1 (20.0)	1 (20.0)	0	0	0
Pyrexia	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Otitis media	1 (20.0)	0	1 (20.0)	0	0
Rhinovirus infection	1 (20.0)	0	1 (20.0)	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0

Timing: >1 year post-CTL019 infusion, Region: Rest of World

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Urinary tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Psychiatric disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Anxiety	1 (20.0)	1 (20.0)	0	0	0

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Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	2 (7.1)	2 (7.1)	7 (25.0)	17 (60.7)
Blood and lymphatic system disorders					
-Total	16 (57.1)	1 (3.6)	1 (3.6)	11 (39.3)	3 (10.7)
Anaemia	8 (28.6)	3 (10.7)	1 (3.6)	4 (14.3)	0
Febrile neutropenia	7 (25.0)	0	0	7 (25.0)	0
Neutropenia	5 (17.9)	0	1 (3.6)	2 (7.1)	2 (7.1)
Disseminated intravascular coagulation	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Thrombocytopenia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Leukopenia	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	19 (67.9)	7 (25.0)	8 (28.6)	4 (14.3)	0
Diarrhoea	8 (28.6)	3 (10.7)	4 (14.3)	1 (3.6)	0
Vomiting	8 (28.6)	6 (21.4)	2 (7.1)	0	0
Abdominal pain	5 (17.9)	0	5 (17.9)	0	0
Constipation	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Nausea	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Abdominal pain upper	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Pancreatitis	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Stomatitis	1 (3.6)	0	0	1 (3.6)	0
General disorders and administration site conditions					
-Total	14 (50.0)	7 (25.0)	5 (17.9)	2 (7.1)	0
Pyrexia	9 (32.1)	4 (14.3)	4 (14.3)	1 (3.6)	0
Asthenia	3 (10.7)	3 (10.7)	0	0	0
Face oedema	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Oedema peripheral	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Fatigue	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Influenza like illness	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					
-Total	22 (78.6)	0	5 (17.9)	9 (32.1)	8 (28.6)
Cytokine release syndrome	19 (67.9)	0	6 (21.4)	5 (17.9)	8 (28.6)
Hypogammaglobulinaemia	10 (35.7)	1 (3.6)	5 (17.9)	4 (14.3)	0
Immunodeficiency	4 (14.3)	0	0	4 (14.3)	0
Infections and infestations					
-Total	20 (71.4)	7 (25.0)	5 (17.9)	3 (10.7)	5 (17.9)
Nasopharyngitis	6 (21.4)	3 (10.7)	3 (10.7)	0	0
Conjunctivitis	5 (17.9)	1 (3.6)	4 (14.3)	0	0
Gastroenteritis	4 (14.3)	2 (7.1)	0	2 (7.1)	0
Nail infection	3 (10.7)	3 (10.7)	0	0	0
Pneumonia	3 (10.7)	0	1 (3.6)	0	2 (7.1)
Respiratory tract infection	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Rhinitis	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Sepsis	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Upper respiratory tract infection	3 (10.7)	3 (10.7)	0	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Rhinovirus infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Bacteraemia	1 (3.6)	0	0	0	1 (3.6)
Encephalitis viral	1 (3.6)	0	0	1 (3.6)	0
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Sinusitis	1 (3.6)	0	0	1 (3.6)	0
Urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Investigations					
-Total	11 (39.3)	1 (3.6)	1 (3.6)	2 (7.1)	7 (25.0)
Lymphocyte count decreased	7 (25.0)	1 (3.6)	0	3 (10.7)	3 (10.7)
Neutrophil count decreased	6 (21.4)	0	0	0	6 (21.4)
Platelet count decreased	6 (21.4)	2 (7.1)	1 (3.6)	1 (3.6)	2 (7.1)
White blood cell count decreased	6 (21.4)	1 (3.6)	0	1 (3.6)	4 (14.3)
Alanine aminotransferase increased	2 (7.1)	0	0	2 (7.1)	0
Aspartate aminotransferase increased	1 (3.6)	0	0	1 (3.6)	0
Blood bilirubin increased	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (3.6)	0	0	0	1 (3.6)
Serum ferritin increased	1 (3.6)	1 (3.6)	0	0	0
Metabolism and nutrition disorders					
-Total	11 (39.3)	2 (7.1)	2 (7.1)	5 (17.9)	2 (7.1)
Decreased appetite	5 (17.9)	2 (7.1)	1 (3.6)	1 (3.6)	1 (3.6)
Hypokalaemia	5 (17.9)	1 (3.6)	1 (3.6)	3 (10.7)	0
Hypophosphataemia	4 (14.3)	0	1 (3.6)	2 (7.1)	1 (3.6)
Hyperglycaemia	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Hyperuricaemia	1 (3.6)	0	1 (3.6)	0	0
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)	0	0
Hypocalcaemia	1 (3.6)	0	0	1 (3.6)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (39.3)	4 (14.3)	6 (21.4)	1 (3.6)	0
Pain in extremity	6 (21.4)	2 (7.1)	4 (14.3)	0	0
Back pain	5 (17.9)	1 (3.6)	3 (10.7)	1 (3.6)	0
Arthralgia	4 (14.3)	2 (7.1)	2 (7.1)	0	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (3.6)	1 (3.6)	0	0	0
Nervous system disorders					
-Total	14 (50.0)	5 (17.9)	5 (17.9)	4 (14.3)	0
Headache	10 (35.7)	6 (21.4)	3 (10.7)	1 (3.6)	0
Encephalopathy	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Seizure	2 (7.1)	0	0	2 (7.1)	0
Psychiatric disorders					
-Total	6 (21.4)	2 (7.1)	3 (10.7)	1 (3.6)	0
Anxiety	4 (14.3)	0	3 (10.7)	1 (3.6)	0
Confusional state	2 (7.1)	2 (7.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (57.1)	8 (28.6)	3 (10.7)	3 (10.7)	2 (7.1)
Cough	10 (35.7)	8 (28.6)	2 (7.1)	0	0
Pulmonary oedema	4 (14.3)	1 (3.6)	0	3 (10.7)	0
Hypoxia	3 (10.7)	0	3 (10.7)	0	0
Oropharyngeal pain	3 (10.7)	3 (10.7)	0	0	0
Dyspnoea	1 (3.6)	0	0	0	1 (3.6)

Timing: Any time post CTL019 infusion, Region: Europe

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	1 (3.6)	1 (3.6)	0	0	0
Pleural effusion	1 (3.6)	0	1 (3.6)	0	0
Respiratory failure	1 (3.6)	0	0	0	1 (3.6)
Tachypnoea	1 (3.6)	0	0	0	1 (3.6)
Skin and subcutaneous tissue disorders					
-Total	7 (25.0)	3 (10.7)	3 (10.7)	1 (3.6)	0
Dermatitis atopic	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Dry skin	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Pruritus	2 (7.1)	0	2 (7.1)	0	0
Rash	2 (7.1)	0	2 (7.1)	0	0
Vascular disorders					
-Total	7 (25.0)	2 (7.1)	2 (7.1)	3 (10.7)	0
Hypotension	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Hypertension	3 (10.7)	1 (3.6)	0	2 (7.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (100)	0	5 (11.1)	13 (28.9)	27 (60.0)
Blood and lymphatic system disorders					
-Total	29 (64.4)	1 (2.2)	3 (6.7)	18 (40.0)	7 (15.6)
Febrile neutropenia	20 (44.4)	0	0	18 (40.0)	2 (4.4)
Anaemia	16 (35.6)	4 (8.9)	7 (15.6)	5 (11.1)	0
Thrombocytopenia	5 (11.1)	0	0	1 (2.2)	4 (8.9)
Disseminated intravascular coagulation	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Neutropenia	3 (6.7)	0	1 (2.2)	0	2 (4.4)
Leukopenia	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	18 (40.0)	7 (15.6)	6 (13.3)	3 (6.7)	2 (4.4)
Tachycardia	17 (37.8)	7 (15.6)	7 (15.6)	2 (4.4)	1 (2.2)
Cardiac failure	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Gastrointestinal disorders					
-Total	33 (73.3)	14 (31.1)	13 (28.9)	6 (13.3)	0
Vomiting	18 (40.0)	11 (24.4)	6 (13.3)	1 (2.2)	0
Diarrhoea	17 (37.8)	13 (28.9)	3 (6.7)	1 (2.2)	0
Nausea	16 (35.6)	9 (20.0)	6 (13.3)	1 (2.2)	0
Constipation	7 (15.6)	4 (8.9)	3 (6.7)	0	0
Abdominal pain	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Pancreatitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Abdominal pain upper	1 (2.2)	1 (2.2)	0	0	0
Stomatitis	1 (2.2)	0	1 (2.2)	0	0
Trichoglossia	1 (2.2)	0	1 (2.2)	0	0
General disorders and administration site conditions					
-Total	35 (77.8)	17 (37.8)	8 (17.8)	8 (17.8)	2 (4.4)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	25 (55.6)	9 (20.0)	6 (13.3)	8 (17.8)	2 (4.4)
Fatigue	16 (35.6)	13 (28.9)	3 (6.7)	0	0
Chills	7 (15.6)	5 (11.1)	2 (4.4)	0	0
Oedema peripheral	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Face oedema	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Pain	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Hepatobiliary disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Hepatic function abnormal	1 (2.2)	0	1 (2.2)	0	0
Immune system disorders					
-Total	41 (91.1)	2 (4.4)	17 (37.8)	12 (26.7)	10 (22.2)
Cytokine release syndrome	36 (80.0)	4 (8.9)	12 (26.7)	10 (22.2)	10 (22.2)
Hypogammaglobulinaemia	19 (42.2)	1 (2.2)	15 (33.3)	3 (6.7)	0
Infections and infestations					
-Total	19 (42.2)	2 (4.4)	11 (24.4)	5 (11.1)	1 (2.2)
Upper respiratory tract infection	8 (17.8)	2 (4.4)	5 (11.1)	1 (2.2)	0
Rhinovirus infection	6 (13.3)	0	6 (13.3)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	5 (11.1)	0	4 (8.9)	1 (2.2)	0
Conjunctivitis	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Otitis media	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Gastroenteritis	2 (4.4)	2 (4.4)	0	0	0
Otitis externa	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Parainfluenzae virus infection	2 (4.4)	0	1 (2.2)	0	1 (2.2)
Pneumonia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Respiratory syncytial virus infection	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Bacteraemia	1 (2.2)	0	1 (2.2)	0	0
Bk virus infection	1 (2.2)	0	0	1 (2.2)	0
Nail infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Investigations					
-Total	33 (73.3)	2 (4.4)	3 (6.7)	13 (28.9)	15 (33.3)
Aspartate aminotransferase increased	18 (40.0)	2 (4.4)	6 (13.3)	7 (15.6)	3 (6.7)
Alanine aminotransferase increased	16 (35.6)	3 (6.7)	8 (17.8)	5 (11.1)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	16 (35.6)	4 (8.9)	2 (4.4)	5 (11.1)	5 (11.1)
Neutrophil count decreased	15 (33.3)	1 (2.2)	2 (4.4)	4 (8.9)	8 (17.8)
White blood cell count decreased	15 (33.3)	2 (4.4)	4 (8.9)	1 (2.2)	8 (17.8)
Blood bilirubin increased	12 (26.7)	1 (2.2)	3 (6.7)	8 (17.8)	0
Lymphocyte count decreased	10 (22.2)	0	1 (2.2)	7 (15.6)	2 (4.4)
International normalised ratio increased	9 (20.0)	6 (13.3)	3 (6.7)	0	0
Blood immunoglobulin a decreased	7 (15.6)	5 (11.1)	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	7 (15.6)	4 (8.9)	1 (2.2)	2 (4.4)	0
Activated partial thromboplastin time prolonged	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Blood creatinine increased	5 (11.1)	1 (2.2)	1 (2.2)	2 (4.4)	1 (2.2)
Electrocardiogram qt prolonged	5 (11.1)	1 (2.2)	2 (4.4)	1 (2.2)	1 (2.2)
Blood fibrinogen decreased	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Serum ferritin increased	4 (8.9)	0	2 (4.4)	2 (4.4)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (2.2)	0	0	0	1 (2.2)
Metabolism and nutrition disorders					
-Total	37 (82.2)	8 (17.8)	8 (17.8)	15 (33.3)	6 (13.3)
Decreased appetite	25 (55.6)	9 (20.0)	6 (13.3)	9 (20.0)	1 (2.2)
Hypocalcaemia	15 (33.3)	2 (4.4)	9 (20.0)	4 (8.9)	0
Hypokalaemia	15 (33.3)	2 (4.4)	5 (11.1)	6 (13.3)	2 (4.4)
Hypophosphataemia	14 (31.1)	3 (6.7)	5 (11.1)	6 (13.3)	0
Hypoalbuminaemia	9 (20.0)	0	8 (17.8)	1 (2.2)	0
Hyperuricaemia	8 (17.8)	7 (15.6)	0	1 (2.2)	0
Hypervolaemia	7 (15.6)	0	2 (4.4)	5 (11.1)	0
Hyperglycaemia	6 (13.3)	0	3 (6.7)	3 (6.7)	0
Hyperphosphataemia	5 (11.1)	4 (8.9)	0	0	1 (2.2)
Hypomagnesaemia	3 (6.7)	3 (6.7)	0	0	0
Metabolic acidosis	3 (6.7)	1 (2.2)	0	0	2 (4.4)
Tumour lysis syndrome	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (51.1)	11 (24.4)	8 (17.8)	4 (8.9)	0
Pain in extremity	10 (22.2)	6 (13.3)	3 (6.7)	1 (2.2)	0
Myalgia	9 (20.0)	5 (11.1)	4 (8.9)	0	0
Arthralgia	8 (17.8)	3 (6.7)	4 (8.9)	1 (2.2)	0
Back pain	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Nervous system disorders					
-Total	21 (46.7)	7 (15.6)	8 (17.8)	6 (13.3)	0
Headache	16 (35.6)	6 (13.3)	8 (17.8)	2 (4.4)	0
Encephalopathy	5 (11.1)	1 (2.2)	1 (2.2)	3 (6.7)	0
Somnolence	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Seizure	1 (2.2)	0	0	1 (2.2)	0
Psychiatric disorders					
-Total	21 (46.7)	7 (15.6)	8 (17.8)	6 (13.3)	0
Anxiety	9 (20.0)	2 (4.4)	6 (13.3)	1 (2.2)	0
Delirium	8 (17.8)	2 (4.4)	3 (6.7)	3 (6.7)	0
Agitation	6 (13.3)	3 (6.7)	3 (6.7)	0	0
Confusional state	5 (11.1)	5 (11.1)	0	0	0
Mental status changes	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	10 (22.2)	2 (4.4)	1 (2.2)	4 (8.9)	3 (6.7)
Acute kidney injury	10 (22.2)	2 (4.4)	2 (4.4)	3 (6.7)	3 (6.7)
Haematuria	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (62.2)	9 (20.0)	1 (2.2)	9 (20.0)	9 (20.0)
Hypoxia	14 (31.1)	0	1 (2.2)	10 (22.2)	3 (6.7)
Cough	13 (28.9)	10 (22.2)	3 (6.7)	0	0
Nasal congestion	9 (20.0)	7 (15.6)	2 (4.4)	0	0
Pulmonary oedema	8 (17.8)	1 (2.2)	3 (6.7)	3 (6.7)	1 (2.2)
Tachypnoea	8 (17.8)	3 (6.7)	1 (2.2)	4 (8.9)	0
Dyspnoea	6 (13.3)	1 (2.2)	2 (4.4)	2 (4.4)	1 (2.2)
Pleural effusion	6 (13.3)	3 (6.7)	0	2 (4.4)	1 (2.2)
Rhinorrhoea	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Epistaxis	5 (11.1)	2 (4.4)	2 (4.4)	1 (2.2)	0
Respiratory failure	5 (11.1)	0	0	0	5 (11.1)
Oropharyngeal pain	4 (8.9)	3 (6.7)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	14 (31.1)	9 (20.0)	5 (11.1)	0	0
Rash	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Dry skin	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Pruritus	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Skin ulcer	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	23 (51.1)	3 (6.7)	5 (11.1)	8 (17.8)	7 (15.6)
Hypotension	19 (42.2)	1 (2.2)	4 (8.9)	7 (15.6)	7 (15.6)
Hypertension	12 (26.7)	3 (6.7)	6 (13.3)	3 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders					
-Total	6 (85.7)	0	2 (28.6)	0	4 (57.1)
Neutropenia	3 (42.9)	0	0	0	3 (42.9)
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)	0	0
Anaemia	1 (14.3)	0	1 (14.3)	0	0
B-cell aplasia	1 (14.3)	0	1 (14.3)	0	0
Hypofibrinogenaemia	1 (14.3)	0	1 (14.3)	0	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	0	1 (14.3)
Cardiac dysfunction	2 (28.6)	2 (28.6)	0	0	0
Cardiac failure	1 (14.3)	0	0	0	1 (14.3)
Gastrointestinal disorders					
-Total	6 (85.7)	2 (28.6)	4 (57.1)	0	0
Constipation	2 (28.6)	2 (28.6)	0	0	0
Nausea	2 (28.6)	2 (28.6)	0	0	0
Pancreatitis	2 (28.6)	0	2 (28.6)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Enteritis	1 (14.3)	0	1 (14.3)	0	0
Enterocolitis	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	1 (14.3)	0	0	0
Trichoglossia	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Face oedema	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza like illness	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)
Hepatic function abnormal	4 (57.1)	0	1 (14.3)	2 (28.6)	1 (14.3)
Immune system disorders					
-Total	7 (100)	0	2 (28.6)	2 (28.6)	3 (42.9)
Cytokine release syndrome	6 (85.7)	1 (14.3)	0	2 (28.6)	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Infections and infestations					
-Total	6 (85.7)	2 (28.6)	0	3 (42.9)	1 (14.3)
Upper respiratory tract infection	2 (28.6)	0	0	2 (28.6)	0
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bk virus infection	1 (14.3)	1 (14.3)	0	0	0
Encephalitis viral	1 (14.3)	0	0	0	1 (14.3)
Meningitis bacterial	1 (14.3)	0	0	1 (14.3)	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	1 (14.3)	0	0
Parainfluenzae virus infection	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	0	1 (14.3)	0
Sinusitis	1 (14.3)	0	1 (14.3)	0	0
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Urinary tract infection viral	1 (14.3)	1 (14.3)	0	0	0
Investigations					
-Total	5 (71.4)	0	0	0	5 (71.4)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Serum ferritin increased	3 (42.9)	0	3 (42.9)	0	0
Blood fibrinogen decreased	2 (28.6)	0	2 (28.6)	0	0
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Blood creatine phosphokinase increased	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Metabolic acidosis	1 (14.3)	0	0	0	1 (14.3)
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Psychiatric disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Anxiety	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	4 (57.1)	1 (14.3)	1 (14.3)	0	2 (28.6)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (28.6)	0	0	0	2 (28.6)
Cystitis haemorrhagic	1 (14.3)	0	1 (14.3)	0	0
Haematuria	1 (14.3)	1 (14.3)	0	0	0
Proteinuria	1 (14.3)	1 (14.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Heavy menstrual bleeding	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	1 (14.3)	2 (28.6)	0	3 (42.9)
Hypoxia	3 (42.9)	0	0	0	3 (42.9)
Pleural effusion	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Epistaxis	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0	0	0
Upper respiratory tract inflammation	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Erythema nodosum	1 (14.3)	1 (14.3)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Skin swelling	1 (14.3)	1 (14.3)	0	0	0
Skin ulcer	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Hypertension	1 (14.3)	0	1 (14.3)	0	0
Hypotension	1 (14.3)	0	0	0	1 (14.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (100)	2 (4.2)	4 (8.3)	17 (35.4)	25 (52.1)
Blood and lymphatic system disorders					
-Total	25 (52.1)	1 (2.1)	3 (6.3)	16 (33.3)	5 (10.4)
Febrile neutropenia	14 (29.2)	0	0	14 (29.2)	0
Anaemia	13 (27.1)	2 (4.2)	4 (8.3)	7 (14.6)	0
Neutropenia	5 (10.4)	0	1 (2.1)	1 (2.1)	3 (6.3)
Thrombocytopenia	4 (8.3)	0	0	1 (2.1)	3 (6.3)
Disseminated intravascular coagulation	3 (6.3)	0	3 (6.3)	0	0
Cardiac disorders					
-Total	7 (14.6)	4 (8.3)	2 (4.2)	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	7 (14.6)	4 (8.3)	2 (4.2)	1 (2.1)	0
Gastrointestinal disorders					
-Total	28 (58.3)	13 (27.1)	11 (22.9)	4 (8.3)	0
Vomiting	14 (29.2)	7 (14.6)	7 (14.6)	0	0
Diarrhoea	12 (25.0)	6 (12.5)	5 (10.4)	1 (2.1)	0
Nausea	12 (25.0)	8 (16.7)	3 (6.3)	1 (2.1)	0
Abdominal pain	9 (18.8)	2 (4.2)	5 (10.4)	2 (4.2)	0
Constipation	5 (10.4)	3 (6.3)	2 (4.2)	0	0
General disorders and administration site conditions					
-Total	18 (37.5)	11 (22.9)	4 (8.3)	2 (4.2)	1 (2.1)
Pyrexia	11 (22.9)	5 (10.4)	3 (6.3)	2 (4.2)	1 (2.1)
Fatigue	6 (12.5)	6 (12.5)	0	0	0
Chills	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Face oedema	4 (8.3)	3 (6.3)	1 (2.1)	0	0
Oedema peripheral	2 (4.2)	2 (4.2)	0	0	0
Immune system disorders					
-Total	41 (85.4)	2 (4.2)	13 (27.1)	15 (31.3)	11 (22.9)
Cytokine release syndrome	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	14 (29.2)	0	9 (18.8)	5 (10.4)	0
Haemophagocytic lymphohistiocytosis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Infections and infestations					
-Total	5 (10.4)	0	3 (6.3)	2 (4.2)	0
Conjunctivitis	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rhinovirus infection	1 (2.1)	0	1 (2.1)	0	0
Sinusitis	1 (2.1)	0	0	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Investigations					
-Total	29 (60.4)	4 (8.3)	4 (8.3)	6 (12.5)	15 (31.3)
Alanine aminotransferase increased	13 (27.1)	3 (6.3)	6 (12.5)	4 (8.3)	0
Neutrophil count decreased	13 (27.1)	0	2 (4.2)	1 (2.1)	10 (20.8)
Platelet count decreased	13 (27.1)	2 (4.2)	1 (2.1)	5 (10.4)	5 (10.4)
White blood cell count decreased	13 (27.1)	3 (6.3)	0	1 (2.1)	9 (18.8)
Aspartate aminotransferase increased	10 (20.8)	2 (4.2)	4 (8.3)	2 (4.2)	2 (4.2)
Lymphocyte count decreased	10 (20.8)	1 (2.1)	0	4 (8.3)	5 (10.4)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	5 (10.4)	0	1 (2.1)	4 (8.3)	0
Blood immunoglobulin a decreased	4 (8.3)	4 (8.3)	0	0	0
Blood immunoglobulin m decreased	4 (8.3)	4 (8.3)	0	0	0
Serum ferritin increased	4 (8.3)	0	3 (6.3)	1 (2.1)	0
International normalised ratio increased	3 (6.3)	3 (6.3)	0	0	0
Electrocardiogram qt prolonged	1 (2.1)	0	0	1 (2.1)	0
Metabolism and nutrition disorders					
-Total	24 (50.0)	6 (12.5)	4 (8.3)	11 (22.9)	3 (6.3)
Decreased appetite	14 (29.2)	6 (12.5)	1 (2.1)	6 (12.5)	1 (2.1)
Hypokalaemia	11 (22.9)	2 (4.2)	2 (4.2)	6 (12.5)	1 (2.1)
Hypophosphataemia	10 (20.8)	3 (6.3)	2 (4.2)	4 (8.3)	1 (2.1)
Hypocalcaemia	6 (12.5)	2 (4.2)	2 (4.2)	2 (4.2)	0
Hypoalbuminaemia	5 (10.4)	0	5 (10.4)	0	0
Hyperglycaemia	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Hyperuricaemia	1 (2.1)	0	1 (2.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (2.1)	0	1 (2.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	20 (41.7)	8 (16.7)	11 (22.9)	1 (2.1)	0
Pain in extremity	9 (18.8)	5 (10.4)	4 (8.3)	0	0
Arthralgia	8 (16.7)	4 (8.3)	4 (8.3)	0	0
Back pain	5 (10.4)	1 (2.1)	3 (6.3)	1 (2.1)	0
Myalgia	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Nervous system disorders					
-Total	16 (33.3)	9 (18.8)	4 (8.3)	3 (6.3)	0
Headache	12 (25.0)	8 (16.7)	2 (4.2)	2 (4.2)	0
Encephalopathy	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Psychiatric disorders					
-Total	7 (14.6)	2 (4.2)	4 (8.3)	1 (2.1)	0
Anxiety	5 (10.4)	1 (2.1)	3 (6.3)	1 (2.1)	0
Delirium	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Renal and urinary disorders					
-Total	3 (6.3)	1 (2.1)	1 (2.1)	0	1 (2.1)
Acute kidney injury	3 (6.3)	1 (2.1)	1 (2.1)	0	1 (2.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	23 (47.9)	10 (20.8)	3 (6.3)	6 (12.5)	4 (8.3)
Hypoxia	8 (16.7)	0	3 (6.3)	2 (4.2)	3 (6.3)
Cough	7 (14.6)	6 (12.5)	1 (2.1)	0	0
Pulmonary oedema	6 (12.5)	2 (4.2)	0	4 (8.3)	0
Tachypnoea	5 (10.4)	3 (6.3)	1 (2.1)	1 (2.1)	0
Pleural effusion	4 (8.3)	3 (6.3)	0	0	1 (2.1)
Epistaxis	3 (6.3)	2 (4.2)	0	1 (2.1)	0
Oropharyngeal pain	3 (6.3)	3 (6.3)	0	0	0
Nasal congestion	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Rhinorrhoea	2 (4.2)	2 (4.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (14.6)	3 (6.3)	4 (8.3)	0	0
Pruritus	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rash	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Dry skin	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

Group term Preferred term	All patients N=48 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	14 (29.2)	4 (8.3)	4 (8.3)	4 (8.3)	2 (4.2)
Hypotension	9 (18.8)	1 (2.1)	3 (6.3)	3 (6.3)	2 (4.2)
Hypertension	6 (12.5)	3 (6.3)	2 (4.2)	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	3 (9.4)	4 (12.5)	4 (12.5)	20 (62.5)
Blood and lymphatic system disorders					
-Total	20 (62.5)	1 (3.1)	2 (6.3)	9 (28.1)	8 (25.0)
Febrile neutropenia	12 (37.5)	0	0	10 (31.3)	2 (6.3)
Anaemia	8 (25.0)	3 (9.4)	4 (12.5)	1 (3.1)	0
Disseminated intravascular coagulation	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Neutropenia	4 (12.5)	0	1 (3.1)	0	3 (9.4)
Thrombocytopenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Cardiac disorders					
-Total	10 (31.3)	3 (9.4)	5 (15.6)	1 (3.1)	1 (3.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	10 (31.3)	3 (9.4)	5 (15.6)	1 (3.1)	1 (3.1)
Gastrointestinal disorders					
-Total	18 (56.3)	9 (28.1)	7 (21.9)	2 (6.3)	0
Vomiting	7 (21.9)	5 (15.6)	1 (3.1)	1 (3.1)	0
Constipation	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Nausea	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Diarrhoea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Abdominal pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	18 (56.3)	9 (28.1)	3 (9.4)	5 (15.6)	1 (3.1)
Pyrexia	13 (40.6)	6 (18.8)	2 (6.3)	4 (12.5)	1 (3.1)
Fatigue	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Face oedema	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Oedema peripheral	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Chills	2 (6.3)	2 (6.3)	0	0	0
Immune system disorders					
-Total	25 (78.1)	1 (3.1)	8 (25.0)	6 (18.8)	10 (31.3)
Cytokine release syndrome	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	9 (28.1)	2 (6.3)	5 (15.6)	2 (6.3)	0
Haemophagocytic lymphohistiocytosis	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Infections and infestations					
-Total	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	19 (59.4)	0	0	8 (25.0)	11 (34.4)
White blood cell count decreased	11 (34.4)	0	3 (9.4)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	9 (28.1)	0	2 (6.3)	6 (18.8)	1 (3.1)
Platelet count decreased	8 (25.0)	2 (6.3)	2 (6.3)	1 (3.1)	3 (9.4)
Blood bilirubin increased	7 (21.9)	1 (3.1)	1 (3.1)	5 (15.6)	0
Neutrophil count decreased	7 (21.9)	0	1 (3.1)	1 (3.1)	5 (15.6)
International normalised ratio increased	6 (18.8)	3 (9.4)	3 (9.4)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (15.6)	1 (3.1)	2 (6.3)	2 (6.3)	0
Lymphocyte count decreased	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Electrocardiogram qt prolonged	4 (12.5)	1 (3.1)	2 (6.3)	0	1 (3.1)
Serum ferritin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Blood immunoglobulin g decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood immunoglobulin m decreased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)	0	0
Metabolism and nutrition disorders					
-Total	20 (62.5)	2 (6.3)	6 (18.8)	9 (28.1)	3 (9.4)
Decreased appetite	10 (31.3)	3 (9.4)	3 (9.4)	4 (12.5)	0
Hypocalcaemia	10 (31.3)	0	7 (21.9)	3 (9.4)	0
Hypokalaemia	8 (25.0)	1 (3.1)	3 (9.4)	3 (9.4)	1 (3.1)
Hypophosphataemia	7 (21.9)	0	3 (9.4)	4 (12.5)	0
Hyperuricaemia	6 (18.8)	5 (15.6)	0	1 (3.1)	0
Hypoalbuminaemia	6 (18.8)	0	5 (15.6)	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	5 (15.6)	0	3 (9.4)	2 (6.3)	0
Hyperphosphataemia	5 (15.6)	4 (12.5)	0	0	1 (3.1)
Hypervolaemia	5 (15.6)	0	1 (3.1)	4 (12.5)	0
Metabolic acidosis	3 (9.4)	1 (3.1)	0	0	2 (6.3)
Musculoskeletal and connective tissue disorders					
-Total	8 (25.0)	5 (15.6)	2 (6.3)	1 (3.1)	0
Myalgia	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Arthralgia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Pain in extremity	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Back pain	1 (3.1)	1 (3.1)	0	0	0
Nervous system disorders					
-Total	14 (43.8)	4 (12.5)	7 (21.9)	3 (9.4)	0
Headache	11 (34.4)	4 (12.5)	7 (21.9)	0	0
Encephalopathy	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Psychiatric disorders					
-Total	6 (18.8)	1 (3.1)	1 (3.1)	4 (12.5)	0
Delirium	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Anxiety	1 (3.1)	0	0	1 (3.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Acute kidney injury	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Respiratory, thoracic and mediastinal disorders					
-Total	16 (50.0)	4 (12.5)	0	6 (18.8)	6 (18.8)
Hypoxia	9 (28.1)	0	2 (6.3)	4 (12.5)	3 (9.4)
Pulmonary oedema	6 (18.8)	0	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory failure	4 (12.5)	0	0	0	4 (12.5)
Cough	3 (9.4)	3 (9.4)	0	0	0
Pleural effusion	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Tachypnoea	3 (9.4)	0	0	3 (9.4)	0
Oropharyngeal pain	2 (6.3)	2 (6.3)	0	0	0
Epistaxis	1 (3.1)	0	1 (3.1)	0	0
Nasal congestion	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Pruritus	3 (9.4)	1 (3.1)	2 (6.3)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Vascular disorders					
-Total	13 (40.6)	0	3 (9.4)	6 (18.8)	4 (12.5)
Hypotension	12 (37.5)	0	3 (9.4)	5 (15.6)	4 (12.5)
Hypertension	7 (21.9)	1 (3.1)	3 (9.4)	3 (9.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (89.6)	8 (16.7)	16 (33.3)	11 (22.9)	8 (16.7)
Blood and lymphatic system disorders					
-Total	10 (20.8)	3 (6.3)	0	4 (8.3)	3 (6.3)
Anaemia	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Febrile neutropenia	3 (6.3)	0	0	3 (6.3)	0
Neutropenia	3 (6.3)	0	0	1 (2.1)	2 (4.2)
Thrombocytopenia	2 (4.2)	0	0	1 (2.1)	1 (2.1)
Disseminated intravascular coagulation	1 (2.1)	0	0	1 (2.1)	0
Cardiac disorders					
-Total	2 (4.2)	2 (4.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (4.2)	2 (4.2)	0	0	0
Gastrointestinal disorders					
-Total	9 (18.8)	6 (12.5)	3 (6.3)	0	0
Nausea	4 (8.3)	3 (6.3)	1 (2.1)	0	0
Vomiting	4 (8.3)	4 (8.3)	0	0	0
Constipation	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Diarrhoea	3 (6.3)	3 (6.3)	0	0	0
Abdominal pain	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	14 (29.2)	9 (18.8)	3 (6.3)	2 (4.2)	0
Pyrexia	10 (20.8)	5 (10.4)	3 (6.3)	2 (4.2)	0
Fatigue	4 (8.3)	4 (8.3)	0	0	0
Chills	1 (2.1)	1 (2.1)	0	0	0
Immune system disorders					
-Total	9 (18.8)	0	9 (18.8)	0	0
Hypogammaglobulinaemia	9 (18.8)	0	9 (18.8)	0	0
Infections and infestations					
-Total	15 (31.3)	4 (8.3)	6 (12.5)	5 (10.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Gastroenteritis	4 (8.3)	2 (4.2)	0	2 (4.2)	0
Rhinovirus infection	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Upper respiratory tract infection	4 (8.3)	1 (2.1)	1 (2.1)	2 (4.2)	0
Sinusitis	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Investigations					
-Total	14 (29.2)	4 (8.3)	2 (4.2)	4 (8.3)	4 (8.3)
Neutrophil count decreased	7 (14.6)	1 (2.1)	1 (2.1)	1 (2.1)	4 (8.3)
White blood cell count decreased	6 (12.5)	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)
Platelet count decreased	4 (8.3)	2 (4.2)	0	1 (2.1)	1 (2.1)
Alanine aminotransferase increased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood bilirubin increased	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Blood immunoglobulin a decreased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Lymphocyte count decreased	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Blood immunoglobulin m decreased	1 (2.1)	0	0	1 (2.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	8 (16.7)	3 (6.3)	1 (2.1)	3 (6.3)	1 (2.1)
Decreased appetite	4 (8.3)	2 (4.2)	1 (2.1)	1 (2.1)	0
Hypokalaemia	3 (6.3)	0	1 (2.1)	1 (2.1)	1 (2.1)
Hyperuricaemia	2 (4.2)	2 (4.2)	0	0	0
Hypervolaemia	1 (2.1)	0	0	1 (2.1)	0
Hypophosphataemia	1 (2.1)	0	1 (2.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (14.6)	3 (6.3)	2 (4.2)	2 (4.2)	0
Back pain	4 (8.3)	2 (4.2)	1 (2.1)	1 (2.1)	0
Pain in extremity	3 (6.3)	1 (2.1)	1 (2.1)	1 (2.1)	0
Arthralgia	2 (4.2)	2 (4.2)	0	0	0
Nervous system disorders					
-Total	6 (12.5)	3 (6.3)	3 (6.3)	0	0
Headache	6 (12.5)	3 (6.3)	3 (6.3)	0	0
Psychiatric disorders					
-Total	3 (6.3)	1 (2.1)	2 (4.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Delirium	1 (2.1)	0	1 (2.1)	0	0
Renal and urinary disorders					
-Total	2 (4.2)	1 (2.1)	0	0	1 (2.1)
Acute kidney injury	2 (4.2)	1 (2.1)	0	0	1 (2.1)
Respiratory, thoracic and mediastinal disorders					
-Total	14 (29.2)	9 (18.8)	3 (6.3)	2 (4.2)	0
Cough	9 (18.8)	7 (14.6)	2 (4.2)	0	0
Nasal congestion	4 (8.3)	4 (8.3)	0	0	0
Rhinorrhoea	3 (6.3)	3 (6.3)	0	0	0
Epistaxis	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Hypoxia	2 (4.2)	0	0	2 (4.2)	0
Pleural effusion	2 (4.2)	1 (2.1)	1 (2.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Dry skin	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Rash	3 (6.3)	2 (4.2)	1 (2.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=48 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	3 (6.3)	1 (2.1)	1 (2.1)	0	1 (2.1)
Hypotension	2 (4.2)	1 (2.1)	0	0	1 (2.1)
Hypertension	1 (2.1)	0	1 (2.1)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (70.4)	3 (11.1)	6 (22.2)	7 (25.9)	3 (11.1)
Blood and lymphatic system disorders					
-Total	3 (11.1)	0	0	2 (7.4)	1 (3.7)
Neutropenia	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Anaemia	1 (3.7)	0	0	1 (3.7)	0
Gastrointestinal disorders					
-Total	5 (18.5)	3 (11.1)	2 (7.4)	0	0
Diarrhoea	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Vomiting	2 (7.4)	2 (7.4)	0	0	0
Abdominal pain	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (3.7)	0	1 (3.7)	0	0
General disorders and administration site conditions					
-Total	8 (29.6)	5 (18.5)	3 (11.1)	0	0
Pyrexia	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Fatigue	2 (7.4)	2 (7.4)	0	0	0
Oedema peripheral	1 (3.7)	1 (3.7)	0	0	0
Immune system disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Hypogammaglobulinaemia	1 (3.7)	0	1 (3.7)	0	0
Infections and infestations					
-Total	7 (25.9)	2 (7.4)	4 (14.8)	1 (3.7)	0
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Nasopharyngitis	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Conjunctivitis	1 (3.7)	0	1 (3.7)	0	0
Gastroenteritis	1 (3.7)	1 (3.7)	0	0	0
Rhinovirus infection	1 (3.7)	0	1 (3.7)	0	0
Sinusitis	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (3.7)	0	0	1 (3.7)	0
Investigations					
-Total	8 (29.6)	2 (7.4)	2 (7.4)	4 (14.8)	0
White blood cell count decreased	4 (14.8)	1 (3.7)	1 (3.7)	2 (7.4)	0
Neutrophil count decreased	3 (11.1)	1 (3.7)	0	2 (7.4)	0
Lymphocyte count decreased	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Blood immunoglobulin g decreased	1 (3.7)	0	1 (3.7)	0	0
Platelet count decreased	1 (3.7)	1 (3.7)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (14.8)	1 (3.7)	2 (7.4)	0	1 (3.7)
Decreased appetite	2 (7.4)	0	2 (7.4)	0	0
Hyperuricaemia	1 (3.7)	1 (3.7)	0	0	0
Metabolic acidosis	1 (3.7)	0	0	0	1 (3.7)
Musculoskeletal and connective tissue disorders					
-Total	4 (14.8)	1 (3.7)	2 (7.4)	1 (3.7)	0
Back pain	2 (7.4)	0	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Arthralgia	1 (3.7)	0	1 (3.7)	0	0
Myalgia	1 (3.7)	0	1 (3.7)	0	0
Nervous system disorders					
-Total	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Headache	4 (14.8)	3 (11.1)	1 (3.7)	0	0
Psychiatric disorders					
-Total	3 (11.1)	0	3 (11.1)	0	0
Anxiety	3 (11.1)	0	3 (11.1)	0	0
Renal and urinary disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Acute kidney injury	1 (3.7)	0	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (14.8)	1 (3.7)	1 (3.7)	1 (3.7)	1 (3.7)
Cough	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Nasal congestion	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Oropharyngeal pain	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Epistaxis	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=27 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (3.7)	0	0	1 (3.7)	0
Respiratory failure	1 (3.7)	0	0	0	1 (3.7)
Skin and subcutaneous tissue disorders					
-Total	5 (18.5)	4 (14.8)	1 (3.7)	0	0
Dry skin	3 (11.1)	3 (11.1)	0	0	0
Pruritus	1 (3.7)	0	1 (3.7)	0	0
Rash	1 (3.7)	1 (3.7)	0	0	0
Vascular disorders					
-Total	2 (7.4)	0	0	1 (3.7)	1 (3.7)
Hypotension	2 (7.4)	0	0	1 (3.7)	1 (3.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (51.5)	5 (15.2)	6 (18.2)	2 (6.1)	4 (12.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	0	1 (3.0)	0	1 (3.0)
Anaemia	1 (3.0)	0	1 (3.0)	0	0
Neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Diarrhoea	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Nausea	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (3.0)	1 (3.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Pyrexia	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Fatigue	1 (3.0)	0	1 (3.0)	0	0
Immune system disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Hypogammaglobulinaemia	2 (6.1)	0	2 (6.1)	0	0
Infections and infestations					
-Total	10 (30.3)	4 (12.1)	5 (15.2)	1 (3.0)	0
Sinusitis	4 (12.1)	0	4 (12.1)	0	0
Conjunctivitis	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Upper respiratory tract infection	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Gastroenteritis	1 (3.0)	1 (3.0)	0	0	0
Rhinovirus infection	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	4 (12.1)	3 (9.1)	0	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (9.1)	2 (6.1)	0	0	1 (3.0)
Platelet count decreased	2 (6.1)	2 (6.1)	0	0	0
Blood bilirubin increased	1 (3.0)	1 (3.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (3.0)	0	0	0	1 (3.0)
Decreased appetite	1 (3.0)	0	0	0	1 (3.0)
Musculoskeletal and connective tissue disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Pain in extremity	2 (6.1)	0	2 (6.1)	0	0
Nervous system disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Headache	1 (3.0)	0	0	1 (3.0)	0
Psychiatric disorders					
-Total	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Anxiety	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (15.2)	3 (9.1)	1 (3.0)	0	1 (3.0)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Rhinorrhoea	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Respiratory failure	1 (3.0)	0	0	0	1 (3.0)
Skin and subcutaneous tissue disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Dry skin	1 (3.0)	1 (3.0)	0	0	0
Vascular disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Hypertension	1 (3.0)	0	1 (3.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (47.1)	0	5 (29.4)	2 (11.8)	1 (5.9)
Gastrointestinal disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Constipation	1 (5.9)	1 (5.9)	0	0	0
Diarrhoea	1 (5.9)	1 (5.9)	0	0	0
General disorders and administration site conditions					
-Total	2 (11.8)	0	2 (11.8)	0	0
Pyrexia	2 (11.8)	0	2 (11.8)	0	0
Immune system disorders					
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	0	0	1 (5.9)
Hypogammaglobulinaemia	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Rhinovirus infection	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Sinusitis	2 (11.8)	0	2 (11.8)	0	0
Upper respiratory tract infection	2 (11.8)	0	2 (11.8)	0	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Staphylococcal bacteraemia	1 (5.9)	0	0	1 (5.9)	0
Investigations					
-Total	1 (5.9)	0	1 (5.9)	0	0
Blood immunoglobulin g decreased	1 (5.9)	0	1 (5.9)	0	0
Metabolism and nutrition disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	0	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Arthralgia	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Headache	1 (5.9)	0	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Cough	1 (5.9)	1 (5.9)	0	0	0
Hypoxia	1 (5.9)	0	0	1 (5.9)	0
Pleural effusion	1 (5.9)	0	1 (5.9)	0	0
Rhinorrhoea	1 (5.9)	0	1 (5.9)	0	0
Tachypnoea	1 (5.9)	0	0	0	1 (5.9)
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Rash	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Vascular disorders					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (5.9)	0	0	1 (5.9)	0
Hypertension	1 (5.9)	0	0	1 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (100)	1 (2.1)	4 (8.3)	15 (31.3)	28 (58.3)
Blood and lymphatic system disorders					
-Total	29 (60.4)	1 (2.1)	3 (6.3)	19 (39.6)	6 (12.5)
Anaemia	16 (33.3)	4 (8.3)	5 (10.4)	7 (14.6)	0
Febrile neutropenia	15 (31.3)	0	0	15 (31.3)	0
Neutropenia	7 (14.6)	0	1 (2.1)	2 (4.2)	4 (8.3)
Thrombocytopenia	5 (10.4)	0	0	2 (4.2)	3 (6.3)
Disseminated intravascular coagulation	4 (8.3)	0	3 (6.3)	1 (2.1)	0
Cardiac disorders					
-Total	7 (14.6)	4 (8.3)	2 (4.2)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	7 (14.6)	4 (8.3)	2 (4.2)	1 (2.1)	0
Gastrointestinal disorders					
-Total	35 (72.9)	15 (31.3)	15 (31.3)	5 (10.4)	0
Diarrhoea	19 (39.6)	11 (22.9)	6 (12.5)	2 (4.2)	0
Vomiting	17 (35.4)	10 (20.8)	7 (14.6)	0	0
Nausea	15 (31.3)	10 (20.8)	4 (8.3)	1 (2.1)	0
Abdominal pain	9 (18.8)	2 (4.2)	5 (10.4)	2 (4.2)	0
Constipation	8 (16.7)	4 (8.3)	4 (8.3)	0	0
General disorders and administration site conditions					
-Total	24 (50.0)	14 (29.2)	4 (8.3)	5 (10.4)	1 (2.1)
Pyrexia	18 (37.5)	9 (18.8)	3 (6.3)	5 (10.4)	1 (2.1)
Fatigue	10 (20.8)	9 (18.8)	1 (2.1)	0	0
Chills	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Face oedema	4 (8.3)	3 (6.3)	1 (2.1)	0	0
Oedema peripheral	2 (4.2)	2 (4.2)	0	0	0
Immune system disorders					
-Total	44 (91.7)	1 (2.1)	17 (35.4)	15 (31.3)	11 (22.9)
Cytokine release syndrome	37 (77.1)	3 (6.3)	11 (22.9)	12 (25.0)	11 (22.9)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	22 (45.8)	0	17 (35.4)	5 (10.4)	0
Haemophagocytic lymphohistiocytosis	2 (4.2)	1 (2.1)	0	1 (2.1)	0
Infections and infestations					
-Total	23 (47.9)	5 (10.4)	10 (20.8)	8 (16.7)	0
Upper respiratory tract infection	7 (14.6)	3 (6.3)	1 (2.1)	3 (6.3)	0
Conjunctivitis	6 (12.5)	2 (4.2)	4 (8.3)	0	0
Gastroenteritis	5 (10.4)	3 (6.3)	0	2 (4.2)	0
Nasopharyngitis	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Rhinovirus infection	5 (10.4)	0	4 (8.3)	1 (2.1)	0
Sinusitis	5 (10.4)	0	3 (6.3)	2 (4.2)	0
Staphylococcal bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Investigations					
-Total	29 (60.4)	3 (6.3)	4 (8.3)	7 (14.6)	15 (31.3)
Neutrophil count decreased	16 (33.3)	1 (2.1)	1 (2.1)	2 (4.2)	12 (25.0)
Platelet count decreased	16 (33.3)	4 (8.3)	1 (2.1)	6 (12.5)	5 (10.4)
White blood cell count decreased	14 (29.2)	3 (6.3)	1 (2.1)	1 (2.1)	9 (18.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	13 (27.1)	2 (4.2)	6 (12.5)	5 (10.4)	0
Lymphocyte count decreased	11 (22.9)	1 (2.1)	0	5 (10.4)	5 (10.4)
Aspartate aminotransferase increased	10 (20.8)	2 (4.2)	4 (8.3)	2 (4.2)	2 (4.2)
Blood bilirubin increased	6 (12.5)	0	2 (4.2)	4 (8.3)	0
Blood immunoglobulin a decreased	6 (12.5)	5 (10.4)	0	1 (2.1)	0
Blood immunoglobulin m decreased	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Serum ferritin increased	4 (8.3)	0	3 (6.3)	1 (2.1)	0
International normalised ratio increased	3 (6.3)	3 (6.3)	0	0	0
Electrocardiogram qt prolonged	1 (2.1)	0	0	1 (2.1)	0
Metabolism and nutrition disorders					
-Total	27 (56.3)	8 (16.7)	4 (8.3)	11 (22.9)	4 (8.3)
Decreased appetite	18 (37.5)	8 (16.7)	2 (4.2)	6 (12.5)	2 (4.2)
Hypokalaemia	12 (25.0)	2 (4.2)	3 (6.3)	6 (12.5)	1 (2.1)
Hypophosphataemia	11 (22.9)	3 (6.3)	3 (6.3)	4 (8.3)	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	6 (12.5)	2 (4.2)	2 (4.2)	2 (4.2)	0
Hypoalbuminaemia	5 (10.4)	0	5 (10.4)	0	0
Hyperglycaemia	3 (6.3)	0	1 (2.1)	2 (4.2)	0
Hyperuricaemia	3 (6.3)	2 (4.2)	1 (2.1)	0	0
Hypervolaemia	2 (4.2)	0	1 (2.1)	1 (2.1)	0
Musculoskeletal and connective tissue disorders					
-Total	24 (50.0)	10 (20.8)	11 (22.9)	3 (6.3)	0
Pain in extremity	13 (27.1)	6 (12.5)	6 (12.5)	1 (2.1)	0
Arthralgia	9 (18.8)	5 (10.4)	4 (8.3)	0	0
Back pain	8 (16.7)	2 (4.2)	4 (8.3)	2 (4.2)	0
Myalgia	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Nervous system disorders					
-Total	19 (39.6)	9 (18.8)	6 (12.5)	4 (8.3)	0
Headache	15 (31.3)	8 (16.7)	4 (8.3)	3 (6.3)	0
Encephalopathy	4 (8.3)	1 (2.1)	2 (4.2)	1 (2.1)	0
Psychiatric disorders					
-Total	11 (22.9)	3 (6.3)	7 (14.6)	1 (2.1)	0
Anxiety	10 (20.8)	3 (6.3)	6 (12.5)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Renal and urinary disorders					
-Total	5 (10.4)	2 (4.2)	1 (2.1)	0	2 (4.2)
Acute kidney injury	5 (10.4)	2 (4.2)	1 (2.1)	0	2 (4.2)
Respiratory, thoracic and mediastinal disorders					
-Total	33 (68.8)	16 (33.3)	5 (10.4)	7 (14.6)	5 (10.4)
Cough	17 (35.4)	13 (27.1)	4 (8.3)	0	0
Hypoxia	10 (20.8)	0	3 (6.3)	4 (8.3)	3 (6.3)
Nasal congestion	6 (12.5)	5 (10.4)	1 (2.1)	0	0
Pulmonary oedema	6 (12.5)	2 (4.2)	0	4 (8.3)	0
Epistaxis	5 (10.4)	4 (8.3)	0	1 (2.1)	0
Pleural effusion	5 (10.4)	3 (6.3)	1 (2.1)	0	1 (2.1)
Rhinorrhoea	5 (10.4)	4 (8.3)	1 (2.1)	0	0
Tachypnoea	5 (10.4)	3 (6.3)	1 (2.1)	1 (2.1)	0
Oropharyngeal pain	4 (8.3)	4 (8.3)	0	0	0
Respiratory failure	1 (2.1)	0	0	0	1 (2.1)
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (22.9)	6 (12.5)	5 (10.4)	0	0
Dry skin	5 (10.4)	3 (6.3)	2 (4.2)	0	0
Rash	4 (8.3)	2 (4.2)	2 (4.2)	0	0
Pruritus	3 (6.3)	1 (2.1)	2 (4.2)	0	0
Vascular disorders					
-Total	16 (33.3)	5 (10.4)	5 (10.4)	3 (6.3)	3 (6.3)
Hypotension	10 (20.8)	2 (4.2)	3 (6.3)	2 (4.2)	3 (6.3)
Hypertension	8 (16.7)	3 (6.3)	4 (8.3)	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	1 (3.1)	5 (15.6)	5 (15.6)	21 (65.6)
Blood and lymphatic system disorders					
-Total	21 (65.6)	1 (3.1)	2 (6.3)	10 (31.3)	8 (25.0)
Febrile neutropenia	12 (37.5)	0	0	10 (31.3)	2 (6.3)
Anaemia	9 (28.1)	3 (9.4)	4 (12.5)	2 (6.3)	0
Disseminated intravascular coagulation	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Neutropenia	4 (12.5)	0	1 (3.1)	0	3 (9.4)
Thrombocytopenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Cardiac disorders					
-Total	10 (31.3)	3 (9.4)	5 (15.6)	1 (3.1)	1 (3.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	10 (31.3)	3 (9.4)	5 (15.6)	1 (3.1)	1 (3.1)
Gastrointestinal disorders					
-Total	21 (65.6)	11 (34.4)	8 (25.0)	2 (6.3)	0
Vomiting	9 (28.1)	7 (21.9)	1 (3.1)	1 (3.1)	0
Diarrhoea	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Nausea	7 (21.9)	2 (6.3)	4 (12.5)	1 (3.1)	0
Constipation	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Abdominal pain	2 (6.3)	0	2 (6.3)	0	0
General disorders and administration site conditions					
-Total	23 (71.9)	9 (28.1)	8 (25.0)	5 (15.6)	1 (3.1)
Pyrexia	17 (53.1)	5 (15.6)	7 (21.9)	4 (12.5)	1 (3.1)
Fatigue	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Oedema peripheral	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Face oedema	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Chills	2 (6.3)	2 (6.3)	0	0	0
Immune system disorders					
-Total	25 (78.1)	1 (3.1)	7 (21.9)	6 (18.8)	11 (34.4)
Cytokine release syndrome	24 (75.0)	2 (6.3)	7 (21.9)	5 (15.6)	10 (31.3)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	11 (34.4)	2 (6.3)	7 (21.9)	2 (6.3)	0
Haemophagocytic lymphohistiocytosis	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
Infections and infestations					
-Total	12 (37.5)	2 (6.3)	6 (18.8)	4 (12.5)	0
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Rhinovirus infection	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Staphylococcal bacteraemia	4 (12.5)	0	0	4 (12.5)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Nasopharyngitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Gastroenteritis	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	20 (62.5)	0	1 (3.1)	8 (25.0)	11 (34.4)
White blood cell count decreased	11 (34.4)	0	3 (9.4)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	9 (28.1)	0	2 (6.3)	6 (18.8)	1 (3.1)
Neutrophil count decreased	8 (25.0)	0	1 (3.1)	2 (6.3)	5 (15.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	8 (25.0)	2 (6.3)	2 (6.3)	1 (3.1)	3 (9.4)
Blood bilirubin increased	7 (21.9)	1 (3.1)	1 (3.1)	5 (15.6)	0
International normalised ratio increased	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Lymphocyte count decreased	6 (18.8)	0	1 (3.1)	5 (15.6)	0
Alanine aminotransferase increased	5 (15.6)	1 (3.1)	2 (6.3)	2 (6.3)	0
Blood immunoglobulin g decreased	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Electrocardiogram qt prolonged	4 (12.5)	1 (3.1)	2 (6.3)	0	1 (3.1)
Serum ferritin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Blood immunoglobulin m decreased	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Blood immunoglobulin a decreased	1 (3.1)	0	1 (3.1)	0	0
Metabolism and nutrition disorders					
-Total	22 (68.8)	2 (6.3)	6 (18.8)	10 (31.3)	4 (12.5)
Decreased appetite	12 (37.5)	3 (9.4)	5 (15.6)	4 (12.5)	0
Hypocalcaemia	10 (31.3)	0	7 (21.9)	3 (9.4)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	8 (25.0)	1 (3.1)	3 (9.4)	3 (9.4)	1 (3.1)
Hypophosphataemia	7 (21.9)	0	3 (9.4)	4 (12.5)	0
Hyperglycaemia	6 (18.8)	0	3 (9.4)	3 (9.4)	0
Hyperuricaemia	6 (18.8)	5 (15.6)	0	1 (3.1)	0
Hypoalbuminaemia	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Hyperphosphataemia	5 (15.6)	4 (12.5)	0	0	1 (3.1)
Hypervolaemia	5 (15.6)	0	1 (3.1)	4 (12.5)	0
Metabolic acidosis	4 (12.5)	1 (3.1)	0	0	3 (9.4)
Musculoskeletal and connective tissue disorders					
-Total	11 (34.4)	5 (15.6)	4 (12.5)	2 (6.3)	0
Myalgia	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Pain in extremity	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Arthralgia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Back pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Nervous system disorders					
-Total	15 (46.9)	5 (15.6)	7 (21.9)	3 (9.4)	0
Headache	12 (37.5)	5 (15.6)	7 (21.9)	0	0
Encephalopathy	4 (12.5)	0	1 (3.1)	3 (9.4)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	9 (28.1)	1 (3.1)	4 (12.5)	4 (12.5)	0
Delirium	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Anxiety	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Renal and urinary disorders					
-Total	7 (21.9)	0	1 (3.1)	3 (9.4)	3 (9.4)
Acute kidney injury	7 (21.9)	0	1 (3.1)	3 (9.4)	3 (9.4)
Respiratory, thoracic and mediastinal disorders					
-Total	17 (53.1)	3 (9.4)	0	6 (18.8)	8 (25.0)
Hypoxia	10 (31.3)	0	1 (3.1)	6 (18.8)	3 (9.4)
Cough	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Pulmonary oedema	6 (18.8)	0	3 (9.4)	2 (6.3)	1 (3.1)
Respiratory failure	5 (15.6)	0	0	0	5 (15.6)
Oropharyngeal pain	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Pleural effusion	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Tachypnoea	4 (12.5)	0	0	3 (9.4)	1 (3.1)
Nasal congestion	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Epistaxis	2 (6.3)	0	2 (6.3)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinorrhoea	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (28.1)	5 (15.6)	4 (12.5)	0	0
Pruritus	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Rash	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Dry skin	3 (9.4)	3 (9.4)	0	0	0
Vascular disorders					
-Total	16 (50.0)	0	3 (9.4)	8 (25.0)	5 (15.6)
Hypotension	14 (43.8)	0	3 (9.4)	6 (18.8)	5 (15.6)
Hypertension	8 (25.0)	1 (3.1)	3 (9.4)	4 (12.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	1 (7.7)	0	5 (38.5)	7 (53.8)
Blood and lymphatic system disorders					
-Total	11 (84.6)	1 (7.7)	2 (15.4)	6 (46.2)	2 (15.4)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)	0	0
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Disseminated intravascular coagulation	1 (7.7)	0	1 (7.7)	0	0
Cardiac disorders					
-Total	6 (46.2)	6 (46.2)	0	0	0
Tachycardia	6 (46.2)	6 (46.2)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Ocular hyperaemia	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	9 (69.2)	5 (38.5)	2 (15.4)	2 (15.4)	0
Nausea	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Vomiting	5 (38.5)	2 (15.4)	3 (23.1)	0	0
Diarrhoea	4 (30.8)	4 (30.8)	0	0	0
Abdominal pain	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Constipation	2 (15.4)	2 (15.4)	0	0	0
Proctalgia	1 (7.7)	0	0	1 (7.7)	0
General disorders and administration site conditions					
-Total	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Fatigue	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Pyrexia	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Hepatobiliary disorders					
-Total	2 (15.4)	0	1 (7.7)	0	1 (7.7)
Hepatic function abnormal	2 (15.4)	0	1 (7.7)	0	1 (7.7)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	12 (92.3)	0	6 (46.2)	5 (38.5)	1 (7.7)
Cytokine release syndrome	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Hypogammaglobulinaemia	2 (15.4)	0	2 (15.4)	0	0
Investigations					
-Total	11 (84.6)	2 (15.4)	0	3 (23.1)	6 (46.2)
Platelet count decreased	8 (61.5)	3 (23.1)	1 (7.7)	4 (30.8)	0
White blood cell count decreased	8 (61.5)	1 (7.7)	2 (15.4)	0	5 (38.5)
Lymphocyte count decreased	7 (53.8)	1 (7.7)	0	4 (30.8)	2 (15.4)
Neutrophil count decreased	7 (53.8)	0	2 (15.4)	0	5 (38.5)
International normalised ratio increased	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Alanine aminotransferase increased	4 (30.8)	0	2 (15.4)	2 (15.4)	0
Aspartate aminotransferase increased	4 (30.8)	0	1 (7.7)	3 (23.1)	0
Blood immunoglobulin a decreased	4 (30.8)	4 (30.8)	0	0	0
Blood immunoglobulin m decreased	4 (30.8)	4 (30.8)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Blood bilirubin increased	3 (23.1)	1 (7.7)	0	2 (15.4)	0
Blood fibrinogen decreased	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Serum ferritin increased	2 (15.4)	0	2 (15.4)	0	0
Metabolism and nutrition disorders					
-Total	8 (61.5)	2 (15.4)	2 (15.4)	4 (30.8)	0
Decreased appetite	7 (53.8)	4 (30.8)	1 (7.7)	2 (15.4)	0
Hypokalaemia	3 (23.1)	0	1 (7.7)	2 (15.4)	0
Hyperphosphataemia	2 (15.4)	2 (15.4)	0	0	0
Hypophosphataemia	2 (15.4)	0	0	2 (15.4)	0
Hyperuricaemia	1 (7.7)	1 (7.7)	0	0	0
Hypoalbuminaemia	1 (7.7)	0	1 (7.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (61.5)	6 (46.2)	2 (15.4)	0	0
Pain in extremity	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Myalgia	4 (30.8)	2 (15.4)	2 (15.4)	0	0
Arthralgia	2 (15.4)	2 (15.4)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Headache	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Psychiatric disorders					
-Total	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Anxiety	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Renal and urinary disorders					
-Total	1 (7.7)	0	0	0	1 (7.7)
Acute kidney injury	1 (7.7)	0	0	0	1 (7.7)
Respiratory, thoracic and mediastinal disorders					
-Total	8 (61.5)	6 (46.2)	0	1 (7.7)	1 (7.7)
Oropharyngeal pain	3 (23.1)	3 (23.1)	0	0	0
Cough	2 (15.4)	2 (15.4)	0	0	0
Hypoxia	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Rhinorrhoea	2 (15.4)	2 (15.4)	0	0	0
Tachypnoea	2 (15.4)	2 (15.4)	0	0	0
Pleural effusion	1 (7.7)	1 (7.7)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	4 (30.8)	4 (30.8)	0	0	0
Pruritus	2 (15.4)	2 (15.4)	0	0	0
Rash papular	2 (15.4)	2 (15.4)	0	0	0
Dry skin	1 (7.7)	1 (7.7)	0	0	0
Eczema	1 (7.7)	1 (7.7)	0	0	0
Vascular disorders					
-Total	4 (30.8)	2 (15.4)	0	1 (7.7)	1 (7.7)
Hypotension	3 (23.1)	1 (7.7)	0	1 (7.7)	1 (7.7)
Hypertension	1 (7.7)	1 (7.7)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	66 (98.5)	4 (6.0)	8 (11.9)	16 (23.9)	38 (56.7)
Blood and lymphatic system disorders					
-Total	34 (50.7)	1 (1.5)	3 (4.5)	19 (28.4)	11 (16.4)
Febrile neutropenia	20 (29.9)	0	0	18 (26.9)	2 (3.0)
Anaemia	13 (19.4)	2 (3.0)	3 (4.5)	8 (11.9)	0
Thrombocytopenia	8 (11.9)	0	0	2 (3.0)	6 (9.0)
Neutropenia	7 (10.4)	0	2 (3.0)	1 (1.5)	4 (6.0)
Disseminated intravascular coagulation	6 (9.0)	0	4 (6.0)	2 (3.0)	0
Cardiac disorders					
-Total	11 (16.4)	1 (1.5)	7 (10.4)	2 (3.0)	1 (1.5)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	11 (16.4)	1 (1.5)	7 (10.4)	2 (3.0)	1 (1.5)
Eye disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	37 (55.2)	17 (25.4)	15 (22.4)	5 (7.5)	0
Vomiting	16 (23.9)	10 (14.9)	5 (7.5)	1 (1.5)	0
Nausea	12 (17.9)	5 (7.5)	5 (7.5)	2 (3.0)	0
Diarrhoea	11 (16.4)	4 (6.0)	6 (9.0)	1 (1.5)	0
Constipation	9 (13.4)	4 (6.0)	5 (7.5)	0	0
Abdominal pain	8 (11.9)	2 (3.0)	5 (7.5)	1 (1.5)	0
General disorders and administration site conditions					
-Total	29 (43.3)	14 (20.9)	6 (9.0)	7 (10.4)	2 (3.0)
Pyrexia	21 (31.3)	9 (13.4)	4 (6.0)	6 (9.0)	2 (3.0)
Face oedema	8 (11.9)	5 (7.5)	2 (3.0)	1 (1.5)	0
Fatigue	6 (9.0)	5 (7.5)	1 (1.5)	0	0
Hepatobiliary disorders					
-Total	3 (4.5)	0	1 (1.5)	2 (3.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Immune system disorders					
-Total	54 (80.6)	3 (4.5)	15 (22.4)	16 (23.9)	20 (29.9)
Cytokine release syndrome	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)
Hypogammaglobulinaemia	21 (31.3)	2 (3.0)	12 (17.9)	7 (10.4)	0
Infections and infestations					
-Total	7 (10.4)	1 (1.5)	6 (9.0)	0	0
Conjunctivitis	5 (7.5)	1 (1.5)	4 (6.0)	0	0
Rhinovirus infection	2 (3.0)	0	2 (3.0)	0	0
Investigations					
-Total	37 (55.2)	2 (3.0)	4 (6.0)	12 (17.9)	19 (28.4)
White blood cell count decreased	16 (23.9)	2 (3.0)	1 (1.5)	2 (3.0)	11 (16.4)
Aspartate aminotransferase increased	15 (22.4)	2 (3.0)	5 (7.5)	5 (7.5)	3 (4.5)
Alanine aminotransferase increased	14 (20.9)	4 (6.0)	6 (9.0)	4 (6.0)	0
Neutrophil count decreased	13 (19.4)	0	1 (1.5)	2 (3.0)	10 (14.9)
Platelet count decreased	13 (19.4)	1 (1.5)	2 (3.0)	2 (3.0)	8 (11.9)
Blood bilirubin increased	9 (13.4)	0	2 (3.0)	7 (10.4)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (11.9)	1 (1.5)	0	4 (6.0)	3 (4.5)
Serum ferritin increased	6 (9.0)	1 (1.5)	3 (4.5)	2 (3.0)	0
Blood fibrinogen decreased	4 (6.0)	0	2 (3.0)	1 (1.5)	1 (1.5)
Activated partial thromboplastin time prolonged	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
International normalised ratio increased	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Blood immunoglobulin m decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)	0	0
Metabolism and nutrition disorders					
-Total	36 (53.7)	6 (9.0)	8 (11.9)	17 (25.4)	5 (7.5)
Decreased appetite	17 (25.4)	5 (7.5)	3 (4.5)	8 (11.9)	1 (1.5)
Hypocalcaemia	16 (23.9)	2 (3.0)	9 (13.4)	5 (7.5)	0
Hypokalaemia	16 (23.9)	3 (4.5)	4 (6.0)	7 (10.4)	2 (3.0)
Hypophosphataemia	15 (22.4)	3 (4.5)	5 (7.5)	6 (9.0)	1 (1.5)
Hypoalbuminaemia	10 (14.9)	0	9 (13.4)	1 (1.5)	0
Hyperglycaemia	8 (11.9)	0	4 (6.0)	4 (6.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Hypervolaemia	6 (9.0)	0	2 (3.0)	4 (6.0)	0
Hyperphosphataemia	3 (4.5)	2 (3.0)	0	0	1 (1.5)
Musculoskeletal and connective tissue disorders					
-Total	20 (29.9)	7 (10.4)	11 (16.4)	2 (3.0)	0
Arthralgia	8 (11.9)	2 (3.0)	5 (7.5)	1 (1.5)	0
Back pain	6 (9.0)	2 (3.0)	3 (4.5)	1 (1.5)	0
Pain in extremity	6 (9.0)	2 (3.0)	4 (6.0)	0	0
Myalgia	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Nervous system disorders					
-Total	27 (40.3)	11 (16.4)	10 (14.9)	6 (9.0)	0
Headache	20 (29.9)	10 (14.9)	8 (11.9)	2 (3.0)	0
Encephalopathy	8 (11.9)	1 (1.5)	3 (4.5)	4 (6.0)	0
Psychiatric disorders					
-Total	14 (20.9)	5 (7.5)	4 (6.0)	5 (7.5)	0
Delirium	7 (10.4)	2 (3.0)	2 (3.0)	3 (4.5)	0
Confusional state	5 (7.5)	5 (7.5)	0	0	0
Anxiety	4 (6.0)	0	2 (3.0)	2 (3.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	8 (11.9)	1 (1.5)	1 (1.5)	3 (4.5)	3 (4.5)
Acute kidney injury	8 (11.9)	1 (1.5)	1 (1.5)	3 (4.5)	3 (4.5)
Respiratory, thoracic and mediastinal disorders					
-Total	28 (41.8)	7 (10.4)	4 (6.0)	10 (14.9)	7 (10.4)
Hypoxia	15 (22.4)	0	5 (7.5)	5 (7.5)	5 (7.5)
Pulmonary oedema	12 (17.9)	2 (3.0)	3 (4.5)	6 (9.0)	1 (1.5)
Cough	8 (11.9)	7 (10.4)	1 (1.5)	0	0
Pleural effusion	6 (9.0)	3 (4.5)	0	2 (3.0)	1 (1.5)
Tachypnoea	6 (9.0)	1 (1.5)	1 (1.5)	4 (6.0)	0
Nasal congestion	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Oropharyngeal pain	2 (3.0)	2 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (13.4)	2 (3.0)	7 (10.4)	0	0
Rash	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Pruritus	4 (6.0)	0	4 (6.0)	0	0
Rash papular	1 (1.5)	0	1 (1.5)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	23 (34.3)	2 (3.0)	7 (10.4)	9 (13.4)	5 (7.5)
Hypotension	18 (26.9)	0	6 (9.0)	7 (10.4)	5 (7.5)
Hypertension	12 (17.9)	3 (4.5)	5 (7.5)	4 (6.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	3 (23.1)	5 (38.5)	2 (15.4)	3 (23.1)
Blood and lymphatic system disorders					
-Total	3 (23.1)	1 (7.7)	0	0	2 (15.4)
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Anaemia	1 (7.7)	1 (7.7)	0	0	0
Eye disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Ocular hyperaemia	1 (7.7)	1 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	3 (23.1)	3 (23.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (15.4)	2 (15.4)	0	0	0
Abdominal pain	1 (7.7)	1 (7.7)	0	0	0
Constipation	1 (7.7)	1 (7.7)	0	0	0
Diarrhoea	1 (7.7)	1 (7.7)	0	0	0
Nausea	1 (7.7)	1 (7.7)	0	0	0
Proctalgia	1 (7.7)	1 (7.7)	0	0	0
General disorders and administration site conditions					
-Total	2 (15.4)	2 (15.4)	0	0	0
Fatigue	2 (15.4)	2 (15.4)	0	0	0
Immune system disorders					
-Total	3 (23.1)	0	3 (23.1)	0	0
Hypogammaglobulinaemia	3 (23.1)	0	3 (23.1)	0	0
Investigations					
-Total	10 (76.9)	3 (23.1)	3 (23.1)	3 (23.1)	1 (7.7)
Neutrophil count decreased	4 (30.8)	1 (7.7)	1 (7.7)	1 (7.7)	1 (7.7)
White blood cell count decreased	3 (23.1)	2 (15.4)	0	1 (7.7)	0
Blood immunoglobulin a decreased	2 (15.4)	1 (7.7)	0	1 (7.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Alanine aminotransferase increased	1 (7.7)	1 (7.7)	0	0	0
Blood bilirubin increased	1 (7.7)	0	1 (7.7)	0	0
Blood immunoglobulin m decreased	1 (7.7)	0	0	1 (7.7)	0
Platelet count decreased	1 (7.7)	1 (7.7)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Decreased appetite	1 (7.7)	1 (7.7)	0	0	0
Hyperuricaemia	1 (7.7)	1 (7.7)	0	0	0
Nervous system disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Headache	2 (15.4)	2 (15.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Cough	3 (23.1)	3 (23.1)	0	0	0
Rhinorrhoea	3 (23.1)	3 (23.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	2 (15.4)	2 (15.4)	0	0	0
Pleural effusion	1 (7.7)	0	1 (7.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Dry skin	2 (15.4)	1 (7.7)	1 (7.7)	0	0

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Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (77.4)	9 (14.5)	18 (29.0)	14 (22.6)	7 (11.3)
Blood and lymphatic system disorders					
-Total	10 (16.1)	2 (3.2)	0	6 (9.7)	2 (3.2)
Anaemia	5 (8.1)	3 (4.8)	0	2 (3.2)	0
Febrile neutropenia	3 (4.8)	0	0	3 (4.8)	0
Neutropenia	3 (4.8)	0	0	2 (3.2)	1 (1.6)
Thrombocytopenia	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Disseminated intravascular coagulation	1 (1.6)	0	0	1 (1.6)	0
Cardiac disorders					
-Total	2 (3.2)	2 (3.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (3.2)	2 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	11 (17.7)	6 (9.7)	5 (8.1)	0	0
Diarrhoea	6 (9.7)	5 (8.1)	1 (1.6)	0	0
Nausea	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Vomiting	4 (6.5)	4 (6.5)	0	0	0
Constipation	2 (3.2)	0	2 (3.2)	0	0
Abdominal pain	1 (1.6)	0	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	19 (30.6)	11 (17.7)	6 (9.7)	2 (3.2)	0
Pyrexia	15 (24.2)	7 (11.3)	6 (9.7)	2 (3.2)	0
Fatigue	4 (6.5)	4 (6.5)	0	0	0
Immune system disorders					
-Total	7 (11.3)	0	7 (11.3)	0	0
Hypogammaglobulinaemia	7 (11.3)	0	7 (11.3)	0	0
Infections and infestations					
-Total	12 (19.4)	2 (3.2)	8 (12.9)	2 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	8 (12.9)	3 (4.8)	3 (4.8)	2 (3.2)	0
Rhinovirus infection	5 (8.1)	0	4 (6.5)	1 (1.6)	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	11 (17.7)	3 (4.8)	0	5 (8.1)	3 (4.8)
White blood cell count decreased	7 (11.3)	2 (3.2)	2 (3.2)	2 (3.2)	1 (1.6)
Neutrophil count decreased	6 (9.7)	1 (1.6)	0	2 (3.2)	3 (4.8)
Platelet count decreased	4 (6.5)	2 (3.2)	0	1 (1.6)	1 (1.6)
Lymphocyte count decreased	2 (3.2)	0	0	2 (3.2)	0
Alanine aminotransferase increased	1 (1.6)	0	0	1 (1.6)	0
Blood bilirubin increased	1 (1.6)	0	0	1 (1.6)	0
Metabolism and nutrition disorders					
-Total	9 (14.5)	2 (3.2)	3 (4.8)	3 (4.8)	1 (1.6)
Decreased appetite	5 (8.1)	1 (1.6)	3 (4.8)	1 (1.6)	0
Hypokalaemia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Hyperuricaemia	2 (3.2)	2 (3.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (1.6)	0	0	1 (1.6)	0
Hypophosphataemia	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (17.7)	4 (6.5)	4 (6.5)	3 (4.8)	0
Back pain	6 (9.7)	2 (3.2)	2 (3.2)	2 (3.2)	0
Pain in extremity	5 (8.1)	2 (3.2)	2 (3.2)	1 (1.6)	0
Arthralgia	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Myalgia	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	8 (12.9)	4 (6.5)	4 (6.5)	0	0
Headache	8 (12.9)	4 (6.5)	4 (6.5)	0	0
Psychiatric disorders					
-Total	6 (9.7)	1 (1.6)	5 (8.1)	0	0
Anxiety	6 (9.7)	1 (1.6)	5 (8.1)	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Renal and urinary disorders					
-Total	3 (4.8)	1 (1.6)	1 (1.6)	0	1 (1.6)
Acute kidney injury	3 (4.8)	1 (1.6)	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	12 (19.4)	6 (9.7)	3 (4.8)	3 (4.8)	0
Cough	8 (12.9)	5 (8.1)	3 (4.8)	0	0
Nasal congestion	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Hypoxia	3 (4.8)	0	0	3 (4.8)	0
Oropharyngeal pain	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Pleural effusion	1 (1.6)	1 (1.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (12.9)	6 (9.7)	2 (3.2)	0	0
Dry skin	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Rash	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Pruritus	1 (1.6)	0	1 (1.6)	0	0
Vascular disorders					
-Total	5 (8.1)	1 (1.6)	1 (1.6)	1 (1.6)	2 (3.2)
Hypotension	4 (6.5)	1 (1.6)	0	1 (1.6)	2 (3.2)
Hypertension	1 (1.6)	0	1 (1.6)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	2 (25.0)	2 (25.0)	2 (25.0)	0
Immune system disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Hypogammaglobulinaemia	2 (25.0)	0	2 (25.0)	0	0
Infections and infestations					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Upper respiratory tract infection	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	2 (25.0)	2 (25.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (25.0)	2 (25.0)	0	0	0
Blood bilirubin increased	1 (12.5)	1 (12.5)	0	0	0
Platelet count decreased	1 (12.5)	1 (12.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Cough	1 (12.5)	1 (12.5)	0	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Eczema	1 (12.5)	0	0	1 (12.5)	0

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Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (40.5)	3 (7.1)	8 (19.0)	2 (4.8)	4 (9.5)
Blood and lymphatic system disorders					
-Total	2 (4.8)	0	1 (2.4)	0	1 (2.4)
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	6 (14.3)	4 (9.5)	1 (2.4)	1 (2.4)	0
Diarrhoea	5 (11.9)	3 (7.1)	1 (2.4)	1 (2.4)	0
Constipation	1 (2.4)	1 (2.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.4)	1 (2.4)	0	0	0
Vomiting	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					
-Total	6 (14.3)	2 (4.8)	3 (7.1)	1 (2.4)	0
Pyrexia	5 (11.9)	2 (4.8)	2 (4.8)	1 (2.4)	0
Fatigue	1 (2.4)	0	1 (2.4)	0	0
Immune system disorders					
-Total	1 (2.4)	0	1 (2.4)	0	0
Hypogammaglobulinaemia	1 (2.4)	0	1 (2.4)	0	0
Infections and infestations					
-Total	8 (19.0)	2 (4.8)	5 (11.9)	1 (2.4)	0
Rhinovirus infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Conjunctivitis	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Upper respiratory tract infection	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Investigations					
-Total	2 (4.8)	1 (2.4)	0	0	1 (2.4)
Neutrophil count decreased	1 (2.4)	0	0	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (2.4)	1 (2.4)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Decreased appetite	1 (2.4)	0	0	0	1 (2.4)
Hyperglycaemia	1 (2.4)	0	0	1 (2.4)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (7.1)	0	3 (7.1)	0	0
Pain in extremity	2 (4.8)	0	2 (4.8)	0	0
Arthralgia	1 (2.4)	0	1 (2.4)	0	0
Nervous system disorders					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Headache	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Psychiatric disorders					
-Total	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Anxiety	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (9.5)	1 (2.4)	1 (2.4)	1 (2.4)	1 (2.4)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Rhinorrhoea	2 (4.8)	0	2 (4.8)	0	0
Hypoxia	1 (2.4)	0	0	1 (2.4)	0
Oropharyngeal pain	1 (2.4)	1 (2.4)	0	0	0
Pleural effusion	1 (2.4)	0	1 (2.4)	0	0
Tachypnoea	1 (2.4)	0	0	0	1 (2.4)
Skin and subcutaneous tissue disorders					
-Total	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Rash	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Dry skin	1 (2.4)	1 (2.4)	0	0	0
Vascular disorders					
-Total	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Hypertension	2 (4.8)	0	1 (2.4)	1 (2.4)	0

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Table 214m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	1 (7.7)	5 (38.5)	7 (53.8)
Blood and lymphatic system disorders					
-Total	11 (84.6)	1 (7.7)	2 (15.4)	6 (46.2)	2 (15.4)
Anaemia	8 (61.5)	3 (23.1)	5 (38.5)	0	0
Febrile neutropenia	6 (46.2)	0	0	6 (46.2)	0
Neutropenia	2 (15.4)	0	0	0	2 (15.4)
Disseminated intravascular coagulation	1 (7.7)	0	1 (7.7)	0	0
Cardiac disorders					
-Total	6 (46.2)	6 (46.2)	0	0	0
Tachycardia	6 (46.2)	6 (46.2)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Ocular hyperaemia	2 (15.4)	2 (15.4)	0	0	0
Gastrointestinal disorders					
-Total	10 (76.9)	6 (46.2)	2 (15.4)	2 (15.4)	0
Nausea	7 (53.8)	6 (46.2)	1 (7.7)	0	0
Vomiting	6 (46.2)	3 (23.1)	3 (23.1)	0	0
Diarrhoea	5 (38.5)	5 (38.5)	0	0	0
Abdominal pain	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Constipation	3 (23.1)	3 (23.1)	0	0	0
Proctalgia	2 (15.4)	1 (7.7)	0	1 (7.7)	0
General disorders and administration site conditions					
-Total	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Fatigue	6 (46.2)	5 (38.5)	1 (7.7)	0	0
Pyrexia	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Hepatobiliary disorders					
-Total	2 (15.4)	0	1 (7.7)	0	1 (7.7)
Hepatic function abnormal	2 (15.4)	0	1 (7.7)	0	1 (7.7)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	13 (100)	0	7 (53.8)	5 (38.5)	1 (7.7)
Cytokine release syndrome	11 (84.6)	0	5 (38.5)	5 (38.5)	1 (7.7)
Hypogammaglobulinaemia	6 (46.2)	0	6 (46.2)	0	0
Infections and infestations					
-Total	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Upper respiratory tract infection	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Conjunctivitis	1 (7.7)	0	1 (7.7)	0	0
Investigations					
-Total	11 (84.6)	1 (7.7)	1 (7.7)	3 (23.1)	6 (46.2)
Neutrophil count decreased	9 (69.2)	1 (7.7)	2 (15.4)	1 (7.7)	5 (38.5)
Platelet count decreased	9 (69.2)	4 (30.8)	1 (7.7)	4 (30.8)	0
White blood cell count decreased	9 (69.2)	2 (15.4)	2 (15.4)	0	5 (38.5)
Lymphocyte count decreased	7 (53.8)	0	1 (7.7)	4 (30.8)	2 (15.4)
Blood immunoglobulin a decreased	6 (46.2)	5 (38.5)	0	1 (7.7)	0
International normalised ratio increased	6 (46.2)	5 (38.5)	1 (7.7)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	5 (38.5)	4 (30.8)	0	1 (7.7)	0
Alanine aminotransferase increased	4 (30.8)	0	2 (15.4)	2 (15.4)	0
Aspartate aminotransferase increased	4 (30.8)	0	1 (7.7)	3 (23.1)	0
Blood bilirubin increased	4 (30.8)	1 (7.7)	1 (7.7)	2 (15.4)	0
Activated partial thromboplastin time prolonged	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Blood fibrinogen decreased	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Serum ferritin increased	2 (15.4)	0	2 (15.4)	0	0
Metabolism and nutrition disorders					
-Total	9 (69.2)	3 (23.1)	2 (15.4)	4 (30.8)	0
Decreased appetite	8 (61.5)	5 (38.5)	1 (7.7)	2 (15.4)	0
Hypokalaemia	3 (23.1)	0	1 (7.7)	2 (15.4)	0
Hyperphosphataemia	2 (15.4)	2 (15.4)	0	0	0
Hyperuricaemia	2 (15.4)	2 (15.4)	0	0	0
Hypophosphataemia	2 (15.4)	0	0	2 (15.4)	0
Hypoalbuminaemia	1 (7.7)	0	1 (7.7)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	8 (61.5)	6 (46.2)	2 (15.4)	0	0
Pain in extremity	5 (38.5)	4 (30.8)	1 (7.7)	0	0
Myalgia	4 (30.8)	2 (15.4)	2 (15.4)	0	0
Arthralgia	2 (15.4)	2 (15.4)	0	0	0
Nervous system disorders					
-Total	4 (30.8)	3 (23.1)	1 (7.7)	0	0
Headache	4 (30.8)	3 (23.1)	1 (7.7)	0	0
Psychiatric disorders					
-Total	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Anxiety	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Renal and urinary disorders					
-Total	1 (7.7)	0	0	0	1 (7.7)
Acute kidney injury	1 (7.7)	0	0	0	1 (7.7)
Respiratory, thoracic and mediastinal disorders					
-Total	10 (76.9)	7 (53.8)	1 (7.7)	1 (7.7)	1 (7.7)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	4 (30.8)	4 (30.8)	0	0	0
Rhinorrhoea	4 (30.8)	4 (30.8)	0	0	0
Oropharyngeal pain	3 (23.1)	3 (23.1)	0	0	0
Hypoxia	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Nasal congestion	2 (15.4)	2 (15.4)	0	0	0
Pleural effusion	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Tachypnoea	2 (15.4)	2 (15.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (38.5)	3 (23.1)	1 (7.7)	1 (7.7)	0
Dry skin	3 (23.1)	2 (15.4)	1 (7.7)	0	0
Eczema	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Pruritus	2 (15.4)	2 (15.4)	0	0	0
Rash papular	2 (15.4)	2 (15.4)	0	0	0
Vascular disorders					
-Total	4 (30.8)	2 (15.4)	0	1 (7.7)	1 (7.7)
Hypotension	3 (23.1)	1 (7.7)	0	1 (7.7)	1 (7.7)
Hypertension	1 (7.7)	1 (7.7)	0	0	0

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Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (100)	3 (4.5)	8 (11.9)	16 (23.9)	40 (59.7)
Blood and lymphatic system disorders					
-Total	39 (58.2)	1 (1.5)	3 (4.5)	23 (34.3)	12 (17.9)
Febrile neutropenia	21 (31.3)	0	0	19 (28.4)	2 (3.0)
Anaemia	17 (25.4)	4 (6.0)	4 (6.0)	9 (13.4)	0
Neutropenia	9 (13.4)	0	2 (3.0)	2 (3.0)	5 (7.5)
Thrombocytopenia	9 (13.4)	0	0	3 (4.5)	6 (9.0)
Disseminated intravascular coagulation	7 (10.4)	0	4 (6.0)	3 (4.5)	0
Cardiac disorders					
-Total	11 (16.4)	1 (1.5)	7 (10.4)	2 (3.0)	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	11 (16.4)	1 (1.5)	7 (10.4)	2 (3.0)	1 (1.5)
Eye disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	46 (68.7)	20 (29.9)	20 (29.9)	6 (9.0)	0
Diarrhoea	21 (31.3)	11 (16.4)	8 (11.9)	2 (3.0)	0
Vomiting	20 (29.9)	14 (20.9)	5 (7.5)	1 (1.5)	0
Nausea	15 (22.4)	6 (9.0)	7 (10.4)	2 (3.0)	0
Constipation	11 (16.4)	4 (6.0)	7 (10.4)	0	0
Abdominal pain	8 (11.9)	1 (1.5)	6 (9.0)	1 (1.5)	0
General disorders and administration site conditions					
-Total	38 (56.7)	15 (22.4)	11 (16.4)	10 (14.9)	2 (3.0)
Pyrexia	32 (47.8)	12 (17.9)	9 (13.4)	9 (13.4)	2 (3.0)
Fatigue	11 (16.4)	9 (13.4)	2 (3.0)	0	0
Face oedema	8 (11.9)	5 (7.5)	2 (3.0)	1 (1.5)	0
Hepatobiliary disorders					
-Total	3 (4.5)	0	1 (1.5)	2 (3.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Immune system disorders					
-Total	56 (83.6)	2 (3.0)	18 (26.9)	16 (23.9)	20 (29.9)
Cytokine release syndrome	50 (74.6)	5 (7.5)	13 (19.4)	12 (17.9)	20 (29.9)
Hypogammaglobulinaemia	27 (40.3)	2 (3.0)	18 (26.9)	7 (10.4)	0
Infections and infestations					
-Total	23 (34.3)	5 (7.5)	15 (22.4)	3 (4.5)	0
Upper respiratory tract infection	11 (16.4)	4 (6.0)	5 (7.5)	2 (3.0)	0
Rhinovirus infection	9 (13.4)	0	7 (10.4)	2 (3.0)	0
Conjunctivitis	7 (10.4)	2 (3.0)	5 (7.5)	0	0
Investigations					
-Total	37 (55.2)	2 (3.0)	3 (4.5)	13 (19.4)	19 (28.4)
White blood cell count decreased	16 (23.9)	1 (1.5)	2 (3.0)	2 (3.0)	11 (16.4)
Aspartate aminotransferase increased	15 (22.4)	2 (3.0)	5 (7.5)	5 (7.5)	3 (4.5)
Neutrophil count decreased	15 (22.4)	0	0	3 (4.5)	12 (17.9)
Platelet count decreased	15 (22.4)	2 (3.0)	2 (3.0)	3 (4.5)	8 (11.9)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	14 (20.9)	3 (4.5)	6 (9.0)	5 (7.5)	0
Lymphocyte count decreased	10 (14.9)	1 (1.5)	0	6 (9.0)	3 (4.5)
Blood bilirubin increased	9 (13.4)	0	2 (3.0)	7 (10.4)	0
Serum ferritin increased	6 (9.0)	1 (1.5)	3 (4.5)	2 (3.0)	0
Blood fibrinogen decreased	4 (6.0)	0	2 (3.0)	1 (1.5)	1 (1.5)
Activated partial thromboplastin time prolonged	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
International normalised ratio increased	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Blood immunoglobulin m decreased	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Blood immunoglobulin a decreased	1 (1.5)	0	1 (1.5)	0	0
Metabolism and nutrition disorders					
-Total	40 (59.7)	7 (10.4)	9 (13.4)	18 (26.9)	6 (9.0)
Decreased appetite	22 (32.8)	6 (9.0)	6 (9.0)	8 (11.9)	2 (3.0)
Hypokalaemia	17 (25.4)	3 (4.5)	5 (7.5)	7 (10.4)	2 (3.0)
Hypocalcaemia	16 (23.9)	2 (3.0)	9 (13.4)	5 (7.5)	0
Hypophosphataemia	16 (23.9)	3 (4.5)	6 (9.0)	6 (9.0)	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	10 (14.9)	0	9 (13.4)	1 (1.5)	0
Hyperglycaemia	9 (13.4)	0	4 (6.0)	5 (7.5)	0
Hyperuricaemia	7 (10.4)	5 (7.5)	1 (1.5)	1 (1.5)	0
Hypervolaemia	7 (10.4)	0	2 (3.0)	5 (7.5)	0
Hyperphosphataemia	3 (4.5)	2 (3.0)	0	0	1 (1.5)
Musculoskeletal and connective tissue disorders					
-Total	27 (40.3)	9 (13.4)	13 (19.4)	5 (7.5)	0
Pain in extremity	12 (17.9)	4 (6.0)	7 (10.4)	1 (1.5)	0
Arthralgia	10 (14.9)	3 (4.5)	6 (9.0)	1 (1.5)	0
Back pain	10 (14.9)	2 (3.0)	5 (7.5)	3 (4.5)	0
Myalgia	6 (9.0)	4 (6.0)	2 (3.0)	0	0
Nervous system disorders					
-Total	30 (44.8)	11 (16.4)	12 (17.9)	7 (10.4)	0
Headache	23 (34.3)	10 (14.9)	10 (14.9)	3 (4.5)	0
Encephalopathy	8 (11.9)	1 (1.5)	3 (4.5)	4 (6.0)	0
Psychiatric disorders					
-Total	21 (31.3)	6 (9.0)	10 (14.9)	5 (7.5)	0
Anxiety	12 (17.9)	2 (3.0)	8 (11.9)	2 (3.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	8 (11.9)	2 (3.0)	3 (4.5)	3 (4.5)	0
Confusional state	5 (7.5)	5 (7.5)	0	0	0
Renal and urinary disorders					
-Total	11 (16.4)	2 (3.0)	2 (3.0)	3 (4.5)	4 (6.0)
Acute kidney injury	11 (16.4)	2 (3.0)	2 (3.0)	3 (4.5)	4 (6.0)
Respiratory, thoracic and mediastinal disorders					
-Total	37 (55.2)	11 (16.4)	6 (9.0)	12 (17.9)	8 (11.9)
Cough	19 (28.4)	14 (20.9)	5 (7.5)	0	0
Hypoxia	18 (26.9)	0	4 (6.0)	9 (13.4)	5 (7.5)
Pulmonary oedema	12 (17.9)	2 (3.0)	3 (4.5)	6 (9.0)	1 (1.5)
Nasal congestion	7 (10.4)	5 (7.5)	2 (3.0)	0	0
Pleural effusion	7 (10.4)	3 (4.5)	1 (1.5)	2 (3.0)	1 (1.5)
Tachypnoea	7 (10.4)	1 (1.5)	1 (1.5)	4 (6.0)	1 (1.5)
Oropharyngeal pain	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Rhinorrhoea	2 (3.0)	0	2 (3.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (25.4)	8 (11.9)	9 (13.4)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	8 (11.9)	4 (6.0)	4 (6.0)	0	0
Dry skin	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Pruritus	5 (7.5)	0	5 (7.5)	0	0
Eczema	1 (1.5)	1 (1.5)	0	0	0
Rash papular	1 (1.5)	0	1 (1.5)	0	0
Vascular disorders					
-Total	28 (41.8)	3 (4.5)	8 (11.9)	10 (14.9)	7 (10.4)
Hypotension	21 (31.3)	1 (1.5)	6 (9.0)	7 (10.4)	7 (10.4)
Hypertension	15 (22.4)	3 (4.5)	7 (10.4)	5 (7.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (100)	1 (3.8)	3 (11.5)	10 (38.5)	12 (46.2)
Blood and lymphatic system disorders					
-Total	18 (69.2)	1 (3.8)	3 (11.5)	9 (34.6)	5 (19.2)
Febrile neutropenia	10 (38.5)	0	0	9 (34.6)	1 (3.8)
Anaemia	8 (30.8)	3 (11.5)	2 (7.7)	3 (11.5)	0
Neutropenia	4 (15.4)	0	1 (3.8)	1 (3.8)	2 (7.7)
Thrombocytopenia	4 (15.4)	0	0	2 (7.7)	2 (7.7)
Leukopenia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Disseminated intravascular coagulation	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (23.1)	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)
Tachycardia	6 (23.1)	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)
Eye disorders					
-Total	2 (7.7)	2 (7.7)	0	0	0
Ocular hyperaemia	2 (7.7)	2 (7.7)	0	0	0
Gastrointestinal disorders					
-Total	12 (46.2)	7 (26.9)	3 (11.5)	2 (7.7)	0
Constipation	5 (19.2)	5 (19.2)	0	0	0
Nausea	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0
Vomiting	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0
Diarrhoea	4 (15.4)	2 (7.7)	2 (7.7)	0	0
Abdominal pain	3 (11.5)	1 (3.8)	2 (7.7)	0	0
General disorders and administration site conditions					
-Total	12 (46.2)	5 (19.2)	5 (19.2)	1 (3.8)	1 (3.8)
Pyrexia	9 (34.6)	4 (15.4)	4 (15.4)	0	1 (3.8)
Face oedema	4 (15.4)	1 (3.8)	2 (7.7)	1 (3.8)	0
Fatigue	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Oedema peripheral	1 (3.8)	0	0	1 (3.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	22 (84.6)	2 (7.7)	11 (42.3)	5 (19.2)	4 (15.4)
Cytokine release syndrome	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Hypogammaglobulinaemia	9 (34.6)	1 (3.8)	6 (23.1)	2 (7.7)	0
Infections and infestations					
-Total	4 (15.4)	0	3 (11.5)	1 (3.8)	0
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)	0	0
Staphylococcal bacteraemia	1 (3.8)	0	0	1 (3.8)	0
Injury, poisoning and procedural complications					
-Total	1 (3.8)	0	1 (3.8)	0	0
Infusion related reaction	1 (3.8)	0	1 (3.8)	0	0
Investigations					
-Total	16 (61.5)	0	1 (3.8)	7 (26.9)	8 (30.8)
White blood cell count decreased	8 (30.8)	1 (3.8)	2 (7.7)	1 (3.8)	4 (15.4)
Platelet count decreased	7 (26.9)	2 (7.7)	1 (3.8)	0	4 (15.4)
Alanine aminotransferase increased	6 (23.1)	2 (7.7)	3 (11.5)	1 (3.8)	0
Neutrophil count decreased	6 (23.1)	0	1 (3.8)	1 (3.8)	4 (15.4)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	5 (19.2)	1 (3.8)	2 (7.7)	1 (3.8)	1 (3.8)
Lymphocyte count decreased	4 (15.4)	0	0	4 (15.4)	0
Serum ferritin increased	4 (15.4)	1 (3.8)	1 (3.8)	2 (7.7)	0
Blood bilirubin increased	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Blood immunoglobulin m decreased	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
C-reactive protein increased	3 (11.5)	0	0	3 (11.5)	0
International normalised ratio increased	3 (11.5)	3 (11.5)	0	0	0
Blood immunoglobulin g decreased	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Blood fibrinogen decreased	1 (3.8)	0	1 (3.8)	0	0
Metabolism and nutrition disorders					
-Total	11 (42.3)	2 (7.7)	3 (11.5)	4 (15.4)	2 (7.7)
Hypocalcaemia	6 (23.1)	0	4 (15.4)	2 (7.7)	0
Hypokalaemia	5 (19.2)	1 (3.8)	0	2 (7.7)	2 (7.7)
Decreased appetite	4 (15.4)	2 (7.7)	1 (3.8)	1 (3.8)	0
Hypophosphataemia	4 (15.4)	0	2 (7.7)	2 (7.7)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	3 (11.5)	3 (11.5)	0	0	0
Hypoalbuminaemia	2 (7.7)	0	2 (7.7)	0	0
Hyperglycaemia	1 (3.8)	0	0	1 (3.8)	0
Hypervolaemia	1 (3.8)	0	0	1 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (26.9)	3 (11.5)	2 (7.7)	2 (7.7)	0
Arthralgia	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Back pain	2 (7.7)	1 (3.8)	0	1 (3.8)	0
Myalgia	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Pain in extremity	2 (7.7)	2 (7.7)	0	0	0
Nervous system disorders					
-Total	7 (26.9)	3 (11.5)	1 (3.8)	3 (11.5)	0
Headache	5 (19.2)	3 (11.5)	1 (3.8)	1 (3.8)	0
Encephalopathy	2 (7.7)	0	0	2 (7.7)	0
Psychiatric disorders					
-Total	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Anxiety	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Renal and urinary disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.8)	0	0	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	0	0	1 (3.8)
Respiratory, thoracic and mediastinal disorders					
-Total	9 (34.6)	4 (15.4)	1 (3.8)	3 (11.5)	1 (3.8)
Cough	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Hypoxia	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Nasal congestion	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Pleural effusion	2 (7.7)	0	0	1 (3.8)	1 (3.8)
Pulmonary oedema	2 (7.7)	0	0	2 (7.7)	0
Epistaxis	1 (3.8)	1 (3.8)	0	0	0
Tachypnoea	1 (3.8)	0	0	1 (3.8)	0
Skin and subcutaneous tissue disorders					
-Total	4 (15.4)	3 (11.5)	1 (3.8)	0	0
Rash	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Erythema	2 (7.7)	2 (7.7)	0	0	0
Pruritus	1 (3.8)	0	1 (3.8)	0	0
Vascular disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (23.1)	1 (3.8)	2 (7.7)	2 (7.7)	1 (3.8)
Hypotension	6 (23.1)	1 (3.8)	2 (7.7)	2 (7.7)	1 (3.8)
Hypertension	1 (3.8)	0	0	1 (3.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (98.1)	4 (7.4)	5 (9.3)	11 (20.4)	33 (61.1)
Blood and lymphatic system disorders					
-Total	28 (51.9)	1 (1.9)	3 (5.6)	16 (29.6)	8 (14.8)
Febrile neutropenia	16 (29.6)	0	0	15 (27.8)	1 (1.9)
Anaemia	13 (24.1)	2 (3.7)	6 (11.1)	5 (9.3)	0
Disseminated intravascular coagulation	5 (9.3)	0	4 (7.4)	1 (1.9)	0
Neutropenia	5 (9.3)	0	1 (1.9)	0	4 (7.4)
Thrombocytopenia	4 (7.4)	0	0	0	4 (7.4)
Cardiac disorders					
-Total	11 (20.4)	4 (7.4)	6 (11.1)	1 (1.9)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	11 (20.4)	4 (7.4)	6 (11.1)	1 (1.9)	0
Gastrointestinal disorders					
-Total	34 (63.0)	15 (27.8)	15 (27.8)	4 (7.4)	0
Vomiting	16 (29.6)	10 (18.5)	6 (11.1)	0	0
Nausea	13 (24.1)	8 (14.8)	4 (7.4)	1 (1.9)	0
Diarrhoea	11 (20.4)	6 (11.1)	4 (7.4)	1 (1.9)	0
Abdominal pain	8 (14.8)	2 (3.7)	4 (7.4)	2 (3.7)	0
Constipation	6 (11.1)	1 (1.9)	5 (9.3)	0	0
General disorders and administration site conditions					
-Total	24 (44.4)	15 (27.8)	2 (3.7)	6 (11.1)	1 (1.9)
Pyrexia	15 (27.8)	7 (13.0)	1 (1.9)	6 (11.1)	1 (1.9)
Fatigue	8 (14.8)	7 (13.0)	1 (1.9)	0	0
Chills	6 (11.1)	4 (7.4)	2 (3.7)	0	0
Oedema peripheral	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Face oedema	4 (7.4)	4 (7.4)	0	0	0
Immune system disorders					
-Total	44 (81.5)	1 (1.9)	10 (18.5)	16 (29.6)	17 (31.5)
Cytokine release syndrome	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	14 (25.9)	1 (1.9)	8 (14.8)	5 (9.3)	0
Infections and infestations					
-Total	6 (11.1)	0	2 (3.7)	4 (7.4)	0
Rhinovirus infection	2 (3.7)	0	2 (3.7)	0	0
Staphylococcal bacteraemia	2 (3.7)	0	0	2 (3.7)	0
Conjunctivitis	1 (1.9)	0	1 (1.9)	0	0
Pneumonia	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	1 (1.9)	0	1 (1.9)	0	0
Infusion related reaction	1 (1.9)	0	1 (1.9)	0	0
Investigations					
-Total	33 (61.1)	4 (7.4)	3 (5.6)	9 (16.7)	17 (31.5)
White blood cell count decreased	16 (29.6)	2 (3.7)	1 (1.9)	1 (1.9)	12 (22.2)
Aspartate aminotransferase increased	14 (25.9)	1 (1.9)	4 (7.4)	7 (13.0)	2 (3.7)
Neutrophil count decreased	14 (25.9)	0	2 (3.7)	1 (1.9)	11 (20.4)
Platelet count decreased	14 (25.9)	2 (3.7)	2 (3.7)	6 (11.1)	4 (7.4)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	12 (22.2)	2 (3.7)	5 (9.3)	5 (9.3)	0
Lymphocyte count decreased	11 (20.4)	2 (3.7)	0	4 (7.4)	5 (9.3)
Blood bilirubin increased	9 (16.7)	1 (1.9)	1 (1.9)	7 (13.0)	0
Blood fibrinogen decreased	6 (11.1)	2 (3.7)	2 (3.7)	1 (1.9)	1 (1.9)
International normalised ratio increased	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Serum ferritin increased	4 (7.4)	0	4 (7.4)	0	0
Blood immunoglobulin m decreased	3 (5.6)	3 (5.6)	0	0	0
C-reactive protein increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	32 (59.3)	6 (11.1)	7 (13.0)	17 (31.5)	2 (3.7)
Decreased appetite	20 (37.0)	7 (13.0)	3 (5.6)	9 (16.7)	1 (1.9)
Hypokalaemia	14 (25.9)	2 (3.7)	5 (9.3)	7 (13.0)	0
Hypophosphataemia	13 (24.1)	3 (5.6)	3 (5.6)	6 (11.1)	1 (1.9)
Hypocalcaemia	10 (18.5)	2 (3.7)	5 (9.3)	3 (5.6)	0
Hypoalbuminaemia	9 (16.7)	0	8 (14.8)	1 (1.9)	0
Hyperglycaemia	7 (13.0)	0	4 (7.4)	3 (5.6)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	5 (9.3)	0	2 (3.7)	3 (5.6)	0
Hyperuricaemia	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	21 (38.9)	10 (18.5)	11 (20.4)	0	0
Pain in extremity	9 (16.7)	4 (7.4)	5 (9.3)	0	0
Arthralgia	8 (14.8)	4 (7.4)	4 (7.4)	0	0
Myalgia	7 (13.0)	5 (9.3)	2 (3.7)	0	0
Back pain	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Nervous system disorders					
-Total	23 (42.6)	10 (18.5)	10 (18.5)	3 (5.6)	0
Headache	18 (33.3)	9 (16.7)	8 (14.8)	1 (1.9)	0
Encephalopathy	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Psychiatric disorders					
-Total	12 (22.2)	4 (7.4)	4 (7.4)	4 (7.4)	0
Delirium	7 (13.0)	2 (3.7)	2 (3.7)	3 (5.6)	0
Agitation	5 (9.3)	2 (3.7)	3 (5.6)	0	0
Anxiety	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Renal and urinary disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (14.8)	1 (1.9)	1 (1.9)	3 (5.6)	3 (5.6)
Acute kidney injury	8 (14.8)	1 (1.9)	1 (1.9)	3 (5.6)	3 (5.6)
Respiratory, thoracic and mediastinal disorders					
-Total	30 (55.6)	10 (18.5)	2 (3.7)	9 (16.7)	9 (16.7)
Hypoxia	15 (27.8)	0	4 (7.4)	5 (9.3)	6 (11.1)
Pulmonary oedema	10 (18.5)	2 (3.7)	3 (5.6)	4 (7.4)	1 (1.9)
Cough	7 (13.0)	7 (13.0)	0	0	0
Tachypnoea	7 (13.0)	3 (5.6)	1 (1.9)	3 (5.6)	0
Oropharyngeal pain	5 (9.3)	5 (9.3)	0	0	0
Pleural effusion	5 (9.3)	4 (7.4)	0	1 (1.9)	0
Respiratory failure	4 (7.4)	0	0	0	4 (7.4)
Epistaxis	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (16.7)	4 (7.4)	5 (9.3)	0	0
Pruritus	5 (9.3)	2 (3.7)	3 (5.6)	0	0
Erythema	2 (3.7)	2 (3.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=54 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	2 (3.7)	0	2 (3.7)	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	21 (38.9)	3 (5.6)	5 (9.3)	8 (14.8)	5 (9.3)
Hypotension	15 (27.8)	0	4 (7.4)	6 (11.1)	5 (9.3)
Hypertension	12 (22.2)	4 (7.4)	5 (9.3)	3 (5.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=25			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (80.0)	4 (16.0)	7 (28.0)	7 (28.0)	2 (8.0)
Blood and lymphatic system disorders					
-Total	6 (24.0)	2 (8.0)	1 (4.0)	2 (8.0)	1 (4.0)
Anaemia	3 (12.0)	2 (8.0)	0	1 (4.0)	0
Disseminated intravascular coagulation	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Leukopenia	1 (4.0)	0	1 (4.0)	0	0
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Cardiac disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (4.0)	1 (4.0)	0	0	0
Eye disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Ocular hyperaemia	1 (4.0)	1 (4.0)	0	0	0
Gastrointestinal disorders					
-Total	5 (20.0)	5 (20.0)	0	0	0
Diarrhoea	4 (16.0)	4 (16.0)	0	0	0
Vomiting	3 (12.0)	3 (12.0)	0	0	0
Nausea	1 (4.0)	1 (4.0)	0	0	0
General disorders and administration site conditions					
-Total	7 (28.0)	5 (20.0)	1 (4.0)	1 (4.0)	0
Pyrexia	5 (20.0)	3 (12.0)	1 (4.0)	1 (4.0)	0
Fatigue	2 (8.0)	2 (8.0)	0	0	0
Immune system disorders					
-Total	5 (20.0)	0	5 (20.0)	0	0
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)	0	0
Infections and infestations					
-Total	8 (32.0)	2 (8.0)	3 (12.0)	3 (12.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (16.0)	2 (8.0)	0	2 (8.0)	0
Respiratory syncytial virus infection	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Parainfluenzae virus infection	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Rhinovirus infection	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Conjunctivitis	1 (4.0)	0	1 (4.0)	0	0
Nasopharyngitis	1 (4.0)	0	1 (4.0)	0	0
Pneumonia	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal bacteraemia	1 (4.0)	0	0	1 (4.0)	0
Injury, poisoning and procedural complications					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Infusion related reaction	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Investigations					
-Total	6 (24.0)	2 (8.0)	1 (4.0)	2 (8.0)	1 (4.0)
Neutrophil count decreased	4 (16.0)	1 (4.0)	1 (4.0)	1 (4.0)	1 (4.0)
White blood cell count decreased	4 (16.0)	2 (8.0)	1 (4.0)	0	1 (4.0)
Lymphocyte count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (8.0)	1 (4.0)	0	0	1 (4.0)
C-reactive protein increased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (16.0)	1 (4.0)	1 (4.0)	1 (4.0)	1 (4.0)
Decreased appetite	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Hypokalaemia	1 (4.0)	0	0	0	1 (4.0)
Hypophosphataemia	1 (4.0)	0	1 (4.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (8.0)	2 (8.0)	0	0	0
Back pain	1 (4.0)	1 (4.0)	0	0	0
Pain in extremity	1 (4.0)	1 (4.0)	0	0	0
Nervous system disorders					
-Total	5 (20.0)	3 (12.0)	2 (8.0)	0	0
Headache	5 (20.0)	3 (12.0)	2 (8.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (16.0)	2 (8.0)	1 (4.0)	1 (4.0)	0
Cough	2 (8.0)	1 (4.0)	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Nasal congestion	2 (8.0)	2 (8.0)	0	0	0
Hypoxia	1 (4.0)	0	0	1 (4.0)	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (12.0)	1 (4.0)	2 (8.0)	0	0
Dry skin	1 (4.0)	0	1 (4.0)	0	0
Erythema	1 (4.0)	0	1 (4.0)	0	0
Rash	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Hypotension	1 (4.0)	1 (4.0)	0	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=50			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (86.0)	8 (16.0)	15 (30.0)	10 (20.0)	10 (20.0)
Blood and lymphatic system disorders					
-Total	8 (16.0)	1 (2.0)	0	4 (8.0)	3 (6.0)
Neutropenia	4 (8.0)	0	0	2 (4.0)	2 (4.0)
Anaemia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Febrile neutropenia	2 (4.0)	0	0	2 (4.0)	0
Thrombocytopenia	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Cardiac disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Tachycardia	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	9 (18.0)	4 (8.0)	5 (10.0)	0	0
Nausea	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Constipation	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Diarrhoea	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Vomiting	3 (6.0)	3 (6.0)	0	0	0
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
General disorders and administration site conditions					
-Total	15 (30.0)	9 (18.0)	5 (10.0)	1 (2.0)	0
Pyrexia	10 (20.0)	4 (8.0)	5 (10.0)	1 (2.0)	0
Fatigue	4 (8.0)	4 (8.0)	0	0	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Oedema peripheral	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	5 (10.0)	0	5 (10.0)	0	0
Hypogammaglobulinaemia	5 (10.0)	0	5 (10.0)	0	0
Infections and infestations					
-Total	17 (34.0)	5 (10.0)	9 (18.0)	1 (2.0)	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasopharyngitis	6 (12.0)	4 (8.0)	2 (4.0)	0	0
Upper respiratory tract infection	4 (8.0)	1 (2.0)	3 (6.0)	0	0
Rhinovirus infection	3 (6.0)	0	3 (6.0)	0	0
Sinusitis	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Parainfluenzae virus infection	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Pneumonia	2 (4.0)	1 (2.0)	0	0	1 (2.0)
Injury, poisoning and procedural complications					
-Total	1 (2.0)	1 (2.0)	0	0	0
Infusion related reaction	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	15 (30.0)	3 (6.0)	3 (6.0)	6 (12.0)	3 (6.0)
Neutrophil count decreased	6 (12.0)	1 (2.0)	0	2 (4.0)	3 (6.0)
White blood cell count decreased	6 (12.0)	2 (4.0)	1 (2.0)	3 (6.0)	0
Platelet count decreased	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Alanine aminotransferase increased	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Blood bilirubin increased	2 (4.0)	0	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Blood immunoglobulin g decreased	1 (2.0)	0	1 (2.0)	0	0
Blood immunoglobulin m decreased	1 (2.0)	0	0	1 (2.0)	0
Metabolism and nutrition disorders					
-Total	7 (14.0)	3 (6.0)	2 (4.0)	2 (4.0)	0
Hyperuricaemia	3 (6.0)	3 (6.0)	0	0	0
Decreased appetite	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Hypokalaemia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hypervolaemia	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (18.0)	2 (4.0)	4 (8.0)	3 (6.0)	0
Back pain	5 (10.0)	1 (2.0)	2 (4.0)	2 (4.0)	0
Pain in extremity	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Arthralgia	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Myalgia	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Headache	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Psychiatric disorders					
-Total	6 (12.0)	1 (2.0)	5 (10.0)	0	0
Anxiety	6 (12.0)	1 (2.0)	5 (10.0)	0	0
Agitation	1 (2.0)	1 (2.0)	0	0	0
Delirium	1 (2.0)	0	1 (2.0)	0	0
Renal and urinary disorders					
-Total	3 (6.0)	1 (2.0)	1 (2.0)	0	1 (2.0)
Acute kidney injury	3 (6.0)	1 (2.0)	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders					
-Total	13 (26.0)	7 (14.0)	3 (6.0)	2 (4.0)	1 (2.0)
Cough	9 (18.0)	7 (14.0)	2 (4.0)	0	0
Nasal congestion	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Hypoxia	2 (4.0)	0	0	2 (4.0)	0
Pleural effusion	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Epistaxis	1 (2.0)	0	1 (2.0)	0	0
Oropharyngeal pain	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Skin and subcutaneous tissue disorders					
-Total	8 (16.0)	6 (12.0)	2 (4.0)	0	0
Dry skin	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Rash	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Pruritus	1 (2.0)	0	1 (2.0)	0	0
Vascular disorders					
-Total	4 (8.0)	0	1 (2.0)	1 (2.0)	2 (4.0)
Hypotension	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Hypertension	1 (2.0)	0	1 (2.0)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	1 (5.0)	7 (35.0)	2 (10.0)	3 (15.0)
Gastrointestinal disorders					
-Total	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Diarrhoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Constipation	1 (5.0)	1 (5.0)	0	0	0
Nausea	1 (5.0)	1 (5.0)	0	0	0
Vomiting	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (20.0)	1 (5.0)	3 (15.0)	0	0
Pyrexia	3 (15.0)	1 (5.0)	2 (10.0)	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	7 (35.0)	1 (5.0)	3 (15.0)	2 (10.0)	1 (5.0)
Rhinovirus infection	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Sinusitis	3 (15.0)	0	3 (15.0)	0	0
Pneumonia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Conjunctivitis	1 (5.0)	1 (5.0)	0	0	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Injury, poisoning and procedural complications					
-Total	1 (5.0)	0	0	1 (5.0)	0
Infusion related reaction	1 (5.0)	0	0	1 (5.0)	0
Investigations					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Neutrophil count decreased	1 (5.0)	0	0	0	1 (5.0)
Metabolism and nutrition disorders					
-Total	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Decreased appetite	1 (5.0)	0	0	0	1 (5.0)
Hyperglycaemia	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Pain in extremity	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Cough	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (5.0)	0	1 (5.0)	0	0
Tachypnoea	1 (5.0)	0	0	0	1 (5.0)
Skin and subcutaneous tissue disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Dry skin	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypertension	2 (10.0)	0	1 (5.0)	1 (5.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (40.0)	4 (13.3)	3 (10.0)	3 (10.0)	2 (6.7)
Blood and lymphatic system disorders					
-Total	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Anaemia	1 (3.3)	0	1 (3.3)	0	0
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Thrombocytopenia	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					
-Total	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Diarrhoea	2 (6.7)	1 (3.3)	0	1 (3.3)	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Pyrexia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Immune system disorders					
-Total	2 (6.7)	0	2 (6.7)	0	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0
Infections and infestations					
-Total	7 (23.3)	2 (6.7)	4 (13.3)	1 (3.3)	0
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Sinusitis	3 (10.0)	0	3 (10.0)	0	0
Upper respiratory tract infection	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	1 (3.3)	0	1 (3.3)	0	0
Investigations					
-Total	3 (10.0)	3 (10.0)	0	0	0
Neutrophil count decreased	2 (6.7)	2 (6.7)	0	0	0
Platelet count decreased	2 (6.7)	2 (6.7)	0	0	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.7)	0	2 (6.7)	0	0
Arthralgia	1 (3.3)	0	1 (3.3)	0	0
Pain in extremity	1 (3.3)	0	1 (3.3)	0	0
Nervous system disorders					
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Headache	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (16.7)	3 (10.0)	0	1 (3.3)	1 (3.3)
Cough	2 (6.7)	2 (6.7)	0	0	0
Epistaxis	1 (3.3)	1 (3.3)	0	0	0
Hypoxia	1 (3.3)	0	0	1 (3.3)	0
Oropharyngeal pain	1 (3.3)	1 (3.3)	0	0	0
Respiratory failure	1 (3.3)	0	0	0	1 (3.3)
Skin and subcutaneous tissue disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Rash	1 (3.3)	0	1 (3.3)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (100)	0	3 (11.5)	10 (38.5)	13 (50.0)
Blood and lymphatic system disorders					
-Total	19 (73.1)	1 (3.8)	3 (11.5)	10 (38.5)	5 (19.2)
Febrile neutropenia	10 (38.5)	0	0	9 (34.6)	1 (3.8)
Anaemia	8 (30.8)	3 (11.5)	2 (7.7)	3 (11.5)	0
Neutropenia	4 (15.4)	0	1 (3.8)	1 (3.8)	2 (7.7)
Thrombocytopenia	4 (15.4)	0	0	2 (7.7)	2 (7.7)
Disseminated intravascular coagulation	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Leukopenia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (23.1)	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)
Tachycardia	6 (23.1)	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)
Eye disorders					
-Total	3 (11.5)	3 (11.5)	0	0	0
Ocular hyperaemia	3 (11.5)	3 (11.5)	0	0	0
Gastrointestinal disorders					
-Total	16 (61.5)	10 (38.5)	4 (15.4)	2 (7.7)	0
Diarrhoea	10 (38.5)	7 (26.9)	3 (11.5)	0	0
Vomiting	8 (30.8)	5 (19.2)	2 (7.7)	1 (3.8)	0
Nausea	6 (23.1)	3 (11.5)	2 (7.7)	1 (3.8)	0
Constipation	5 (19.2)	5 (19.2)	0	0	0
Abdominal pain	3 (11.5)	1 (3.8)	2 (7.7)	0	0
General disorders and administration site conditions					
-Total	16 (61.5)	6 (23.1)	7 (26.9)	2 (7.7)	1 (3.8)
Pyrexia	12 (46.2)	4 (15.4)	6 (23.1)	1 (3.8)	1 (3.8)
Fatigue	5 (19.2)	3 (11.5)	2 (7.7)	0	0
Face oedema	4 (15.4)	1 (3.8)	2 (7.7)	1 (3.8)	0
Oedema peripheral	1 (3.8)	0	0	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	23 (88.5)	1 (3.8)	13 (50.0)	5 (19.2)	4 (15.4)
Cytokine release syndrome	18 (69.2)	3 (11.5)	8 (30.8)	3 (11.5)	4 (15.4)
Hypogammaglobulinaemia	14 (53.8)	1 (3.8)	11 (42.3)	2 (7.7)	0
Infections and infestations					
-Total	15 (57.7)	3 (11.5)	6 (23.1)	5 (19.2)	1 (3.8)
Upper respiratory tract infection	6 (23.1)	3 (11.5)	1 (3.8)	2 (7.7)	0
Conjunctivitis	4 (15.4)	1 (3.8)	3 (11.5)	0	0
Rhinovirus infection	4 (15.4)	0	2 (7.7)	2 (7.7)	0
Parainfluenzae virus infection	3 (11.5)	1 (3.8)	0	2 (7.7)	0
Pneumonia	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Respiratory syncytial virus infection	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Sinusitis	3 (11.5)	0	3 (11.5)	0	0
Staphylococcal bacteraemia	3 (11.5)	0	0	3 (11.5)	0
Nasopharyngitis	1 (3.8)	0	1 (3.8)	0	0
Injury, poisoning and procedural complications					
-Total	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
Investigations					
-Total	17 (65.4)	0	2 (7.7)	7 (26.9)	8 (30.8)
Neutrophil count decreased	8 (30.8)	0	1 (3.8)	2 (7.7)	5 (19.2)
White blood cell count decreased	8 (30.8)	1 (3.8)	2 (7.7)	1 (3.8)	4 (15.4)
Platelet count decreased	7 (26.9)	2 (7.7)	1 (3.8)	0	4 (15.4)
Alanine aminotransferase increased	6 (23.1)	2 (7.7)	3 (11.5)	1 (3.8)	0
Aspartate aminotransferase increased	5 (19.2)	1 (3.8)	2 (7.7)	1 (3.8)	1 (3.8)
Lymphocyte count decreased	5 (19.2)	0	0	5 (19.2)	0
C-reactive protein increased	4 (15.4)	1 (3.8)	0	3 (11.5)	0
Serum ferritin increased	4 (15.4)	1 (3.8)	1 (3.8)	2 (7.7)	0
Blood bilirubin increased	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Blood immunoglobulin g decreased	3 (11.5)	1 (3.8)	2 (7.7)	0	0
Blood immunoglobulin m decreased	3 (11.5)	1 (3.8)	1 (3.8)	1 (3.8)	0
International normalised ratio increased	3 (11.5)	3 (11.5)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (3.8)	0	1 (3.8)	0	0
Metabolism and nutrition disorders					
-Total	14 (53.8)	3 (11.5)	3 (11.5)	5 (19.2)	3 (11.5)
Decreased appetite	8 (30.8)	3 (11.5)	3 (11.5)	1 (3.8)	1 (3.8)
Hypocalcaemia	6 (23.1)	0	4 (15.4)	2 (7.7)	0
Hypokalaemia	5 (19.2)	1 (3.8)	0	2 (7.7)	2 (7.7)
Hypophosphataemia	5 (19.2)	0	3 (11.5)	2 (7.7)	0
Hyperuricaemia	3 (11.5)	3 (11.5)	0	0	0
Hyperglycaemia	2 (7.7)	0	0	2 (7.7)	0
Hypoalbuminaemia	2 (7.7)	0	2 (7.7)	0	0
Hypervolaemia	1 (3.8)	0	0	1 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (34.6)	5 (19.2)	2 (7.7)	2 (7.7)	0
Pain in extremity	4 (15.4)	3 (11.5)	1 (3.8)	0	0
Back pain	3 (11.5)	2 (7.7)	0	1 (3.8)	0
Arthralgia	2 (7.7)	0	1 (3.8)	1 (3.8)	0
Myalgia	2 (7.7)	1 (3.8)	1 (3.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	10 (38.5)	5 (19.2)	2 (7.7)	3 (11.5)	0
Headache	8 (30.8)	5 (19.2)	2 (7.7)	1 (3.8)	0
Encephalopathy	2 (7.7)	0	0	2 (7.7)	0
Psychiatric disorders					
-Total	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0
Anxiety	5 (19.2)	2 (7.7)	2 (7.7)	1 (3.8)	0
Renal and urinary disorders					
-Total	1 (3.8)	0	0	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	0	0	1 (3.8)
Respiratory, thoracic and mediastinal disorders					
-Total	12 (46.2)	5 (19.2)	2 (7.7)	3 (11.5)	2 (7.7)
Cough	6 (23.1)	3 (11.5)	3 (11.5)	0	0
Nasal congestion	4 (15.4)	3 (11.5)	1 (3.8)	0	0
Epistaxis	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Hypoxia	3 (11.5)	0	1 (3.8)	2 (7.7)	0
Pleural effusion	3 (11.5)	0	1 (3.8)	1 (3.8)	1 (3.8)
Pulmonary oedema	2 (7.7)	0	0	2 (7.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	2 (7.7)	0	0	1 (3.8)	1 (3.8)
Oropharyngeal pain	1 (3.8)	0	1 (3.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (30.8)	5 (19.2)	3 (11.5)	0	0
Rash	4 (15.4)	3 (11.5)	1 (3.8)	0	0
Erythema	3 (11.5)	2 (7.7)	1 (3.8)	0	0
Dry skin	2 (7.7)	1 (3.8)	1 (3.8)	0	0
Pruritus	1 (3.8)	0	1 (3.8)	0	0
Vascular disorders					
-Total	9 (34.6)	2 (7.7)	3 (11.5)	3 (11.5)	1 (3.8)
Hypotension	7 (26.9)	2 (7.7)	2 (7.7)	2 (7.7)	1 (3.8)
Hypertension	3 (11.5)	0	1 (3.8)	2 (7.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (100)	2 (3.7)	5 (9.3)	11 (20.4)	36 (66.7)
Blood and lymphatic system disorders					
-Total	32 (59.3)	1 (1.9)	3 (5.6)	19 (35.2)	9 (16.7)
Anaemia	17 (31.5)	4 (7.4)	7 (13.0)	6 (11.1)	0
Febrile neutropenia	17 (31.5)	0	0	16 (29.6)	1 (1.9)
Neutropenia	7 (13.0)	0	1 (1.9)	1 (1.9)	5 (9.3)
Disseminated intravascular coagulation	5 (9.3)	0	4 (7.4)	1 (1.9)	0
Thrombocytopenia	5 (9.3)	0	0	1 (1.9)	4 (7.4)
Cardiac disorders					
-Total	11 (20.4)	4 (7.4)	6 (11.1)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	11 (20.4)	4 (7.4)	6 (11.1)	1 (1.9)	0
Gastrointestinal disorders					
-Total	40 (74.1)	16 (29.6)	19 (35.2)	5 (9.3)	0
Vomiting	18 (33.3)	12 (22.2)	6 (11.1)	0	0
Diarrhoea	16 (29.6)	9 (16.7)	5 (9.3)	2 (3.7)	0
Nausea	16 (29.6)	9 (16.7)	6 (11.1)	1 (1.9)	0
Constipation	9 (16.7)	2 (3.7)	7 (13.0)	0	0
Abdominal pain	8 (14.8)	1 (1.9)	5 (9.3)	2 (3.7)	0
General disorders and administration site conditions					
-Total	31 (57.4)	17 (31.5)	5 (9.3)	8 (14.8)	1 (1.9)
Pyrexia	23 (42.6)	10 (18.5)	4 (7.4)	8 (14.8)	1 (1.9)
Fatigue	12 (22.2)	11 (20.4)	1 (1.9)	0	0
Chills	7 (13.0)	5 (9.3)	2 (3.7)	0	0
Oedema peripheral	6 (11.1)	5 (9.3)	1 (1.9)	0	0
Face oedema	4 (7.4)	4 (7.4)	0	0	0
Immune system disorders					
-Total	46 (85.2)	1 (1.9)	12 (22.2)	16 (29.6)	17 (31.5)
Cytokine release syndrome	43 (79.6)	2 (3.7)	10 (18.5)	14 (25.9)	17 (31.5)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	19 (35.2)	1 (1.9)	13 (24.1)	5 (9.3)	0
Infections and infestations					
-Total	24 (44.4)	6 (11.1)	10 (18.5)	6 (11.1)	2 (3.7)
Upper respiratory tract infection	7 (13.0)	2 (3.7)	4 (7.4)	1 (1.9)	0
Nasopharyngitis	6 (11.1)	4 (7.4)	2 (3.7)	0	0
Rhinovirus infection	5 (9.3)	0	5 (9.3)	0	0
Conjunctivitis	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Sinusitis	4 (7.4)	0	2 (3.7)	2 (3.7)	0
Pneumonia	3 (5.6)	1 (1.9)	0	1 (1.9)	1 (1.9)
Parainfluenzae virus infection	2 (3.7)	0	1 (1.9)	0	1 (1.9)
Staphylococcal bacteraemia	2 (3.7)	0	0	2 (3.7)	0
Injury, poisoning and procedural complications					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Infusion related reaction	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Investigations					
-Total	33 (61.1)	3 (5.6)	3 (5.6)	10 (18.5)	17 (31.5)
Platelet count decreased	17 (31.5)	4 (7.4)	2 (3.7)	7 (13.0)	4 (7.4)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	17 (31.5)	2 (3.7)	2 (3.7)	1 (1.9)	12 (22.2)
Neutrophil count decreased	16 (29.6)	1 (1.9)	1 (1.9)	2 (3.7)	12 (22.2)
Aspartate aminotransferase increased	14 (25.9)	1 (1.9)	4 (7.4)	7 (13.0)	2 (3.7)
Alanine aminotransferase increased	12 (22.2)	1 (1.9)	5 (9.3)	6 (11.1)	0
Lymphocyte count decreased	12 (22.2)	1 (1.9)	1 (1.9)	5 (9.3)	5 (9.3)
Blood bilirubin increased	10 (18.5)	1 (1.9)	2 (3.7)	7 (13.0)	0
Blood fibrinogen decreased	6 (11.1)	2 (3.7)	2 (3.7)	1 (1.9)	1 (1.9)
International normalised ratio increased	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Blood immunoglobulin m decreased	4 (7.4)	3 (5.6)	0	1 (1.9)	0
Serum ferritin increased	4 (7.4)	0	4 (7.4)	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
C-reactive protein increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	34 (63.0)	7 (13.0)	8 (14.8)	17 (31.5)	2 (3.7)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	22 (40.7)	8 (14.8)	4 (7.4)	9 (16.7)	1 (1.9)
Hypokalaemia	15 (27.8)	2 (3.7)	6 (11.1)	7 (13.0)	0
Hypophosphataemia	13 (24.1)	3 (5.6)	3 (5.6)	6 (11.1)	1 (1.9)
Hypocalcaemia	10 (18.5)	2 (3.7)	5 (9.3)	3 (5.6)	0
Hypoalbuminaemia	9 (16.7)	0	8 (14.8)	1 (1.9)	0
Hyperglycaemia	7 (13.0)	0	4 (7.4)	3 (5.6)	0
Hyperuricaemia	6 (11.1)	4 (7.4)	1 (1.9)	1 (1.9)	0
Hypervolaemia	6 (11.1)	0	2 (3.7)	4 (7.4)	0
Musculoskeletal and connective tissue disorders					
-Total	26 (48.1)	10 (18.5)	13 (24.1)	3 (5.6)	0
Pain in extremity	13 (24.1)	5 (9.3)	7 (13.0)	1 (1.9)	0
Arthralgia	10 (18.5)	5 (9.3)	5 (9.3)	0	0
Myalgia	8 (14.8)	5 (9.3)	3 (5.6)	0	0
Back pain	7 (13.0)	0	5 (9.3)	2 (3.7)	0
Nervous system disorders					
-Total	24 (44.4)	9 (16.7)	11 (20.4)	4 (7.4)	0
Headache	19 (35.2)	8 (14.8)	9 (16.7)	2 (3.7)	0
Encephalopathy	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	17 (31.5)	4 (7.4)	9 (16.7)	4 (7.4)	0
Anxiety	9 (16.7)	1 (1.9)	7 (13.0)	1 (1.9)	0
Delirium	8 (14.8)	2 (3.7)	3 (5.6)	3 (5.6)	0
Agitation	6 (11.1)	3 (5.6)	3 (5.6)	0	0
Renal and urinary disorders					
-Total	11 (20.4)	2 (3.7)	2 (3.7)	3 (5.6)	4 (7.4)
Acute kidney injury	11 (20.4)	2 (3.7)	2 (3.7)	3 (5.6)	4 (7.4)
Respiratory, thoracic and mediastinal disorders					
-Total	38 (70.4)	14 (25.9)	3 (5.6)	10 (18.5)	11 (20.4)
Cough	17 (31.5)	15 (27.8)	2 (3.7)	0	0
Hypoxia	17 (31.5)	0	3 (5.6)	8 (14.8)	6 (11.1)
Pulmonary oedema	10 (18.5)	2 (3.7)	3 (5.6)	4 (7.4)	1 (1.9)
Oropharyngeal pain	7 (13.0)	7 (13.0)	0	0	0
Tachypnoea	7 (13.0)	3 (5.6)	1 (1.9)	3 (5.6)	0
Pleural effusion	6 (11.1)	4 (7.4)	1 (1.9)	1 (1.9)	0
Respiratory failure	6 (11.1)	0	0	0	6 (11.1)
Nasal congestion	5 (9.3)	4 (7.4)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	15 (27.8)	8 (14.8)	7 (13.0)	0	0
Dry skin	6 (11.1)	5 (9.3)	1 (1.9)	0	0
Pruritus	6 (11.1)	2 (3.7)	4 (7.4)	0	0
Rash	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Erythema	2 (3.7)	2 (3.7)	0	0	0
Vascular disorders					
-Total	23 (42.6)	3 (5.6)	5 (9.3)	8 (14.8)	7 (13.0)
Hypotension	17 (31.5)	0	4 (7.4)	6 (11.1)	7 (13.0)
Hypertension	13 (24.1)	4 (7.4)	6 (11.1)	3 (5.6)	0

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Table 214o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	2 (18.2)	2 (18.2)	4 (36.4)	3 (27.3)
Blood and lymphatic system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)	0	0
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Gastrointestinal disorders					
-Total	3 (27.3)	3 (27.3)	0	0	0
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Constipation	1 (9.1)	1 (9.1)	0	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Pyrexia	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Face oedema	1 (9.1)	1 (9.1)	0	0	0
Immune system disorders					
-Total	7 (63.6)	1 (9.1)	2 (18.2)	3 (27.3)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hypogammaglobulinaemia	3 (27.3)	1 (9.1)	0	2 (18.2)	0
Infections and infestations					
-Total	1 (9.1)	0	1 (9.1)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Platelet count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Blood bilirubin increased	1 (9.1)	0	0	1 (9.1)	0
Serum ferritin increased	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Decreased appetite	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Headache	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	1 (9.1)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Hypertension	1 (9.1)	0	0	1 (9.1)	0

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Table 214o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (98.6)	3 (4.3)	6 (8.7)	17 (24.6)	42 (60.9)
Blood and lymphatic system disorders					
-Total	42 (60.9)	2 (2.9)	4 (5.8)	24 (34.8)	12 (17.4)
Febrile neutropenia	25 (36.2)	0	0	23 (33.3)	2 (2.9)
Anaemia	20 (29.0)	5 (7.2)	7 (10.1)	8 (11.6)	0
Neutropenia	8 (11.6)	0	2 (2.9)	1 (1.4)	5 (7.2)
Thrombocytopenia	8 (11.6)	0	0	2 (2.9)	6 (8.7)
Disseminated intravascular coagulation	7 (10.1)	0	5 (7.2)	2 (2.9)	0
Cardiac disorders					
-Total	17 (24.6)	7 (10.1)	7 (10.1)	2 (2.9)	1 (1.4)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (24.6)	7 (10.1)	7 (10.1)	2 (2.9)	1 (1.4)
Gastrointestinal disorders					
-Total	43 (62.3)	19 (27.5)	18 (26.1)	6 (8.7)	0
Vomiting	20 (29.0)	11 (15.9)	8 (11.6)	1 (1.4)	0
Nausea	18 (26.1)	10 (14.5)	6 (8.7)	2 (2.9)	0
Diarrhoea	15 (21.7)	8 (11.6)	6 (8.7)	1 (1.4)	0
Abdominal pain	10 (14.5)	2 (2.9)	6 (8.7)	2 (2.9)	0
Constipation	10 (14.5)	5 (7.2)	5 (7.2)	0	0
General disorders and administration site conditions					
-Total	32 (46.4)	17 (24.6)	6 (8.7)	7 (10.1)	2 (2.9)
Pyrexia	20 (29.0)	8 (11.6)	4 (5.8)	6 (8.7)	2 (2.9)
Fatigue	11 (15.9)	9 (13.0)	2 (2.9)	0	0
Face oedema	7 (10.1)	4 (5.8)	2 (2.9)	1 (1.4)	0
Chills	6 (8.7)	4 (5.8)	2 (2.9)	0	0
Oedema peripheral	6 (8.7)	4 (5.8)	1 (1.4)	1 (1.4)	0
Pain	1 (1.4)	0	0	1 (1.4)	0
Immune system disorders					
-Total	59 (85.5)	2 (2.9)	19 (27.5)	18 (26.1)	20 (29.0)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Hypogammaglobulinaemia	20 (29.0)	1 (1.4)	14 (20.3)	5 (7.2)	0
Infections and infestations					
-Total	7 (10.1)	1 (1.4)	5 (7.2)	1 (1.4)	0
Conjunctivitis	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Rhinovirus infection	2 (2.9)	0	2 (2.9)	0	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	43 (62.3)	4 (5.8)	3 (4.3)	14 (20.3)	22 (31.9)
White blood cell count decreased	23 (33.3)	3 (4.3)	3 (4.3)	2 (2.9)	15 (21.7)
Aspartate aminotransferase increased	18 (26.1)	1 (1.4)	6 (8.7)	8 (11.6)	3 (4.3)
Neutrophil count decreased	18 (26.1)	0	3 (4.3)	2 (2.9)	13 (18.8)
Platelet count decreased	18 (26.1)	4 (5.8)	3 (4.3)	6 (8.7)	5 (7.2)
Alanine aminotransferase increased	15 (21.7)	3 (4.3)	7 (10.1)	5 (7.2)	0
Lymphocyte count decreased	13 (18.8)	2 (2.9)	0	8 (11.6)	3 (4.3)
Blood bilirubin increased	11 (15.9)	1 (1.4)	2 (2.9)	8 (11.6)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	9 (13.0)	6 (8.7)	3 (4.3)	0	0
Serum ferritin increased	7 (10.1)	1 (1.4)	5 (7.2)	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.7)	4 (5.8)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	5 (7.2)	4 (5.8)	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	41 (59.4)	7 (10.1)	10 (14.5)	21 (30.4)	3 (4.3)
Decreased appetite	23 (33.3)	8 (11.6)	4 (5.8)	10 (14.5)	1 (1.4)
Hypokalaemia	19 (27.5)	3 (4.3)	5 (7.2)	9 (13.0)	2 (2.9)
Hypocalcaemia	16 (23.2)	2 (2.9)	9 (13.0)	5 (7.2)	0
Hypophosphataemia	16 (23.2)	3 (4.3)	5 (7.2)	8 (11.6)	0
Hypoalbuminaemia	11 (15.9)	0	10 (14.5)	1 (1.4)	0
Hyperglycaemia	8 (11.6)	0	4 (5.8)	4 (5.8)	0
Hyperuricaemia	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Hypervolaemia	6 (8.7)	0	2 (2.9)	4 (5.8)	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	27 (39.1)	13 (18.8)	12 (17.4)	2 (2.9)	0
Pain in extremity	11 (15.9)	6 (8.7)	5 (7.2)	0	0
Arthralgia	9 (13.0)	4 (5.8)	4 (5.8)	1 (1.4)	0
Myalgia	9 (13.0)	6 (8.7)	3 (4.3)	0	0
Back pain	6 (8.7)	2 (2.9)	3 (4.3)	1 (1.4)	0
Nervous system disorders					
-Total	27 (39.1)	12 (17.4)	10 (14.5)	5 (7.2)	0
Headache	20 (29.0)	11 (15.9)	8 (11.6)	1 (1.4)	0
Encephalopathy	8 (11.6)	1 (1.4)	3 (4.3)	4 (5.8)	0
Psychiatric disorders					
-Total	13 (18.8)	3 (4.3)	5 (7.2)	5 (7.2)	0
Delirium	7 (10.1)	2 (2.9)	2 (2.9)	3 (4.3)	0
Anxiety	6 (8.7)	1 (1.4)	3 (4.3)	2 (2.9)	0
Renal and urinary disorders					
-Total	9 (13.0)	1 (1.4)	1 (1.4)	3 (4.3)	4 (5.8)
Acute kidney injury	9 (13.0)	1 (1.4)	1 (1.4)	3 (4.3)	4 (5.8)
Respiratory, thoracic and mediastinal disorders					
-Total	36 (52.2)	13 (18.8)	4 (5.8)	10 (14.5)	9 (13.0)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	17 (24.6)	0	5 (7.2)	6 (8.7)	6 (8.7)
Pulmonary oedema	12 (17.4)	2 (2.9)	3 (4.3)	6 (8.7)	1 (1.4)
Cough	10 (14.5)	9 (13.0)	1 (1.4)	0	0
Tachypnoea	8 (11.6)	3 (4.3)	1 (1.4)	4 (5.8)	0
Pleural effusion	7 (10.1)	4 (5.8)	0	2 (2.9)	1 (1.4)
Oropharyngeal pain	5 (7.2)	5 (7.2)	0	0	0
Dyspnoea	3 (4.3)	0	0	2 (2.9)	1 (1.4)
Nasal congestion	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (14.5)	4 (5.8)	6 (8.7)	0	0
Pruritus	6 (8.7)	2 (2.9)	4 (5.8)	0	0
Rash	4 (5.8)	1 (1.4)	3 (4.3)	0	0
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	26 (37.7)	4 (5.8)	7 (10.1)	9 (13.0)	6 (8.7)
Hypotension	21 (30.4)	1 (1.4)	6 (8.7)	8 (11.6)	6 (8.7)
Hypertension	12 (17.4)	4 (5.8)	5 (7.2)	3 (4.3)	0

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Table 214o
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	5 (45.5)	2 (18.2)	0
Blood and lymphatic system disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Anaemia	1 (9.1)	1 (9.1)	0	0	0
Disseminated intravascular coagulation	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Constipation	2 (18.2)	0	2 (18.2)	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	2 (18.2)	0	0	0
Pyrexia	2 (18.2)	2 (18.2)	0	0	0
Immune system disorders					
-Total	3 (27.3)	0	3 (27.3)	0	0
Hypogammaglobulinaemia	3 (27.3)	0	3 (27.3)	0	0
Infections and infestations					
-Total	1 (9.1)	0	0	1 (9.1)	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Hypophosphataemia	1 (9.1)	0	1 (9.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Headache	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Hypotension	1 (9.1)	1 (9.1)	0	0	0

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (84.4)	10 (15.6)	20 (31.3)	14 (21.9)	10 (15.6)
Blood and lymphatic system disorders					
-Total	11 (17.2)	2 (3.1)	0	5 (7.8)	4 (6.3)
Anaemia	5 (7.8)	3 (4.7)	0	2 (3.1)	0
Neutropenia	5 (7.8)	0	0	2 (3.1)	3 (4.7)
Febrile neutropenia	3 (4.7)	0	0	3 (4.7)	0
Thrombocytopenia	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Cardiac disorders					
-Total	2 (3.1)	2 (3.1)	0	0	0
Tachycardia	2 (3.1)	2 (3.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	12 (18.8)	9 (14.1)	3 (4.7)	0	0
Diarrhoea	7 (10.9)	6 (9.4)	1 (1.6)	0	0
Vomiting	6 (9.4)	6 (9.4)	0	0	0
Nausea	5 (7.8)	3 (4.7)	2 (3.1)	0	0
Abdominal pain	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Constipation	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	21 (32.8)	12 (18.8)	6 (9.4)	3 (4.7)	0
Pyrexia	13 (20.3)	5 (7.8)	6 (9.4)	2 (3.1)	0
Fatigue	6 (9.4)	6 (9.4)	0	0	0
Pain	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Chills	1 (1.6)	1 (1.6)	0	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	7 (10.9)	0	7 (10.9)	0	0
Hypogammaglobulinaemia	7 (10.9)	0	7 (10.9)	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (31.3)	6 (9.4)	12 (18.8)	2 (3.1)	0
Nasopharyngitis	7 (10.9)	4 (6.3)	3 (4.7)	0	0
Upper respiratory tract infection	7 (10.9)	3 (4.7)	3 (4.7)	1 (1.6)	0
Rhinovirus infection	4 (6.3)	0	4 (6.3)	0	0
Sinusitis	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Conjunctivitis	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	21 (32.8)	6 (9.4)	3 (4.7)	8 (12.5)	4 (6.3)
Neutrophil count decreased	10 (15.6)	2 (3.1)	1 (1.6)	3 (4.7)	4 (6.3)
White blood cell count decreased	10 (15.6)	4 (6.3)	2 (3.1)	3 (4.7)	1 (1.6)
Platelet count decreased	5 (7.8)	3 (4.7)	0	1 (1.6)	1 (1.6)
Lymphocyte count decreased	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Alanine aminotransferase increased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Blood bilirubin increased	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Blood immunoglobulin a decreased	2 (3.1)	1 (1.6)	0	1 (1.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.6)	0	0	1 (1.6)	0
Metabolism and nutrition disorders					
-Total	10 (15.6)	4 (6.3)	3 (4.7)	2 (3.1)	1 (1.6)
Decreased appetite	5 (7.8)	2 (3.1)	3 (4.7)	0	0
Hyperuricaemia	3 (4.7)	3 (4.7)	0	0	0
Hypokalaemia	3 (4.7)	0	1 (1.6)	1 (1.6)	1 (1.6)
Hypervolaemia	1 (1.6)	0	0	1 (1.6)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (14.1)	3 (4.7)	3 (4.7)	3 (4.7)	0
Pain in extremity	5 (7.8)	2 (3.1)	2 (3.1)	1 (1.6)	0
Back pain	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Arthralgia	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Myalgia	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	8 (12.5)	5 (7.8)	3 (4.7)	0	0
Headache	8 (12.5)	5 (7.8)	3 (4.7)	0	0
Psychiatric disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (9.4)	1 (1.6)	5 (7.8)	0	0
Anxiety	6 (9.4)	1 (1.6)	5 (7.8)	0	0
Delirium	1 (1.6)	0	1 (1.6)	0	0
Renal and urinary disorders					
-Total	3 (4.7)	1 (1.6)	1 (1.6)	0	1 (1.6)
Acute kidney injury	3 (4.7)	1 (1.6)	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders					
-Total	15 (23.4)	9 (14.1)	3 (4.7)	3 (4.7)	0
Cough	10 (15.6)	8 (12.5)	2 (3.1)	0	0
Nasal congestion	6 (9.4)	5 (7.8)	1 (1.6)	0	0
Hypoxia	3 (4.7)	0	0	3 (4.7)	0
Oropharyngeal pain	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Pleural effusion	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Dyspnoea	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (14.1)	6 (9.4)	3 (4.7)	0	0
Dry skin	6 (9.4)	4 (6.3)	2 (3.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Pruritus	1 (1.6)	0	1 (1.6)	0	0
Vascular disorders					
-Total	4 (6.3)	0	1 (1.6)	1 (1.6)	2 (3.1)
Hypotension	3 (4.7)	0	0	1 (1.6)	2 (3.1)
Hypertension	1 (1.6)	0	1 (1.6)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=9			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (44.4)	0	2 (22.2)	0	2 (22.2)
Gastrointestinal disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	1 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pain	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pyrexia	1 (11.1)	1 (11.1)	0	0	0
Infections and infestations					
-Total	2 (22.2)	0	2 (22.2)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (22.2)	0	2 (22.2)	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Investigations					
-Total	1 (11.1)	0	0	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Metabolism and nutrition disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Decreased appetite	1 (11.1)	0	0	0	1 (11.1)
Psychiatric disorders					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Anxiety	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Vascular disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Hypertension	1 (11.1)	0	1 (11.1)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 214o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=41			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (46.3)	5 (12.2)	9 (22.0)	3 (7.3)	2 (4.9)
Blood and lymphatic system disorders					
-Total	2 (4.9)	0	1 (2.4)	0	1 (2.4)
Anaemia	1 (2.4)	0	1 (2.4)	0	0
Neutropenia	1 (2.4)	0	0	0	1 (2.4)
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	5 (12.2)	3 (7.3)	1 (2.4)	1 (2.4)	0
Diarrhoea	4 (9.8)	2 (4.9)	1 (2.4)	1 (2.4)	0
Constipation	1 (2.4)	1 (2.4)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.4)	1 (2.4)	0	0	0
Vomiting	1 (2.4)	1 (2.4)	0	0	0
General disorders and administration site conditions					
-Total	5 (12.2)	1 (2.4)	3 (7.3)	1 (2.4)	0
Pyrexia	4 (9.8)	1 (2.4)	2 (4.9)	1 (2.4)	0
Fatigue	1 (2.4)	0	1 (2.4)	0	0
Immune system disorders					
-Total	3 (7.3)	0	3 (7.3)	0	0
Hypogammaglobulinaemia	3 (7.3)	0	3 (7.3)	0	0
Infections and infestations					
-Total	11 (26.8)	3 (7.3)	6 (14.6)	2 (4.9)	0
Upper respiratory tract infection	5 (12.2)	2 (4.9)	2 (4.9)	1 (2.4)	0
Conjunctivitis	4 (9.8)	2 (4.9)	2 (4.9)	0	0
Sinusitis	4 (9.8)	0	4 (9.8)	0	0
Rhinovirus infection	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Investigations					
-Total	3 (7.3)	3 (7.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (4.9)	2 (4.9)	0	0	0
Platelet count decreased	2 (4.9)	2 (4.9)	0	0	0
Blood bilirubin increased	1 (2.4)	1 (2.4)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (2.4)	0	0	1 (2.4)	0
Hyperglycaemia	1 (2.4)	0	0	1 (2.4)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (7.3)	0	3 (7.3)	0	0
Pain in extremity	2 (4.9)	0	2 (4.9)	0	0
Arthralgia	1 (2.4)	0	1 (2.4)	0	0
Nervous system disorders					
-Total	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Headache	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (12.2)	2 (4.9)	1 (2.4)	1 (2.4)	1 (2.4)
Cough	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Dyspnoea	3 (7.3)	1 (2.4)	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (2.4)	0	0	1 (2.4)	0
Oropharyngeal pain	1 (2.4)	1 (2.4)	0	0	0
Pleural effusion	1 (2.4)	0	1 (2.4)	0	0
Tachypnoea	1 (2.4)	0	0	0	1 (2.4)
Skin and subcutaneous tissue disorders					
-Total	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Rash	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Dry skin	1 (2.4)	1 (2.4)	0	0	0
Vascular disorders					
-Total	1 (2.4)	0	0	1 (2.4)	0
Hypertension	1 (2.4)	0	0	1 (2.4)	0

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Table 214o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	2 (18.2)	2 (18.2)	3 (27.3)	4 (36.4)
Blood and lymphatic system disorders					
-Total	4 (36.4)	0	1 (9.1)	2 (18.2)	1 (9.1)
Anaemia	1 (9.1)	0	1 (9.1)	0	0
Disseminated intravascular coagulation	1 (9.1)	0	0	1 (9.1)	0
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Gastrointestinal disorders					
-Total	5 (45.5)	3 (27.3)	2 (18.2)	0	0
Constipation	3 (27.3)	1 (9.1)	2 (18.2)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	1 (9.1)	0	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	5 (45.5)	3 (27.3)	2 (18.2)	0	0
Pyrexia	4 (36.4)	3 (27.3)	1 (9.1)	0	0
Pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Face oedema	1 (9.1)	1 (9.1)	0	0	0
Immune system disorders					
-Total	8 (72.7)	0	4 (36.4)	3 (27.3)	1 (9.1)
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Hypogammaglobulinaemia	6 (54.5)	1 (9.1)	3 (27.3)	2 (18.2)	0
Infections and infestations					
-Total	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Conjunctivitis	1 (9.1)	0	1 (9.1)	0	0
Rhinovirus infection	1 (9.1)	0	0	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Platelet count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Blood bilirubin increased	1 (9.1)	0	0	1 (9.1)	0
Serum ferritin increased	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	3 (27.3)	1 (9.1)	0	0	2 (18.2)
Decreased appetite	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Hypophosphataemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Back pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Headache	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Psychiatric disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Anxiety	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Hypertension	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hypotension	1 (9.1)	1 (9.1)	0	0	0

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Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (100)	1 (1.4)	7 (10.1)	18 (26.1)	43 (62.3)
Blood and lymphatic system disorders					
-Total	46 (66.7)	2 (2.9)	4 (5.8)	27 (39.1)	13 (18.8)
Febrile neutropenia	26 (37.7)	0	0	24 (34.8)	2 (2.9)
Anaemia	24 (34.8)	7 (10.1)	8 (11.6)	9 (13.0)	0
Neutropenia	10 (14.5)	0	2 (2.9)	2 (2.9)	6 (8.7)
Thrombocytopenia	9 (13.0)	0	0	3 (4.3)	6 (8.7)
Disseminated intravascular coagulation	7 (10.1)	0	5 (7.2)	2 (2.9)	0
Cardiac disorders					
-Total	17 (24.6)	7 (10.1)	7 (10.1)	2 (2.9)	1 (1.4)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (24.6)	7 (10.1)	7 (10.1)	2 (2.9)	1 (1.4)
Gastrointestinal disorders					
-Total	51 (73.9)	23 (33.3)	21 (30.4)	7 (10.1)	0
Diarrhoea	25 (36.2)	15 (21.7)	8 (11.6)	2 (2.9)	0
Vomiting	25 (36.2)	16 (23.2)	8 (11.6)	1 (1.4)	0
Nausea	22 (31.9)	12 (17.4)	8 (11.6)	2 (2.9)	0
Constipation	11 (15.9)	6 (8.7)	5 (7.2)	0	0
Abdominal pain	10 (14.5)	1 (1.4)	7 (10.1)	2 (2.9)	0
General disorders and administration site conditions					
-Total	43 (62.3)	20 (29.0)	11 (15.9)	10 (14.5)	2 (2.9)
Pyrexia	31 (44.9)	11 (15.9)	9 (13.0)	9 (13.0)	2 (2.9)
Fatigue	17 (24.6)	14 (20.3)	3 (4.3)	0	0
Chills	7 (10.1)	5 (7.2)	2 (2.9)	0	0
Face oedema	7 (10.1)	4 (5.8)	2 (2.9)	1 (1.4)	0
Oedema peripheral	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Pain	3 (4.3)	0	1 (1.4)	2 (2.9)	0
Immune system disorders					
-Total	61 (88.4)	2 (2.9)	21 (30.4)	18 (26.1)	20 (29.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	55 (79.7)	4 (5.8)	15 (21.7)	16 (23.2)	20 (29.0)
Hypogammaglobulinaemia	27 (39.1)	1 (1.4)	21 (30.4)	5 (7.2)	0
Infections and infestations					
-Total	30 (43.5)	9 (13.0)	16 (23.2)	5 (7.2)	0
Upper respiratory tract infection	12 (17.4)	5 (7.2)	5 (7.2)	2 (2.9)	0
Rhinovirus infection	8 (11.6)	0	7 (10.1)	1 (1.4)	0
Conjunctivitis	7 (10.1)	2 (2.9)	5 (7.2)	0	0
Nasopharyngitis	7 (10.1)	4 (5.8)	3 (4.3)	0	0
Sinusitis	5 (7.2)	0	3 (4.3)	2 (2.9)	0
Investigations					
-Total	43 (62.3)	3 (4.3)	3 (4.3)	15 (21.7)	22 (31.9)
White blood cell count decreased	24 (34.8)	3 (4.3)	4 (5.8)	2 (2.9)	15 (21.7)
Neutrophil count decreased	22 (31.9)	1 (1.4)	2 (2.9)	4 (5.8)	15 (21.7)
Platelet count decreased	21 (30.4)	6 (8.7)	3 (4.3)	7 (10.1)	5 (7.2)
Aspartate aminotransferase increased	18 (26.1)	1 (1.4)	6 (8.7)	8 (11.6)	3 (4.3)
Alanine aminotransferase increased	15 (21.7)	2 (2.9)	7 (10.1)	6 (8.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	15 (21.7)	1 (1.4)	1 (1.4)	10 (14.5)	3 (4.3)
Blood bilirubin increased	12 (17.4)	1 (1.4)	3 (4.3)	8 (11.6)	0
International normalised ratio increased	9 (13.0)	6 (8.7)	3 (4.3)	0	0
Blood immunoglobulin a decreased	7 (10.1)	5 (7.2)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	7 (10.1)	4 (5.8)	1 (1.4)	2 (2.9)	0
Serum ferritin increased	7 (10.1)	1 (1.4)	5 (7.2)	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	45 (65.2)	9 (13.0)	11 (15.9)	22 (31.9)	3 (4.3)
Decreased appetite	28 (40.6)	10 (14.5)	7 (10.1)	10 (14.5)	1 (1.4)
Hypokalaemia	20 (29.0)	3 (4.3)	6 (8.7)	9 (13.0)	2 (2.9)
Hypocalcaemia	16 (23.2)	2 (2.9)	9 (13.0)	5 (7.2)	0
Hypophosphataemia	16 (23.2)	3 (4.3)	5 (7.2)	8 (11.6)	0
Hypoalbuminaemia	11 (15.9)	0	10 (14.5)	1 (1.4)	0
Hyperglycaemia	9 (13.0)	0	4 (5.8)	5 (7.2)	0
Hyperuricaemia	9 (13.0)	7 (10.1)	1 (1.4)	1 (1.4)	0
Hypervolaemia	7 (10.1)	0	2 (2.9)	5 (7.2)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	32 (46.4)	14 (20.3)	13 (18.8)	5 (7.2)	0
Pain in extremity	17 (24.6)	8 (11.6)	8 (11.6)	1 (1.4)	0
Arthralgia	11 (15.9)	5 (7.2)	5 (7.2)	1 (1.4)	0
Myalgia	10 (14.5)	6 (8.7)	4 (5.8)	0	0
Back pain	8 (11.6)	1 (1.4)	4 (5.8)	3 (4.3)	0
Nervous system disorders					
-Total	31 (44.9)	13 (18.8)	12 (17.4)	6 (8.7)	0
Headache	24 (34.8)	12 (17.4)	10 (14.5)	2 (2.9)	0
Encephalopathy	8 (11.6)	1 (1.4)	3 (4.3)	4 (5.8)	0
Psychiatric disorders					
-Total	18 (26.1)	3 (4.3)	10 (14.5)	5 (7.2)	0
Anxiety	12 (17.4)	2 (2.9)	8 (11.6)	2 (2.9)	0
Delirium	8 (11.6)	2 (2.9)	3 (4.3)	3 (4.3)	0
Renal and urinary disorders					
-Total	12 (17.4)	2 (2.9)	2 (2.9)	3 (4.3)	5 (7.2)
Acute kidney injury	12 (17.4)	2 (2.9)	2 (2.9)	3 (4.3)	5 (7.2)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	46 (66.7)	18 (26.1)	6 (8.7)	12 (17.4)	10 (14.5)
Cough	22 (31.9)	18 (26.1)	4 (5.8)	0	0
Hypoxia	20 (29.0)	0	4 (5.8)	10 (14.5)	6 (8.7)
Pulmonary oedema	12 (17.4)	2 (2.9)	3 (4.3)	6 (8.7)	1 (1.4)
Nasal congestion	9 (13.0)	7 (10.1)	2 (2.9)	0	0
Pleural effusion	9 (13.0)	4 (5.8)	2 (2.9)	2 (2.9)	1 (1.4)
Tachypnoea	9 (13.0)	3 (4.3)	1 (1.4)	4 (5.8)	1 (1.4)
Oropharyngeal pain	8 (11.6)	7 (10.1)	1 (1.4)	0	0
Dyspnoea	7 (10.1)	1 (1.4)	2 (2.9)	2 (2.9)	2 (2.9)
Skin and subcutaneous tissue disorders					
-Total	19 (27.5)	10 (14.5)	9 (13.0)	0	0
Dry skin	8 (11.6)	6 (8.7)	2 (2.9)	0	0
Pruritus	7 (10.1)	2 (2.9)	5 (7.2)	0	0
Rash	7 (10.1)	3 (4.3)	4 (5.8)	0	0
Vascular disorders					
-Total	29 (42.0)	4 (5.8)	7 (10.1)	10 (14.5)	8 (11.6)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	23 (33.3)	1 (1.4)	6 (8.7)	8 (11.6)	8 (11.6)
Hypertension	14 (20.3)	4 (5.8)	6 (8.7)	4 (5.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	1 (16.7)	3 (50.0)	0
Febrile neutropenia	3 (50.0)	0	0	3 (50.0)	0
Anaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	2 (33.3)	0	2 (33.3)	0	0
Splenomegaly	1 (16.7)	1 (16.7)	0	0	0
Cardiac disorders					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Tachycardia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (16.7)	0	1 (16.7)	0	0
Ear and labyrinth disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Ear pruritus	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Conjunctival haemorrhage	2 (33.3)	2 (33.3)	0	0	0
Ocular hyperaemia	1 (16.7)	1 (16.7)	0	0	0
Periorbital oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	1 (16.7)	1 (16.7)
Diarrhoea	2 (33.3)	2 (33.3)	0	0	0
Abdominal compartment syndrome	1 (16.7)	0	0	0	1 (16.7)
Anal fissure	1 (16.7)	0	1 (16.7)	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Dysphagia	1 (16.7)	0	0	1 (16.7)	0
Enterocolitis	1 (16.7)	0	1 (16.7)	0	0
Gingival erythema	1 (16.7)	1 (16.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (16.7)	0	1 (16.7)	0	0
Vomiting	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Face oedema	2 (33.3)	2 (33.3)	0	0	0
Generalised oedema	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Fatigue	1 (16.7)	1 (16.7)	0	0	0
Localised oedema	1 (16.7)	1 (16.7)	0	0	0
Pyrexia	1 (16.7)	1 (16.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Hepatic function abnormal	1 (16.7)	0	0	0	1 (16.7)
Hyperbilirubinaemia	1 (16.7)	0	1 (16.7)	0	0
Hypertransaminasaemia	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Cytokine release syndrome	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	2 (33.3)	0	2 (33.3)	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)	0	0
Injury, poisoning and procedural complications					
-Total	2 (33.3)	0	2 (33.3)	0	0
Contusion	1 (16.7)	1 (16.7)	0	0	0
Skin abrasion	1 (16.7)	1 (16.7)	0	0	0
Transfusion reaction	1 (16.7)	0	1 (16.7)	0	0
Wound	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	6 (100)	0	0	1 (16.7)	5 (83.3)
White blood cell count decreased	4 (66.7)	1 (16.7)	0	0	3 (50.0)
Platelet count decreased	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Blood creatinine increased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Neutrophil count decreased	2 (33.3)	0	0	0	2 (33.3)
Serum ferritin increased	2 (33.3)	0	2 (33.3)	0	0
Urine output decreased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)	0	0
Aspartate aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Blood bicarbonate decreased	1 (16.7)	0	1 (16.7)	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	1 (16.7)	0
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (16.7)	1 (16.7)	0	0	0
Cardiac murmur	1 (16.7)	1 (16.7)	0	0	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)	0	0
Oxygen saturation decreased	1 (16.7)	1 (16.7)	0	0	0
Weight increased	1 (16.7)	1 (16.7)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (100)	0	3 (50.0)	2 (33.3)	1 (16.7)
Hypocalcaemia	4 (66.7)	1 (16.7)	3 (50.0)	0	0
Hypokalaemia	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Hypophosphataemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Decreased appetite	2 (33.3)	0	0	2 (33.3)	0
Hyperphosphataemia	2 (33.3)	2 (33.3)	0	0	0
Hypoalbuminaemia	2 (33.3)	0	2 (33.3)	0	0
Hypercalcaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperchloraemia	1 (16.7)	1 (16.7)	0	0	0
Hyperglycaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperkalaemia	1 (16.7)	0	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypervolaemia	1 (16.7)	0	1 (16.7)	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Metabolic acidosis	1 (16.7)	0	0	0	1 (16.7)
Tumour lysis syndrome	1 (16.7)	0	0	1 (16.7)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Muscle rigidity	1 (16.7)	1 (16.7)	0	0	0
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	0	0	1 (16.7)
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)	0	0
Headache	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	0	1 (16.7)	0
Tremor	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Agitation	1 (16.7)	0	1 (16.7)	0	0
Automatism	1 (16.7)	1 (16.7)	0	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Delirium	1 (16.7)	0	1 (16.7)	0	0
Insomnia	1 (16.7)	0	1 (16.7)	0	0
Irritability	1 (16.7)	1 (16.7)	0	0	0
Mental status changes	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Acute kidney injury	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anuria	1 (16.7)	1 (16.7)	0	0	0
Azotaemia	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Perineal rash	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	5 (83.3)	2 (33.3)	0	1 (16.7)	2 (33.3)
Hypoxia	3 (50.0)	0	1 (16.7)	0	2 (33.3)
Pleural effusion	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Epistaxis	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Pulmonary oedema	2 (33.3)	0	2 (33.3)	0	0
Cough	1 (16.7)	1 (16.7)	0	0	0
Nasal discomfort	1 (16.7)	0	1 (16.7)	0	0
Pharyngeal haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Respiratory distress	1 (16.7)	0	1 (16.7)	0	0
Tachypnoea	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	4 (66.7)	1 (16.7)	3 (50.0)	0	0
Blister	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Dermatitis diaper	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Scab	1 (16.7)	1 (16.7)	0	0	0
Skin discolouration	1 (16.7)	1 (16.7)	0	0	0
Skin ulcer	1 (16.7)	0	1 (16.7)	0	0
Vascular disorders					
-Total	4 (66.7)	1 (16.7)	0	1 (16.7)	2 (33.3)
Hypertension	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Hypotension	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Thrombosis	1 (16.7)	0	1 (16.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	73 (98.6)	4 (5.4)	9 (12.2)	20 (27.0)	40 (54.1)
Blood and lymphatic system disorders					
-Total	42 (56.8)	2 (2.7)	5 (6.8)	22 (29.7)	13 (17.6)
Febrile neutropenia	23 (31.1)	0	0	21 (28.4)	2 (2.7)
Anaemia	19 (25.7)	5 (6.8)	7 (9.5)	7 (9.5)	0
Neutropenia	9 (12.2)	0	2 (2.7)	1 (1.4)	6 (8.1)
Thrombocytopenia	8 (10.8)	0	0	2 (2.7)	6 (8.1)
Disseminated intravascular coagulation	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Splenomegaly	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (20.3)	7 (9.5)	6 (8.1)	1 (1.4)	1 (1.4)
Tachycardia	15 (20.3)	7 (9.5)	6 (8.1)	1 (1.4)	1 (1.4)
Bradycardia	2 (2.7)	2 (2.7)	0	0	0
Endocrine disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Hypothyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	42 (56.8)	19 (25.7)	17 (23.0)	6 (8.1)	0
Vomiting	20 (27.0)	11 (14.9)	8 (10.8)	1 (1.4)	0
Nausea	17 (23.0)	10 (13.5)	5 (6.8)	2 (2.7)	0
Diarrhoea	13 (17.6)	6 (8.1)	6 (8.1)	1 (1.4)	0
Abdominal pain	11 (14.9)	3 (4.1)	6 (8.1)	2 (2.7)	0
Constipation	10 (13.5)	5 (6.8)	5 (6.8)	0	0
General disorders and administration site conditions					

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (43.2)	16 (21.6)	7 (9.5)	7 (9.5)	2 (2.7)
Pyrexia	23 (31.1)	10 (13.5)	5 (6.8)	6 (8.1)	2 (2.7)
Fatigue	10 (13.5)	8 (10.8)	2 (2.7)	0	0
Face oedema	6 (8.1)	3 (4.1)	2 (2.7)	1 (1.4)	0
Chills	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Generalised oedema	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Localised oedema	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	9 (12.2)	2 (2.7)	4 (5.4)	3 (4.1)	0
Hepatic function abnormal	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Hyperbilirubinaemia	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	60 (81.1)	2 (2.7)	20 (27.0)	20 (27.0)	18 (24.3)
Cytokine release syndrome	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Hypogammaglobulinaemia	21 (28.4)	2 (2.7)	13 (17.6)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	4 (5.4)	1 (1.4)	0	2 (2.7)	1 (1.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	13 (17.6)	3 (4.1)	8 (10.8)	2 (2.7)	0
Conjunctivitis	5 (6.8)	1 (1.4)	4 (5.4)	0	0
Staphylococcal infection	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Nail infection	2 (2.7)	2 (2.7)	0	0	0
Rhinovirus infection	2 (2.7)	0	2 (2.7)	0	0
Sinusitis	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Transfusion reaction	1 (1.4)	1 (1.4)	0	0	0
Wound	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	45 (60.8)	4 (5.4)	5 (6.8)	15 (20.3)	21 (28.4)
White blood cell count decreased	20 (27.0)	2 (2.7)	3 (4.1)	2 (2.7)	13 (17.6)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	8 (10.8)	2 (2.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	18 (24.3)	0	3 (4.1)	2 (2.7)	13 (17.6)
Platelet count decreased	18 (24.3)	4 (5.4)	2 (2.7)	5 (6.8)	7 (9.5)
Alanine aminotransferase increased	16 (21.6)	3 (4.1)	7 (9.5)	6 (8.1)	0
Lymphocyte count decreased	15 (20.3)	2 (2.7)	0	8 (10.8)	5 (6.8)
Blood bilirubin increased	11 (14.9)	1 (1.4)	2 (2.7)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	6 (8.1)	2 (2.7)	0	0
Blood fibrinogen decreased	6 (8.1)	2 (2.7)	2 (2.7)	1 (1.4)	1 (1.4)
Serum ferritin increased	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Blood immunoglobulin a decreased	4 (5.4)	4 (5.4)	0	0	0
Blood lactate dehydrogenase increased	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Weight increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	0	1 (1.4)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	39 (52.7)	8 (10.8)	6 (8.1)	20 (27.0)	5 (6.8)
Decreased appetite	22 (29.7)	9 (12.2)	4 (5.4)	8 (10.8)	1 (1.4)
Hypokalaemia	16 (21.6)	1 (1.4)	5 (6.8)	8 (10.8)	2 (2.7)
Hypophosphataemia	14 (18.9)	2 (2.7)	3 (4.1)	8 (10.8)	1 (1.4)
Hypocalcaemia	12 (16.2)	1 (1.4)	6 (8.1)	5 (6.8)	0
Hypoalbuminaemia	9 (12.2)	0	8 (10.8)	1 (1.4)	0
Hyperglycaemia	7 (9.5)	0	4 (5.4)	3 (4.1)	0
Hyperuricaemia	7 (9.5)	5 (6.8)	1 (1.4)	1 (1.4)	0
Hypervolaemia	5 (6.8)	0	1 (1.4)	4 (5.4)	0
Hyperphosphataemia	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Tumour lysis syndrome	3 (4.1)	0	0	3 (4.1)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Metabolic acidosis	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Hyperkalaemia	1 (1.4)	0	0	0	1 (1.4)
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	28 (37.8)	12 (16.2)	14 (18.9)	2 (2.7)	0
Pain in extremity	11 (14.9)	6 (8.1)	5 (6.8)	0	0
Arthralgia	10 (13.5)	4 (5.4)	5 (6.8)	1 (1.4)	0
Myalgia	8 (10.8)	5 (6.8)	3 (4.1)	0	0
Back pain	6 (8.1)	2 (2.7)	3 (4.1)	1 (1.4)	0
Bone pain	2 (2.7)	0	2 (2.7)	0	0
Nervous system disorders					
-Total	30 (40.5)	13 (17.6)	12 (16.2)	5 (6.8)	0
Headache	22 (29.7)	12 (16.2)	8 (10.8)	2 (2.7)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	5 (6.8)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Psychiatric disorders					
-Total	21 (28.4)	12 (16.2)	4 (5.4)	5 (6.8)	0
Anxiety	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Delirium	6 (8.1)	2 (2.7)	1 (1.4)	3 (4.1)	0
Agitation	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Insomnia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Irritability	2 (2.7)	2 (2.7)	0	0	0
Mental status changes	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Renal and urinary disorders					
-Total	7 (9.5)	1 (1.4)	1 (1.4)	2 (2.7)	3 (4.1)
Acute kidney injury	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Anuria	1 (1.4)	0	0	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	33 (44.6)	11 (14.9)	5 (6.8)	10 (13.5)	7 (9.5)
Hypoxia	14 (18.9)	0	4 (5.4)	6 (8.1)	4 (5.4)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	10 (13.5)	2 (2.7)	1 (1.4)	6 (8.1)	1 (1.4)
Cough	9 (12.2)	8 (10.8)	1 (1.4)	0	0
Tachypnoea	7 (9.5)	3 (4.1)	1 (1.4)	3 (4.1)	0
Oropharyngeal pain	5 (6.8)	5 (6.8)	0	0	0
Pleural effusion	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Dyspnoea	3 (4.1)	0	0	2 (2.7)	1 (1.4)
Nasal congestion	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Epistaxis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Respiratory distress	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Rhinorrhoea	2 (2.7)	2 (2.7)	0	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (16.2)	7 (9.5)	3 (4.1)	2 (2.7)	0
Rash	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Erythema	3 (4.1)	3 (4.1)	0	0	0
Rash maculo-papular	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blister	1 (1.4)	1 (1.4)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	1 (1.4)	1 (1.4)	0	0	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	0	1 (1.4)	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	23 (31.1)	3 (4.1)	7 (9.5)	9 (12.2)	4 (5.4)
Hypotension	18 (24.3)	1 (1.4)	6 (8.1)	7 (9.5)	4 (5.4)
Hypertension	10 (13.5)	2 (2.7)	4 (5.4)	4 (5.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	3 (60.0)	1 (20.0)
Endocrine disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hypothyroidism	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Constipation	1 (20.0)	1 (20.0)	0	0	0
Diarrhoea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (60.0)	3 (60.0)	0	0	0
Pyrexia	2 (40.0)	2 (40.0)	0	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hypertransaminasaemia	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hypogammaglobulinaemia	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Cellulitis	1 (20.0)	0	1 (20.0)	0	0
Ear infection	1 (20.0)	0	1 (20.0)	0	0
Metapneumovirus infection	1 (20.0)	0	0	1 (20.0)	0
Nasopharyngitis	1 (20.0)	1 (20.0)	0	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (80.0)	0	0	3 (60.0)	1 (20.0)
Lymphocyte count decreased	2 (40.0)	0	0	2 (40.0)	0
Neutrophil count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
White blood cell count decreased	2 (40.0)	0	2 (40.0)	0	0
Alanine aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood lactate dehydrogenase increased	1 (20.0)	1 (20.0)	0	0	0
Blood thyroid stimulating hormone increased	1 (20.0)	1 (20.0)	0	0	0
C-reactive protein increased	1 (20.0)	1 (20.0)	0	0	0
Weight increased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Metabolic syndrome	1 (20.0)	0	1 (20.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Bone pain	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (20.0)	1 (20.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Dysmenorrhoea	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Cough	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Nasal congestion	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hypoxia	1 (20.0)	0	0	1 (20.0)	0
Rhinitis allergic	1 (20.0)	0	1 (20.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (60.0)	3 (60.0)	0	0	0
Eczema	1 (20.0)	1 (20.0)	0	0	0
Miliaria	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	1 (20.0)	0	0	0
Skin swelling	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (82.9)	10 (14.3)	24 (34.3)	13 (18.6)	11 (15.7)
Blood and lymphatic system disorders					
-Total	13 (18.6)	3 (4.3)	0	6 (8.6)	4 (5.7)
Anaemia	6 (8.6)	4 (5.7)	0	2 (2.9)	0
Neutropenia	5 (7.1)	0	0	2 (2.9)	3 (4.3)
Febrile neutropenia	3 (4.3)	0	0	3 (4.3)	0
Thrombocytopenia	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	0	0	1 (1.4)	0
Cardiac disorders					
-Total	2 (2.9)	2 (2.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.9)	2 (2.9)	0	0	0
Eye disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	12 (17.1)	7 (10.0)	5 (7.1)	0	0
Diarrhoea	6 (8.6)	5 (7.1)	1 (1.4)	0	0
Nausea	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Vomiting	5 (7.1)	5 (7.1)	0	0	0
Abdominal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Constipation	2 (2.9)	0	2 (2.9)	0	0
General disorders and administration site conditions					
-Total	18 (25.7)	10 (14.3)	6 (8.6)	2 (2.9)	0
Pyrexia	13 (18.6)	5 (7.1)	6 (8.6)	2 (2.9)	0
Fatigue	5 (7.1)	5 (7.1)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	9 (12.9)	0	9 (12.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	9 (12.9)	0	9 (12.9)	0	0
Infections and infestations					
-Total	21 (30.0)	4 (5.7)	11 (15.7)	6 (8.6)	0
Upper respiratory tract infection	7 (10.0)	2 (2.9)	3 (4.3)	2 (2.9)	0
Nasopharyngitis	6 (8.6)	3 (4.3)	3 (4.3)	0	0
Rhinovirus infection	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Otitis media	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Metapneumovirus infection	2 (2.9)	0	0	2 (2.9)	0
Otitis externa	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Sinusitis	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Ear infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Nail infection	1 (1.4)	1 (1.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (2.9)	2 (2.9)	0	0	0
Contusion	1 (1.4)	1 (1.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	21 (30.0)	6 (8.6)	4 (5.7)	7 (10.0)	4 (5.7)
Neutrophil count decreased	8 (11.4)	2 (2.9)	1 (1.4)	2 (2.9)	3 (4.3)
White blood cell count decreased	8 (11.4)	4 (5.7)	0	3 (4.3)	1 (1.4)
Platelet count decreased	5 (7.1)	3 (4.3)	0	1 (1.4)	1 (1.4)
Blood bilirubin increased	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Blood immunoglobulin a decreased	2 (2.9)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.9)	0	0	1 (1.4)	1 (1.4)
Lymphocyte count decreased	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0	0	0
Blood creatinine increased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin m decreased	1 (1.4)	0	0	1 (1.4)	0
Oxygen saturation decreased	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	12 (17.1)	4 (5.7)	2 (2.9)	3 (4.3)	3 (4.3)
Decreased appetite	6 (8.6)	2 (2.9)	3 (4.3)	1 (1.4)	0
Hyperuricaemia	3 (4.3)	3 (4.3)	0	0	0
Hypokalaemia	3 (4.3)	0	1 (1.4)	1 (1.4)	1 (1.4)
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)	0	0
Hypervolaemia	1 (1.4)	0	0	1 (1.4)	0
Hypophosphataemia	1 (1.4)	0	1 (1.4)	0	0
Metabolic acidosis	1 (1.4)	0	0	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	0	0	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	11 (15.7)	3 (4.3)	5 (7.1)	3 (4.3)	0
Back pain	6 (8.6)	2 (2.9)	2 (2.9)	2 (2.9)	0
Pain in extremity	4 (5.7)	1 (1.4)	2 (2.9)	1 (1.4)	0
Arthralgia	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	11 (15.7)	6 (8.6)	4 (5.7)	0	1 (1.4)
Headache	10 (14.3)	6 (8.6)	4 (5.7)	0	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Psychiatric disorders					
-Total	8 (11.4)	1 (1.4)	6 (8.6)	1 (1.4)	0
Anxiety	6 (8.6)	1 (1.4)	5 (7.1)	0	0
Mental status changes	2 (2.9)	0	1 (1.4)	1 (1.4)	0
Agitation	1 (1.4)	1 (1.4)	0	0	0
Delirium	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Acute kidney injury	3 (4.3)	1 (1.4)	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	15 (21.4)	9 (12.9)	3 (4.3)	2 (2.9)	1 (1.4)
Cough	9 (12.9)	7 (10.0)	2 (2.9)	0	0
Nasal congestion	4 (5.7)	4 (5.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	3 (4.3)	1 (1.4)	2 (2.9)	0	0
Rhinorrhoea	3 (4.3)	3 (4.3)	0	0	0
Hypoxia	2 (2.9)	0	0	2 (2.9)	0
Oropharyngeal pain	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Pleural effusion	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Rhinitis allergic	1 (1.4)	1 (1.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (12.9)	6 (8.6)	3 (4.3)	0	0
Dry skin	6 (8.6)	4 (5.7)	2 (2.9)	0	0
Rash	3 (4.3)	2 (2.9)	1 (1.4)	0	0
Erythema	1 (1.4)	0	1 (1.4)	0	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	5 (7.1)	1 (1.4)	1 (1.4)	1 (1.4)	2 (2.9)
Hypotension	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)
Hypertension	1 (1.4)	0	1 (1.4)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	0	3 (75.0)	0
Gastrointestinal disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Seasonal allergy	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Upper respiratory tract infection	3 (75.0)	0	2 (50.0)	1 (25.0)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	2 (50.0)	0	2 (50.0)	0	0
Bronchiolitis	1 (25.0)	0	0	1 (25.0)	0
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Folliculitis	1 (25.0)	0	1 (25.0)	0	0
Gastroenteritis viral	1 (25.0)	0	1 (25.0)	0	0
Nail infection	1 (25.0)	0	1 (25.0)	0	0
Pneumonia respiratory syncytial viral	1 (25.0)	0	0	1 (25.0)	0
Rhinovirus infection	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Skin infection	1 (25.0)	0	1 (25.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	1 (25.0)	0	0	0
Abdominal injury	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hyperlipidaemia	1 (25.0)	0	1 (25.0)	0	0
Obesity	1 (25.0)	0	0	1 (25.0)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Dyspnoea	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0	1 (25.0)	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Sleep apnoea syndrome	1 (25.0)	0	1 (25.0)	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Rash	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Rash erythematous	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (45.7)	3 (6.5)	12 (26.1)	2 (4.3)	4 (8.7)
Blood and lymphatic system disorders					
-Total	2 (4.3)	0	1 (2.2)	0	1 (2.2)
Anaemia	1 (2.2)	0	1 (2.2)	0	0
Neutropenia	1 (2.2)	0	0	0	1 (2.2)
Thrombocytopenia	1 (2.2)	0	1 (2.2)	0	0
Endocrine disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Hypothyroidism	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.9)	3 (6.5)	1 (2.2)	1 (2.2)	0
Diarrhoea	5 (10.9)	3 (6.5)	1 (2.2)	1 (2.2)	0
Nausea	1 (2.2)	1 (2.2)	0	0	0
Vomiting	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	6 (13.0)	2 (4.3)	3 (6.5)	1 (2.2)	0
Pyrexia	5 (10.9)	2 (4.3)	2 (4.3)	1 (2.2)	0
Fatigue	1 (2.2)	0	1 (2.2)	0	0
Immune system disorders					
-Total	6 (13.0)	2 (4.3)	3 (6.5)	0	1 (2.2)
Hypogammaglobulinaemia	3 (6.5)	0	3 (6.5)	0	0
Seasonal allergy	2 (4.3)	2 (4.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	0	0	1 (2.2)
Infections and infestations					
-Total	11 (23.9)	2 (4.3)	7 (15.2)	2 (4.3)	0
Sinusitis	5 (10.9)	0	5 (10.9)	0	0
Conjunctivitis	4 (8.7)	2 (4.3)	2 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (6.5)	0	2 (4.3)	1 (2.2)	0
Skin infection	2 (4.3)	0	2 (4.3)	0	0
Upper respiratory tract infection	2 (4.3)	2 (4.3)	0	0	0
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Ear infection	1 (2.2)	0	0	1 (2.2)	0
Investigations					
-Total	6 (13.0)	3 (6.5)	1 (2.2)	1 (2.2)	1 (2.2)
Neutrophil count decreased	3 (6.5)	2 (4.3)	0	0	1 (2.2)
Platelet count decreased	2 (4.3)	2 (4.3)	0	0	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0	0	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0
Oxygen saturation decreased	1 (2.2)	0	0	1 (2.2)	0
Metabolism and nutrition disorders					
-Total	2 (4.3)	0	0	1 (2.2)	1 (2.2)
Decreased appetite	1 (2.2)	0	0	0	1 (2.2)
Hyperglycaemia	1 (2.2)	0	0	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (6.5)	0	3 (6.5)	0	0
Pain in extremity	2 (4.3)	0	2 (4.3)	0	0
Arthralgia	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorders					
-Total	1 (2.2)	0	0	1 (2.2)	0
Headache	1 (2.2)	0	0	1 (2.2)	0
Psychiatric disorders					
-Total	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Anxiety	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (13.0)	4 (8.7)	1 (2.2)	0	1 (2.2)
Cough	4 (8.7)	3 (6.5)	1 (2.2)	0	0
Dyspnoea	2 (4.3)	1 (2.2)	0	0	1 (2.2)
Rhinorrhoea	2 (4.3)	1 (2.2)	1 (2.2)	0	0
Epistaxis	1 (2.2)	1 (2.2)	0	0	0
Oropharyngeal pain	1 (2.2)	1 (2.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (2.2)	0	1 (2.2)	0	0
Sleep apnoea syndrome	1 (2.2)	1 (2.2)	0	0	0
Tachypnoea	1 (2.2)	0	0	0	1 (2.2)
Skin and subcutaneous tissue disorders					
-Total	2 (4.3)	1 (2.2)	0	1 (2.2)	0
Dry skin	1 (2.2)	1 (2.2)	0	0	0
Eczema	1 (2.2)	0	0	1 (2.2)	0
Vascular disorders					
-Total	2 (4.3)	0	1 (2.2)	1 (2.2)	0
Hypertension	2 (4.3)	0	1 (2.2)	1 (2.2)	0

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Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	1 (16.7)	3 (50.0)	0
Febrile neutropenia	3 (50.0)	0	0	3 (50.0)	0
Anaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	2 (33.3)	0	2 (33.3)	0	0
Splenomegaly	1 (16.7)	1 (16.7)	0	0	0
Cardiac disorders					
-Total	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Tachycardia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (16.7)	0	1 (16.7)	0	0
Ear and labyrinth disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Ear pruritus	1 (16.7)	1 (16.7)	0	0	0
Endocrine disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypothyroidism	1 (16.7)	0	1 (16.7)	0	0
Eye disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Conjunctival haemorrhage	2 (33.3)	2 (33.3)	0	0	0
Ocular hyperaemia	1 (16.7)	1 (16.7)	0	0	0
Periorbital oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	5 (83.3)	1 (16.7)	2 (33.3)	1 (16.7)	1 (16.7)
Diarrhoea	3 (50.0)	3 (50.0)	0	0	0
Constipation	2 (33.3)	2 (33.3)	0	0	0
Vomiting	2 (33.3)	2 (33.3)	0	0	0
Abdominal compartment syndrome	1 (16.7)	0	0	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (16.7)	0	1 (16.7)	0	0
Dysphagia	1 (16.7)	0	0	1 (16.7)	0
Enterocolitis	1 (16.7)	0	1 (16.7)	0	0
Gingival erythema	1 (16.7)	1 (16.7)	0	0	0
Nausea	1 (16.7)	0	1 (16.7)	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	3 (50.0)	1 (16.7)	0	0
Pyrexia	3 (50.0)	3 (50.0)	0	0	0
Face oedema	2 (33.3)	2 (33.3)	0	0	0
Fatigue	2 (33.3)	2 (33.3)	0	0	0
Generalised oedema	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Localised oedema	1 (16.7)	1 (16.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Hepatic function abnormal	1 (16.7)	0	0	0	1 (16.7)
Hyperbilirubinaemia	1 (16.7)	0	1 (16.7)	0	0
Hypertransaminasaemia	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Cytokine release syndrome	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Hypogammaglobulinaemia	3 (50.0)	0	2 (33.3)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)	0	0
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	5 (83.3)	0	2 (33.3)	3 (50.0)	0
Upper respiratory tract infection	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Otitis media	2 (33.3)	0	2 (33.3)	0	0
Bronchiolitis	1 (16.7)	0	0	1 (16.7)	0
Bronchitis	1 (16.7)	0	1 (16.7)	0	0
Cellulitis	1 (16.7)	0	1 (16.7)	0	0
Ear infection	1 (16.7)	0	1 (16.7)	0	0
Folliculitis	1 (16.7)	0	1 (16.7)	0	0
Gastroenteritis viral	1 (16.7)	0	1 (16.7)	0	0
Metapneumovirus infection	1 (16.7)	0	0	1 (16.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	1 (16.7)	0	1 (16.7)	0	0
Nasopharyngitis	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia respiratory syncytial viral	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Skin infection	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)	0	0
Injury, poisoning and procedural complications					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Abdominal injury	1 (16.7)	1 (16.7)	0	0	0
Contusion	1 (16.7)	1 (16.7)	0	0	0
Skin abrasion	1 (16.7)	1 (16.7)	0	0	0
Transfusion reaction	1 (16.7)	0	1 (16.7)	0	0
Wound	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	6 (100)	0	0	1 (16.7)	5 (83.3)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Platelet count decreased	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Alanine aminotransferase increased	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Blood creatinine increased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Lymphocyte count decreased	2 (33.3)	0	0	2 (33.3)	0
Serum ferritin increased	2 (33.3)	0	2 (33.3)	0	0
Urine output decreased	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)	0	0
Aspartate aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Blood bicarbonate decreased	1 (16.7)	0	1 (16.7)	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	1 (16.7)	0
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin a decreased	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	0	1 (16.7)	0
Blood lactate dehydrogenase increased	1 (16.7)	1 (16.7)	0	0	0
Blood thyroid stimulating hormone increased	1 (16.7)	1 (16.7)	0	0	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0	0	0
C-reactive protein increased	1 (16.7)	1 (16.7)	0	0	0
Cardiac murmur	1 (16.7)	1 (16.7)	0	0	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)	0	0
Oxygen saturation decreased	1 (16.7)	1 (16.7)	0	0	0
Weight increased	1 (16.7)	0	0	1 (16.7)	0
Metabolism and nutrition disorders					
-Total	6 (100)	0	2 (33.3)	3 (50.0)	1 (16.7)
Hypocalcaemia	4 (66.7)	1 (16.7)	3 (50.0)	0	0
Hypokalaemia	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Hypophosphataemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (33.3)	0	0	2 (33.3)	0
Hyperphosphataemia	2 (33.3)	2 (33.3)	0	0	0
Hypoalbuminaemia	2 (33.3)	0	2 (33.3)	0	0
Hypercalcaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperchloraemia	1 (16.7)	1 (16.7)	0	0	0
Hyperglycaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperkalaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperlipidaemia	1 (16.7)	0	1 (16.7)	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypervolaemia	1 (16.7)	0	1 (16.7)	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Metabolic acidosis	1 (16.7)	0	0	0	1 (16.7)
Metabolic syndrome	1 (16.7)	0	1 (16.7)	0	0
Obesity	1 (16.7)	0	0	1 (16.7)	0
Tumour lysis syndrome	1 (16.7)	0	0	1 (16.7)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (50.0)	3 (50.0)	0	0	0
Bone pain	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle rigidity	1 (16.7)	1 (16.7)	0	0	0
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Pain in extremity	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	0	0	1 (16.7)
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Generalised tonic-clonic seizure	1 (16.7)	0	1 (16.7)	0	0
Headache	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	0	1 (16.7)	0
Tremor	1 (16.7)	0	1 (16.7)	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Agitation	1 (16.7)	0	1 (16.7)	0	0
Automatism	1 (16.7)	1 (16.7)	0	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Delirium	1 (16.7)	0	1 (16.7)	0	0
Insomnia	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (16.7)	1 (16.7)	0	0	0
Mental status changes	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Acute kidney injury	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anuria	1 (16.7)	1 (16.7)	0	0	0
Azotaemia	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Dysmenorrhoea	1 (16.7)	0	1 (16.7)	0	0
Perineal rash	1 (16.7)	0	1 (16.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (100)	1 (16.7)	1 (16.7)	2 (33.3)	2 (33.3)
Hypoxia	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Cough	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Pleural effusion	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Epistaxis	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Pulmonary oedema	2 (33.3)	0	2 (33.3)	0	0
Dyspnoea	1 (16.7)	0	1 (16.7)	0	0
Nasal discomfort	1 (16.7)	0	1 (16.7)	0	0
Pharyngeal haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Respiratory distress	1 (16.7)	0	1 (16.7)	0	0
Rhinitis allergic	1 (16.7)	0	1 (16.7)	0	0
Rhinorrhoea	1 (16.7)	0	1 (16.7)	0	0
Sleep apnoea syndrome	1 (16.7)	0	1 (16.7)	0	0
Tachypnoea	1 (16.7)	0	0	1 (16.7)	0
Wheezing	1 (16.7)	0	1 (16.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (83.3)	2 (33.3)	3 (50.0)	0	0
Blister	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Dermatitis diaper	1 (16.7)	0	1 (16.7)	0	0
Eczema	1 (16.7)	1 (16.7)	0	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Miliaria	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	1 (16.7)	0	0
Rash erythematous	1 (16.7)	1 (16.7)	0	0	0
Rash maculo-papular	1 (16.7)	1 (16.7)	0	0	0
Scab	1 (16.7)	1 (16.7)	0	0	0
Skin discolouration	1 (16.7)	1 (16.7)	0	0	0
Skin swelling	1 (16.7)	1 (16.7)	0	0	0
Skin ulcer	1 (16.7)	0	1 (16.7)	0	0
Vascular disorders					
-Total	4 (66.7)	1 (16.7)	0	1 (16.7)	2 (33.3)
Hypertension	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Hypotension	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Thrombosis	1 (16.7)	0	1 (16.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	74 (100)	2 (2.7)	10 (13.5)	20 (27.0)	42 (56.8)
Blood and lymphatic system disorders					
-Total	47 (63.5)	2 (2.7)	5 (6.8)	26 (35.1)	14 (18.9)
Febrile neutropenia	24 (32.4)	0	0	22 (29.7)	2 (2.7)
Anaemia	23 (31.1)	7 (9.5)	8 (10.8)	8 (10.8)	0
Neutropenia	11 (14.9)	0	2 (2.7)	2 (2.7)	7 (9.5)
Thrombocytopenia	9 (12.2)	0	0	3 (4.1)	6 (8.1)
Disseminated intravascular coagulation	6 (8.1)	0	3 (4.1)	3 (4.1)	0
Splenomegaly	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (20.3)	7 (9.5)	6 (8.1)	1 (1.4)	1 (1.4)
Tachycardia	15 (20.3)	7 (9.5)	6 (8.1)	1 (1.4)	1 (1.4)
Bradycardia	2 (2.7)	2 (2.7)	0	0	0
Endocrine disorders					
-Total	2 (2.7)	0	2 (2.7)	0	0
Hypothyroidism	2 (2.7)	0	2 (2.7)	0	0
Eye disorders					
-Total	2 (2.7)	2 (2.7)	0	0	0
Ocular hyperaemia	2 (2.7)	2 (2.7)	0	0	0
Gastrointestinal disorders					
-Total	51 (68.9)	22 (29.7)	22 (29.7)	7 (9.5)	0
Vomiting	24 (32.4)	15 (20.3)	8 (10.8)	1 (1.4)	0
Diarrhoea	23 (31.1)	13 (17.6)	8 (10.8)	2 (2.7)	0
Nausea	21 (28.4)	12 (16.2)	7 (9.5)	2 (2.7)	0
Constipation	12 (16.2)	5 (6.8)	7 (9.5)	0	0
Abdominal pain	11 (14.9)	2 (2.7)	7 (9.5)	2 (2.7)	0
General disorders and administration site conditions					
-Total	40 (54.1)	16 (21.6)	12 (16.2)	10 (13.5)	2 (2.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	32 (43.2)	11 (14.9)	10 (13.5)	9 (12.2)	2 (2.7)
Fatigue	15 (20.3)	12 (16.2)	3 (4.1)	0	0
Chills	6 (8.1)	4 (5.4)	2 (2.7)	0	0
Face oedema	6 (8.1)	3 (4.1)	2 (2.7)	1 (1.4)	0
Generalised oedema	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Localised oedema	1 (1.4)	1 (1.4)	0	0	0
Hepatobiliary disorders					
-Total	9 (12.2)	2 (2.7)	4 (5.4)	3 (4.1)	0
Hepatic function abnormal	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Hyperbilirubinaemia	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Hypertransaminasaemia	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	63 (85.1)	1 (1.4)	23 (31.1)	20 (27.0)	19 (25.7)
Cytokine release syndrome	55 (74.3)	3 (4.1)	17 (23.0)	17 (23.0)	18 (24.3)
Hypogammaglobulinaemia	30 (40.5)	2 (2.7)	22 (29.7)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Seasonal allergy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (44.6)	5 (6.8)	18 (24.3)	10 (13.5)	0
Upper respiratory tract infection	9 (12.2)	4 (5.4)	3 (4.1)	2 (2.7)	0
Conjunctivitis	8 (10.8)	2 (2.7)	6 (8.1)	0	0
Rhinovirus infection	8 (10.8)	0	6 (8.1)	2 (2.7)	0
Nasopharyngitis	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Sinusitis	6 (8.1)	0	4 (5.4)	2 (2.7)	0
Staphylococcal infection	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Nail infection	3 (4.1)	3 (4.1)	0	0	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Ear infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Metapneumovirus infection	2 (2.7)	0	0	2 (2.7)	0
Otitis externa	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (4.1)	2 (2.7)	0	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (1.4)	1 (1.4)	0	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Transfusion reaction	1 (1.4)	1 (1.4)	0	0	0
Wound	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	47 (63.5)	3 (4.1)	6 (8.1)	16 (21.6)	22 (29.7)
Neutrophil count decreased	21 (28.4)	1 (1.4)	2 (2.7)	3 (4.1)	15 (20.3)
Platelet count decreased	21 (28.4)	6 (8.1)	2 (2.7)	6 (8.1)	7 (9.5)
White blood cell count decreased	21 (28.4)	3 (4.1)	3 (4.1)	2 (2.7)	13 (17.6)
Aspartate aminotransferase increased	18 (24.3)	2 (2.7)	6 (8.1)	8 (10.8)	2 (2.7)
Alanine aminotransferase increased	16 (21.6)	3 (4.1)	7 (9.5)	6 (8.1)	0
Lymphocyte count decreased	15 (20.3)	1 (1.4)	1 (1.4)	8 (10.8)	5 (6.8)
Blood bilirubin increased	12 (16.2)	1 (1.4)	3 (4.1)	8 (10.8)	0
International normalised ratio increased	8 (10.8)	6 (8.1)	2 (2.7)	0	0
Blood fibrinogen decreased	6 (8.1)	2 (2.7)	2 (2.7)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	6 (8.1)	5 (6.8)	0	1 (1.4)	0
Blood immunoglobulin m decreased	6 (8.1)	4 (5.4)	1 (1.4)	1 (1.4)	0
Serum ferritin increased	6 (8.1)	1 (1.4)	3 (4.1)	2 (2.7)	0
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Blood lactate dehydrogenase increased	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
C-reactive protein increased	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Blood creatinine increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Blood immunoglobulin g decreased	3 (4.1)	0	3 (4.1)	0	0
Blood uric acid increased	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Weight increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Oxygen saturation decreased	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blood creatine phosphokinase increased	1 (1.4)	0	0	0	1 (1.4)
Metabolism and nutrition disorders					
-Total	44 (59.5)	10 (13.5)	7 (9.5)	19 (25.7)	8 (10.8)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	28 (37.8)	11 (14.9)	7 (9.5)	8 (10.8)	2 (2.7)
Hypokalaemia	17 (23.0)	1 (1.4)	6 (8.1)	8 (10.8)	2 (2.7)
Hypophosphataemia	15 (20.3)	2 (2.7)	4 (5.4)	8 (10.8)	1 (1.4)
Hypocalcaemia	12 (16.2)	1 (1.4)	6 (8.1)	5 (6.8)	0
Hyperuricaemia	9 (12.2)	7 (9.5)	1 (1.4)	1 (1.4)	0
Hypoalbuminaemia	9 (12.2)	0	8 (10.8)	1 (1.4)	0
Hyperglycaemia	8 (10.8)	0	4 (5.4)	4 (5.4)	0
Hypervolaemia	6 (8.1)	0	1 (1.4)	5 (6.8)	0
Tumour lysis syndrome	4 (5.4)	0	0	3 (4.1)	1 (1.4)
Hyperphosphataemia	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Metabolic acidosis	3 (4.1)	1 (1.4)	0	0	2 (2.7)
Hypercalcaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyperkalaemia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Hyponatraemia	2 (2.7)	2 (2.7)	0	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	35 (47.3)	13 (17.6)	17 (23.0)	5 (6.8)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	16 (21.6)	7 (9.5)	8 (10.8)	1 (1.4)	0
Arthralgia	12 (16.2)	5 (6.8)	6 (8.1)	1 (1.4)	0
Back pain	10 (13.5)	2 (2.7)	5 (6.8)	3 (4.1)	0
Myalgia	9 (12.2)	5 (6.8)	4 (5.4)	0	0
Bone pain	3 (4.1)	0	3 (4.1)	0	0
Nervous system disorders					
-Total	35 (47.3)	14 (18.9)	14 (18.9)	6 (8.1)	1 (1.4)
Headache	26 (35.1)	13 (17.6)	10 (13.5)	3 (4.1)	0
Encephalopathy	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Tremor	5 (6.8)	5 (6.8)	0	0	0
Somnolence	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Cerebral haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Psychiatric disorders					
-Total	30 (40.5)	13 (17.6)	11 (14.9)	6 (8.1)	0
Anxiety	14 (18.9)	3 (4.1)	9 (12.2)	2 (2.7)	0
Delirium	7 (9.5)	2 (2.7)	2 (2.7)	3 (4.1)	0
Confusional state	6 (8.1)	6 (8.1)	0	0	0
Agitation	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Mental status changes	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Irritability	2 (2.7)	2 (2.7)	0	0	0
Renal and urinary disorders					
-Total	10 (13.5)	2 (2.7)	2 (2.7)	2 (2.7)	4 (5.4)
Acute kidney injury	9 (12.2)	2 (2.7)	2 (2.7)	2 (2.7)	3 (4.1)
Anuria	1 (1.4)	0	0	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	44 (59.5)	18 (24.3)	8 (10.8)	10 (13.5)	8 (10.8)
Cough	20 (27.0)	16 (21.6)	4 (5.4)	0	0
Hypoxia	16 (21.6)	0	4 (5.4)	8 (10.8)	4 (5.4)
Pulmonary oedema	10 (13.5)	2 (2.7)	1 (1.4)	6 (8.1)	1 (1.4)
Oropharyngeal pain	8 (10.8)	7 (9.5)	1 (1.4)	0	0
Tachypnoea	8 (10.8)	3 (4.1)	1 (1.4)	3 (4.1)	1 (1.4)
Nasal congestion	7 (9.5)	6 (8.1)	1 (1.4)	0	0
Dyspnoea	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Pleural effusion	6 (8.1)	2 (2.7)	2 (2.7)	1 (1.4)	1 (1.4)
Epistaxis	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Rhinorrhoea	5 (6.8)	4 (5.4)	1 (1.4)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	3 (4.1)	0	1 (1.4)	0	2 (2.7)
Rhinitis allergic	1 (1.4)	1 (1.4)	0	0	0
Sleep apnoea syndrome	1 (1.4)	1 (1.4)	0	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (25.7)	11 (14.9)	5 (6.8)	3 (4.1)	0
Dry skin	8 (10.8)	6 (8.1)	2 (2.7)	0	0
Rash	6 (8.1)	3 (4.1)	3 (4.1)	0	0
Erythema	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Eczema	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Rash maculo-papular	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Blister	1 (1.4)	1 (1.4)	0	0	0
Petechiae	1 (1.4)	0	0	1 (1.4)	0
Skin discolouration	1 (1.4)	1 (1.4)	0	0	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	28 (37.8)	4 (5.4)	8 (10.8)	10 (13.5)	6 (8.1)
Hypotension	21 (28.4)	2 (2.7)	6 (8.1)	7 (9.5)	6 (8.1)

Timing: Any time post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	13 (17.6)	2 (2.7)	6 (8.1)	5 (6.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (97.5)	3 (7.5)	1 (2.5)	11 (27.5)	24 (60.0)
Blood and lymphatic system disorders					
-Total	24 (60.0)	1 (2.5)	3 (7.5)	11 (27.5)	9 (22.5)
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Anaemia	10 (25.0)	1 (2.5)	3 (7.5)	6 (15.0)	0
Neutropenia	7 (17.5)	0	1 (2.5)	1 (2.5)	5 (12.5)
Thrombocytopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Disseminated intravascular coagulation	4 (10.0)	0	4 (10.0)	0	0
Cardiac disorders					
-Total	3 (7.5)	1 (2.5)	2 (5.0)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Gastrointestinal disorders					
-Total	22 (55.0)	9 (22.5)	10 (25.0)	3 (7.5)	0
Vomiting	10 (25.0)	5 (12.5)	5 (12.5)	0	0
Diarrhoea	9 (22.5)	3 (7.5)	6 (15.0)	0	0
Nausea	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Abdominal pain	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Constipation	4 (10.0)	2 (5.0)	2 (5.0)	0	0
General disorders and administration site conditions					
-Total	15 (37.5)	7 (17.5)	3 (7.5)	4 (10.0)	1 (2.5)
Pyrexia	10 (25.0)	4 (10.0)	2 (5.0)	3 (7.5)	1 (2.5)
Chills	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Oedema peripheral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Fatigue	2 (5.0)	2 (5.0)	0	0	0
Hepatobiliary disorders					
-Total	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	34 (85.0)	2 (5.0)	8 (20.0)	14 (35.0)	10 (25.0)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	14 (35.0)	1 (2.5)	7 (17.5)	6 (15.0)	0
Immunodeficiency	3 (7.5)	0	0	3 (7.5)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	1 (2.5)	0	0	0
Infections and infestations					
-Total	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Conjunctivitis	3 (7.5)	0	3 (7.5)	0	0
Pneumonia	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	0	0	1 (2.5)	0
Investigations					
-Total	22 (55.0)	3 (7.5)	2 (5.0)	3 (7.5)	14 (35.0)
White blood cell count decreased	12 (30.0)	2 (5.0)	0	1 (2.5)	9 (22.5)
Neutrophil count decreased	11 (27.5)	0	1 (2.5)	1 (2.5)	9 (22.5)
Platelet count decreased	11 (27.5)	2 (5.0)	1 (2.5)	4 (10.0)	4 (10.0)
Lymphocyte count decreased	7 (17.5)	1 (2.5)	0	3 (7.5)	3 (7.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Aspartate aminotransferase increased	5 (12.5)	1 (2.5)	1 (2.5)	2 (5.0)	1 (2.5)
Serum ferritin increased	5 (12.5)	1 (2.5)	4 (10.0)	0	0
Blood bilirubin increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)	0	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0	0	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (42.5)	4 (10.0)	5 (12.5)	7 (17.5)	1 (2.5)
Decreased appetite	9 (22.5)	4 (10.0)	2 (5.0)	2 (5.0)	1 (2.5)
Hypokalaemia	8 (20.0)	2 (5.0)	1 (2.5)	5 (12.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hypophosphataemia	6 (15.0)	1 (2.5)	2 (5.0)	3 (7.5)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypocalcaemia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Hyperuricaemia	1 (2.5)	0	0	1 (2.5)	0
Hypervolaemia	1 (2.5)	0	1 (2.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	15 (37.5)	7 (17.5)	7 (17.5)	1 (2.5)	0
Arthralgia	6 (15.0)	4 (10.0)	2 (5.0)	0	0
Pain in extremity	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Back pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Nervous system disorders					
-Total	13 (32.5)	7 (17.5)	4 (10.0)	2 (5.0)	0
Headache	10 (25.0)	7 (17.5)	2 (5.0)	1 (2.5)	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Psychiatric disorders					
-Total	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Agitation	1 (2.5)	1 (2.5)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (2.5)	0	0	1 (2.5)	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Acute kidney injury	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders					
-Total	18 (45.0)	7 (17.5)	1 (2.5)	7 (17.5)	3 (7.5)
Hypoxia	7 (17.5)	0	2 (5.0)	2 (5.0)	3 (7.5)
Cough	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Pulmonary oedema	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Epistaxis	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Oropharyngeal pain	3 (7.5)	3 (7.5)	0	0	0
Tachypnoea	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Dyspnoea	2 (5.0)	0	0	2 (5.0)	0
Pleural effusion	2 (5.0)	2 (5.0)	0	0	0
Nasal congestion	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rash	1 (2.5)	0	1 (2.5)	0	0
Vascular disorders					
-Total	9 (22.5)	3 (7.5)	3 (7.5)	3 (7.5)	0
Hypertension	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Hypotension	5 (12.5)	0	2 (5.0)	3 (7.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	2 (5.0)	7 (17.5)	10 (25.0)	21 (52.5)
Blood and lymphatic system disorders					
-Total	21 (52.5)	1 (2.5)	2 (5.0)	14 (35.0)	4 (10.0)
Febrile neutropenia	15 (37.5)	0	0	14 (35.0)	1 (2.5)
Anaemia	11 (27.5)	4 (10.0)	5 (12.5)	2 (5.0)	0
Disseminated intravascular coagulation	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Thrombocytopenia	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Neutropenia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Cardiac disorders					
-Total	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)
Gastrointestinal disorders					
-Total	24 (60.0)	13 (32.5)	8 (20.0)	3 (7.5)	0
Vomiting	11 (27.5)	7 (17.5)	3 (7.5)	1 (2.5)	0
Nausea	10 (25.0)	6 (15.0)	4 (10.0)	0	0
Constipation	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Diarrhoea	6 (15.0)	5 (12.5)	0	1 (2.5)	0
Abdominal pain	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions					
-Total	21 (52.5)	13 (32.5)	4 (10.0)	3 (7.5)	1 (2.5)
Pyrexia	14 (35.0)	7 (17.5)	3 (7.5)	3 (7.5)	1 (2.5)
Fatigue	9 (22.5)	7 (17.5)	2 (5.0)	0	0
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Oedema peripheral	3 (7.5)	3 (7.5)	0	0	0
Chills	1 (2.5)	1 (2.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Hepatic function abnormal	1 (2.5)	0	1 (2.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	32 (80.0)	1 (2.5)	12 (30.0)	8 (20.0)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Hypogammaglobulinaemia	9 (22.5)	1 (2.5)	7 (17.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Infections and infestations					
-Total	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Staphylococcal bacteraemia	3 (7.5)	0	0	3 (7.5)	0
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rhinovirus infection	2 (5.0)	0	2 (5.0)	0	0
Investigations					
-Total	27 (67.5)	1 (2.5)	2 (5.0)	11 (27.5)	13 (32.5)
Aspartate aminotransferase increased	14 (35.0)	1 (2.5)	5 (12.5)	6 (15.0)	2 (5.0)
Alanine aminotransferase increased	12 (30.0)	2 (5.0)	7 (17.5)	3 (7.5)	0
White blood cell count decreased	12 (30.0)	1 (2.5)	3 (7.5)	1 (2.5)	7 (17.5)
Blood bilirubin increased	10 (25.0)	1 (2.5)	1 (2.5)	8 (20.0)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (25.0)	2 (5.0)	2 (5.0)	2 (5.0)	4 (10.0)
Neutrophil count decreased	9 (22.5)	0	2 (5.0)	1 (2.5)	6 (15.0)
International normalised ratio increased	8 (20.0)	5 (12.5)	3 (7.5)	0	0
Lymphocyte count decreased	8 (20.0)	1 (2.5)	0	5 (12.5)	2 (5.0)
Activated partial thromboplastin time prolonged	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood fibrinogen decreased	5 (12.5)	2 (5.0)	1 (2.5)	1 (2.5)	1 (2.5)
Electrocardiogram qt prolonged	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Blood immunoglobulin a decreased	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Blood creatinine increased	3 (7.5)	0	0	2 (5.0)	1 (2.5)
Serum ferritin increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Blood uric acid increased	2 (5.0)	2 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	28 (70.0)	5 (12.5)	5 (12.5)	14 (35.0)	4 (10.0)
Decreased appetite	15 (37.5)	5 (12.5)	2 (5.0)	8 (20.0)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Hypokalaemia	11 (27.5)	1 (2.5)	4 (10.0)	4 (10.0)	2 (5.0)
Hypophosphataemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Hyperuricaemia	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Hyperphosphataemia	5 (12.5)	4 (10.0)	0	0	1 (2.5)
Hypervolaemia	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Hypoalbuminaemia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypomagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (32.5)	6 (15.0)	6 (15.0)	1 (2.5)	0
Pain in extremity	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Arthralgia	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Myalgia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Back pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Nervous system disorders					
-Total	17 (42.5)	6 (15.0)	7 (17.5)	4 (10.0)	0
Headache	13 (32.5)	5 (12.5)	7 (17.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Psychiatric disorders					
-Total	17 (42.5)	9 (22.5)	3 (7.5)	5 (12.5)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Anxiety	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Insomnia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Mental status changes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Renal and urinary disorders					
-Total	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Acute kidney injury	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Respiratory, thoracic and mediastinal disorders					
-Total	21 (52.5)	6 (15.0)	3 (7.5)	4 (10.0)	8 (20.0)
Hypoxia	10 (25.0)	0	3 (7.5)	4 (10.0)	3 (7.5)
Pulmonary oedema	7 (17.5)	1 (2.5)	3 (7.5)	2 (5.0)	1 (2.5)
Cough	5 (12.5)	5 (12.5)	0	0	0
Pleural effusion	5 (12.5)	2 (5.0)	0	2 (5.0)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Respiratory failure	4 (10.0)	0	0	0	4 (10.0)
Respiratory distress	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Nasal congestion	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Oropharyngeal pain	2 (5.0)	2 (5.0)	0	0	0
Rhinorrhoea	2 (5.0)	2 (5.0)	0	0	0
Dyspnoea	1 (2.5)	0	0	0	1 (2.5)
Epistaxis	1 (2.5)	0	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (20.0)	4 (10.0)	4 (10.0)	0	0
Pruritus	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Rash	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	18 (45.0)	1 (2.5)	4 (10.0)	7 (17.5)	6 (15.0)
Hypotension	16 (40.0)	1 (2.5)	4 (10.0)	5 (12.5)	6 (15.0)
Hypertension	8 (20.0)	1 (2.5)	3 (7.5)	4 (10.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	6 (15.0)	9 (22.5)	10 (25.0)	10 (25.0)
Blood and lymphatic system disorders					
-Total	9 (22.5)	2 (5.0)	0	3 (7.5)	4 (10.0)
Neutropenia	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Anaemia	3 (7.5)	3 (7.5)	0	0	0
Disseminated intravascular coagulation	1 (2.5)	0	0	1 (2.5)	0
Febrile neutropenia	1 (2.5)	0	0	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Gastrointestinal disorders					
-Total	5 (12.5)	4 (10.0)	1 (2.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (7.5)	3 (7.5)	0	0	0
Constipation	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Diarrhoea	2 (5.0)	2 (5.0)	0	0	0
Nausea	2 (5.0)	2 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Pyrexia	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Fatigue	2 (5.0)	2 (5.0)	0	0	0
Immune system disorders					
-Total	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hypogammaglobulinaemia	2 (5.0)	0	2 (5.0)	0	0
Immunodeficiency	1 (2.5)	0	0	1 (2.5)	0
Infections and infestations					
-Total	18 (45.0)	6 (15.0)	5 (12.5)	5 (12.5)	2 (5.0)
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Gastroenteritis	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Upper respiratory tract infection	5 (12.5)	2 (5.0)	2 (5.0)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Pneumonia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Rhinovirus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Sinusitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Investigations					
-Total	10 (25.0)	2 (5.0)	1 (2.5)	4 (10.0)	3 (7.5)
White blood cell count decreased	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Neutrophil count decreased	5 (12.5)	0	0	2 (5.0)	3 (7.5)
Alanine aminotransferase increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Platelet count decreased	2 (5.0)	2 (5.0)	0	0	0
Blood bilirubin increased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin a decreased	1 (2.5)	0	0	1 (2.5)	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Lymphocyte count decreased	1 (2.5)	0	0	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Decreased appetite	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hyperuricaemia	2 (5.0)	2 (5.0)	0	0	0
Hypokalaemia	1 (2.5)	0	0	1 (2.5)	0
Hypophosphataemia	1 (2.5)	0	1 (2.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Back pain	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Arthralgia	2 (5.0)	2 (5.0)	0	0	0
Pain in extremity	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Nervous system disorders					
-Total	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Headache	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Psychiatric disorders					
-Total	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (2.5)	1 (2.5)	0	0	0
Delirium	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (25.0)	5 (12.5)	2 (5.0)	2 (5.0)	1 (2.5)
Cough	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Nasal congestion	3 (7.5)	3 (7.5)	0	0	0
Hypoxia	2 (5.0)	0	0	2 (5.0)	0
Epistaxis	1 (2.5)	0	1 (2.5)	0	0
Oropharyngeal pain	1 (2.5)	1 (2.5)	0	0	0
Pleural effusion	1 (2.5)	0	1 (2.5)	0	0
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Skin and subcutaneous tissue disorders					
-Total	4 (10.0)	4 (10.0)	0	0	0
Dry skin	3 (7.5)	3 (7.5)	0	0	0
Rash	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Hypotension	2 (5.0)	1 (2.5)	0	0	1 (2.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (80.0)	6 (17.1)	10 (28.6)	9 (25.7)	3 (8.6)
Blood and lymphatic system disorders					
-Total	4 (11.4)	1 (2.9)	0	3 (8.6)	0
Anaemia	3 (8.6)	1 (2.9)	0	2 (5.7)	0
Febrile neutropenia	2 (5.7)	0	0	2 (5.7)	0
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
Cardiac disorders					
-Total	2 (5.7)	2 (5.7)	0	0	0
Tachycardia	2 (5.7)	2 (5.7)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (25.7)	5 (14.3)	4 (11.4)	0	0
Diarrhoea	5 (14.3)	4 (11.4)	1 (2.9)	0	0
Nausea	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Vomiting	3 (8.6)	3 (8.6)	0	0	0
Abdominal pain	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Constipation	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	13 (37.1)	8 (22.9)	3 (8.6)	2 (5.7)	0
Pyrexia	8 (22.9)	3 (8.6)	3 (8.6)	2 (5.7)	0
Fatigue	4 (11.4)	4 (11.4)	0	0	0
Chills	1 (2.9)	1 (2.9)	0	0	0
Oedema peripheral	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	8 (22.9)	0	8 (22.9)	0	0
Hypogammaglobulinaemia	8 (22.9)	0	8 (22.9)	0	0
Infections and infestations					
-Total	7 (20.0)	1 (2.9)	5 (14.3)	1 (2.9)	0
Rhinovirus infection	3 (8.6)	0	3 (8.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	1 (2.9)	0	0	0
Sinusitis	1 (2.9)	0	1 (2.9)	0	0
Investigations					
-Total	13 (37.1)	4 (11.4)	2 (5.7)	5 (14.3)	2 (5.7)
Neutrophil count decreased	5 (14.3)	2 (5.7)	1 (2.9)	1 (2.9)	1 (2.9)
White blood cell count decreased	4 (11.4)	2 (5.7)	1 (2.9)	0	1 (2.9)
Lymphocyte count decreased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Platelet count decreased	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Blood uric acid increased	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Blood bilirubin increased	1 (2.9)	0	0	1 (2.9)	0
Blood creatinine increased	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin a decreased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (17.1)	1 (2.9)	3 (8.6)	1 (2.9)	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Hypokalaemia	2 (5.7)	0	1 (2.9)	0	1 (2.9)
Hyperuricaemia	1 (2.9)	1 (2.9)	0	0	0
Hypervolaemia	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (17.1)	3 (8.6)	2 (5.7)	1 (2.9)	0
Back pain	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Pain in extremity	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Arthralgia	1 (2.9)	0	1 (2.9)	0	0
Myalgia	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	7 (20.0)	4 (11.4)	3 (8.6)	0	0
Headache	7 (20.0)	4 (11.4)	3 (8.6)	0	0
Psychiatric disorders					
-Total	3 (8.6)	0	3 (8.6)	0	0
Anxiety	2 (5.7)	0	2 (5.7)	0	0
Mental status changes	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Acute kidney injury	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders					
-Total	8 (22.9)	4 (11.4)	2 (5.7)	1 (2.9)	1 (2.9)
Cough	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Nasal congestion	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Rhinorrhoea	3 (8.6)	3 (8.6)	0	0	0
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Dyspnoea	1 (2.9)	0	1 (2.9)	0	0
Hypoxia	1 (2.9)	0	0	1 (2.9)	0
Oropharyngeal pain	1 (2.9)	0	1 (2.9)	0	0
Pleural effusion	1 (2.9)	1 (2.9)	0	0	0
Respiratory distress	1 (2.9)	0	0	0	1 (2.9)
Skin and subcutaneous tissue disorders					
-Total	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Dry skin	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Rash	3 (8.6)	2 (5.7)	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	3 (8.6)	0	1 (2.9)	1 (2.9)	1 (2.9)
Hypotension	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Hypertension	1 (2.9)	0	1 (2.9)	0	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (33.3)	3 (10.0)	2 (6.7)	1 (3.3)	4 (13.3)
Blood and lymphatic system disorders					
-Total	1 (3.3)	0	0	0	1 (3.3)
Neutropenia	1 (3.3)	0	0	0	1 (3.3)
Gastrointestinal disorders					
-Total	2 (6.7)	2 (6.7)	0	0	0
Diarrhoea	2 (6.7)	2 (6.7)	0	0	0
General disorders and administration site conditions					
-Total	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Pyrexia	3 (10.0)	2 (6.7)	1 (3.3)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	1 (3.3)	0	0	0	1 (3.3)
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	0	0	1 (3.3)
Infections and infestations					
-Total	8 (26.7)	3 (10.0)	3 (10.0)	1 (3.3)	1 (3.3)
Sinusitis	3 (10.0)	0	3 (10.0)	0	0
Upper respiratory tract infection	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Conjunctivitis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Rhinovirus infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Parainfluenzae virus infection	1 (3.3)	0	0	1 (3.3)	0
Pneumonia	1 (3.3)	0	0	0	1 (3.3)
Investigations					
-Total	3 (10.0)	2 (6.7)	0	0	1 (3.3)
Neutrophil count decreased	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Platelet count decreased	2 (6.7)	2 (6.7)	0	0	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Decreased appetite	1 (3.3)	0	0	0	1 (3.3)
Hyperglycaemia	1 (3.3)	0	0	1 (3.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Pain in extremity	1 (3.3)	0	1 (3.3)	0	0
Psychiatric disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Anxiety	1 (3.3)	1 (3.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (10.0)	2 (6.7)	0	0	1 (3.3)
Cough	2 (6.7)	2 (6.7)	0	0	0
Dyspnoea	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Epistaxis	1 (3.3)	1 (3.3)	0	0	0
Pleural effusion	1 (3.3)	0	1 (3.3)	0	0
Rhinorrhoea	1 (3.3)	1 (3.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	1 (3.3)	0	0	0	1 (3.3)
Skin and subcutaneous tissue disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	1 (3.3)	0	0	1 (3.3)	0
Hypertension	1 (3.3)	0	0	1 (3.3)	0

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Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (70.0)	2 (10.0)	7 (35.0)	4 (20.0)	1 (5.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Anaemia	1 (5.0)	0	1 (5.0)	0	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Diarrhoea	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Constipation	1 (5.0)	1 (5.0)	0	0	0
Nausea	1 (5.0)	1 (5.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Pyrexia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Fatigue	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)	0	0
Infections and infestations					
-Total	7 (35.0)	1 (5.0)	4 (20.0)	2 (10.0)	0
Sinusitis	3 (15.0)	0	3 (15.0)	0	0
Conjunctivitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rhinovirus infection	2 (10.0)	0	2 (10.0)	0	0
Upper respiratory tract infection	2 (10.0)	0	2 (10.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Investigations					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	1 (5.0)	0	0	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Arthralgia	1 (5.0)	0	1 (5.0)	0	0
Pain in extremity	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Headache	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Psychiatric disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Cough	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rhinorrhoea	2 (10.0)	0	2 (10.0)	0	0
Dyspnoea	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (5.0)	0	0	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	1 (5.0)	0	0	0
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Skin and subcutaneous tissue disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Vascular disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypertension	1 (5.0)	0	1 (5.0)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	2 (5.0)	1 (2.5)	11 (27.5)	26 (65.0)
Blood and lymphatic system disorders					
-Total	27 (67.5)	1 (2.5)	3 (7.5)	13 (32.5)	10 (25.0)
Anaemia	12 (30.0)	3 (7.5)	3 (7.5)	6 (15.0)	0
Febrile neutropenia	11 (27.5)	0	0	10 (25.0)	1 (2.5)
Neutropenia	9 (22.5)	0	1 (2.5)	2 (5.0)	6 (15.0)
Disseminated intravascular coagulation	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Thrombocytopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Cardiac disorders					
-Total	3 (7.5)	1 (2.5)	2 (5.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Gastrointestinal disorders					
-Total	26 (65.0)	12 (30.0)	11 (27.5)	3 (7.5)	0
Diarrhoea	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Vomiting	12 (30.0)	7 (17.5)	5 (12.5)	0	0
Nausea	9 (22.5)	5 (12.5)	2 (5.0)	2 (5.0)	0
Abdominal pain	7 (17.5)	1 (2.5)	5 (12.5)	1 (2.5)	0
Constipation	6 (15.0)	3 (7.5)	3 (7.5)	0	0
General disorders and administration site conditions					
-Total	19 (47.5)	9 (22.5)	5 (12.5)	4 (10.0)	1 (2.5)
Pyrexia	15 (37.5)	7 (17.5)	4 (10.0)	3 (7.5)	1 (2.5)
Chills	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Fatigue	4 (10.0)	4 (10.0)	0	0	0
Oedema peripheral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders					
-Total	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	35 (87.5)	1 (2.5)	8 (20.0)	15 (37.5)	11 (27.5)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	16 (40.0)	1 (2.5)	9 (22.5)	6 (15.0)	0
Immunodeficiency	4 (10.0)	0	0	4 (10.0)	0
Haemophagocytic lymphohistiocytosis	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Infections and infestations					
-Total	22 (55.0)	6 (15.0)	6 (15.0)	7 (17.5)	3 (7.5)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Gastroenteritis	6 (15.0)	4 (10.0)	0	2 (5.0)	0
Conjunctivitis	4 (10.0)	0	4 (10.0)	0	0
Parainfluenzae virus infection	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Pneumonia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Sinusitis	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Rhinovirus infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	22 (55.0)	2 (5.0)	3 (7.5)	3 (7.5)	14 (35.0)
Neutrophil count decreased	13 (32.5)	1 (2.5)	0	2 (5.0)	10 (25.0)
Platelet count decreased	12 (30.0)	3 (7.5)	1 (2.5)	4 (10.0)	4 (10.0)
White blood cell count decreased	12 (30.0)	1 (2.5)	1 (2.5)	1 (2.5)	9 (22.5)
Lymphocyte count decreased	8 (20.0)	1 (2.5)	0	4 (10.0)	3 (7.5)
Alanine aminotransferase increased	6 (15.0)	1 (2.5)	1 (2.5)	4 (10.0)	0
Aspartate aminotransferase increased	5 (12.5)	1 (2.5)	1 (2.5)	2 (5.0)	1 (2.5)
Serum ferritin increased	5 (12.5)	1 (2.5)	4 (10.0)	0	0
Blood bilirubin increased	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)	0	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	19 (47.5)	4 (10.0)	5 (12.5)	8 (20.0)	2 (5.0)
Decreased appetite	11 (27.5)	5 (12.5)	2 (5.0)	2 (5.0)	2 (5.0)
Hypokalaemia	8 (20.0)	2 (5.0)	1 (2.5)	5 (12.5)	0
Hypophosphataemia	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hyperglycaemia	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Hypocalcaemia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Hyperuricaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Hypervolaemia	1 (2.5)	0	1 (2.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	17 (42.5)	7 (17.5)	7 (17.5)	3 (7.5)	0
Pain in extremity	8 (20.0)	2 (5.0)	5 (12.5)	1 (2.5)	0
Arthralgia	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Back pain	6 (15.0)	1 (2.5)	3 (7.5)	2 (5.0)	0
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	14 (35.0)	7 (17.5)	5 (12.5)	2 (5.0)	0
Headache	11 (27.5)	7 (17.5)	3 (7.5)	1 (2.5)	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Psychiatric disorders					
-Total	9 (22.5)	3 (7.5)	4 (10.0)	2 (5.0)	0
Anxiety	6 (15.0)	2 (5.0)	3 (7.5)	1 (2.5)	0
Agitation	2 (5.0)	2 (5.0)	0	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Delirium	2 (5.0)	0	2 (5.0)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Renal and urinary disorders					
-Total	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Acute kidney injury	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders					
-Total	26 (65.0)	10 (25.0)	3 (7.5)	8 (20.0)	5 (12.5)
Cough	14 (35.0)	12 (30.0)	2 (5.0)	0	0
Hypoxia	9 (22.5)	0	2 (5.0)	4 (10.0)	3 (7.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Dyspnoea	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Epistaxis	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Nasal congestion	4 (10.0)	4 (10.0)	0	0	0
Oropharyngeal pain	4 (10.0)	4 (10.0)	0	0	0
Pleural effusion	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Tachypnoea	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Rhinorrhoea	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Dry skin	4 (10.0)	4 (10.0)	0	0	0
Pruritus	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Rash	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Vascular disorders					
-Total	12 (30.0)	4 (10.0)	3 (7.5)	4 (10.0)	1 (2.5)
Hypotension	7 (17.5)	1 (2.5)	2 (5.0)	3 (7.5)	1 (2.5)
Hypertension	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	6 (15.0)	11 (27.5)	23 (57.5)
Blood and lymphatic system disorders					
-Total	23 (57.5)	1 (2.5)	2 (5.0)	16 (40.0)	4 (10.0)
Febrile neutropenia	16 (40.0)	0	0	15 (37.5)	1 (2.5)
Anaemia	13 (32.5)	4 (10.0)	6 (15.0)	3 (7.5)	0
Thrombocytopenia	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Disseminated intravascular coagulation	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Neutropenia	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Cardiac disorders					
-Total	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (35.0)	6 (15.0)	5 (12.5)	2 (5.0)	1 (2.5)
Gastrointestinal disorders					
-Total	30 (75.0)	14 (35.0)	12 (30.0)	4 (10.0)	0
Diarrhoea	14 (35.0)	10 (25.0)	2 (5.0)	2 (5.0)	0
Vomiting	14 (35.0)	10 (25.0)	3 (7.5)	1 (2.5)	0
Nausea	13 (32.5)	7 (17.5)	6 (15.0)	0	0
Constipation	8 (20.0)	4 (10.0)	4 (10.0)	0	0
Abdominal pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
General disorders and administration site conditions					
-Total	28 (70.0)	14 (35.0)	7 (17.5)	6 (15.0)	1 (2.5)
Pyrexia	20 (50.0)	7 (17.5)	6 (15.0)	6 (15.0)	1 (2.5)
Fatigue	13 (32.5)	10 (25.0)	3 (7.5)	0	0
Face oedema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Oedema peripheral	4 (10.0)	4 (10.0)	0	0	0
Chills	2 (5.0)	2 (5.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Hepatic function abnormal	1 (2.5)	0	1 (2.5)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	35 (87.5)	1 (2.5)	15 (37.5)	8 (20.0)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Hypogammaglobulinaemia	17 (42.5)	1 (2.5)	15 (37.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Infections and infestations					
-Total	17 (42.5)	2 (5.0)	9 (22.5)	6 (15.0)	0
Rhinovirus infection	6 (15.0)	0	6 (15.0)	0	0
Upper respiratory tract infection	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Conjunctivitis	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Staphylococcal bacteraemia	4 (10.0)	0	0	4 (10.0)	0
Sinusitis	3 (7.5)	0	3 (7.5)	0	0
Pneumonia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	28 (70.0)	1 (2.5)	1 (2.5)	12 (30.0)	14 (35.0)
Aspartate aminotransferase increased	14 (35.0)	1 (2.5)	5 (12.5)	6 (15.0)	2 (5.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	13 (32.5)	2 (5.0)	3 (7.5)	1 (2.5)	7 (17.5)
Alanine aminotransferase increased	12 (30.0)	2 (5.0)	7 (17.5)	3 (7.5)	0
Platelet count decreased	12 (30.0)	3 (7.5)	2 (5.0)	3 (7.5)	4 (10.0)
Neutrophil count decreased	11 (27.5)	0	2 (5.0)	2 (5.0)	7 (17.5)
Blood bilirubin increased	10 (25.0)	1 (2.5)	1 (2.5)	8 (20.0)	0
Lymphocyte count decreased	9 (22.5)	0	1 (2.5)	6 (15.0)	2 (5.0)
International normalised ratio increased	8 (20.0)	5 (12.5)	3 (7.5)	0	0
Activated partial thromboplastin time prolonged	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood fibrinogen decreased	5 (12.5)	2 (5.0)	1 (2.5)	1 (2.5)	1 (2.5)
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Electrocardiogram qt prolonged	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Blood creatinine increased	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Blood uric acid increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Metabolism and nutrition disorders					
-Total	30 (75.0)	6 (15.0)	6 (15.0)	14 (35.0)	4 (10.0)
Decreased appetite	19 (47.5)	6 (15.0)	5 (12.5)	8 (20.0)	0
Hypocalcaemia	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Hypokalaemia	12 (30.0)	1 (2.5)	5 (12.5)	4 (10.0)	2 (5.0)
Hypophosphataemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Hyperuricaemia	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Hypervolaemia	6 (15.0)	0	1 (2.5)	5 (12.5)	0
Hyperphosphataemia	5 (12.5)	4 (10.0)	0	0	1 (2.5)
Hypoalbuminaemia	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypomagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (45.0)	8 (20.0)	8 (20.0)	2 (5.0)	0
Pain in extremity	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Arthralgia	5 (12.5)	0	4 (10.0)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Back pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Nervous system disorders					
-Total	20 (50.0)	7 (17.5)	8 (20.0)	5 (12.5)	0
Headache	16 (40.0)	6 (15.0)	8 (20.0)	2 (5.0)	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Psychiatric disorders					
-Total	21 (52.5)	9 (22.5)	7 (17.5)	5 (12.5)	0
Anxiety	8 (20.0)	1 (2.5)	6 (15.0)	1 (2.5)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Insomnia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Mental status changes	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Renal and urinary disorders					
-Total	7 (17.5)	1 (2.5)	1 (2.5)	2 (5.0)	3 (7.5)
Acute kidney injury	7 (17.5)	1 (2.5)	1 (2.5)	2 (5.0)	3 (7.5)
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (60.0)	8 (20.0)	3 (7.5)	4 (10.0)	9 (22.5)
Hypoxia	11 (27.5)	0	2 (5.0)	6 (15.0)	3 (7.5)
Cough	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Pulmonary oedema	7 (17.5)	1 (2.5)	3 (7.5)	2 (5.0)	1 (2.5)
Nasal congestion	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Pleural effusion	5 (12.5)	2 (5.0)	0	2 (5.0)	1 (2.5)
Respiratory failure	5 (12.5)	0	0	0	5 (12.5)
Rhinorrhoea	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Tachypnoea	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Oropharyngeal pain	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Respiratory distress	4 (10.0)	0	2 (5.0)	0	2 (5.0)
Dyspnoea	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Epistaxis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (32.5)	6 (15.0)	7 (17.5)	0	0
Rash	6 (15.0)	3 (7.5)	3 (7.5)	0	0
Pruritus	5 (12.5)	1 (2.5)	4 (10.0)	0	0
Dry skin	4 (10.0)	2 (5.0)	2 (5.0)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	20 (50.0)	1 (2.5)	5 (12.5)	7 (17.5)	7 (17.5)
Hypotension	17 (42.5)	1 (2.5)	4 (10.0)	5 (12.5)	7 (17.5)
Hypertension	10 (25.0)	1 (2.5)	5 (12.5)	4 (10.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	1 (16.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	2 (33.3)	0	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	1 (16.7)	1 (16.7)	1 (16.7)	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	1 (16.7)	0	1 (16.7)	0	0
Fatigue	1 (16.7)	1 (16.7)	0	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (16.7)	0	0	0	1 (16.7)
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Nasal congestion	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	2 (33.3)	0	1 (16.7)	0
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	2 (9.1)	2 (9.1)	2 (9.1)	16 (72.7)
Blood and lymphatic system disorders					
-Total	13 (59.1)	2 (9.1)	2 (9.1)	3 (13.6)	6 (27.3)
Febrile neutropenia	6 (27.3)	0	0	5 (22.7)	1 (4.5)
Anaemia	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Coagulopathy	2 (9.1)	0	2 (9.1)	0	0
Disseminated intravascular coagulation	2 (9.1)	0	2 (9.1)	0	0
Splenomegaly	1 (4.5)	1 (4.5)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	7 (31.8)	2 (9.1)	3 (13.6)	2 (9.1)	0
Tachycardia	7 (31.8)	2 (9.1)	3 (13.6)	2 (9.1)	0
Endocrine disorders					
-Total	4 (18.2)	0	4 (18.2)	0	0
Adrenal insufficiency	3 (13.6)	0	3 (13.6)	0	0
Hypothyroidism	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	16 (72.7)	5 (22.7)	6 (27.3)	5 (22.7)	0
Vomiting	7 (31.8)	4 (18.2)	2 (9.1)	1 (4.5)	0
Nausea	6 (27.3)	2 (9.1)	3 (13.6)	1 (4.5)	0
Constipation	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Abdominal pain	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Diarrhoea	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pancreatitis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Mouth haemorrhage	1 (4.5)	0	0	1 (4.5)	0
General disorders and administration site conditions					
-Total	9 (40.9)	3 (13.6)	2 (9.1)	2 (9.1)	2 (9.1)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	5 (22.7)	2 (9.1)	1 (4.5)	1 (4.5)	1 (4.5)
Oedema peripheral	4 (18.2)	3 (13.6)	0	1 (4.5)	0
Face oedema	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Fatigue	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Chills	1 (4.5)	1 (4.5)	0	0	0
Generalised oedema	1 (4.5)	0	1 (4.5)	0	0
Multiple organ dysfunction syndrome	1 (4.5)	0	0	0	1 (4.5)
Hepatobiliary disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Gallbladder enlargement	1 (4.5)	1 (4.5)	0	0	0
Immune system disorders					
-Total	19 (86.4)	1 (4.5)	7 (31.8)	5 (22.7)	6 (27.3)
Cytokine release syndrome	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Hypogammaglobulinaemia	9 (40.9)	1 (4.5)	7 (31.8)	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	2 (9.1)	0	0	2 (9.1)	0
Infections and infestations					
-Total	7 (31.8)	1 (4.5)	3 (13.6)	3 (13.6)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Rhinovirus infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal infection	1 (4.5)	0	1 (4.5)	0	0
Investigations					
-Total	16 (72.7)	1 (4.5)	0	6 (27.3)	9 (40.9)
Aspartate aminotransferase increased	8 (36.4)	0	2 (9.1)	5 (22.7)	1 (4.5)
White blood cell count decreased	8 (36.4)	0	1 (4.5)	2 (9.1)	5 (22.7)
Blood bilirubin increased	6 (27.3)	0	1 (4.5)	5 (22.7)	0
Alanine aminotransferase increased	5 (22.7)	1 (4.5)	4 (18.2)	0	0
Platelet count decreased	5 (22.7)	1 (4.5)	1 (4.5)	1 (4.5)	2 (9.1)
Blood fibrinogen decreased	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Lymphocyte count decreased	4 (18.2)	0	0	3 (13.6)	1 (4.5)
Neutrophil count decreased	4 (18.2)	0	0	0	4 (18.2)
Serum ferritin increased	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin m decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Electrocardiogram qt prolonged	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
International normalised ratio increased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Blood immunoglobulin a decreased	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Blood creatinine increased	1 (4.5)	0	0	1 (4.5)	0
Blood immunoglobulin g decreased	1 (4.5)	1 (4.5)	0	0	0
Lipase increased	1 (4.5)	1 (4.5)	0	0	0
Oxygen saturation decreased	1 (4.5)	1 (4.5)	0	0	0
Weight increased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	14 (63.6)	2 (9.1)	4 (18.2)	6 (27.3)	2 (9.1)
Decreased appetite	7 (31.8)	1 (4.5)	1 (4.5)	5 (22.7)	0
Hypocalcaemia	7 (31.8)	1 (4.5)	4 (18.2)	2 (9.1)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	5 (22.7)	1 (4.5)	3 (13.6)	1 (4.5)	0
Hyperglycaemia	4 (18.2)	0	2 (9.1)	2 (9.1)	0
Hypervolaemia	4 (18.2)	0	0	4 (18.2)	0
Hypoalbuminaemia	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Hyperuricaemia	3 (13.6)	3 (13.6)	0	0	0
Hypophosphataemia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Metabolic acidosis	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Acidosis	1 (4.5)	0	0	0	1 (4.5)
Hyperkalaemia	1 (4.5)	0	0	1 (4.5)	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (31.8)	5 (22.7)	1 (4.5)	1 (4.5)	0
Pain in extremity	3 (13.6)	3 (13.6)	0	0	0
Arthralgia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Back pain	1 (4.5)	1 (4.5)	0	0	0
Myalgia	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (27.3)	3 (13.6)	2 (9.1)	1 (4.5)	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Headache	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Somnolence	1 (4.5)	0	0	1 (4.5)	0
Psychiatric disorders					
-Total	7 (31.8)	2 (9.1)	1 (4.5)	4 (18.2)	0
Delirium	4 (18.2)	1 (4.5)	0	3 (13.6)	0
Agitation	2 (9.1)	0	2 (9.1)	0	0
Anxiety	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Confusional state	2 (9.1)	2 (9.1)	0	0	0
Renal and urinary disorders					
-Total	4 (18.2)	0	1 (4.5)	1 (4.5)	2 (9.1)
Acute kidney injury	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Urinary retention	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (59.1)	3 (13.6)	1 (4.5)	2 (9.1)	7 (31.8)
Hypoxia	6 (27.3)	0	1 (4.5)	2 (9.1)	3 (13.6)
Pulmonary oedema	6 (27.3)	1 (4.5)	2 (9.1)	2 (9.1)	1 (4.5)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	4 (18.2)	4 (18.2)	0	0	0
Pleural effusion	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Respiratory failure	3 (13.6)	0	0	0	3 (13.6)
Respiratory distress	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Tachypnoea	2 (9.1)	2 (9.1)	0	0	0
Acute respiratory distress syndrome	1 (4.5)	0	0	0	1 (4.5)
Atelectasis	1 (4.5)	0	0	1 (4.5)	0
Rhinorrhoea	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (22.7)	3 (13.6)	2 (9.1)	0	0
Pruritus	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Dry skin	1 (4.5)	1 (4.5)	0	0	0
Erythema	1 (4.5)	1 (4.5)	0	0	0
Hyperhidrosis	1 (4.5)	0	1 (4.5)	0	0
Vascular disorders					
-Total	8 (36.4)	0	2 (9.1)	3 (13.6)	3 (13.6)
Hypotension	8 (36.4)	0	2 (9.1)	3 (13.6)	3 (13.6)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (94.1)	0	3 (17.6)	3 (17.6)	10 (58.8)
Blood and lymphatic system disorders					
-Total	11 (64.7)	0	1 (5.9)	8 (47.1)	2 (11.8)
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Anaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Neutropenia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Splenomegaly	2 (11.8)	2 (11.8)	0	0	0
Disseminated intravascular coagulation	1 (5.9)	0	0	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Cardiac disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (29.4)	3 (17.6)	1 (5.9)	0	1 (5.9)
Tachycardia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Cardiac arrest	1 (5.9)	0	0	0	1 (5.9)
Sinus tachycardia	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	7 (41.2)	5 (29.4)	2 (11.8)	0	0
Vomiting	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Constipation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Diarrhoea	2 (11.8)	2 (11.8)	0	0	0
Nausea	2 (11.8)	2 (11.8)	0	0	0
Pancreatitis	1 (5.9)	0	1 (5.9)	0	0
General disorders and administration site conditions					
-Total	9 (52.9)	5 (29.4)	2 (11.8)	2 (11.8)	0
Pyrexia	5 (29.4)	2 (11.8)	1 (5.9)	2 (11.8)	0
Fatigue	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Generalised oedema	2 (11.8)	2 (11.8)	0	0	0
Face oedema	1 (5.9)	1 (5.9)	0	0	0
Oedema peripheral	1 (5.9)	1 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Cytokine release syndrome	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	2 (11.8)	0	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Procedural pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Wound	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	11 (64.7)	0	1 (5.9)	3 (17.6)	7 (41.2)
Aspartate aminotransferase increased	5 (29.4)	1 (5.9)	3 (17.6)	0	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (29.4)	0	1 (5.9)	2 (11.8)	2 (11.8)
White blood cell count decreased	5 (29.4)	0	0	0	5 (29.4)
Alanine aminotransferase increased	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Activated partial thromboplastin time prolonged	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Blood bilirubin increased	3 (17.6)	0	0	3 (17.6)	0
Lymphocyte count decreased	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Neutrophil count decreased	3 (17.6)	0	0	0	3 (17.6)
Blood creatinine increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Blood fibrinogen decreased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Gamma-glutamyltransferase increased	2 (11.8)	0	0	2 (11.8)	0
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Weight increased	1 (5.9)	1 (5.9)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (52.9)	0	1 (5.9)	5 (29.4)	3 (17.6)
Hypokalaemia	5 (29.4)	0	0	4 (23.5)	1 (5.9)
Hypophosphataemia	5 (29.4)	0	1 (5.9)	3 (17.6)	1 (5.9)
Decreased appetite	4 (23.5)	1 (5.9)	1 (5.9)	2 (11.8)	0
Hypocalcaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Hypoalbuminaemia	3 (17.6)	0	3 (17.6)	0	0
Hyperphosphataemia	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Hyperkalaemia	1 (5.9)	0	0	0	1 (5.9)
Hyperuricaemia	1 (5.9)	1 (5.9)	0	0	0
Hypervolaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Hyponatraemia	1 (5.9)	1 (5.9)	0	0	0
Metabolic acidosis	1 (5.9)	0	0	0	1 (5.9)
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Arthralgia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Myalgia	1 (5.9)	0	1 (5.9)	0	0
Pain in extremity	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					
-Total	5 (29.4)	0	4 (23.5)	1 (5.9)	0
Headache	5 (29.4)	0	5 (29.4)	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Somnolence	1 (5.9)	0	0	1 (5.9)	0
Tremor	1 (5.9)	0	1 (5.9)	0	0
Psychiatric disorders					
-Total	5 (29.4)	3 (17.6)	2 (11.8)	0	0
Confusional state	3 (17.6)	3 (17.6)	0	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Delirium	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Anxiety	1 (5.9)	0	1 (5.9)	0	0
Renal and urinary disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Acute kidney injury	1 (5.9)	0	0	1 (5.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	8 (47.1)	3 (17.6)	1 (5.9)	2 (11.8)	2 (11.8)
Hypoxia	3 (17.6)	0	1 (5.9)	1 (5.9)	1 (5.9)
Cough	2 (11.8)	2 (11.8)	0	0	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0	0	0
Pleural effusion	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Tachypnoea	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Epistaxis	1 (5.9)	0	1 (5.9)	0	0
Nasal congestion	1 (5.9)	0	1 (5.9)	0	0
Pulmonary oedema	1 (5.9)	0	1 (5.9)	0	0
Respiratory distress	1 (5.9)	0	1 (5.9)	0	0
Respiratory failure	1 (5.9)	0	0	0	1 (5.9)
Wheezing	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Petechiae	1 (5.9)	0	1 (5.9)	0	0
Pruritus	1 (5.9)	1 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	7 (41.2)	0	2 (11.8)	3 (17.6)	2 (11.8)
Hypotension	5 (29.4)	0	2 (11.8)	1 (5.9)	2 (11.8)
Hypertension	3 (17.6)	0	1 (5.9)	2 (11.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (100)	1 (2.9)	2 (5.7)	16 (45.7)	16 (45.7)
Blood and lymphatic system disorders					
-Total	20 (57.1)	1 (2.9)	4 (11.4)	12 (34.3)	3 (8.6)
Anaemia	10 (28.6)	2 (5.7)	2 (5.7)	6 (17.1)	0
Febrile neutropenia	9 (25.7)	0	0	9 (25.7)	0
Neutropenia	4 (11.4)	0	1 (2.9)	1 (2.9)	2 (5.7)
Disseminated intravascular coagulation	3 (8.6)	0	3 (8.6)	0	0
Thrombocytopenia	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Coagulopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Splenomegaly	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Tachycardia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Sinus tachycardia	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Eyelid oedema	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	22 (62.9)	9 (25.7)	10 (28.6)	3 (8.6)	0
Diarrhoea	11 (31.4)	5 (14.3)	5 (14.3)	1 (2.9)	0
Vomiting	11 (31.4)	6 (17.1)	5 (14.3)	0	0
Nausea	9 (25.7)	5 (14.3)	3 (8.6)	1 (2.9)	0
Abdominal pain	7 (20.0)	1 (2.9)	5 (14.3)	1 (2.9)	0
Constipation	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Abdominal distension	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Ascites	2 (5.7)	1 (2.9)	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Pancreatitis	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	14 (40.0)	8 (22.9)	3 (8.6)	2 (5.7)	1 (2.9)
Pyrexia	11 (31.4)	6 (17.1)	2 (5.7)	2 (5.7)	1 (2.9)
Fatigue	5 (14.3)	5 (14.3)	0	0	0
Chills	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Face oedema	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Catheter site pain	1 (2.9)	0	0	1 (2.9)	0
Generalised oedema	1 (2.9)	0	1 (2.9)	0	0
Pain	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Cholelithiasis	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	30 (85.7)	2 (5.7)	7 (20.0)	12 (34.3)	9 (25.7)
Cytokine release syndrome	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)
Hypogammaglobulinaemia	10 (28.6)	0	6 (17.1)	4 (11.4)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	9 (25.7)	2 (5.7)	3 (8.6)	4 (11.4)	0
Nail infection	2 (5.7)	2 (5.7)	0	0	0
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Conjunctivitis	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	0	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Sinusitis	1 (2.9)	0	0	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	1 (2.9)	0	1 (2.9)	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Investigations					
-Total	20 (57.1)	3 (8.6)	2 (5.7)	6 (17.1)	9 (25.7)
Neutrophil count decreased	10 (28.6)	0	3 (8.6)	1 (2.9)	6 (17.1)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (28.6)	3 (8.6)	1 (2.9)	3 (8.6)	3 (8.6)
White blood cell count decreased	9 (25.7)	3 (8.6)	1 (2.9)	0	5 (14.3)
Alanine aminotransferase increased	8 (22.9)	3 (8.6)	2 (5.7)	3 (8.6)	0
Lymphocyte count decreased	7 (20.0)	2 (5.7)	0	2 (5.7)	3 (8.6)
Aspartate aminotransferase increased	5 (14.3)	1 (2.9)	1 (2.9)	2 (5.7)	1 (2.9)
Serum ferritin increased	4 (11.4)	0	3 (8.6)	1 (2.9)	0
International normalised ratio increased	3 (8.6)	3 (8.6)	0	0	0
Blood bilirubin increased	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0	0	0
Blood creatine phosphokinase increased	1 (2.9)	0	0	1 (2.9)	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0	0	0
Weight increased	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	17 (48.6)	6 (17.1)	4 (11.4)	6 (17.1)	1 (2.9)
Decreased appetite	11 (31.4)	6 (17.1)	1 (2.9)	3 (8.6)	1 (2.9)
Hypokalaemia	8 (22.9)	2 (5.7)	2 (5.7)	4 (11.4)	0
Hypophosphataemia	6 (17.1)	2 (5.7)	2 (5.7)	2 (5.7)	0
Hyperglycaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Hypoalbuminaemia	3 (8.6)	0	3 (8.6)	0	0
Hypocalcaemia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Hypomagnesaemia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Hypermagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hypernatraemia	1 (2.9)	1 (2.9)	0	0	0
Hyperphosphataemia	1 (2.9)	1 (2.9)	0	0	0
Hyperuricaemia	1 (2.9)	0	1 (2.9)	0	0
Hypervolaemia	1 (2.9)	0	1 (2.9)	0	0
Hyponatraemia	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	17 (48.6)	6 (17.1)	10 (28.6)	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	7 (20.0)	3 (8.6)	4 (11.4)	0	0
Arthralgia	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Myalgia	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Back pain	5 (14.3)	1 (2.9)	3 (8.6)	1 (2.9)	0
Nervous system disorders					
-Total	16 (45.7)	9 (25.7)	4 (11.4)	3 (8.6)	0
Headache	12 (34.3)	8 (22.9)	2 (5.7)	2 (5.7)	0
Tremor	4 (11.4)	4 (11.4)	0	0	0
Encephalopathy	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Psychiatric disorders					
-Total	6 (17.1)	2 (5.7)	3 (8.6)	1 (2.9)	0
Anxiety	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Agitation	1 (2.9)	1 (2.9)	0	0	0
Confusional state	1 (2.9)	1 (2.9)	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders					
-Total	16 (45.7)	6 (17.1)	2 (5.7)	6 (17.1)	2 (5.7)
Hypoxia	7 (20.0)	0	3 (8.6)	2 (5.7)	2 (5.7)
Pulmonary oedema	5 (14.3)	1 (2.9)	0	4 (11.4)	0
Cough	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Epistaxis	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Oropharyngeal pain	3 (8.6)	3 (8.6)	0	0	0
Dyspnoea	2 (5.7)	0	0	2 (5.7)	0
Pleural effusion	2 (5.7)	2 (5.7)	0	0	0
Tachypnoea	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Atelectasis	1 (2.9)	0	1 (2.9)	0	0
Nasal congestion	1 (2.9)	1 (2.9)	0	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (20.0)	1 (2.9)	6 (17.1)	0	0
Rash	3 (8.6)	1 (2.9)	2 (5.7)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema	2 (5.7)	2 (5.7)	0	0	0
Pruritus	2 (5.7)	0	2 (5.7)	0	0
Hyperhidrosis	1 (2.9)	0	1 (2.9)	0	0
Skin ulcer	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	10 (28.6)	4 (11.4)	3 (8.6)	3 (8.6)	0
Hypotension	6 (17.1)	1 (2.9)	2 (5.7)	3 (8.6)	0
Hypertension	5 (14.3)	3 (8.6)	2 (5.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Lymphocytosis	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	0	2 (40.0)	0	0
Gastroenteritis	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal infection	1 (20.0)	1 (20.0)	0	0	0
Otitis externa	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Fibula fracture	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	1 (20.0)	0
White blood cell count decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Persistent depressive disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Dry skin	2 (40.0)	2 (40.0)	0	0	0
Skin hypopigmentation	1 (20.0)	1 (20.0)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (85.0)	4 (20.0)	3 (15.0)	5 (25.0)	5 (25.0)
Blood and lymphatic system disorders					
-Total	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Anaemia	1 (5.0)	0	0	1 (5.0)	0
Cardiac disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Tachycardia	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	7 (35.0)	5 (25.0)	2 (10.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	4 (20.0)	4 (20.0)	0	0	0
Vomiting	4 (20.0)	4 (20.0)	0	0	0
Nausea	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	6 (30.0)	3 (15.0)	2 (10.0)	1 (5.0)	0
Pyrexia	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Fatigue	1 (5.0)	1 (5.0)	0	0	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	7 (35.0)	3 (15.0)	2 (10.0)	1 (5.0)	1 (5.0)
Nasopharyngitis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Parainfluenzae virus infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rhinovirus infection	2 (10.0)	0	2 (10.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (10.0)	2 (10.0)	0	0	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	8 (40.0)	3 (15.0)	1 (5.0)	3 (15.0)	1 (5.0)
White blood cell count decreased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	3 (15.0)	0	0	0
Neutrophil count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Blood bilirubin increased	1 (5.0)	0	0	1 (5.0)	0
Blood creatinine increased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Oxygen saturation decreased	1 (5.0)	0	1 (5.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	3 (15.0)	0	1 (5.0)	1 (5.0)	1 (5.0)
Decreased appetite	1 (5.0)	0	1 (5.0)	0	0
Hypervolaemia	1 (5.0)	0	0	1 (5.0)	0
Metabolic acidosis	1 (5.0)	0	0	0	1 (5.0)
Musculoskeletal and connective tissue disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Arthralgia	1 (5.0)	0	1 (5.0)	0	0
Back pain	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Headache	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Psychiatric disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (30.0)	3 (15.0)	0	1 (5.0)	2 (10.0)
Cough	2 (10.0)	2 (10.0)	0	0	0
Epistaxis	1 (5.0)	0	1 (5.0)	0	0
Hypoxia	1 (5.0)	0	0	1 (5.0)	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Respiratory distress	1 (5.0)	0	0	0	1 (5.0)
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Dry skin	1 (5.0)	1 (5.0)	0	0	0
Erythema	1 (5.0)	0	1 (5.0)	0	0
Pruritus	1 (5.0)	0	1 (5.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Hypertension	1 (5.0)	0	1 (5.0)	0	0
Hypotension	1 (5.0)	0	0	0	1 (5.0)

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (86.7)	2 (13.3)	4 (26.7)	3 (20.0)	4 (26.7)
Blood and lymphatic system disorders					
-Total	3 (20.0)	0	0	1 (6.7)	2 (13.3)
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Neutropenia	1 (6.7)	0	0	0	1 (6.7)
Thrombocytopenia	1 (6.7)	0	0	0	1 (6.7)
Cardiac disorders					
-Total	2 (13.3)	1 (6.7)	0	0	1 (6.7)
Cardiac arrest	1 (6.7)	0	0	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (6.7)	1 (6.7)	0	0	0
Endocrine disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Hypothyroidism	1 (6.7)	0	1 (6.7)	0	0
Gastrointestinal disorders					
-Total	4 (26.7)	2 (13.3)	1 (6.7)	1 (6.7)	0
Diarrhoea	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Constipation	1 (6.7)	0	1 (6.7)	0	0
Nausea	1 (6.7)	1 (6.7)	0	0	0
Pancreatitis	1 (6.7)	0	0	1 (6.7)	0
Vomiting	1 (6.7)	1 (6.7)	0	0	0
General disorders and administration site conditions					
-Total	7 (46.7)	4 (26.7)	2 (13.3)	1 (6.7)	0
Pyrexia	4 (26.7)	1 (6.7)	2 (13.3)	1 (6.7)	0
Fatigue	2 (13.3)	2 (13.3)	0	0	0
Oedema peripheral	1 (6.7)	1 (6.7)	0	0	0
Immune system disorders					
-Total	3 (20.0)	0	3 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	3 (20.0)	0	3 (20.0)	0	0
Infections and infestations					
-Total	6 (40.0)	1 (6.7)	4 (26.7)	1 (6.7)	0
Respiratory syncytial virus infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Respiratory tract infection	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Upper respiratory tract infection	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Nail infection	1 (6.7)	1 (6.7)	0	0	0
Nasopharyngitis	1 (6.7)	1 (6.7)	0	0	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Injury, poisoning and procedural complications					
-Total	1 (6.7)	1 (6.7)	0	0	0
Infusion related reaction	1 (6.7)	1 (6.7)	0	0	0
Investigations					
-Total	4 (26.7)	1 (6.7)	0	2 (13.3)	1 (6.7)
Neutrophil count decreased	2 (13.3)	1 (6.7)	0	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Platelet count decreased	1 (6.7)	0	0	0	1 (6.7)
Weight increased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	3 (20.0)	1 (6.7)	1 (6.7)	0	1 (6.7)
Decreased appetite	3 (20.0)	1 (6.7)	2 (13.3)	0	0
Hyperkalaemia	1 (6.7)	0	1 (6.7)	0	0
Hypokalaemia	1 (6.7)	0	0	0	1 (6.7)
Musculoskeletal and connective tissue disorders					
-Total	4 (26.7)	2 (13.3)	0	2 (13.3)	0
Pain in extremity	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Back pain	2 (13.3)	0	0	2 (13.3)	0
Arthralgia	1 (6.7)	1 (6.7)	0	0	0
Myalgia	1 (6.7)	0	1 (6.7)	0	0
Nervous system disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Headache	1 (6.7)	1 (6.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	3 (20.0)	0	3 (20.0)	0	0
Anxiety	3 (20.0)	0	3 (20.0)	0	0
Delirium	1 (6.7)	0	1 (6.7)	0	0
Renal and urinary disorders					
-Total	1 (6.7)	0	1 (6.7)	0	0
Acute kidney injury	1 (6.7)	0	1 (6.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Cough	1 (6.7)	0	1 (6.7)	0	0
Nasal congestion	1 (6.7)	0	1 (6.7)	0	0
Rhinorrhoea	1 (6.7)	1 (6.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (13.3)	2 (13.3)	0	0	0
Dry skin	1 (6.7)	1 (6.7)	0	0	0
Rash	1 (6.7)	1 (6.7)	0	0	0
Vascular disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	0	0	1 (6.7)	0
Hypotension	1 (6.7)	0	0	1 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (91.4)	5 (14.3)	12 (34.3)	8 (22.9)	7 (20.0)
Blood and lymphatic system disorders					
-Total	7 (20.0)	3 (8.6)	0	3 (8.6)	1 (2.9)
Anaemia	4 (11.4)	4 (11.4)	0	0	0
Neutropenia	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Disseminated intravascular coagulation	1 (2.9)	0	0	1 (2.9)	0
Febrile neutropenia	1 (2.9)	0	0	1 (2.9)	0
Thrombocytopenia	1 (2.9)	0	0	1 (2.9)	0
Cardiac disorders					
-Total	1 (2.9)	0	0	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.9)	0	0	0	1 (2.9)
Gastrointestinal disorders					
-Total	5 (14.3)	4 (11.4)	1 (2.9)	0	0
Constipation	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Mouth haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Nausea	1 (2.9)	1 (2.9)	0	0	0
Pancreatitis	1 (2.9)	1 (2.9)	0	0	0
Vomiting	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	9 (25.7)	6 (17.1)	2 (5.7)	1 (2.9)	0
Pyrexia	7 (20.0)	4 (11.4)	3 (8.6)	0	0
Fatigue	2 (5.7)	2 (5.7)	0	0	0
Chills	1 (2.9)	1 (2.9)	0	0	0
Pain	1 (2.9)	0	0	1 (2.9)	0
Immune system disorders					
-Total	6 (17.1)	0	6 (17.1)	0	0
Hypogammaglobulinaemia	6 (17.1)	0	6 (17.1)	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (42.9)	3 (8.6)	5 (14.3)	5 (14.3)	2 (5.7)
Gastroenteritis	4 (11.4)	2 (5.7)	0	2 (5.7)	0
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Rhinovirus infection	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Upper respiratory tract infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Pneumonia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Sinusitis	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Otitis externa	1 (2.9)	0	0	1 (2.9)	0
Otitis media	1 (2.9)	0	0	1 (2.9)	0
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (25.7)	1 (2.9)	3 (8.6)	3 (8.6)	2 (5.7)
Neutrophil count decreased	4 (11.4)	0	1 (2.9)	1 (2.9)	2 (5.7)
Lymphocyte count decreased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
White blood cell count decreased	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Alanine aminotransferase increased	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Blood bilirubin increased	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin a decreased	1 (2.9)	0	0	1 (2.9)	0
Blood immunoglobulin m decreased	1 (2.9)	0	0	1 (2.9)	0
Platelet count decreased	1 (2.9)	0	0	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	5 (14.3)	2 (5.7)	1 (2.9)	2 (5.7)	0
Decreased appetite	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Hyperuricaemia	2 (5.7)	2 (5.7)	0	0	0
Hypokalaemia	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Hypophosphataemia	1 (2.9)	0	1 (2.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	5 (14.3)	2 (5.7)	2 (5.7)	1 (2.9)	0
Back pain	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Pain in extremity	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Arthralgia	1 (2.9)	1 (2.9)	0	0	0
Nervous system disorders					
-Total	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Headache	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Psychiatric disorders					
-Total	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Anxiety	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Agitation	1 (2.9)	1 (2.9)	0	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	1 (2.9)	0	0	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	0	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (28.6)	4 (11.4)	3 (8.6)	2 (5.7)	1 (2.9)
Cough	7 (20.0)	5 (14.3)	2 (5.7)	0	0
Nasal congestion	3 (8.6)	3 (8.6)	0	0	0
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hypoxia	2 (5.7)	0	0	2 (5.7)	0
Acute respiratory distress syndrome	1 (2.9)	0	0	0	1 (2.9)
Dyspnoea	1 (2.9)	0	1 (2.9)	0	0
Pleural effusion	1 (2.9)	0	1 (2.9)	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (14.3)	2 (5.7)	2 (5.7)	1 (2.9)	0
Rash	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Dry skin	2 (5.7)	0	2 (5.7)	0	0
Decubitus ulcer	1 (2.9)	0	0	1 (2.9)	0
Vascular disorders					
-Total	2 (5.7)	1 (2.9)	0	0	1 (2.9)
Hypotension	2 (5.7)	1 (2.9)	0	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Irritable bowel syndrome	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=3 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis escherichia coli	1 (33.3)	0	0	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	0	1 (33.3)	0
Rhinovirus infection	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (38.5)	1 (7.7)	2 (15.4)	1 (7.7)	1 (7.7)
Gastrointestinal disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Constipation	1 (7.7)	1 (7.7)	0	0	0
Diarrhoea	1 (7.7)	1 (7.7)	0	0	0
General disorders and administration site conditions					
-Total	1 (7.7)	0	0	0	1 (7.7)
Multiple organ dysfunction syndrome	1 (7.7)	0	0	0	1 (7.7)
Pyrexia	1 (7.7)	0	1 (7.7)	0	0
Immune system disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.7)	0	0	0	1 (7.7)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	0	0	1 (7.7)
Infections and infestations					
-Total	4 (30.8)	1 (7.7)	1 (7.7)	1 (7.7)	1 (7.7)
Conjunctivitis	1 (7.7)	1 (7.7)	0	0	0
Gastroenteritis	1 (7.7)	1 (7.7)	0	0	0
Parainfluenzae virus infection	1 (7.7)	0	0	1 (7.7)	0
Pneumonia	1 (7.7)	0	0	0	1 (7.7)
Rhinovirus infection	1 (7.7)	0	0	1 (7.7)	0
Staphylococcal bacteraemia	1 (7.7)	0	0	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	0	1 (7.7)	0	0
Injury, poisoning and procedural complications					
-Total	1 (7.7)	0	0	1 (7.7)	0
Infusion related reaction	1 (7.7)	0	0	1 (7.7)	0
Investigations					
-Total	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (7.7)	0	1 (7.7)	0	0
Oxygen saturation decreased	1 (7.7)	0	0	1 (7.7)	0
Platelet count decreased	1 (7.7)	1 (7.7)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (7.7)	0	0	1 (7.7)	0
Hyperglycaemia	1 (7.7)	0	0	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (7.7)	0	0	0	1 (7.7)
Cough	1 (7.7)	1 (7.7)	0	0	0
Dyspnoea	1 (7.7)	0	0	0	1 (7.7)
Pleural effusion	1 (7.7)	0	1 (7.7)	0	0
Tachypnoea	1 (7.7)	0	0	0	1 (7.7)
Skin and subcutaneous tissue disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0
Rash	1 (7.7)	1 (7.7)	0	0	0
Vascular disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (7.7)	0	0	1 (7.7)	0
Hypertension	1 (7.7)	0	0	1 (7.7)	0

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Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (54.5)	1 (9.1)	4 (36.4)	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Hypothyroidism	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Diarrhoea	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Nausea	1 (9.1)	1 (9.1)	0	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	1 (9.1)	0	0
Fatigue	1 (9.1)	0	1 (9.1)	0	0
Immune system disorders					
-Total	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Seasonal allergy	3 (27.3)	2 (18.2)	1 (9.1)	0	0
Hypogammaglobulinaemia	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	2 (18.2)	0	2 (18.2)	0	0
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Nail infection	1 (9.1)	0	1 (9.1)	0	0
Otitis media	1 (9.1)	0	1 (9.1)	0	0
Rhinovirus infection	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	1 (9.1)	1 (9.1)	0	0	0
Neutrophil count decreased	1 (9.1)	1 (9.1)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	1 (9.1)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Rhinorrhoea	2 (18.2)	0	2 (18.2)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Dyspnoea	1 (9.1)	0	1 (9.1)	0	0
Hypoxia	1 (9.1)	0	0	1 (9.1)	0
Wheezing	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Rash	1 (9.1)	0	1 (9.1)	0	0
Vascular disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=11 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

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Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (56.5)	3 (13.0)	4 (17.4)	2 (8.7)	4 (17.4)
Blood and lymphatic system disorders					
-Total	2 (8.7)	0	1 (4.3)	0	1 (4.3)
Anaemia	1 (4.3)	0	1 (4.3)	0	0
Neutropenia	1 (4.3)	0	0	0	1 (4.3)
Thrombocytopenia	1 (4.3)	0	1 (4.3)	0	0
Eye disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Eyelid oedema	1 (4.3)	1 (4.3)	0	0	0
Gastrointestinal disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Diarrhoea	2 (8.7)	1 (4.3)	0	1 (4.3)	0
General disorders and administration site conditions					
-Total	4 (17.4)	2 (8.7)	1 (4.3)	1 (4.3)	0
Pyrexia	3 (13.0)	2 (8.7)	0	1 (4.3)	0
Pain	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Immune system disorders					
-Total	2 (8.7)	0	2 (8.7)	0	0
Hypogammaglobulinaemia	2 (8.7)	0	2 (8.7)	0	0
Infections and infestations					
-Total	8 (34.8)	3 (13.0)	4 (17.4)	1 (4.3)	0
Conjunctivitis	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Sinusitis	3 (13.0)	0	3 (13.0)	0	0
Upper respiratory tract infection	3 (13.0)	2 (8.7)	0	1 (4.3)	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Rhinovirus infection	1 (4.3)	0	1 (4.3)	0	0
Investigations					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Neutrophil count decreased	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Blood bilirubin increased	1 (4.3)	1 (4.3)	0	0	0
Platelet count decreased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Decreased appetite	1 (4.3)	0	0	0	1 (4.3)
Hypernatraemia	1 (4.3)	0	0	1 (4.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (8.7)	0	2 (8.7)	0	0
Pain in extremity	2 (8.7)	0	2 (8.7)	0	0
Nervous system disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Headache	1 (4.3)	0	0	1 (4.3)	0
Psychiatric disorders					
-Total	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Anxiety	2 (8.7)	1 (4.3)	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=23 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	4 (17.4)	3 (13.0)	0	0	1 (4.3)
Cough	2 (8.7)	2 (8.7)	0	0	0
Dyspnoea	1 (4.3)	1 (4.3)	0	0	0
Epistaxis	1 (4.3)	1 (4.3)	0	0	0
Oropharyngeal pain	1 (4.3)	1 (4.3)	0	0	0
Respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Rhinorrhoea	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Dry skin	1 (4.3)	1 (4.3)	0	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders					
-Total	5 (83.3)	0	1 (16.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Anaemia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Coagulopathy	1 (16.7)	0	0	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	0	0	1 (16.7)	0
Lymphocytosis	1 (16.7)	0	1 (16.7)	0	0
Thrombocytopenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Tachycardia	3 (50.0)	1 (16.7)	1 (16.7)	0	1 (16.7)
Sinus tachycardia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Eyelid oedema	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Abdominal distension	1 (16.7)	0	1 (16.7)	0	0
Ascites	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
Irritable bowel syndrome	1 (16.7)	0	1 (16.7)	0	0
Melaena	1 (16.7)	0	0	1 (16.7)	0
Mouth haemorrhage	1 (16.7)	0	1 (16.7)	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	4 (66.7)	1 (16.7)	1 (16.7)	1 (16.7)	1 (16.7)
Pyrexia	3 (50.0)	0	2 (33.3)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	2 (33.3)	2 (33.3)	0	0	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	1 (16.7)	0	0	0
Face oedema	1 (16.7)	0	1 (16.7)	0	0
Generalised oedema	1 (16.7)	0	1 (16.7)	0	0
Multiple organ dysfunction syndrome	1 (16.7)	0	0	0	1 (16.7)
Oedema peripheral	1 (16.7)	0	1 (16.7)	0	0
Systemic inflammatory response syndrome	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Cholelithiasis	1 (16.7)	1 (16.7)	0	0	0
Cholestasis	1 (16.7)	0	0	0	1 (16.7)
Gallbladder enlargement	1 (16.7)	1 (16.7)	0	0	0
Immune system disorders					
-Total	5 (83.3)	0	3 (50.0)	0	2 (33.3)
Cytokine release syndrome	5 (83.3)	1 (16.7)	2 (33.3)	0	2 (33.3)
Hypogammaglobulinaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	0	0	1 (16.7)
Seasonal allergy	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Encephalitis	1 (16.7)	0	0	0	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0	0	0
Gastroenteritis escherichia coli	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal infection	1 (16.7)	1 (16.7)	0	0	0
Localised infection	1 (16.7)	1 (16.7)	0	0	0
Otitis externa	1 (16.7)	0	1 (16.7)	0	0
Pneumonia	1 (16.7)	0	0	1 (16.7)	0
Rhinovirus infection	1 (16.7)	0	1 (16.7)	0	0
Sinusitis	1 (16.7)	0	1 (16.7)	0	0
Upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (50.0)	0	2 (33.3)	0	1 (16.7)
Fibula fracture	1 (16.7)	0	1 (16.7)	0	0
Infusion related reaction	1 (16.7)	0	1 (16.7)	0	0
Skin injury	1 (16.7)	0	1 (16.7)	0	0
Skin wound	1 (16.7)	1 (16.7)	0	0	0
Vasoplegia syndrome	1 (16.7)	0	0	0	1 (16.7)
Wound	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	0	1 (16.7)	2 (33.3)
White blood cell count decreased	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	0	0	1 (16.7)	0
Blood alkaline phosphatase increased	1 (16.7)	1 (16.7)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (16.7)	0	0	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	0	0	1 (16.7)
Blood creatinine increased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin g decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	0	1 (16.7)	0	0
Electrocardiogram qt prolonged	1 (16.7)	0	1 (16.7)	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	0	0	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	5 (83.3)	1 (16.7)	1 (16.7)	2 (33.3)	1 (16.7)
Hypophosphataemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Decreased appetite	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Hypocalcaemia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Acidosis	1 (16.7)	0	0	1 (16.7)	0
Haemosiderosis	1 (16.7)	0	1 (16.7)	0	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)	0	0
Hyperlactacidaemia	1 (16.7)	1 (16.7)	0	0	0
Hypermagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hypernatraemia	1 (16.7)	0	0	0	1 (16.7)
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)	0	0
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Hypomagnesaemia	1 (16.7)	1 (16.7)	0	0	0
Hyponatraemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Myositis	1 (16.7)	0	1 (16.7)	0	0
Rhabdomyolysis	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (66.7)	1 (16.7)	2 (33.3)	1 (16.7)	0
Headache	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Encephalopathy	1 (16.7)	0	0	1 (16.7)	0
Monoparesis	1 (16.7)	0	1 (16.7)	0	0
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Tremor	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Confusional state	1 (16.7)	1 (16.7)	0	0	0
Persistent depressive disorder	1 (16.7)	0	1 (16.7)	0	0
Sleep disorder	1 (16.7)	0	1 (16.7)	0	0
Renal and urinary disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Bladder dilatation	1 (16.7)	0	1 (16.7)	0	0
Renal tubular necrosis	1 (16.7)	0	0	0	1 (16.7)
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Reproductive system and breast disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	1 (16.7)	0
Vaginal ulceration	1 (16.7)	0	0	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (50.0)	1 (16.7)	0	1 (16.7)	1 (16.7)
Nasal congestion	2 (33.3)	2 (33.3)	0	0	0
Tachypnoea	2 (33.3)	0	0	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	0	0	1 (16.7)
Acute respiratory failure	1 (16.7)	0	0	1 (16.7)	0
Atelectasis	1 (16.7)	0	0	1 (16.7)	0
Cough	1 (16.7)	1 (16.7)	0	0	0
Dyspnoea	1 (16.7)	0	0	0	1 (16.7)
Hypoxia	1 (16.7)	0	0	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0	0	0
Respiratory acidosis	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	4 (66.7)	3 (50.0)	0	1 (16.7)	0
Dry skin	2 (33.3)	2 (33.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Decubitus ulcer	1 (16.7)	0	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Hyperhidrosis	1 (16.7)	1 (16.7)	0	0	0
Petechiae	1 (16.7)	0	0	1 (16.7)	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0
Skin hypopigmentation	1 (16.7)	1 (16.7)	0	0	0
Skin necrosis	1 (16.7)	0	0	1 (16.7)	0
Skin ulcer	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	0	0	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	0	3 (13.6)	2 (9.1)	17 (77.3)
Blood and lymphatic system disorders					
-Total	14 (63.6)	2 (9.1)	2 (9.1)	4 (18.2)	6 (27.3)
Anaemia	6 (27.3)	2 (9.1)	2 (9.1)	2 (9.1)	0
Febrile neutropenia	6 (27.3)	0	0	5 (22.7)	1 (4.5)
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Coagulopathy	2 (9.1)	0	2 (9.1)	0	0
Disseminated intravascular coagulation	2 (9.1)	0	2 (9.1)	0	0
Splenomegaly	1 (4.5)	1 (4.5)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	7 (31.8)	2 (9.1)	3 (13.6)	2 (9.1)	0
Tachycardia	7 (31.8)	2 (9.1)	3 (13.6)	2 (9.1)	0
Endocrine disorders					
-Total	4 (18.2)	0	4 (18.2)	0	0
Adrenal insufficiency	3 (13.6)	0	3 (13.6)	0	0
Hypothyroidism	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	17 (77.3)	5 (22.7)	7 (31.8)	5 (22.7)	0
Vomiting	10 (45.5)	7 (31.8)	2 (9.1)	1 (4.5)	0
Nausea	8 (36.4)	2 (9.1)	5 (22.7)	1 (4.5)	0
Diarrhoea	6 (27.3)	5 (22.7)	1 (4.5)	0	0
Constipation	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Abdominal pain	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Pancreatitis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Mouth haemorrhage	1 (4.5)	0	0	1 (4.5)	0
General disorders and administration site conditions					
-Total	12 (54.5)	3 (13.6)	3 (13.6)	3 (13.6)	3 (13.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	8 (36.4)	2 (9.1)	3 (13.6)	2 (9.1)	1 (4.5)
Oedema peripheral	4 (18.2)	3 (13.6)	0	1 (4.5)	0
Face oedema	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Fatigue	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Multiple organ dysfunction syndrome	2 (9.1)	0	0	0	2 (9.1)
Chills	1 (4.5)	1 (4.5)	0	0	0
Generalised oedema	1 (4.5)	0	1 (4.5)	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Hepatobiliary disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Gallbladder enlargement	1 (4.5)	1 (4.5)	0	0	0
Immune system disorders					
-Total	20 (90.9)	1 (4.5)	7 (31.8)	5 (22.7)	7 (31.8)
Cytokine release syndrome	15 (68.2)	1 (4.5)	4 (18.2)	4 (18.2)	6 (27.3)
Hypogammaglobulinaemia	10 (45.5)	1 (4.5)	8 (36.4)	1 (4.5)	0
Haemophagocytic lymphohistiocytosis	3 (13.6)	0	0	2 (9.1)	1 (4.5)
Infections and infestations					

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (59.1)	4 (18.2)	4 (18.2)	3 (13.6)	2 (9.1)
Clostridium difficile infection	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Parainfluenzae virus infection	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Staphylococcal bacteraemia	3 (13.6)	0	0	3 (13.6)	0
Upper respiratory tract infection	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Nasopharyngitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pneumonia	2 (9.1)	0	0	0	2 (9.1)
Gastroenteritis	1 (4.5)	1 (4.5)	0	0	0
Otitis media	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	0	1 (4.5)	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.5)	0	0	1 (4.5)	0
Infusion related reaction	1 (4.5)	0	0	1 (4.5)	0
Investigations					
-Total	17 (77.3)	1 (4.5)	1 (4.5)	6 (27.3)	9 (40.9)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	9 (40.9)	1 (4.5)	1 (4.5)	2 (9.1)	5 (22.7)
Aspartate aminotransferase increased	8 (36.4)	0	2 (9.1)	5 (22.7)	1 (4.5)
Platelet count decreased	7 (31.8)	3 (13.6)	1 (4.5)	1 (4.5)	2 (9.1)
Blood bilirubin increased	6 (27.3)	0	1 (4.5)	5 (22.7)	0
Alanine aminotransferase increased	5 (22.7)	1 (4.5)	4 (18.2)	0	0
Lymphocyte count decreased	5 (22.7)	0	0	4 (18.2)	1 (4.5)
Neutrophil count decreased	5 (22.7)	0	0	1 (4.5)	4 (18.2)
Blood fibrinogen decreased	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Serum ferritin increased	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Activated partial thromboplastin time prolonged	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin a decreased	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Blood immunoglobulin g decreased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Blood immunoglobulin m decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
International normalised ratio increased	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Oxygen saturation decreased	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Blood creatinine increased	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Lipase increased	1 (4.5)	1 (4.5)	0	0	0
Weight increased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	14 (63.6)	1 (4.5)	3 (13.6)	7 (31.8)	3 (13.6)
Decreased appetite	8 (36.4)	1 (4.5)	2 (9.1)	5 (22.7)	0
Hypocalcaemia	7 (31.8)	1 (4.5)	4 (18.2)	2 (9.1)	0
Hyperglycaemia	5 (22.7)	0	2 (9.1)	3 (13.6)	0
Hypervolaemia	5 (22.7)	0	0	5 (22.7)	0
Hypokalaemia	5 (22.7)	1 (4.5)	3 (13.6)	1 (4.5)	0
Hypoalbuminaemia	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Hyperuricaemia	3 (13.6)	3 (13.6)	0	0	0
Hypophosphataemia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Metabolic acidosis	3 (13.6)	1 (4.5)	0	0	2 (9.1)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Acidosis	1 (4.5)	0	0	0	1 (4.5)
Hyperkalaemia	1 (4.5)	0	0	1 (4.5)	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (31.8)	4 (18.2)	2 (9.1)	1 (4.5)	0
Pain in extremity	3 (13.6)	3 (13.6)	0	0	0
Arthralgia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Back pain	1 (4.5)	0	1 (4.5)	0	0
Myalgia	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					
-Total	7 (31.8)	4 (18.2)	2 (9.1)	1 (4.5)	0
Headache	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Somnolence	1 (4.5)	0	0	1 (4.5)	0
Psychiatric disorders					
-Total	8 (36.4)	2 (9.1)	2 (9.1)	4 (18.2)	0
Delirium	4 (18.2)	1 (4.5)	0	3 (13.6)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Agitation	2 (9.1)	0	2 (9.1)	0	0
Confusional state	2 (9.1)	2 (9.1)	0	0	0
Renal and urinary disorders					
-Total	5 (22.7)	1 (4.5)	1 (4.5)	1 (4.5)	2 (9.1)
Acute kidney injury	4 (18.2)	1 (4.5)	0	1 (4.5)	2 (9.1)
Urinary retention	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (72.7)	4 (18.2)	1 (4.5)	2 (9.1)	9 (40.9)
Hypoxia	7 (31.8)	0	1 (4.5)	3 (13.6)	3 (13.6)
Cough	6 (27.3)	6 (27.3)	0	0	0
Pulmonary oedema	6 (27.3)	1 (4.5)	2 (9.1)	2 (9.1)	1 (4.5)
Pleural effusion	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Respiratory failure	4 (18.2)	0	0	0	4 (18.2)
Respiratory distress	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Tachypnoea	3 (13.6)	2 (9.1)	0	0	1 (4.5)
Acute respiratory distress syndrome	1 (4.5)	0	0	0	1 (4.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	1 (4.5)	0	0	1 (4.5)	0
Dyspnoea	1 (4.5)	0	0	0	1 (4.5)
Epistaxis	1 (4.5)	0	1 (4.5)	0	0
Nasal congestion	1 (4.5)	1 (4.5)	0	0	0
Oropharyngeal pain	1 (4.5)	0	1 (4.5)	0	0
Rhinorrhoea	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (40.9)	5 (22.7)	4 (18.2)	0	0
Pruritus	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Dry skin	2 (9.1)	2 (9.1)	0	0	0
Erythema	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hyperhidrosis	1 (4.5)	0	1 (4.5)	0	0
Rash	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					
-Total	10 (45.5)	0	2 (9.1)	4 (18.2)	4 (18.2)
Hypotension	9 (40.9)	0	2 (9.1)	3 (13.6)	4 (18.2)
Hypertension	6 (27.3)	1 (4.5)	3 (13.6)	2 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	3 (17.6)	3 (17.6)	11 (64.7)
Blood and lymphatic system disorders					
-Total	11 (64.7)	0	1 (5.9)	8 (47.1)	2 (11.8)
Febrile neutropenia	8 (47.1)	0	0	8 (47.1)	0
Anaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Neutropenia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Splenomegaly	2 (11.8)	2 (11.8)	0	0	0
Disseminated intravascular coagulation	1 (5.9)	0	0	1 (5.9)	0
Thrombocytopenia	1 (5.9)	0	0	0	1 (5.9)
Cardiac disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (35.3)	3 (17.6)	1 (5.9)	0	2 (11.8)
Tachycardia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Cardiac arrest	2 (11.8)	0	0	0	2 (11.8)
Sinus tachycardia	1 (5.9)	1 (5.9)	0	0	0
Endocrine disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0
Hypothyroidism	2 (11.8)	0	2 (11.8)	0	0
Gastrointestinal disorders					
-Total	12 (70.6)	7 (41.2)	4 (23.5)	1 (5.9)	0
Diarrhoea	7 (41.2)	5 (29.4)	2 (11.8)	0	0
Vomiting	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Nausea	4 (23.5)	4 (23.5)	0	0	0
Constipation	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Pancreatitis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions					
-Total	14 (82.4)	7 (41.2)	4 (23.5)	3 (17.6)	0
Pyrexia	9 (52.9)	3 (17.6)	3 (17.6)	3 (17.6)	0
Fatigue	6 (35.3)	4 (23.5)	2 (11.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	2 (11.8)	2 (11.8)	0	0	0
Oedema peripheral	2 (11.8)	2 (11.8)	0	0	0
Face oedema	1 (5.9)	1 (5.9)	0	0	0
Immune system disorders					
-Total	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Cytokine release syndrome	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	6 (35.3)	1 (5.9)	4 (23.5)	1 (5.9)	0
Seasonal allergy	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	9 (52.9)	1 (5.9)	5 (29.4)	3 (17.6)	0
Upper respiratory tract infection	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Nail infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Otitis media	2 (11.8)	0	2 (11.8)	0	0
Respiratory syncytial virus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Sinusitis	2 (11.8)	0	2 (11.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal infection	2 (11.8)	0	2 (11.8)	0	0
Conjunctivitis	1 (5.9)	1 (5.9)	0	0	0
Nasopharyngitis	1 (5.9)	1 (5.9)	0	0	0
Rhinovirus infection	1 (5.9)	0	1 (5.9)	0	0
Injury, poisoning and procedural complications					
-Total	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Procedural pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Infusion related reaction	1 (5.9)	1 (5.9)	0	0	0
Wound	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	11 (64.7)	0	1 (5.9)	3 (17.6)	7 (41.2)
Aspartate aminotransferase increased	5 (29.4)	1 (5.9)	3 (17.6)	0	1 (5.9)
Platelet count decreased	5 (29.4)	0	1 (5.9)	2 (11.8)	2 (11.8)
White blood cell count decreased	5 (29.4)	0	0	0	5 (29.4)
Alanine aminotransferase increased	4 (23.5)	0	2 (11.8)	2 (11.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (23.5)	0	0	0	4 (23.5)
Activated partial thromboplastin time prolonged	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Blood bilirubin increased	3 (17.6)	0	0	3 (17.6)	0
Lymphocyte count decreased	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Blood creatinine increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Blood fibrinogen decreased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Gamma-glutamyltransferase increased	2 (11.8)	0	0	2 (11.8)	0
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0
Blood immunoglobulin m decreased	1 (5.9)	1 (5.9)	0	0	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Weight increased	1 (5.9)	0	0	1 (5.9)	0
Metabolism and nutrition disorders					
-Total	11 (64.7)	1 (5.9)	2 (11.8)	5 (29.4)	3 (17.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	7 (41.2)	2 (11.8)	3 (17.6)	2 (11.8)	0
Hypokalaemia	5 (29.4)	0	0	4 (23.5)	1 (5.9)
Hypophosphataemia	5 (29.4)	0	1 (5.9)	3 (17.6)	1 (5.9)
Hypocalcaemia	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Hypoalbuminaemia	3 (17.6)	0	3 (17.6)	0	0
Hyperkalaemia	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Hyperphosphataemia	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Hyperuricaemia	1 (5.9)	1 (5.9)	0	0	0
Hypervolaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Hyponatraemia	1 (5.9)	1 (5.9)	0	0	0
Metabolic acidosis	1 (5.9)	0	0	0	1 (5.9)
Musculoskeletal and connective tissue disorders					
-Total	8 (47.1)	3 (17.6)	3 (17.6)	2 (11.8)	0
Arthralgia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Pain in extremity	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Back pain	2 (11.8)	0	0	2 (11.8)	0
Myalgia	2 (11.8)	0	2 (11.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	5 (29.4)	0	4 (23.5)	1 (5.9)	0
Headache	5 (29.4)	0	5 (29.4)	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Somnolence	1 (5.9)	0	0	1 (5.9)	0
Tremor	1 (5.9)	0	1 (5.9)	0	0
Psychiatric disorders					
-Total	8 (47.1)	3 (17.6)	5 (29.4)	0	0
Anxiety	4 (23.5)	0	4 (23.5)	0	0
Confusional state	3 (17.6)	3 (17.6)	0	0	0
Delirium	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Renal and urinary disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Acute kidney injury	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (47.1)	3 (17.6)	1 (5.9)	2 (11.8)	2 (11.8)
Cough	4 (23.5)	2 (11.8)	2 (11.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Rhinorrhoea	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Nasal congestion	2 (11.8)	0	2 (11.8)	0	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0	0	0
Pleural effusion	2 (11.8)	1 (5.9)	0	0	1 (5.9)
Tachypnoea	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Wheezing	2 (11.8)	0	2 (11.8)	0	0
Dyspnoea	1 (5.9)	0	1 (5.9)	0	0
Epistaxis	1 (5.9)	0	1 (5.9)	0	0
Pulmonary oedema	1 (5.9)	0	1 (5.9)	0	0
Respiratory distress	1 (5.9)	0	1 (5.9)	0	0
Respiratory failure	1 (5.9)	0	0	0	1 (5.9)
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Dry skin	1 (5.9)	1 (5.9)	0	0	0
Petechiae	1 (5.9)	0	1 (5.9)	0	0
Pruritus	1 (5.9)	1 (5.9)	0	0	0
Rash	1 (5.9)	0	1 (5.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	9 (52.9)	0	3 (17.6)	4 (23.5)	2 (11.8)
Hypotension	6 (35.3)	0	2 (11.8)	2 (11.8)	2 (11.8)
Hypertension	4 (23.5)	0	2 (11.8)	2 (11.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 214r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (100)	1 (2.9)	1 (2.9)	14 (40.0)	19 (54.3)
Blood and lymphatic system disorders					
-Total	23 (65.7)	0	4 (11.4)	15 (42.9)	4 (11.4)
Anaemia	13 (37.1)	4 (11.4)	3 (8.6)	6 (17.1)	0
Febrile neutropenia	10 (28.6)	0	0	10 (28.6)	0
Neutropenia	6 (17.1)	0	1 (2.9)	2 (5.7)	3 (8.6)
Disseminated intravascular coagulation	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Thrombocytopenia	4 (11.4)	0	0	2 (5.7)	2 (5.7)
Coagulopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Splenomegaly	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	5 (14.3)	2 (5.7)	2 (5.7)	0	1 (2.9)
Tachycardia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Cardiac arrest	1 (2.9)	0	0	0	1 (2.9)
Sinus tachycardia	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Eyelid oedema	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	27 (77.1)	12 (34.3)	11 (31.4)	4 (11.4)	0
Diarrhoea	13 (37.1)	6 (17.1)	5 (14.3)	2 (5.7)	0
Vomiting	11 (31.4)	6 (17.1)	5 (14.3)	0	0
Nausea	9 (25.7)	5 (14.3)	3 (8.6)	1 (2.9)	0
Abdominal pain	7 (20.0)	1 (2.9)	5 (14.3)	1 (2.9)	0
Constipation	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Mouth haemorrhage	3 (8.6)	2 (5.7)	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal distension	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Ascites	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Pancreatitis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	18 (51.4)	10 (28.6)	4 (11.4)	3 (8.6)	1 (2.9)
Pyrexia	15 (42.9)	9 (25.7)	2 (5.7)	3 (8.6)	1 (2.9)
Fatigue	6 (17.1)	6 (17.1)	0	0	0
Chills	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Pain	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Face oedema	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Catheter site pain	1 (2.9)	0	0	1 (2.9)	0
Generalised oedema	1 (2.9)	0	1 (2.9)	0	0
Hepatobiliary disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Cholelithiasis	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	32 (91.4)	1 (2.9)	10 (28.6)	12 (34.3)	9 (25.7)
Cytokine release syndrome	29 (82.9)	3 (8.6)	8 (22.9)	9 (25.7)	9 (25.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	15 (42.9)	0	11 (31.4)	4 (11.4)	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	22 (62.9)	4 (11.4)	7 (20.0)	9 (25.7)	2 (5.7)
Upper respiratory tract infection	6 (17.1)	3 (8.6)	1 (2.9)	2 (5.7)	0
Conjunctivitis	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Gastroenteritis	4 (11.4)	2 (5.7)	0	2 (5.7)	0
Nasopharyngitis	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Rhinovirus infection	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Sinusitis	4 (11.4)	0	2 (5.7)	2 (5.7)	0
Pneumonia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Nail infection	2 (5.7)	2 (5.7)	0	0	0
Otitis externa	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Otitis media	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Staphylococcal infection	2 (5.7)	0	0	2 (5.7)	0
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (2.9)	0	0	0	1 (2.9)
Respiratory syncytial virus infection	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Investigations					
-Total	20 (57.1)	2 (5.7)	2 (5.7)	7 (20.0)	9 (25.7)
Neutrophil count decreased	12 (34.3)	1 (2.9)	2 (5.7)	2 (5.7)	7 (20.0)
Platelet count decreased	11 (31.4)	3 (8.6)	1 (2.9)	4 (11.4)	3 (8.6)
White blood cell count decreased	9 (25.7)	2 (5.7)	2 (5.7)	0	5 (14.3)
Alanine aminotransferase increased	8 (22.9)	2 (5.7)	2 (5.7)	4 (11.4)	0
Lymphocyte count decreased	8 (22.9)	1 (2.9)	1 (2.9)	3 (8.6)	3 (8.6)
Aspartate aminotransferase increased	5 (14.3)	1 (2.9)	1 (2.9)	2 (5.7)	1 (2.9)
Serum ferritin increased	4 (11.4)	0	3 (8.6)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Blood immunoglobulin a decreased	3 (8.6)	2 (5.7)	0	1 (2.9)	0
International normalised ratio increased	3 (8.6)	3 (8.6)	0	0	0
Blood immunoglobulin m decreased	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Blood creatine phosphokinase increased	1 (2.9)	0	0	1 (2.9)	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)	0	0
Weight increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	20 (57.1)	7 (20.0)	4 (11.4)	7 (20.0)	2 (5.7)
Decreased appetite	13 (37.1)	7 (20.0)	1 (2.9)	3 (8.6)	2 (5.7)
Hypokalaemia	9 (25.7)	2 (5.7)	3 (8.6)	4 (11.4)	0
Hypophosphataemia	7 (20.0)	2 (5.7)	3 (8.6)	2 (5.7)	0
Hyperglycaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Hyperuricaemia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Hypoalbuminaemia	3 (8.6)	0	3 (8.6)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Hypomagnesaemia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Hypernatraemia	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Hypermagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hyperphosphataemia	1 (2.9)	1 (2.9)	0	0	0
Hypervolaemia	1 (2.9)	0	1 (2.9)	0	0
Hyponatraemia	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	19 (54.3)	7 (20.0)	10 (28.6)	2 (5.7)	0
Pain in extremity	10 (28.6)	3 (8.6)	6 (17.1)	1 (2.9)	0
Back pain	7 (20.0)	2 (5.7)	4 (11.4)	1 (2.9)	0
Arthralgia	6 (17.1)	3 (8.6)	3 (8.6)	0	0
Myalgia	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Nervous system disorders					
-Total	19 (54.3)	9 (25.7)	6 (17.1)	4 (11.4)	0
Headache	15 (42.9)	8 (22.9)	4 (11.4)	3 (8.6)	0
Tremor	4 (11.4)	4 (11.4)	0	0	0
Encephalopathy	3 (8.6)	0	2 (5.7)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Psychiatric disorders					
-Total	10 (28.6)	3 (8.6)	6 (17.1)	1 (2.9)	0
Anxiety	7 (20.0)	3 (8.6)	3 (8.6)	1 (2.9)	0
Agitation	2 (5.7)	2 (5.7)	0	0	0
Sleep disorder	2 (5.7)	0	2 (5.7)	0	0
Confusional state	1 (2.9)	1 (2.9)	0	0	0
Delirium	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	4 (11.4)	1 (2.9)	1 (2.9)	0	2 (5.7)
Acute kidney injury	4 (11.4)	1 (2.9)	1 (2.9)	0	2 (5.7)
Respiratory, thoracic and mediastinal disorders					
-Total	25 (71.4)	10 (28.6)	4 (11.4)	7 (20.0)	4 (11.4)
Cough	12 (34.3)	9 (25.7)	3 (8.6)	0	0
Hypoxia	9 (25.7)	0	3 (8.6)	4 (11.4)	2 (5.7)
Epistaxis	5 (14.3)	4 (11.4)	0	1 (2.9)	0
Pulmonary oedema	5 (14.3)	1 (2.9)	0	4 (11.4)	0
Dyspnoea	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	4 (11.4)	4 (11.4)	0	0	0
Oropharyngeal pain	4 (11.4)	4 (11.4)	0	0	0
Pleural effusion	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Rhinorrhoea	2 (5.7)	2 (5.7)	0	0	0
Tachypnoea	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Acute respiratory distress syndrome	1 (2.9)	0	0	0	1 (2.9)
Atelectasis	1 (2.9)	0	1 (2.9)	0	0
Respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Skin and subcutaneous tissue disorders					
-Total	11 (31.4)	3 (8.6)	7 (20.0)	1 (2.9)	0
Rash	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Dry skin	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Erythema	2 (5.7)	2 (5.7)	0	0	0
Pruritus	2 (5.7)	0	2 (5.7)	0	0
Decubitus ulcer	1 (2.9)	0	0	1 (2.9)	0
Hyperhidrosis	1 (2.9)	0	1 (2.9)	0	0
Skin ulcer	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	11 (31.4)	5 (14.3)	3 (8.6)	2 (5.7)	1 (2.9)
Hypotension	7 (20.0)	2 (5.7)	2 (5.7)	2 (5.7)	1 (2.9)
Hypertension	5 (14.3)	3 (8.6)	2 (5.7)	0	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (75.6)	2 (4.9)	4 (9.8)	14 (34.1)	11 (26.8)
Blood and lymphatic system disorders					
-Total	21 (51.2)	0	2 (4.9)	14 (34.1)	5 (12.2)
Febrile neutropenia	11 (26.8)	0	0	11 (26.8)	0
Anaemia	9 (22.0)	1 (2.4)	2 (4.9)	6 (14.6)	0
Neutropenia	4 (9.8)	0	0	0	4 (9.8)
Thrombocytopenia	4 (9.8)	1 (2.4)	0	1 (2.4)	2 (4.9)
Pancytopenia	1 (2.4)	0	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	6 (14.6)	1 (2.4)	2 (4.9)	3 (7.3)	0
Abdominal pain	4 (9.8)	1 (2.4)	1 (2.4)	2 (4.9)	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (4.9)	0	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions					
-Total	5 (12.2)	2 (4.9)	2 (4.9)	1 (2.4)	0
Pyrexia	4 (9.8)	1 (2.4)	2 (4.9)	1 (2.4)	0
Fatigue	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Immune system disorders					
-Total	4 (9.8)	0	3 (7.3)	1 (2.4)	0
Hypogammaglobulinaemia	4 (9.8)	0	3 (7.3)	1 (2.4)	0
Investigations					
-Total	13 (31.7)	1 (2.4)	0	5 (12.2)	7 (17.1)
Neutrophil count decreased	7 (17.1)	0	0	3 (7.3)	4 (9.8)
White blood cell count decreased	3 (7.3)	0	0	0	3 (7.3)
C-reactive protein increased	2 (4.9)	1 (2.4)	0	1 (2.4)	0
Platelet count decreased	2 (4.9)	0	0	0	2 (4.9)
Lymphocyte count decreased	1 (2.4)	0	0	1 (2.4)	0
Metabolism and nutrition disorders					
-Total	1 (2.4)	1 (2.4)	0	0	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Arthralgia	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Nervous system disorders					
-Total	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Headache	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Epistaxis	1 (2.4)	0	0	1 (2.4)	0
Hypoxia	1 (2.4)	0	1 (2.4)	0	0
Vascular disorders					
-Total	2 (4.9)	0	2 (4.9)	0	0
Hypertension	2 (4.9)	0	2 (4.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	4 (10.0)	4 (10.0)	10 (25.0)	10 (25.0)
Blood and lymphatic system disorders					
-Total	16 (40.0)	1 (2.5)	0	10 (25.0)	5 (12.5)
Anaemia	10 (25.0)	1 (2.5)	1 (2.5)	7 (17.5)	1 (2.5)
Febrile neutropenia	6 (15.0)	0	0	6 (15.0)	0
Neutropenia	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Thrombocytopenia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Gastrointestinal disorders					
-Total	9 (22.5)	1 (2.5)	8 (20.0)	0	0
Constipation	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Abdominal pain	4 (10.0)	1 (2.5)	3 (7.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (7.5)	0	3 (7.5)	0	0
General disorders and administration site conditions					
-Total	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Pyrexia	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Fatigue	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	1 (2.5)	0	0	1 (2.5)	0
Catheter site infection	1 (2.5)	0	0	1 (2.5)	0
Investigations					
-Total	6 (15.0)	1 (2.5)	1 (2.5)	0	4 (10.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	0	0	3 (7.5)
C-reactive protein increased	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
White blood cell count decreased	2 (5.0)	1 (2.5)	0	0	1 (2.5)

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (2.5)	0	0	1 (2.5)	0
Decreased appetite	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (20.0)	3 (7.5)	3 (7.5)	2 (5.0)	0
Pain in extremity	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Back pain	3 (7.5)	0	3 (7.5)	0	0
Arthralgia	2 (5.0)	2 (5.0)	0	0	0
Nervous system disorders					
-Total	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Headache	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Psychiatric disorders					
-Total	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Anxiety	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Epistaxis	1 (2.5)	1 (2.5)	0	0	0
Hypoxia	1 (2.5)	0	1 (2.5)	0	0
Vascular disorders					
-Total	9 (22.5)	3 (7.5)	2 (5.0)	3 (7.5)	1 (2.5)
Hypotension	5 (12.5)	1 (2.5)	0	3 (7.5)	1 (2.5)
Hypertension	4 (10.0)	2 (5.0)	2 (5.0)	0	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215a
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (94.1)	0	3 (17.6)	5 (29.4)	8 (47.1)
Blood and lymphatic system disorders					
-Total	11 (64.7)	0	0	6 (35.3)	5 (29.4)
Febrile neutropenia	6 (35.3)	0	0	5 (29.4)	1 (5.9)
Anaemia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Neutropenia	3 (17.6)	0	0	0	3 (17.6)
Pancytopenia	3 (17.6)	0	0	1 (5.9)	2 (11.8)
Thrombocytopenia	1 (5.9)	0	0	1 (5.9)	0
Gastrointestinal disorders					
-Total	3 (17.6)	0	3 (17.6)	0	0

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	2 (11.8)	0	2 (11.8)	0	0
Nausea	2 (11.8)	1 (5.9)	1 (5.9)	0	0
General disorders and administration site conditions					
-Total	6 (35.3)	1 (5.9)	5 (29.4)	0	0
Pyrexia	4 (23.5)	1 (5.9)	3 (17.6)	0	0
Fatigue	2 (11.8)	0	2 (11.8)	0	0
Immune system disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0
Hypogammaglobulinaemia	2 (11.8)	0	2 (11.8)	0	0
Infections and infestations					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Catheter site infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Investigations					
-Total	6 (35.3)	0	0	1 (5.9)	5 (29.4)
Platelet count decreased	4 (23.5)	0	0	0	4 (23.5)
White blood cell count decreased	3 (17.6)	0	0	0	3 (17.6)
C-reactive protein increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (11.8)	0	0	0	2 (11.8)
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)
Metabolism and nutrition disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Decreased appetite	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (29.4)	2 (11.8)	2 (11.8)	1 (5.9)	0
Arthralgia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Back pain	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Pain in extremity	1 (5.9)	0	1 (5.9)	0	0
Nervous system disorders					
-Total	4 (23.5)	2 (11.8)	0	2 (11.8)	0
Headache	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Neuropathy peripheral	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Paraesthesia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Hypoxia	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Vascular disorders					
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Hypertension	1 (5.9)	0	1 (5.9)	0	0
Hypotension	1 (5.9)	0	0	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (61.8)	2 (3.6)	4 (7.3)	14 (25.5)	14 (25.5)
Blood and lymphatic system disorders					
-Total	27 (49.1)	1 (1.8)	1 (1.8)	16 (29.1)	9 (16.4)
Anaemia	16 (29.1)	1 (1.8)	4 (7.3)	10 (18.2)	1 (1.8)
Febrile neutropenia	9 (16.4)	0	0	9 (16.4)	0
Neutropenia	8 (14.5)	0	0	1 (1.8)	7 (12.7)
Thrombocytopenia	6 (10.9)	1 (1.8)	1 (1.8)	2 (3.6)	2 (3.6)
General disorders and administration site conditions					
-Total	8 (14.5)	3 (5.5)	3 (5.5)	2 (3.6)	0
Pyrexia	8 (14.5)	3 (5.5)	3 (5.5)	2 (3.6)	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	14 (25.5)	3 (5.5)	2 (3.6)	4 (7.3)	5 (9.1)
Alanine aminotransferase increased	7 (12.7)	2 (3.6)	2 (3.6)	3 (5.5)	0
Neutrophil count decreased	7 (12.7)	1 (1.8)	0	2 (3.6)	4 (7.3)
Platelet count decreased	3 (5.5)	0	0	0	3 (5.5)
Nervous system disorders					
-Total	6 (10.9)	2 (3.6)	3 (5.5)	1 (1.8)	0
Headache	6 (10.9)	2 (3.6)	3 (5.5)	1 (1.8)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215b
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (55.8)	2 (4.7)	1 (2.3)	12 (27.9)	9 (20.9)
Blood and lymphatic system disorders					
-Total	19 (44.2)	1 (2.3)	0	13 (30.2)	5 (11.6)
Febrile neutropenia	14 (32.6)	0	0	13 (30.2)	1 (2.3)
Anaemia	7 (16.3)	1 (2.3)	0	6 (14.0)	0
Neutropenia	3 (7.0)	1 (2.3)	0	0	2 (4.7)
Thrombocytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
General disorders and administration site conditions					
-Total	6 (14.0)	0	6 (14.0)	0	0
Pyrexia	6 (14.0)	0	6 (14.0)	0	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	9 (20.9)	0	0	2 (4.7)	7 (16.3)
Neutrophil count decreased	5 (11.6)	0	0	1 (2.3)	4 (9.3)
Platelet count decreased	5 (11.6)	0	0	0	5 (11.6)
Alanine aminotransferase increased	1 (2.3)	0	0	1 (2.3)	0
Nervous system disorders					
-Total	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Headache	2 (4.7)	1 (2.3)	0	1 (2.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (68.6)	0	7 (10.0)	23 (32.9)	18 (25.7)
Blood and lymphatic system disorders					
-Total	33 (47.1)	1 (1.4)	1 (1.4)	23 (32.9)	8 (11.4)
Anaemia	16 (22.9)	1 (1.4)	3 (4.3)	11 (15.7)	1 (1.4)
Febrile neutropenia	16 (22.9)	0	0	16 (22.9)	0
Neutropenia	7 (10.0)	1 (1.4)	0	1 (1.4)	5 (7.1)
Thrombocytopenia	6 (8.6)	1 (1.4)	1 (1.4)	2 (2.9)	2 (2.9)
Gastrointestinal disorders					
-Total	10 (14.3)	3 (4.3)	4 (5.7)	3 (4.3)	0
Constipation	7 (10.0)	3 (4.3)	4 (5.7)	0	0
Stomatitis	4 (5.7)	0	1 (1.4)	3 (4.3)	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	13 (18.6)	3 (4.3)	8 (11.4)	2 (2.9)	0
Pyrexia	13 (18.6)	3 (4.3)	8 (11.4)	2 (2.9)	0
Investigations					
-Total	20 (28.6)	1 (1.4)	2 (2.9)	5 (7.1)	12 (17.1)
Neutrophil count decreased	11 (15.7)	1 (1.4)	0	3 (4.3)	7 (10.0)
Platelet count decreased	6 (8.6)	0	0	0	6 (8.6)
White blood cell count decreased	6 (8.6)	1 (1.4)	0	0	5 (7.1)
Alanine aminotransferase increased	5 (7.1)	2 (2.9)	2 (2.9)	1 (1.4)	0
C-reactive protein increased	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Serum ferritin increased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Hypokalaemia	4 (5.7)	1 (1.4)	1 (1.4)	2 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Pain in extremity	4 (5.7)	0	3 (4.3)	1 (1.4)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	7 (10.0)	2 (2.9)	3 (4.3)	2 (2.9)	0
Headache	7 (10.0)	2 (2.9)	3 (4.3)	2 (2.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (40.0)	1 (6.7)	0	3 (20.0)	2 (13.3)
Blood and lymphatic system disorders					
-Total	4 (26.7)	0	0	2 (13.3)	2 (13.3)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Febrile neutropenia	2 (13.3)	0	0	2 (13.3)	0
Thrombocytopenia	2 (13.3)	0	0	0	2 (13.3)
Neutropenia	1 (6.7)	0	0	0	1 (6.7)
Gastrointestinal disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Stomatitis	1 (6.7)	0	0	1 (6.7)	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	1 (6.7)	0	1 (6.7)	0	0
Pyrexia	1 (6.7)	0	1 (6.7)	0	0
Investigations					
-Total	4 (26.7)	0	0	4 (26.7)	0
Alanine aminotransferase increased	3 (20.0)	0	0	3 (20.0)	0
Serum ferritin increased	3 (20.0)	1 (6.7)	0	2 (13.3)	0
C-reactive protein increased	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Pain in extremity	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Nervous system disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Headache	1 (6.7)	1 (6.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215c
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (76.9)	1 (7.7)	0	2 (15.4)	7 (53.8)
Blood and lymphatic system disorders					
-Total	9 (69.2)	1 (7.7)	0	4 (30.8)	4 (30.8)
Febrile neutropenia	5 (38.5)	0	0	4 (30.8)	1 (7.7)
Anaemia	4 (30.8)	1 (7.7)	1 (7.7)	2 (15.4)	0
Neutropenia	3 (23.1)	0	0	0	3 (23.1)
Thrombocytopenia	1 (7.7)	0	0	1 (7.7)	0
Gastrointestinal disorders					
-Total	2 (15.4)	0	0	2 (15.4)	0
Stomatitis	2 (15.4)	0	0	2 (15.4)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	4 (30.8)	0	0	0	4 (30.8)
Platelet count decreased	2 (15.4)	0	0	0	2 (15.4)
White blood cell count decreased	2 (15.4)	0	0	0	2 (15.4)
C-reactive protein increased	1 (7.7)	0	0	0	1 (7.7)
Neutrophil count decreased	1 (7.7)	0	0	0	1 (7.7)
Serum ferritin increased	1 (7.7)	0	0	0	1 (7.7)
Metabolism and nutrition disorders					
-Total	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Hypokalaemia	2 (15.4)	1 (7.7)	0	1 (7.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	2 (11.1)	2 (11.1)	8 (44.4)	5 (27.8)
Blood and lymphatic system disorders					
-Total	6 (33.3)	1 (5.6)	0	3 (16.7)	2 (11.1)
Anaemia	4 (22.2)	1 (5.6)	1 (5.6)	1 (5.6)	1 (5.6)
Febrile neutropenia	2 (11.1)	0	0	2 (11.1)	0
Thrombocytopenia	2 (11.1)	0	0	2 (11.1)	0
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Gastrointestinal disorders					
-Total	4 (22.2)	1 (5.6)	1 (5.6)	2 (11.1)	0
Nausea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Stomatitis	2 (11.1)	0	0	2 (11.1)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0
Pyrexia	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0
Immune system disorders					
-Total	2 (11.1)	0	2 (11.1)	0	0
Hypogammaglobulinaemia	2 (11.1)	0	2 (11.1)	0	0
Infections and infestations					
-Total	2 (11.1)	0	0	2 (11.1)	0
Bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Procedural pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Investigations					
-Total	6 (33.3)	0	0	2 (11.1)	4 (22.2)
Platelet count decreased	3 (16.7)	0	0	0	3 (16.7)
Blood lactate dehydrogenase increased	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	0	0	0	2 (11.1)
Metabolism and nutrition disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Decreased appetite	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Hypomagnesaemia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Arthralgia	2 (11.1)	2 (11.1)	0	0	0
Pain in extremity	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Psychiatric disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Mental status changes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oropharyngeal pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Vascular disorders					

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Hypertension	3 (16.7)	2 (11.1)	1 (5.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215d
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (63.8)	2 (2.5)	5 (6.3)	23 (28.8)	21 (26.3)
Blood and lymphatic system disorders					
-Total	40 (50.0)	1 (1.3)	1 (1.3)	26 (32.5)	12 (15.0)
Febrile neutropenia	21 (26.3)	0	0	20 (25.0)	1 (1.3)
Anaemia	19 (23.8)	1 (1.3)	3 (3.8)	15 (18.8)	0
Neutropenia	10 (12.5)	1 (1.3)	0	1 (1.3)	8 (10.0)
Thrombocytopenia	7 (8.8)	1 (1.3)	1 (1.3)	1 (1.3)	4 (5.0)
Gastrointestinal disorders					
-Total	15 (18.8)	1 (1.3)	7 (8.8)	7 (8.8)	0
Abdominal pain	8 (10.0)	2 (2.5)	4 (5.0)	2 (2.5)	0
Nausea	5 (6.3)	0	4 (5.0)	1 (1.3)	0

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	5 (6.3)	0	1 (1.3)	4 (5.0)	0
General disorders and administration site conditions					
-Total	10 (12.5)	2 (2.5)	7 (8.8)	1 (1.3)	0
Pyrexia	10 (12.5)	2 (2.5)	7 (8.8)	1 (1.3)	0
Immune system disorders					
-Total	5 (6.3)	0	4 (5.0)	1 (1.3)	0
Hypogammaglobulinaemia	5 (6.3)	0	4 (5.0)	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	1 (1.3)	1 (1.3)	0	0	0
Procedural pain	1 (1.3)	1 (1.3)	0	0	0
Investigations					
-Total	15 (18.8)	1 (1.3)	0	3 (3.8)	11 (13.8)
Neutrophil count decreased	10 (12.5)	1 (1.3)	0	2 (2.5)	7 (8.8)
White blood cell count decreased	6 (7.5)	1 (1.3)	0	0	5 (6.3)
Platelet count decreased	5 (6.3)	0	0	0	5 (6.3)
Blood lactate dehydrogenase increased	1 (1.3)	0	0	1 (1.3)	0

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Decreased appetite	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Hypomagnesaemia	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (10.0)	3 (3.8)	4 (5.0)	1 (1.3)	0
Arthralgia	4 (5.0)	2 (2.5)	2 (2.5)	0	0
Pain in extremity	4 (5.0)	1 (1.3)	2 (2.5)	1 (1.3)	0
Psychiatric disorders					
-Total	1 (1.3)	0	0	1 (1.3)	0
Mental status changes	1 (1.3)	0	0	1 (1.3)	0
Vascular disorders					
-Total	4 (5.0)	0	4 (5.0)	0	0
Hypertension	4 (5.0)	0	4 (5.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	5 (62.5)	3 (37.5)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Tachycardia	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Gastrointestinal disorders					
-Total	4 (50.0)	1 (12.5)	0	2 (25.0)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
Tooth pulp haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Pyrexia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0	0	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (12.5)	1 (12.5)	0	0	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Hypocalcaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Acute kidney injury	2 (25.0)	2 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (37.5)	1 (12.5)	0	0	2 (25.0)
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (25.0)	0	0	2 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215e
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (65.6)	2 (2.2)	6 (6.7)	26 (28.9)	25 (27.8)
Blood and lymphatic system disorders					
-Total	42 (46.7)	2 (2.2)	1 (1.1)	26 (28.9)	13 (14.4)
Anaemia	21 (23.3)	2 (2.2)	4 (4.4)	14 (15.6)	1 (1.1)
Febrile neutropenia	21 (23.3)	0	0	20 (22.2)	1 (1.1)
Neutropenia	11 (12.2)	1 (1.1)	0	1 (1.1)	9 (10.0)
Thrombocytopenia	8 (8.9)	1 (1.1)	1 (1.1)	3 (3.3)	3 (3.3)
Cardiac disorders					
-Total	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Tachycardia	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders					

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (13.3)	3 (3.3)	3 (3.3)	6 (6.7)	0
Abdominal pain	7 (7.8)	2 (2.2)	4 (4.4)	1 (1.1)	0
Stomatitis	6 (6.7)	0	1 (1.1)	5 (5.6)	0
Haematemesis	1 (1.1)	1 (1.1)	0	0	0
General disorders and administration site conditions					
-Total	12 (13.3)	1 (1.1)	9 (10.0)	2 (2.2)	0
Pyrexia	11 (12.2)	3 (3.3)	7 (7.8)	1 (1.1)	0
Pain	4 (4.4)	0	3 (3.3)	1 (1.1)	0
Chills	1 (1.1)	0	1 (1.1)	0	0
Immune system disorders					
-Total	6 (6.7)	0	5 (5.6)	1 (1.1)	0
Hypogammaglobulinaemia	6 (6.7)	0	5 (5.6)	1 (1.1)	0
Infections and infestations					
-Total	5 (5.6)	0	1 (1.1)	4 (4.4)	0
Staphylococcal bacteraemia	2 (2.2)	0	0	2 (2.2)	0
Clostridium difficile colitis	1 (1.1)	0	1 (1.1)	0	0
Localised infection	1 (1.1)	0	0	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Procedural pain	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Investigations					
-Total	19 (21.1)	0	0	7 (7.8)	12 (13.3)
Neutrophil count decreased	11 (12.2)	1 (1.1)	0	3 (3.3)	7 (7.8)
White blood cell count decreased	7 (7.8)	0	0	0	7 (7.8)
Alanine aminotransferase increased	6 (6.7)	1 (1.1)	2 (2.2)	3 (3.3)	0
Aspartate aminotransferase increased	4 (4.4)	0	1 (1.1)	3 (3.3)	0
Lymphocyte count decreased	3 (3.3)	0	0	1 (1.1)	2 (2.2)
Blood creatinine increased	1 (1.1)	0	0	1 (1.1)	0
Metabolism and nutrition disorders					
-Total	8 (8.9)	3 (3.3)	3 (3.3)	2 (2.2)	0
Hypokalaemia	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Hypomagnesaemia	2 (2.2)	1 (1.1)	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (1.1)	0	1 (1.1)	0	0
Hypocalcaemia	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (5.6)	1 (1.1)	3 (3.3)	1 (1.1)	0
Pain in extremity	5 (5.6)	1 (1.1)	3 (3.3)	1 (1.1)	0
Nervous system disorders					
-Total	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Neuropathy peripheral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (3.3)	0	1 (1.1)	0	2 (2.2)
Respiratory failure	2 (2.2)	0	0	0	2 (2.2)
Oropharyngeal pain	1 (1.1)	0	1 (1.1)	0	0
Vascular disorders					
-Total	4 (4.4)	1 (1.1)	0	1 (1.1)	2 (2.2)
Hypotension	4 (4.4)	1 (1.1)	0	1 (1.1)	2 (2.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Device related bacteraemia	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal infection	1 (50.0)	0	1 (50.0)	0	0
Tonsillitis	1 (50.0)	0	1 (50.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	0	1 (50.0)	0	0
Transfusion reaction	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215f
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (56.3)	3 (3.1)	4 (4.2)	29 (30.2)	18 (18.8)
Blood and lymphatic system disorders					
-Total	45 (46.9)	2 (2.1)	2 (2.1)	31 (32.3)	10 (10.4)
Anaemia	23 (24.0)	2 (2.1)	4 (4.2)	16 (16.7)	1 (1.0)
Febrile neutropenia	23 (24.0)	0	0	22 (22.9)	1 (1.0)
Neutropenia	10 (10.4)	1 (1.0)	0	1 (1.0)	8 (8.3)
General disorders and administration site conditions					
-Total	14 (14.6)	3 (3.1)	9 (9.4)	2 (2.1)	0
Pyrexia	14 (14.6)	3 (3.1)	9 (9.4)	2 (2.1)	0
Hepatobiliary disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.0)	0	0	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	0	0	1 (1.0)	0
Injury, poisoning and procedural complications					
-Total	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Transfusion reaction	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Investigations					
-Total	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)
Neutrophil count decreased	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Anal fissure	1 (100)	0	1 (100)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215g
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (55.7)	3 (3.1)	4 (4.1)	28 (28.9)	19 (19.6)
Blood and lymphatic system disorders					
-Total	46 (47.4)	2 (2.1)	2 (2.1)	31 (32.0)	11 (11.3)
Anaemia	23 (23.7)	2 (2.1)	4 (4.1)	16 (16.5)	1 (1.0)
Febrile neutropenia	23 (23.7)	0	0	22 (22.7)	1 (1.0)
Neutropenia	11 (11.3)	1 (1.0)	0	1 (1.0)	9 (9.3)
General disorders and administration site conditions					
-Total	14 (14.4)	3 (3.1)	9 (9.3)	2 (2.1)	0
Pyrexia	14 (14.4)	3 (3.1)	9 (9.3)	2 (2.1)	0
Investigations					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (12.4)	1 (1.0)	0	3 (3.1)	8 (8.2)
Neutrophil count decreased	12 (12.4)	1 (1.0)	0	3 (3.1)	8 (8.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Cardiac disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	0	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (33.3)	0	0	0	1 (33.3)
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pain	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Injury, poisoning and procedural complications					
-Total	1 (33.3)	0	0	1 (33.3)	0
Post procedural haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Aspartate aminotransferase increased	1 (33.3)	0	0	0	1 (33.3)
Blood creatinine increased	1 (33.3)	1 (33.3)	0	0	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Acute kidney injury	1 (33.3)	1 (33.3)	0	0	0

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypotension	2 (66.7)	0	0	2 (66.7)	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215h
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (60.0)	1 (1.1)	4 (4.2)	27 (28.4)	25 (26.3)
Blood and lymphatic system disorders					
-Total	45 (47.4)	2 (2.1)	2 (2.1)	30 (31.6)	11 (11.6)
Febrile neutropenia	23 (24.2)	0	0	22 (23.2)	1 (1.1)
Anaemia	22 (23.2)	2 (2.1)	4 (4.2)	15 (15.8)	1 (1.1)
Neutropenia	11 (11.6)	1 (1.1)	0	1 (1.1)	9 (9.5)
Cardiac disorders					
-Total	5 (5.3)	2 (2.1)	1 (1.1)	2 (2.1)	0
Tachycardia	5 (5.3)	2 (2.1)	1 (1.1)	2 (2.1)	0
General disorders and administration site conditions					

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (14.7)	1 (1.1)	10 (10.5)	3 (3.2)	0
Pyrexia	13 (13.7)	3 (3.2)	8 (8.4)	2 (2.1)	0
Pain	4 (4.2)	0	3 (3.2)	1 (1.1)	0
Infections and infestations					
-Total	1 (1.1)	0	0	1 (1.1)	0
Staphylococcal infection	1 (1.1)	0	0	1 (1.1)	0
Investigations					
-Total	20 (21.1)	0	0	7 (7.4)	13 (13.7)
Neutrophil count decreased	11 (11.6)	1 (1.1)	0	2 (2.1)	8 (8.4)
Alanine aminotransferase increased	7 (7.4)	1 (1.1)	2 (2.1)	4 (4.2)	0
White blood cell count decreased	7 (7.4)	0	0	0	7 (7.4)
Aspartate aminotransferase increased	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Lymphocyte count decreased	3 (3.2)	0	0	1 (1.1)	2 (2.1)
Blood creatinine increased	1 (1.1)	0	0	1 (1.1)	0
Metabolism and nutrition disorders					
-Total	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	0
Hypocalcaemia	2 (2.1)	1 (1.1)	1 (1.1)	0	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (1.1)	0	1 (1.1)	0	0
Metabolic acidosis	1 (1.1)	0	0	1 (1.1)	0
Renal and urinary disorders					
-Total	1 (1.1)	1 (1.1)	0	0	0
Acute kidney injury	1 (1.1)	1 (1.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (3.2)	0	0	0	3 (3.2)
Respiratory failure	3 (3.2)	0	0	0	3 (3.2)
Vascular disorders					
-Total	4 (4.2)	1 (1.1)	0	1 (1.1)	2 (2.1)
Hypotension	4 (4.2)	1 (1.1)	0	1 (1.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	2 (100)	0	0	2 (100)	0
Immune system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypersensitivity	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Acute sinusitis	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215i
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (57.3)	2 (2.1)	5 (5.2)	27 (28.1)	21 (21.9)
Blood and lymphatic system disorders					
-Total	44 (45.8)	2 (2.1)	2 (2.1)	29 (30.2)	11 (11.5)
Anaemia	23 (24.0)	2 (2.1)	4 (4.2)	16 (16.7)	1 (1.0)
Febrile neutropenia	21 (21.9)	0	0	20 (20.8)	1 (1.0)
Neutropenia	11 (11.5)	1 (1.0)	0	1 (1.0)	9 (9.4)
General disorders and administration site conditions					
-Total	14 (14.6)	3 (3.1)	9 (9.4)	2 (2.1)	0
Pyrexia	14 (14.6)	3 (3.1)	9 (9.4)	2 (2.1)	0
Infections and infestations					

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.0)	0	1 (1.0)	0	0
Acute sinusitis	1 (1.0)	0	1 (1.0)	0	0
Investigations					
-Total	21 (21.9)	1 (1.0)	2 (2.1)	6 (6.3)	12 (12.5)
Neutrophil count decreased	12 (12.5)	1 (1.0)	0	3 (3.1)	8 (8.3)
Alanine aminotransferase increased	7 (7.3)	1 (1.0)	2 (2.1)	4 (4.2)	0
White blood cell count decreased	7 (7.3)	1 (1.0)	0	0	6 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (66.7)	1 (3.3)	1 (3.3)	7 (23.3)	11 (36.7)
Blood and lymphatic system disorders					
-Total	14 (46.7)	1 (3.3)	1 (3.3)	9 (30.0)	3 (10.0)
Anaemia	9 (30.0)	1 (3.3)	2 (6.7)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	0	0	6 (20.0)	0
Neutropenia	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Thrombocytopenia	2 (6.7)	1 (3.3)	0	0	1 (3.3)
Cardiac disorders					
-Total	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Tachycardia	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Gastrointestinal disorders					
-Total	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0
General disorders and administration site conditions					
-Total	7 (23.3)	2 (6.7)	5 (16.7)	0	0
Pyrexia	6 (20.0)	1 (3.3)	5 (16.7)	0	0
Fatigue	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Infections and infestations					
-Total	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Pneumonia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Investigations					
-Total	9 (30.0)	0	0	1 (3.3)	8 (26.7)
Neutrophil count decreased	6 (20.0)	1 (3.3)	0	0	5 (16.7)
Platelet count decreased	4 (13.3)	0	0	0	4 (13.3)
Aspartate aminotransferase increased	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Lymphocyte count decreased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
White blood cell count decreased	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Metabolism and nutrition disorders					
-Total	4 (13.3)	1 (3.3)	0	3 (10.0)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (10.0)	0	0	0	3 (10.0)
Respiratory failure	3 (10.0)	0	0	0	3 (10.0)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215j
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (60.3)	2 (2.9)	4 (5.9)	17 (25.0)	18 (26.5)
Blood and lymphatic system disorders					
-Total	32 (47.1)	1 (1.5)	0	20 (29.4)	11 (16.2)
Febrile neutropenia	17 (25.0)	0	0	16 (23.5)	1 (1.5)
Anaemia	14 (20.6)	1 (1.5)	2 (2.9)	10 (14.7)	1 (1.5)
Neutropenia	8 (11.8)	0	0	1 (1.5)	7 (10.3)
Thrombocytopenia	7 (10.3)	0	1 (1.5)	3 (4.4)	3 (4.4)
Cardiac disorders					
-Total	2 (2.9)	0	0	2 (2.9)	0
Tachycardia	2 (2.9)	0	0	2 (2.9)	0
Gastrointestinal disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Abdominal pain	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions					
-Total	10 (14.7)	2 (2.9)	6 (8.8)	2 (2.9)	0
Pyrexia	8 (11.8)	2 (2.9)	4 (5.9)	2 (2.9)	0
Fatigue	2 (2.9)	0	2 (2.9)	0	0
Infections and infestations					
-Total	1 (1.5)	0	0	0	1 (1.5)
Pneumonia	1 (1.5)	0	0	0	1 (1.5)
Investigations					
-Total	13 (19.1)	0	0	5 (7.4)	8 (11.8)
Neutrophil count decreased	6 (8.8)	0	0	3 (4.4)	3 (4.4)
White blood cell count decreased	5 (7.4)	0	0	0	5 (7.4)
Platelet count decreased	4 (5.9)	0	0	0	4 (5.9)
Aspartate aminotransferase increased	2 (2.9)	0	0	2 (2.9)	0
Lymphocyte count decreased	1 (1.5)	0	0	0	1 (1.5)
Metabolism and nutrition disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Hypokalaemia	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (1.5)	0	0	0	1 (1.5)
Respiratory failure	1 (1.5)	0	0	0	1 (1.5)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (81.3)	2 (6.3)	1 (3.1)	7 (21.9)	16 (50.0)
Blood and lymphatic system disorders					
-Total	19 (59.4)	0	0	11 (34.4)	8 (25.0)
Febrile neutropenia	8 (25.0)	0	0	7 (21.9)	1 (3.1)
Anaemia	7 (21.9)	0	1 (3.1)	6 (18.8)	0
Neutropenia	7 (21.9)	0	0	0	7 (21.9)
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Gastrointestinal disorders					
-Total	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Abdominal pain	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Constipation	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Pyrexia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Fatigue	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Hypogammaglobulinaemia	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Investigations					
-Total	9 (28.1)	0	0	1 (3.1)	8 (25.0)
Neutrophil count decreased	6 (18.8)	1 (3.1)	0	1 (3.1)	4 (12.5)
White blood cell count decreased	5 (15.6)	0	0	0	5 (15.6)
Platelet count decreased	4 (12.5)	0	0	0	4 (12.5)
Alanine aminotransferase increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Musculoskeletal and connective tissue disorders					

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Arthralgia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Pain in extremity	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Headache	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Vascular disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Hypertension	1 (3.1)	0	1 (3.1)	0	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (70.2)	4 (7.0)	7 (12.3)	18 (31.6)	11 (19.3)
Blood and lymphatic system disorders					
-Total	26 (45.6)	2 (3.5)	1 (1.8)	17 (29.8)	6 (10.5)
Anaemia	16 (28.1)	2 (3.5)	3 (5.3)	10 (17.5)	1 (1.8)
Febrile neutropenia	14 (24.6)	0	0	14 (24.6)	0
Thrombocytopenia	8 (14.0)	1 (1.8)	1 (1.8)	2 (3.5)	4 (7.0)
Neutropenia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Gastrointestinal disorders					
-Total	10 (17.5)	2 (3.5)	7 (12.3)	1 (1.8)	0
Constipation	6 (10.5)	2 (3.5)	4 (7.0)	0	0
Abdominal pain	4 (7.0)	0	3 (5.3)	1 (1.8)	0

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	12 (21.1)	2 (3.5)	9 (15.8)	1 (1.8)	0
Pyrexia	11 (19.3)	2 (3.5)	8 (14.0)	1 (1.8)	0
Fatigue	3 (5.3)	0	3 (5.3)	0	0
Immune system disorders					
-Total	2 (3.5)	0	2 (3.5)	0	0
Hypogammaglobulinaemia	2 (3.5)	0	2 (3.5)	0	0
Investigations					
-Total	15 (26.3)	1 (1.8)	2 (3.5)	5 (8.8)	7 (12.3)
Alanine aminotransferase increased	7 (12.3)	1 (1.8)	2 (3.5)	4 (7.0)	0
Neutrophil count decreased	6 (10.5)	0	0	2 (3.5)	4 (7.0)
Platelet count decreased	4 (7.0)	0	0	0	4 (7.0)
White blood cell count decreased	3 (5.3)	1 (1.8)	0	0	2 (3.5)
Musculoskeletal and connective tissue disorders					
-Total	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Pain in extremity	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Arthralgia	3 (5.3)	2 (3.5)	1 (1.8)	0	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Headache	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Vascular disorders					
-Total	6 (10.5)	2 (3.5)	4 (7.0)	0	0
Hypertension	6 (10.5)	2 (3.5)	4 (7.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215k
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (66.7)	0	2 (22.2)	3 (33.3)	1 (11.1)
Blood and lymphatic system disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Gastrointestinal disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Duodenal perforation	1 (11.1)	0	0	1 (11.1)	0
Gastritis	1 (11.1)	0	1 (11.1)	0	0
Haemorrhoids	1 (11.1)	0	1 (11.1)	0	0
General disorders and administration site conditions					

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	0	1 (11.1)	0	0
Fatigue	1 (11.1)	0	1 (11.1)	0	0
Infections and infestations					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (22.2)	2 (22.2)	0	0	0
Arthralgia	1 (11.1)	1 (11.1)	0	0	0
Pain in extremity	1 (11.1)	1 (11.1)	0	0	0
Nervous system disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Haemorrhage intracranial	1 (11.1)	0	0	0	1 (11.1)

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Reproductive system and breast disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Heavy menstrual bleeding	1 (11.1)	0	1 (11.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Erythema nodosum	1 (11.1)	1 (11.1)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (58.6)	2 (3.4)	3 (5.2)	15 (25.9)	14 (24.1)
Blood and lymphatic system disorders					
-Total	25 (43.1)	0	1 (1.7)	17 (29.3)	7 (12.1)
Febrile neutropenia	14 (24.1)	0	0	13 (22.4)	1 (1.7)
Anaemia	10 (17.2)	0	2 (3.4)	8 (13.8)	0
Neutropenia	6 (10.3)	0	0	0	6 (10.3)
Thrombocytopenia	3 (5.2)	0	1 (1.7)	1 (1.7)	1 (1.7)
Gastrointestinal disorders					
-Total	6 (10.3)	2 (3.4)	1 (1.7)	3 (5.2)	0
Constipation	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Stomatitis	3 (5.2)	0	0	3 (5.2)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	6 (10.3)	1 (1.7)	4 (6.9)	1 (1.7)	0
Pyrexia	6 (10.3)	1 (1.7)	4 (6.9)	1 (1.7)	0
Immune system disorders					
-Total	6 (10.3)	0	5 (8.6)	1 (1.7)	0
Hypogammaglobulinaemia	6 (10.3)	0	5 (8.6)	1 (1.7)	0
Investigations					
-Total	15 (25.9)	1 (1.7)	1 (1.7)	4 (6.9)	9 (15.5)
Neutrophil count decreased	11 (19.0)	1 (1.7)	0	3 (5.2)	7 (12.1)
Platelet count decreased	6 (10.3)	0	0	0	6 (10.3)
Alanine aminotransferase increased	3 (5.2)	0	1 (1.7)	2 (3.4)	0
Serum ferritin increased	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Pain in extremity	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	7 (12.1)	3 (5.2)	3 (5.2)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	7 (12.1)	3 (5.2)	3 (5.2)	1 (1.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215l
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	2 (5.0)	3 (7.5)	13 (32.5)	10 (25.0)
Blood and lymphatic system disorders					
-Total	21 (52.5)	2 (5.0)	0	12 (30.0)	7 (17.5)
Anaemia	13 (32.5)	2 (5.0)	2 (5.0)	8 (20.0)	1 (2.5)
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	0	2 (5.0)	3 (7.5)
Neutropenia	5 (12.5)	1 (2.5)	0	1 (2.5)	3 (7.5)
Gastrointestinal disorders					
-Total	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Constipation	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Stomatitis	4 (10.0)	0	1 (2.5)	3 (7.5)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	8 (20.0)	2 (5.0)	5 (12.5)	1 (2.5)	0
Pyrexia	8 (20.0)	2 (5.0)	5 (12.5)	1 (2.5)	0
Immune system disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	10 (25.0)	2 (5.0)	1 (2.5)	3 (7.5)	4 (10.0)
Alanine aminotransferase increased	5 (12.5)	2 (5.0)	1 (2.5)	2 (5.0)	0
Serum ferritin increased	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
Neutrophil count decreased	1 (2.5)	0	0	0	1 (2.5)
Musculoskeletal and connective tissue disorders					
-Total	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Pain in extremity	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Nervous system disorders					
-Total	1 (2.5)	0	0	1 (2.5)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (2.5)	0	0	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (41.2)	0	0	6 (35.3)	1 (5.9)
Blood and lymphatic system disorders					
-Total	7 (41.2)	0	0	7 (41.2)	0
Febrile neutropenia	7 (41.2)	0	0	7 (41.2)	0
Infections and infestations					
-Total	3 (17.6)	0	0	3 (17.6)	0
Catheter site infection	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Investigations					
-Total	1 (5.9)	0	0	0	1 (5.9)
Neutrophil count decreased	1 (5.9)	0	0	0	1 (5.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215m
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (59.3)	3 (3.7)	5 (6.2)	20 (24.7)	20 (24.7)
Blood and lymphatic system disorders					
-Total	39 (48.1)	2 (2.5)	1 (1.2)	22 (27.2)	14 (17.3)
Anaemia	23 (28.4)	2 (2.5)	4 (4.9)	16 (19.8)	1 (1.2)
Febrile neutropenia	16 (19.8)	0	0	15 (18.5)	1 (1.2)
Neutropenia	11 (13.6)	1 (1.2)	0	1 (1.2)	9 (11.1)
Thrombocytopenia	9 (11.1)	1 (1.2)	1 (1.2)	3 (3.7)	4 (4.9)
General disorders and administration site conditions					
-Total	14 (17.3)	3 (3.7)	9 (11.1)	2 (2.5)	0
Pyrexia	14 (17.3)	3 (3.7)	9 (11.1)	2 (2.5)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Catheter site infection	1 (1.2)	0	1 (1.2)	0	0
Staphylococcal bacteraemia	1 (1.2)	0	0	1 (1.2)	0
Investigations					
-Total	11 (13.6)	1 (1.2)	0	3 (3.7)	7 (8.6)
Neutrophil count decreased	11 (13.6)	1 (1.2)	0	3 (3.7)	7 (8.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (64.3)	0	3 (10.7)	9 (32.1)	6 (21.4)
Blood and lymphatic system disorders					
-Total	14 (50.0)	1 (3.6)	0	8 (28.6)	5 (17.9)
Anaemia	7 (25.0)	1 (3.6)	1 (3.6)	5 (17.9)	0
Febrile neutropenia	5 (17.9)	0	0	5 (17.9)	0
Thrombocytopenia	5 (17.9)	0	1 (3.6)	2 (7.1)	2 (7.1)
Neutropenia	3 (10.7)	0	0	0	3 (10.7)
Gastrointestinal disorders					
-Total	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Nausea	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Abdominal pain	1 (3.6)	0	0	1 (3.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Pyrexia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Infections and infestations					
-Total	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Sinusitis	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Investigations					
-Total	6 (21.4)	0	1 (3.6)	3 (10.7)	2 (7.1)
Alanine aminotransferase increased	4 (14.3)	0	1 (3.6)	3 (10.7)	0
Neutrophil count decreased	2 (7.1)	0	0	1 (3.6)	1 (3.6)
White blood cell count decreased	1 (3.6)	0	0	0	1 (3.6)
Nervous system disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Headache	1 (3.6)	0	1 (3.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215n
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (62.9)	1 (1.4)	4 (5.7)	18 (25.7)	21 (30.0)
Blood and lymphatic system disorders					
-Total	32 (45.7)	1 (1.4)	1 (1.4)	21 (30.0)	9 (12.9)
Febrile neutropenia	18 (25.7)	0	0	17 (24.3)	1 (1.4)
Anaemia	16 (22.9)	1 (1.4)	3 (4.3)	11 (15.7)	1 (1.4)
Neutropenia	8 (11.4)	1 (1.4)	0	1 (1.4)	6 (8.6)
Thrombocytopenia	4 (5.7)	1 (1.4)	0	1 (1.4)	2 (2.9)
Gastrointestinal disorders					
-Total	15 (21.4)	2 (2.9)	6 (8.6)	7 (10.0)	0
Abdominal pain	7 (10.0)	2 (2.9)	4 (5.7)	1 (1.4)	0
Stomatitis	7 (10.0)	0	1 (1.4)	6 (8.6)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	4 (5.7)	1 (1.4)	3 (4.3)	0	0
General disorders and administration site conditions					
-Total	11 (15.7)	1 (1.4)	8 (11.4)	2 (2.9)	0
Pyrexia	11 (15.7)	1 (1.4)	8 (11.4)	2 (2.9)	0
Investigations					
-Total	22 (31.4)	1 (1.4)	2 (2.9)	5 (7.1)	14 (20.0)
Neutrophil count decreased	10 (14.3)	1 (1.4)	0	2 (2.9)	7 (10.0)
Platelet count decreased	8 (11.4)	0	0	0	8 (11.4)
C-reactive protein increased	7 (10.0)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.4)
White blood cell count decreased	7 (10.0)	1 (1.4)	0	0	6 (8.6)
Alanine aminotransferase increased	4 (5.7)	2 (2.9)	1 (1.4)	1 (1.4)	0
Nervous system disorders					
-Total	7 (10.0)	3 (4.3)	2 (2.9)	2 (2.9)	0
Headache	7 (10.0)	3 (4.3)	2 (2.9)	2 (2.9)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	2 (18.2)	5 (45.5)	1 (9.1)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	4 (36.4)	1 (9.1)
Febrile neutropenia	3 (27.3)	0	0	3 (27.3)	0
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Gastrointestinal disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Nausea	2 (18.2)	0	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions					

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Pyrexia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Hepatobiliary disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hepatic cytolysis	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	2 (18.2)	0	0
Sinusitis	2 (18.2)	0	2 (18.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0
Pruritus	2 (18.2)	2 (18.2)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215o
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (55.2)	2 (2.3)	4 (4.6)	24 (27.6)	18 (20.7)
Blood and lymphatic system disorders					
-Total	41 (47.1)	2 (2.3)	2 (2.3)	27 (31.0)	10 (11.5)
Anaemia	22 (25.3)	2 (2.3)	4 (4.6)	15 (17.2)	1 (1.1)
Febrile neutropenia	20 (23.0)	0	0	19 (21.8)	1 (1.1)
Neutropenia	10 (11.5)	1 (1.1)	0	1 (1.1)	8 (9.2)
Gastrointestinal disorders					
-Total	5 (5.7)	1 (1.1)	4 (4.6)	0	0
Nausea	5 (5.7)	1 (1.1)	4 (4.6)	0	0
General disorders and administration site conditions					

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	12 (13.8)	2 (2.3)	8 (9.2)	2 (2.3)	0
Pyrexia	12 (13.8)	2 (2.3)	8 (9.2)	2 (2.3)	0
Infections and infestations					
-Total	1 (1.1)	0	0	1 (1.1)	0
Sinusitis	1 (1.1)	0	0	1 (1.1)	0
Investigations					
-Total	12 (13.8)	1 (1.1)	0	3 (3.4)	8 (9.2)
Neutrophil count decreased	12 (13.8)	1 (1.1)	0	3 (3.4)	8 (9.2)
Skin and subcutaneous tissue disorders					
-Total	2 (2.3)	0	2 (2.3)	0	0
Pruritus	2 (2.3)	0	2 (2.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Blood and lymphatic system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Neutropenia	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypothyroidism	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Constipation	1 (14.3)	0	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Duodenal perforation	1 (14.3)	0	0	1 (14.3)	0
Gastritis	1 (14.3)	0	1 (14.3)	0	0
Hypoaesthesia oral	1 (14.3)	0	1 (14.3)	0	0
Oral pain	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Complication associated with device	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Decreased appetite	1 (14.3)	1 (14.3)	0	0	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0	0	0
Hypocalcaemia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	0	0	1 (14.3)
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Haemorrhage intracranial	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Atelectasis	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215p
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (60.4)	1 (1.1)	4 (4.4)	28 (30.8)	22 (24.2)
Blood and lymphatic system disorders					
-Total	45 (49.5)	2 (2.2)	2 (2.2)	30 (33.0)	11 (12.1)
Anaemia	23 (25.3)	2 (2.2)	4 (4.4)	16 (17.6)	1 (1.1)
Febrile neutropenia	22 (24.2)	0	0	21 (23.1)	1 (1.1)
Neutropenia	10 (11.0)	0	0	1 (1.1)	9 (9.9)
Endocrine disorders					
-Total	1 (1.1)	0	1 (1.1)	0	0
Hypothyroidism	1 (1.1)	0	1 (1.1)	0	0
Gastrointestinal disorders					
-Total	12 (13.2)	3 (3.3)	3 (3.3)	6 (6.6)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	6 (6.6)	3 (3.3)	3 (3.3)	0	0
Stomatitis	6 (6.6)	0	0	6 (6.6)	0
Oral pain	1 (1.1)	0	0	1 (1.1)	0
General disorders and administration site conditions					
-Total	14 (15.4)	3 (3.3)	9 (9.9)	2 (2.2)	0
Pyrexia	14 (15.4)	3 (3.3)	9 (9.9)	2 (2.2)	0
Infections and infestations					
-Total	4 (4.4)	0	0	3 (3.3)	1 (1.1)
Pneumonia	3 (3.3)	0	0	2 (2.2)	1 (1.1)
Escherichia bacteraemia	1 (1.1)	0	0	1 (1.1)	0
Investigations					
-Total	16 (17.6)	1 (1.1)	0	2 (2.2)	13 (14.3)
Neutrophil count decreased	11 (12.1)	1 (1.1)	0	2 (2.2)	8 (8.8)
White blood cell count decreased	7 (7.7)	1 (1.1)	0	0	6 (6.6)
Fibrin d dimer increased	1 (1.1)	0	0	0	1 (1.1)
Metabolism and nutrition disorders					
-Total	5 (5.5)	0	3 (3.3)	2 (2.2)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Hypocalcaemia	2 (2.2)	0	2 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (1.1)	1 (1.1)	0	0	0
Oropharyngeal pain	1 (1.1)	1 (1.1)	0	0	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (67.5)		2 (5.0)	9 (22.5)	16 (40.0)
Blood and lymphatic system disorders					
-Total	22 (55.0)	0	0	13 (32.5)	9 (22.5)
Febrile neutropenia	10 (25.0)	0	0	10 (25.0)	0
Anaemia	9 (22.5)	0	1 (2.5)	8 (20.0)	0
Neutropenia	9 (22.5)	0	0	0	9 (22.5)
Thrombocytopenia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Pancytopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					
-Total	1 (2.5)	0	0	1 (2.5)	0
Tachycardia	1 (2.5)	0	0	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Constipation	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Nausea	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal pain	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Pyrexia	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Fatigue	1 (2.5)	0	1 (2.5)	0	0
Pain	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	6 (15.0)	0	5 (12.5)	1 (2.5)	0
Hypogammaglobulinaemia	6 (15.0)	0	5 (12.5)	1 (2.5)	0
Investigations					
-Total	13 (32.5)	0	1 (2.5)	3 (7.5)	9 (22.5)
Neutrophil count decreased	7 (17.5)	0	0	2 (5.0)	5 (12.5)
Platelet count decreased	5 (12.5)	0	0	0	5 (12.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	5 (12.5)	0	0	0	5 (12.5)
Alanine aminotransferase increased	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
C-reactive protein increased	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	2 (5.0)	0	0	2 (5.0)	0
Hypokalaemia	1 (2.5)	0	0	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0
Nervous system disorders					
-Total	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Headache	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Vascular disorders					
-Total	1 (2.5)	0	0	0	1 (2.5)
Hypotension	1 (2.5)	0	0	0	1 (2.5)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (72.5)		8 (20.0)	12 (30.0)	9 (22.5)
Blood and lymphatic system disorders					
-Total	18 (45.0)	1 (2.5)	2 (5.0)	12 (30.0)	3 (7.5)
Anaemia	11 (27.5)	2 (5.0)	3 (7.5)	5 (12.5)	1 (2.5)
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	1 (2.5)	2 (5.0)	2 (5.0)
Neutropenia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0
Cardiac disorders					
-Total	2 (5.0)	2 (5.0)	0	0	0
Tachycardia	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	13 (32.5)	3 (7.5)	9 (22.5)	1 (2.5)	0
Abdominal pain	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Constipation	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Nausea	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Diarrhoea	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	11 (27.5)	1 (2.5)	10 (25.0)	0	0
Pyrexia	7 (17.5)	2 (5.0)	5 (12.5)	0	0
Fatigue	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Catheter site pain	2 (5.0)	0	2 (5.0)	0	0
Pain	2 (5.0)	0	2 (5.0)	0	0
Hepatobiliary disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Hyperbilirubinaemia	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
			All patients N=40		
Hypogammaglobulinaemia	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	10 (25.0)	0	2 (5.0)	2 (5.0)	6 (15.0)
Neutrophil count decreased	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Alanine aminotransferase increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
C-reactive protein increased	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Platelet count decreased	2 (5.0)	0	0	0	2 (5.0)
White blood cell count decreased	2 (5.0)	0	0	0	2 (5.0)
Metabolism and nutrition disorders					
-Total	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Hypokalaemia	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0	0	0
Nervous system disorders					
-Total	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Headache	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Psychiatric disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Mental status changes	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (2.5)	0	0	0	1 (2.5)
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Vascular disorders					
-Total	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Hypertension	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Hypotension	1 (2.5)	1 (2.5)	0	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215q
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)		2 (11.1)	5 (27.8)	8 (44.4)
Blood and lymphatic system disorders					
-Total	8 (44.4)	0	0	5 (27.8)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Tachycardia	3 (16.7)	0	1 (5.6)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	4 (22.2)	0	3 (16.7)	1 (5.6)	0
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Nausea	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					
-Total	7 (38.9)	1 (5.6)	3 (16.7)	3 (16.7)	0
Pyrexia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Investigations					
-Total	5 (27.8)	1 (5.6)	0	3 (16.7)	1 (5.6)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (27.8)	0	1 (5.6)	3 (16.7)	1 (5.6)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Headache	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	2 (11.1)	2 (11.1)	0	0	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	2 (11.1)	2 (11.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	5 (62.5)	3 (37.5)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Tachycardia	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Gastrointestinal disorders					
-Total	4 (50.0)	1 (12.5)	0	2 (25.0)	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
Tooth pulp haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Pyrexia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Localised infection	1 (12.5)	1 (12.5)	0	0	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (12.5)	1 (12.5)	0	0	0
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Hypocalcaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Acute kidney injury	2 (25.0)	2 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (37.5)	1 (12.5)	0	0	2 (25.0)
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (25.0)	0	0	2 (25.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 215r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (80.0)	2 (6.7)	4 (13.3)	10 (33.3)	8 (26.7)
Blood and lymphatic system disorders					
-Total	10 (33.3)	1 (3.3)	0	5 (16.7)	4 (13.3)
Anaemia	7 (23.3)	1 (3.3)	1 (3.3)	5 (16.7)	0
Thrombocytopenia	4 (13.3)	0	0	2 (6.7)	2 (6.7)
Febrile neutropenia	3 (10.0)	0	0	3 (10.0)	0
Neutropenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Gastrointestinal disorders					
-Total	8 (26.7)	1 (3.3)	3 (10.0)	4 (13.3)	0
Constipation	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Nausea	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (6.7)	0	0	2 (6.7)	0
Abdominal pain	1 (3.3)	0	0	1 (3.3)	0
General disorders and administration site conditions					
-Total	7 (23.3)	2 (6.7)	4 (13.3)	1 (3.3)	0
Pyrexia	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Catheter site pain	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Pain	2 (6.7)	0	2 (6.7)	0	0
Infections and infestations					
-Total	3 (10.0)	0	0	3 (10.0)	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Oral herpes	1 (3.3)	0	0	1 (3.3)	0
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Investigations					
-Total	8 (26.7)	0	0	5 (16.7)	3 (10.0)
C-reactive protein increased	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Serum ferritin increased	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Alanine aminotransferase increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.3)	0	1 (3.3)	0	0
Lymphocyte count decreased	1 (3.3)	0	0	1 (3.3)	0
Neutrophil count decreased	1 (3.3)	0	0	1 (3.3)	0
Platelet count decreased	1 (3.3)	0	0	0	1 (3.3)
White blood cell count decreased	1 (3.3)	0	0	0	1 (3.3)
Metabolism and nutrition disorders					
-Total	6 (20.0)	1 (3.3)	3 (10.0)	2 (6.7)	0
Decreased appetite	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Hypokalaemia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Hypoalbuminaemia	1 (3.3)	0	1 (3.3)	0	0
Hypomagnesaemia	1 (3.3)	0	1 (3.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Pain in extremity	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Arthralgia	1 (3.3)	1 (3.3)	0	0	0
Nervous system disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0

Number of previous relapses: 1

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (3.3)	1 (3.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Oropharyngeal pain	1 (3.3)	0	1 (3.3)	0	0
Vascular disorders					
-Total	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)
Hypotension	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Hypertension	1 (3.3)	0	1 (3.3)	0	0

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Table 215r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (88.9)	1 (5.6)	2 (11.1)	8 (44.4)	5 (27.8)
Blood and lymphatic system disorders					
-Total	12 (66.7)	1 (5.6)	0	8 (44.4)	3 (16.7)
Febrile neutropenia	7 (38.9)	0	0	7 (38.9)	0
Anaemia	6 (33.3)	1 (5.6)	2 (11.1)	2 (11.1)	1 (5.6)
Neutropenia	3 (16.7)	1 (5.6)	0	0	2 (11.1)
Thrombocytopenia	3 (16.7)	1 (5.6)	0	1 (5.6)	1 (5.6)
Gastrointestinal disorders					
-Total	5 (27.8)	1 (5.6)	3 (16.7)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	2 (11.1)	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Stomatitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Constipation	1 (5.6)	0	1 (5.6)	0	0
Haematemesis	1 (5.6)	1 (5.6)	0	0	0
Nausea	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					
-Total	3 (16.7)	0	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	3 (16.7)	0	0
Infections and infestations					
-Total	7 (38.9)	0	3 (16.7)	4 (22.2)	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Pneumonia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Sinusitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	0	0	1 (5.6)	0
Staphylococcal infection	1 (5.6)	0	0	1 (5.6)	0
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	3 (16.7)	1 (5.6)	0	2 (11.1)	0
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Serum ferritin increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	0	0	1 (5.6)	0
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
White blood cell count decreased	1 (5.6)	0	0	0	1 (5.6)
Metabolism and nutrition disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Hypocalcaemia	1 (5.6)	1 (5.6)	0	0	0
Hypokalaemia	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Arthralgia	2 (11.1)	2 (11.1)	0	0	0
Pain in extremity	1 (5.6)	0	0	1 (5.6)	0
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0

Number of previous relapses: 2

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Vascular disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Hypertension	1 (5.6)	0	1 (5.6)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 215r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (66.7)	2 (4.8)	2 (4.8)	9 (21.4)	15 (35.7)
Blood and lymphatic system disorders					
-Total	20 (47.6)	0	1 (2.4)	13 (31.0)	6 (14.3)
Febrile neutropenia	11 (26.2)	0	0	10 (23.8)	1 (2.4)
Anaemia	8 (19.0)	0	1 (2.4)	7 (16.7)	0
Neutropenia	5 (11.9)	0	0	0	5 (11.9)
Thrombocytopenia	1 (2.4)	0	1 (2.4)	0	0
Cardiac disorders					
-Total	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Tachycardia	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	8 (19.0)	1 (2.4)	5 (11.9)	2 (4.8)	0
Abdominal pain	4 (9.5)	2 (4.8)	2 (4.8)	0	0
Constipation	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Nausea	3 (7.1)	0	3 (7.1)	0	0
Stomatitis	2 (4.8)	0	0	2 (4.8)	0
General disorders and administration site conditions					
-Total	6 (14.3)	0	5 (11.9)	1 (2.4)	0
Pyrexia	4 (9.5)	0	4 (9.5)	0	0
Catheter site pain	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Pain	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Chills	1 (2.4)	0	1 (2.4)	0	0
Immune system disorders					
-Total	6 (14.3)	0	5 (11.9)	1 (2.4)	0
Hypogammaglobulinaemia	6 (14.3)	0	5 (11.9)	1 (2.4)	0
Infections and infestations					
-Total	5 (11.9)	0	2 (4.8)	2 (4.8)	1 (2.4)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (4.8)	0	0	1 (2.4)	1 (2.4)
Clostridium difficile colitis	1 (2.4)	0	1 (2.4)	0	0
Sinusitis	1 (2.4)	0	1 (2.4)	0	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Injury, poisoning and procedural complications					
-Total	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Procedural pain	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Investigations					
-Total	12 (28.6)	0	0	2 (4.8)	10 (23.8)
Neutrophil count decreased	9 (21.4)	1 (2.4)	0	1 (2.4)	7 (16.7)
Platelet count decreased	6 (14.3)	0	0	0	6 (14.3)
White blood cell count decreased	5 (11.9)	0	0	0	5 (11.9)
Aspartate aminotransferase increased	2 (4.8)	0	0	2 (4.8)	0
C-reactive protein increased	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Lymphocyte count decreased	2 (4.8)	0	0	0	2 (4.8)
Alanine aminotransferase increased	1 (2.4)	0	1 (2.4)	0	0
Blood creatinine increased	1 (2.4)	0	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	4 (9.5)	2 (4.8)	1 (2.4)	1 (2.4)	0
Hypokalaemia	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Decreased appetite	1 (2.4)	0	1 (2.4)	0	0
Hypomagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (9.5)	1 (2.4)	3 (7.1)	0	0
Arthralgia	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Pain in extremity	1 (2.4)	0	1 (2.4)	0	0
Nervous system disorders					
-Total	7 (16.7)	2 (4.8)	3 (7.1)	2 (4.8)	0
Headache	5 (11.9)	1 (2.4)	3 (7.1)	1 (2.4)	0
Neuropathy peripheral	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (4.8)	0	0	0	2 (4.8)
Respiratory failure	2 (4.8)	0	0	0	2 (4.8)
Vascular disorders					

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (16.7)	3 (7.1)	3 (7.1)	0	1 (2.4)
Hypertension	5 (11.9)	2 (4.8)	3 (7.1)	0	0
Hypotension	2 (4.8)	1 (2.4)	0	0	1 (2.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216a
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (61.8)	4 (11.8)	6 (17.6)	0	11 (32.4)
Blood and lymphatic system disorders					
-Total	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Anaemia	4 (11.8)	0	1 (2.9)	3 (8.8)	0
Gastrointestinal disorders					
-Total	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Nausea	5 (14.7)	3 (8.8)	2 (5.9)	0	0
General disorders and administration site conditions					
-Total	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Pyrexia	6 (17.6)	4 (11.8)	2 (5.9)	0	0

Age: <10 years

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	12 (35.3)	0	1 (2.9)	0	11 (32.4)
White blood cell count decreased	7 (20.6)	0	1 (2.9)	1 (2.9)	5 (14.7)
Lymphocyte count decreased	5 (14.7)	0	0	0	5 (14.7)
Platelet count decreased	5 (14.7)	0	0	1 (2.9)	4 (11.8)
Neutrophil count decreased	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Skin and subcutaneous tissue disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Pruritus	1 (2.9)	0	1 (2.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216a
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (35.5)	2 (6.5)	3 (9.7)	2 (6.5)	4 (12.9)
Blood and lymphatic system disorders					
-Total	4 (12.9)	1 (3.2)	0	3 (9.7)	0
Anaemia	4 (12.9)	1 (3.2)	0	3 (9.7)	0
Febrile neutropenia	2 (6.5)	0	0	2 (6.5)	0
Gastrointestinal disorders					
-Total	5 (16.1)	1 (3.2)	3 (9.7)	1 (3.2)	0
Nausea	5 (16.1)	1 (3.2)	3 (9.7)	1 (3.2)	0
General disorders and administration site conditions					
-Total	1 (3.2)	0	1 (3.2)	0	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	5 (16.1)	0	0	1 (3.2)	4 (12.9)
White blood cell count decreased	4 (12.9)	0	0	1 (3.2)	3 (9.7)
Neutrophil count decreased	3 (9.7)	0	1 (3.2)	0	2 (6.5)
Lymphocyte count decreased	1 (3.2)	0	0	0	1 (3.2)
Platelet count decreased	1 (3.2)	0	0	0	1 (3.2)
Skin and subcutaneous tissue disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Pruritus	1 (3.2)	1 (3.2)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216a
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (46.2)	1 (7.7)	3 (23.1)	2 (15.4)	0
Blood and lymphatic system disorders					
-Total	2 (15.4)	0	0	2 (15.4)	0
Febrile neutropenia	2 (15.4)	0	0	2 (15.4)	0
Gastrointestinal disorders					
-Total	3 (23.1)	1 (7.7)	2 (15.4)	0	0
Nausea	3 (23.1)	1 (7.7)	2 (15.4)	0	0
General disorders and administration site conditions					
-Total	1 (7.7)	0	1 (7.7)	0	0

Age: >=18

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	1 (7.7)	0	1 (7.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Pruritus	2 (15.4)	1 (7.7)	1 (7.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216b
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (39.1)	4 (8.7)	6 (13.0)	3 (6.5)	5 (10.9)
Blood and lymphatic system disorders					
-Total	5 (10.9)	0	0	5 (10.9)	0
Anaemia	5 (10.9)	0	0	5 (10.9)	0
Gastrointestinal disorders					
-Total	7 (15.2)	4 (8.7)	2 (4.3)	1 (2.2)	0
Nausea	5 (10.9)	2 (4.3)	2 (4.3)	1 (2.2)	0
Vomiting	3 (6.5)	3 (6.5)	0	0	0
General disorders and administration site conditions					

Gender: Male

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (15.2)	4 (8.7)	3 (6.5)	0	0
Pyrexia	7 (15.2)	4 (8.7)	3 (6.5)	0	0
Investigations					
-Total	7 (15.2)	0	1 (2.2)	1 (2.2)	5 (10.9)
White blood cell count decreased	6 (13.0)	0	1 (2.2)	1 (2.2)	4 (8.7)
Neutrophil count decreased	3 (6.5)	0	0	0	3 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216b
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (53.1)	4 (12.5)	6 (18.8)	2 (6.3)	5 (15.6)
Blood and lymphatic system disorders					
-Total	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Anaemia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders					
-Total	11 (34.4)	4 (12.5)	6 (18.8)	1 (3.1)	0
Nausea	8 (25.0)	3 (9.4)	5 (15.6)	0	0
Vomiting	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions					

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	1 (3.1)	0	0
Pyrexia	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	6 (18.8)	0	0	1 (3.1)	5 (15.6)
White blood cell count decreased	5 (15.6)	0	0	1 (3.1)	4 (12.5)
Neutrophil count decreased	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
Skin and subcutaneous tissue disorders					
-Total	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Pruritus	4 (12.5)	2 (6.3)	2 (6.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216c
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (56.1)	8 (14.0)	10 (17.5)	3 (5.3)	11 (19.3)
Blood and lymphatic system disorders					
-Total	7 (12.3)	1 (1.8)	0	6 (10.5)	0
Anaemia	6 (10.5)	1 (1.8)	0	5 (8.8)	0
Febrile neutropenia	2 (3.5)	0	0	2 (3.5)	0
Gastrointestinal disorders					
-Total	12 (21.1)	7 (12.3)	4 (7.0)	1 (1.8)	0
Nausea	9 (15.8)	4 (7.0)	4 (7.0)	1 (1.8)	0
Vomiting	5 (8.8)	5 (8.8)	0	0	0
Abdominal pain	2 (3.5)	2 (3.5)	0	0	0

Race: White

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	7 (12.3)	3 (5.3)	4 (7.0)	0	0
Pyrexia	7 (12.3)	3 (5.3)	4 (7.0)	0	0
Investigations					
-Total	15 (26.3)	2 (3.5)	1 (1.8)	1 (1.8)	11 (19.3)
White blood cell count decreased	9 (15.8)	0	1 (1.8)	2 (3.5)	6 (10.5)
Neutrophil count decreased	6 (10.5)	0	1 (1.8)	1 (1.8)	4 (7.0)
Lymphocyte count decreased	4 (7.0)	0	0	0	4 (7.0)
Platelet count decreased	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Blood fibrinogen decreased	1 (1.8)	1 (1.8)	0	0	0
International normalised ratio increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Decreased appetite	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Nervous system disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Headache	1 (1.8)	1 (1.8)	0	0	0

Race: White

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Pruritus	1 (1.8)	0	1 (1.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216c
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (70.0)	5 (50.0)	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders					
-Total	5 (50.0)	3 (30.0)	1 (10.0)	1 (10.0)	0
Nausea	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Abdominal pain	1 (10.0)	1 (10.0)	0	0	0
Constipation	1 (10.0)	1 (10.0)	0	0	0
Haematemesis	1 (10.0)	1 (10.0)	0	0	0
Vomiting	1 (10.0)	0	0	1 (10.0)	0
Immune system disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0

Race: Asian

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (10.0)	0	1 (10.0)	0	0
Infections and infestations					
-Total	1 (10.0)	1 (10.0)	0	0	0
Tinea pedis	1 (10.0)	1 (10.0)	0	0	0
Investigations					
-Total	1 (10.0)	0	0	1 (10.0)	0
Blood fibrinogen decreased	1 (10.0)	0	0	1 (10.0)	0
International normalised ratio increased	1 (10.0)	1 (10.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (20.0)	2 (20.0)	0	0	0
Decreased appetite	1 (10.0)	1 (10.0)	0	0	0
Vitamin d deficiency	1 (10.0)	1 (10.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Muscular weakness	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0

Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (10.0)	1 (10.0)	0	0	0
Posterior reversible encephalopathy syndrome	1 (10.0)	0	1 (10.0)	0	0
Seizure	1 (10.0)	0	1 (10.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (20.0)	2 (20.0)	0	0	0
Pruritus	2 (20.0)	2 (20.0)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216c
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	2 (18.2)	1 (9.1)	4 (36.4)
Blood and lymphatic system disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Anaemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Gastrointestinal disorders					
-Total	3 (27.3)	0	3 (27.3)	0	0
Nausea	2 (18.2)	0	2 (18.2)	0	0
Constipation	1 (9.1)	0	1 (9.1)	0	0
Vomiting	1 (9.1)	0	1 (9.1)	0	0

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	1 (9.1)	1 (9.1)	0	0	0
Pyrexia	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Platelet count decreased	2 (18.2)	0	0	0	2 (18.2)
White blood cell count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hypomagnesaemia	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Hypophosphataemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					

Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (9.1)	0	1 (9.1)	0	0
Pruritus	1 (9.1)	0	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216d
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (78.6)	2 (14.3)	3 (21.4)	2 (14.3)	4 (28.6)
Blood and lymphatic system disorders					
-Total	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Anaemia	3 (21.4)	1 (7.1)	0	2 (14.3)	0
Febrile neutropenia	2 (14.3)	0	0	2 (14.3)	0
Gastrointestinal disorders					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Vomiting	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Nausea	2 (14.3)	0	2 (14.3)	0	0
General disorders and administration site conditions					

Ethnicity: Hispanic or Latino

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Chills	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pyrexia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Investigations					
-Total	5 (35.7)	0	0	1 (7.1)	4 (28.6)
Neutrophil count decreased	3 (21.4)	0	1 (7.1)	0	2 (14.3)
White blood cell count decreased	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Platelet count decreased	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Metabolism and nutrition disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hypomagnesaemia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216d
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (40.6)	6 (9.4)	8 (12.5)	4 (6.3)	8 (12.5)
Blood and lymphatic system disorders					
-Total	6 (9.4)	0	1 (1.6)	5 (7.8)	0
Anaemia	5 (7.8)	0	1 (1.6)	4 (6.3)	0
Febrile neutropenia	2 (3.1)	0	0	2 (3.1)	0
Gastrointestinal disorders					
-Total	13 (20.3)	6 (9.4)	5 (7.8)	2 (3.1)	0
Nausea	11 (17.2)	5 (7.8)	5 (7.8)	1 (1.6)	0
Vomiting	4 (6.3)	3 (4.7)	0	1 (1.6)	0
General disorders and administration site conditions					

Ethnicity: Other

Group term Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Pyrexia	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Investigations					
-Total	10 (15.6)	0	1 (1.6)	1 (1.6)	8 (12.5)
White blood cell count decreased	8 (12.5)	0	1 (1.6)	1 (1.6)	6 (9.4)
Neutrophil count decreased	4 (6.3)	0	0	1 (1.6)	3 (4.7)
Platelet count decreased	4 (6.3)	0	0	0	4 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216e
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	1 (16.7)	2 (33.3)	0
Blood and lymphatic system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Anaemia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Eyelid oedema	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Abdominal pain	2 (33.3)	2 (33.3)	0	0	0

Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (16.7)	1 (16.7)	0	0	0
Stomatitis	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vulval cellulitis	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)	0	0
White blood cell count decreased	1 (16.7)	0	0	1 (16.7)	0
Metabolism and nutrition disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Decreased appetite	2 (33.3)	2 (33.3)	0	0	0

Response status at study entry: Primary refractory

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Pain in extremity	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0
Somnolence	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Irritability	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Dysuria	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Petechiae	1 (16.7)	1 (16.7)	0	0	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Hypotension	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216e
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (50.0)	6 (8.3)	15 (20.8)	5 (6.9)	10 (13.9)
Blood and lymphatic system disorders					
-Total	7 (9.7)	0	1 (1.4)	6 (8.3)	0
Anaemia	7 (9.7)	0	1 (1.4)	6 (8.3)	0
Gastrointestinal disorders					
-Total	14 (19.4)	4 (5.6)	9 (12.5)	1 (1.4)	0
Nausea	12 (16.7)	4 (5.6)	7 (9.7)	1 (1.4)	0
Stomatitis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Abdominal pain	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					

Response status at study entry: Relapsed disease

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (11.1)	4 (5.6)	4 (5.6)	0	0
Pyrexia	8 (11.1)	4 (5.6)	4 (5.6)	0	0
Immune system disorders					
-Total	1 (1.4)	0	0	1 (1.4)	0
Hypogammaglobulinaemia	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	12 (16.7)	0	1 (1.4)	1 (1.4)	10 (13.9)
White blood cell count decreased	10 (13.9)	0	1 (1.4)	1 (1.4)	8 (11.1)
Neutrophil count decreased	6 (8.3)	0	0	1 (1.4)	5 (6.9)
Alanine aminotransferase increased	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Aspartate aminotransferase increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Decreased appetite	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Nervous system disorders					
-Total	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Headache	2 (2.8)	1 (1.4)	1 (1.4)	0	0

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Pruritus	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hypotension	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216f
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Immune system disorders					
-Total	1 (100)	0	0	1 (100)	0
Hypogammaglobulinaemia	1 (100)	0	0	1 (100)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Pleural effusion	1 (100)	0	1 (100)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216f
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (40.3)	7 (9.1)	12 (15.6)	4 (5.2)	8 (10.4)
Blood and lymphatic system disorders					
-Total	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Gastrointestinal disorders					
-Total	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Nausea	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
General disorders and administration site conditions					
-Total	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

Group term Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immune system disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Hypogammaglobulinaemia	1 (1.3)	0	1 (1.3)	0	0
Investigations					
-Total	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216g
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216g
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (39.0)	7 (9.1)	11 (14.3)	4 (5.2)	8 (10.4)
Blood and lymphatic system disorders					
-Total	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Gastrointestinal disorders					
-Total	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Nausea	12 (15.6)	4 (5.2)	7 (9.1)	1 (1.3)	0
Abdominal pain	2 (2.6)	2 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	8 (10.4)	4 (5.2)	4 (5.2)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Investigations					
-Total	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216h
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Lymphocyte count decreased	1 (100)	0	0	0	1 (100)
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216h
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (44.2)	7 (9.1)	11 (14.3)	3 (3.9)	13 (16.9)
Blood and lymphatic system disorders					
-Total	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Gastrointestinal disorders					
-Total	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Nausea	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
General disorders and administration site conditions					
-Total	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	15 (19.5)	0	1 (1.3)	1 (1.3)	13 (16.9)
White blood cell count decreased	10 (13.0)	0	1 (1.3)	2 (2.6)	7 (9.1)
Neutrophil count decreased	6 (7.8)	0	1 (1.3)	0	5 (6.5)
Lymphocyte count decreased	5 (6.5)	0	0	0	5 (6.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216i
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=77				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (39.0)	7 (9.1)	11 (14.3)	4 (5.2)	8 (10.4)
Blood and lymphatic system disorders					
-Total	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Anaemia	8 (10.4)	1 (1.3)	1 (1.3)	6 (7.8)	0
Gastrointestinal disorders					
-Total	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
Nausea	13 (16.9)	5 (6.5)	7 (9.1)	1 (1.3)	0
General disorders and administration site conditions					
-Total	8 (10.4)	4 (5.2)	4 (5.2)	0	0
Pyrexia	8 (10.4)	4 (5.2)	4 (5.2)	0	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=77 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)
White blood cell count decreased	11 (14.3)	0	1 (1.3)	2 (2.6)	8 (10.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216j
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (40.7)	5 (18.5)	4 (14.8)	1 (3.7)	1 (3.7)
Blood and lymphatic system disorders					
-Total	1 (3.7)	0	0	1 (3.7)	0
Anaemia	1 (3.7)	0	0	1 (3.7)	0
Gastrointestinal disorders					
-Total	8 (29.6)	5 (18.5)	2 (7.4)	1 (3.7)	0
Nausea	6 (22.2)	3 (11.1)	2 (7.4)	1 (3.7)	0
Vomiting	3 (11.1)	3 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Investigations					
-Total	2 (7.4)	0	1 (3.7)	0	1 (3.7)
Neutrophil count decreased	1 (3.7)	0	0	0	1 (3.7)
White blood cell count decreased	1 (3.7)	0	1 (3.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216j
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (51.0)	3 (5.9)	7 (13.7)	2 (3.9)	14 (27.5)
Blood and lymphatic system disorders					
-Total	7 (13.7)	1 (2.0)	1 (2.0)	5 (9.8)	0
Anaemia	7 (13.7)	1 (2.0)	1 (2.0)	5 (9.8)	0
Gastrointestinal disorders					
-Total	10 (19.6)	3 (5.9)	6 (11.8)	1 (2.0)	0
Nausea	7 (13.7)	2 (3.9)	5 (9.8)	0	0
Vomiting	4 (7.8)	2 (3.9)	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions					
-Total	6 (11.8)	3 (5.9)	3 (5.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	6 (11.8)	3 (5.9)	3 (5.9)	0	0
Investigations					
-Total	15 (29.4)	0	0	1 (2.0)	14 (27.5)
White blood cell count decreased	10 (19.6)	0	0	2 (3.9)	8 (15.7)
Lymphocyte count decreased	6 (11.8)	0	0	0	6 (11.8)
Neutrophil count decreased	6 (11.8)	0	1 (2.0)	1 (2.0)	4 (7.8)
Platelet count decreased	6 (11.8)	0	0	1 (2.0)	5 (9.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216k
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Europe

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (44.4)	1 (3.7)	4 (14.8)	1 (3.7)	6 (22.2)
Blood and lymphatic system disorders					
-Total	2 (7.4)	0	0	2 (7.4)	0
Anaemia	2 (7.4)	0	0	2 (7.4)	0
Gastrointestinal disorders					
-Total	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Nausea	2 (7.4)	0	2 (7.4)	0	0
Vomiting	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	5 (18.5)	2 (7.4)	3 (11.1)	0	0

Region: Europe

Group term Preferred term	All patients N=27 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	5 (18.5)	2 (7.4)	3 (11.1)	0	0
Investigations					
-Total	6 (22.2)	0	0	0	6 (22.2)
Lymphocyte count decreased	5 (18.5)	0	0	0	5 (18.5)
White blood cell count decreased	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Neutrophil count decreased	2 (7.4)	0	0	1 (3.7)	1 (3.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216k
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (61.4)	7 (15.9)	9 (20.5)	3 (6.8)	8 (18.2)
Blood and lymphatic system disorders					
-Total	6 (13.6)	1 (2.3)	1 (2.3)	4 (9.1)	0
Anaemia	6 (13.6)	1 (2.3)	1 (2.3)	4 (9.1)	0
Gastrointestinal disorders					
-Total	14 (31.8)	6 (13.6)	6 (13.6)	2 (4.5)	0
Nausea	10 (22.7)	4 (9.1)	5 (11.4)	1 (2.3)	0
Vomiting	6 (13.6)	4 (9.1)	1 (2.3)	1 (2.3)	0
Constipation	1 (2.3)	0	1 (2.3)	0	0
General disorders and administration site conditions					

Region: US

Group term Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Pyrexia	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Investigations					
-Total	10 (22.7)	0	1 (2.3)	1 (2.3)	8 (18.2)
White blood cell count decreased	7 (15.9)	0	1 (2.3)	1 (2.3)	5 (11.4)
Neutrophil count decreased	5 (11.4)	0	1 (2.3)	0	4 (9.1)
Lymphocyte count decreased	1 (2.3)	0	0	0	1 (2.3)
Metabolism and nutrition disorders					
-Total	6 (13.6)	3 (6.8)	3 (6.8)	0	0
Decreased appetite	6 (13.6)	3 (6.8)	3 (6.8)	0	0
Nervous system disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Headache	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Pruritus	3 (6.8)	1 (2.3)	2 (4.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216k
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: Rest of World

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	4 (57.1)	0	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Nausea	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	1 (14.3)	1 (14.3)	0	0	0
Tinea pedis	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0

Region: Rest of World

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216l
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=46				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (43.5)	5 (10.9)	6 (13.0)	1 (2.2)	8 (17.4)
Blood and lymphatic system disorders					
-Total	4 (8.7)	0	1 (2.2)	3 (6.5)	0
Anaemia	4 (8.7)	0	1 (2.2)	3 (6.5)	0
Gastrointestinal disorders					
-Total	7 (15.2)	3 (6.5)	4 (8.7)	0	0
Nausea	7 (15.2)	3 (6.5)	4 (8.7)	0	0
General disorders and administration site conditions					
-Total	6 (13.0)	3 (6.5)	3 (6.5)	0	0
Pyrexia	6 (13.0)	3 (6.5)	3 (6.5)	0	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=46 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	9 (19.6)	0	0	1 (2.2)	8 (17.4)
White blood cell count decreased	8 (17.4)	0	0	1 (2.2)	7 (15.2)
Neutrophil count decreased	5 (10.9)	0	0	1 (2.2)	4 (8.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216l
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (37.5)	2 (6.3)	5 (15.6)	3 (9.4)	2 (6.3)
Blood and lymphatic system disorders					
-Total	4 (12.5)	1 (3.1)	0	3 (9.4)	0
Anaemia	4 (12.5)	1 (3.1)	0	3 (9.4)	0
Gastrointestinal disorders					
-Total	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Nausea	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
General disorders and administration site conditions					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Prior SCT therapy: No

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	4 (12.5)	0	1 (3.1)	1 (3.1)	2 (6.3)
White blood cell count decreased	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Neutrophil count decreased	2 (6.3)	0	1 (3.1)	0	1 (3.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216m
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (46.2)	4 (30.8)	2 (15.4)	0	0
Gastrointestinal disorders					
-Total	6 (46.2)	4 (30.8)	2 (15.4)	0	0
Nausea	6 (46.2)	4 (30.8)	2 (15.4)	0	0
Vomiting	2 (15.4)	2 (15.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (15.4)	2 (15.4)	0	0	0
Rash papular	2 (15.4)	2 (15.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216m
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (43.1)	4 (6.2)	9 (13.8)	5 (7.7)	10 (15.4)
Blood and lymphatic system disorders					
-Total	8 (12.3)	1 (1.5)	1 (1.5)	6 (9.2)	0
Anaemia	8 (12.3)	1 (1.5)	1 (1.5)	6 (9.2)	0
Gastrointestinal disorders					
-Total	12 (18.5)	4 (6.2)	6 (9.2)	2 (3.1)	0
Nausea	7 (10.8)	1 (1.5)	5 (7.7)	1 (1.5)	0
Vomiting	5 (7.7)	3 (4.6)	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions					
-Total	8 (12.3)	4 (6.2)	4 (6.2)	0	0

Eligibility for SCT: No

	All patients N=65				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	8 (12.3)	4 (6.2)	4 (6.2)	0	0
Investigations					
-Total	13 (20.0)	0	1 (1.5)	2 (3.1)	10 (15.4)
White blood cell count decreased	11 (16.9)	0	1 (1.5)	2 (3.1)	8 (12.3)
Neutrophil count decreased	7 (10.8)	0	1 (1.5)	1 (1.5)	5 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216n
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (52.0)	2 (8.0)	7 (28.0)	2 (8.0)	2 (8.0)
Blood and lymphatic system disorders					
-Total	3 (12.0)	0	0	3 (12.0)	0
Anaemia	3 (12.0)	0	0	3 (12.0)	0
Gastrointestinal disorders					
-Total	7 (28.0)	1 (4.0)	5 (20.0)	1 (4.0)	0
Nausea	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Stomatitis	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Vomiting	3 (12.0)	2 (8.0)	1 (4.0)	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: Low

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Pyrexia	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Investigations					
-Total	3 (12.0)	0	1 (4.0)	0	2 (8.0)
White blood cell count decreased	3 (12.0)	0	1 (4.0)	0	2 (8.0)
Metabolism and nutrition disorders					
-Total	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Decreased appetite	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Vascular disorders					
-Total	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0
Hypotension	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216n
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (47.2)	6 (11.3)	9 (17.0)	4 (7.5)	6 (11.3)
Blood and lymphatic system disorders					
-Total	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Anaemia	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Gastrointestinal disorders					
-Total	13 (24.5)	6 (11.3)	6 (11.3)	1 (1.9)	0
Nausea	9 (17.0)	4 (7.5)	5 (9.4)	0	0
Vomiting	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Stomatitis	1 (1.9)	0	1 (1.9)	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (11.3)	3 (5.7)	3 (5.7)	0	0
Pyrexia	6 (11.3)	3 (5.7)	3 (5.7)	0	0
Investigations					
-Total	8 (15.1)	0	0	2 (3.8)	6 (11.3)
White blood cell count decreased	8 (15.1)	0	0	2 (3.8)	6 (11.3)
Metabolism and nutrition disorders					
-Total	2 (3.8)	0	2 (3.8)	0	0
Decreased appetite	2 (3.8)	0	2 (3.8)	0	0
Vascular disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Hypotension	1 (1.9)	1 (1.9)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216o
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	1 (9.1)	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Nausea	2 (18.2)	0	2 (18.2)	0	0
General disorders and administration site conditions					
-Total	1 (9.1)	1 (9.1)	0	0	0
Pyrexia	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	1 (9.1)	0	0	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216o
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (43.3)	6 (9.0)	10 (14.9)	4 (6.0)	9 (13.4)
Blood and lymphatic system disorders					
-Total	8 (11.9)	1 (1.5)	1 (1.5)	6 (9.0)	0
Anaemia	8 (11.9)	1 (1.5)	1 (1.5)	6 (9.0)	0
Gastrointestinal disorders					
-Total	11 (16.4)	5 (7.5)	5 (7.5)	1 (1.5)	0
Nausea	11 (16.4)	5 (7.5)	5 (7.5)	1 (1.5)	0
General disorders and administration site conditions					
-Total	7 (10.4)	3 (4.5)	4 (6.0)	0	0
Pyrexia	7 (10.4)	3 (4.5)	4 (6.0)	0	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	12 (17.9)	0	1 (1.5)	2 (3.0)	9 (13.4)
White blood cell count decreased	10 (14.9)	0	1 (1.5)	2 (3.0)	7 (10.4)
Neutrophil count decreased	7 (10.4)	0	1 (1.5)	1 (1.5)	5 (7.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216p
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	2 (33.3)	1 (16.7)	0	3 (50.0)
Blood and lymphatic system disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Anaemia	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Constipation	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	1 (16.7)	0	1 (16.7)	0	0
Catheter site pain	1 (16.7)	0	1 (16.7)	0	0

Down syndrome: Yes

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (16.7)	1 (16.7)	0	0	0
Paronychia	1 (16.7)	1 (16.7)	0	0	0
Investigations					
-Total	3 (50.0)	0	0	0	3 (50.0)
Platelet count decreased	2 (33.3)	0	0	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)	0	0
Lymphocyte count decreased	1 (16.7)	0	0	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	1 (16.7)	0	0	0
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Hyperphosphataemia	1 (16.7)	1 (16.7)	0	0	0
Hypoalbuminaemia	1 (16.7)	1 (16.7)	0	0	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					

Down syndrome: Yes

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Erythema	1 (16.7)	1 (16.7)	0	0	0
Ingrowing nail	1 (16.7)	0	1 (16.7)	0	0
Rash	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216p
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (47.2)	7 (9.7)	12 (16.7)	3 (4.2)	12 (16.7)
Blood and lymphatic system disorders					
-Total	7 (9.7)	1 (1.4)	1 (1.4)	5 (6.9)	0
Anaemia	7 (9.7)	1 (1.4)	1 (1.4)	5 (6.9)	0
Gastrointestinal disorders					
-Total	13 (18.1)	5 (6.9)	7 (9.7)	1 (1.4)	0
Nausea	13 (18.1)	5 (6.9)	7 (9.7)	1 (1.4)	0
Constipation	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	8 (11.1)	4 (5.6)	4 (5.6)	0	0

Down syndrome: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	8 (11.1)	4 (5.6)	4 (5.6)	0	0
Infections and infestations					
-Total	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	14 (19.4)	0	1 (1.4)	1 (1.4)	12 (16.7)
White blood cell count decreased	10 (13.9)	0	1 (1.4)	2 (2.8)	7 (9.7)
Neutrophil count decreased	6 (8.3)	0	1 (1.4)	1 (1.4)	4 (5.6)
Lymphocyte count decreased	5 (6.9)	0	0	0	5 (6.9)
Platelet count decreased	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Alanine aminotransferase increased	2 (2.8)	2 (2.8)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Hyperphosphataemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	1 (1.4)	0	0	0
Hypocalcaemia	1 (1.4)	0	0	1 (1.4)	0
Skin and subcutaneous tissue disorders					

Down syndrome: No

Group term Preferred term	All patients N=72 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216q
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (39.5)	2 (5.3)	2 (5.3)	1 (2.6)	10 (26.3)
Blood and lymphatic system disorders					
-Total	5 (13.2)	1 (2.6)	1 (2.6)	3 (7.9)	0
Anaemia	5 (13.2)	1 (2.6)	1 (2.6)	3 (7.9)	0
Cardiac disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Tachycardia	1 (2.6)	1 (2.6)	0	0	0
Gastrointestinal disorders					
-Total	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Nausea	3 (7.9)	2 (5.3)	1 (2.6)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (2.6)	1 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	4 (10.5)	2 (5.3)	2 (5.3)	0	0
Pyrexia	4 (10.5)	2 (5.3)	2 (5.3)	0	0
Investigations					
-Total	11 (28.9)	0	0	1 (2.6)	10 (26.3)
White blood cell count decreased	8 (21.1)	0	0	2 (5.3)	6 (15.8)
Lymphocyte count decreased	5 (13.2)	0	0	0	5 (13.2)
Neutrophil count decreased	4 (10.5)	0	1 (2.6)	1 (2.6)	2 (5.3)
Platelet count decreased	4 (10.5)	0	0	0	4 (10.5)
Metabolism and nutrition disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Decreased appetite	1 (2.6)	0	1 (2.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216q
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (64.1)	8 (20.5)	10 (25.6)	2 (5.1)	5 (12.8)
Blood and lymphatic system disorders					
-Total	3 (7.7)	0	0	3 (7.7)	0
Anaemia	3 (7.7)	0	0	3 (7.7)	0
Gastrointestinal disorders					
-Total	15 (38.5)	6 (15.4)	7 (17.9)	2 (5.1)	0
Nausea	10 (25.6)	3 (7.7)	6 (15.4)	1 (2.6)	0
Vomiting	6 (15.4)	4 (10.3)	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions					
-Total	4 (10.3)	2 (5.1)	2 (5.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Investigations					
-Total	6 (15.4)	0	1 (2.6)	0	5 (12.8)
Neutrophil count decreased	3 (7.7)	0	0	0	3 (7.7)
White blood cell count decreased	3 (7.7)	0	1 (2.6)	0	2 (5.1)
Platelet count decreased	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Lymphocyte count decreased	1 (2.6)	0	0	0	1 (2.6)
Metabolism and nutrition disorders					
-Total	5 (12.8)	3 (7.7)	2 (5.1)	0	0
Decreased appetite	5 (12.8)	3 (7.7)	2 (5.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216q
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Cardiac disorders					
-Total	1 (100)	1 (100)	0	0	0
Tachycardia	1 (100)	1 (100)	0	0	0
General disorders and administration site conditions					
-Total	1 (100)	0	0	1 (100)	0
Generalised oedema	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungaemia	1 (100)	0	0	0	1 (100)
Renal and urinary disorders					
-Total	1 (100)	1 (100)	0	0	0
Acute kidney injury	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	0	1 (100)
Pulmonary haemorrhage	1 (100)	0	0	0	1 (100)
Respiratory failure	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	1 (16.7)	2 (33.3)	0
Blood and lymphatic system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Anaemia	1 (16.7)	1 (16.7)	0	0	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Eyelid oedema	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Abdominal pain	2 (33.3)	2 (33.3)	0	0	0

Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (16.7)	1 (16.7)	0	0	0
Stomatitis	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Hypogammaglobulinaemia	1 (16.7)	0	1 (16.7)	0	0
Infections and infestations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Vulval cellulitis	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	1 (16.7)	0	0	1 (16.7)	0
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)	0	0
White blood cell count decreased	1 (16.7)	0	0	1 (16.7)	0
Metabolism and nutrition disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Decreased appetite	2 (33.3)	2 (33.3)	0	0	0

Number of previous relapses: 0

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Pain in extremity	1 (16.7)	1 (16.7)	0	0	0
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0
Somnolence	1 (16.7)	1 (16.7)	0	0	0
Psychiatric disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Irritability	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Dysuria	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Petechiae	1 (16.7)	1 (16.7)	0	0	0
Pruritus	1 (16.7)	0	1 (16.7)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Hypotension	1 (16.7)	1 (16.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (63.6)	3 (13.6)	3 (13.6)	3 (13.6)	5 (22.7)
Blood and lymphatic system disorders					
-Total	3 (13.6)	0	0	3 (13.6)	0
Anaemia	3 (13.6)	0	0	3 (13.6)	0
Gastrointestinal disorders					
-Total	6 (27.3)	3 (13.6)	2 (9.1)	1 (4.5)	0
Nausea	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Vomiting	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Abdominal pain	1 (4.5)	1 (4.5)	0	0	0
Stomatitis	1 (4.5)	0	0	1 (4.5)	0

Number of previous relapses: 1

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Pyrexia	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Investigations					
-Total	6 (27.3)	0	1 (4.5)	0	5 (22.7)
Lymphocyte count decreased	3 (13.6)	0	0	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Neutrophil count decreased	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Metabolism and nutrition disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Decreased appetite	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pruritus	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Vascular disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Hypotension	1 (4.5)	0	0	1 (4.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 216r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (53.3)	3 (20.0)	3 (20.0)	1 (6.7)	1 (6.7)
Blood and lymphatic system disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Gastrointestinal disorders					
-Total	6 (40.0)	2 (13.3)	3 (20.0)	1 (6.7)	0
Nausea	4 (26.7)	1 (6.7)	3 (20.0)	0	0
Vomiting	2 (13.3)	1 (6.7)	0	1 (6.7)	0
General disorders and administration site conditions					

Number of previous relapses: 2

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	1 (6.7)	0	0	0
Pyrexia	1 (6.7)	1 (6.7)	0	0	0
Investigations					
-Total	1 (6.7)	0	0	0	1 (6.7)
Neutrophil count decreased	1 (6.7)	0	0	0	1 (6.7)
White blood cell count decreased	1 (6.7)	0	0	0	1 (6.7)
Nervous system disorders					
-Total	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Headache	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Pruritus	1 (6.7)	1 (6.7)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 216r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (54.3)	1 (2.9)	9 (25.7)	1 (2.9)	8 (22.9)
Blood and lymphatic system disorders					
-Total	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Anaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Gastrointestinal disorders					
-Total	7 (20.0)	2 (5.7)	5 (14.3)	0	0
Nausea	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Vomiting	3 (8.6)	3 (8.6)	0	0	0
Stomatitis	2 (5.7)	0	2 (5.7)	0	0

Number of previous relapses: >=3

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Pyrexia	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Immune system disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Hypogammaglobulinaemia	1 (2.9)	0	0	1 (2.9)	0
Investigations					
-Total	8 (22.9)	0	0	0	8 (22.9)
White blood cell count decreased	6 (17.1)	0	0	1 (2.9)	5 (14.3)
Lymphocyte count decreased	3 (8.6)	0	0	0	3 (8.6)
Neutrophil count decreased	3 (8.6)	0	0	0	3 (8.6)
Alanine aminotransferase increased	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (8.6)	0	3 (8.6)	0	0
Decreased appetite	3 (8.6)	0	3 (8.6)	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hypotension	2 (5.7)	1 (2.9)	1 (2.9)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- Apatient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	2 (25.0)	6 (75.0)
Blood and lymphatic system disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Anaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	0	0	1 (12.5)	0
Cardiac disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Tachycardia	1 (12.5)	0	1 (12.5)	0	0
Endocrine disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)

Age: <10 years

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia of malignancy	1 (12.5)	0	0	0	1 (12.5)
Gastrointestinal disorders					
-Total	3 (37.5)	0	0	3 (37.5)	0
Abdominal pain	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Diarrhoea	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Duodenal perforation	1 (12.5)	0	0	1 (12.5)	0
Gastritis	1 (12.5)	0	1 (12.5)	0	0
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Catheter site pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Oedema peripheral	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Generalised oedema	1 (12.5)	0	0	1 (12.5)	0
Pain	1 (12.5)	0	0	1 (12.5)	0
Pyrexia	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0

Age: <10 years

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypersensitivity	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Acute sinusitis	1 (12.5)	0	0	1 (12.5)	0
Aspergillus infection	1 (12.5)	0	0	0	1 (12.5)
Device related infection	1 (12.5)	0	0	1 (12.5)	0
Fungaemia	1 (12.5)	0	0	0	1 (12.5)
Fungal skin infection	1 (12.5)	0	0	1 (12.5)	0
Peritonitis	1 (12.5)	0	0	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	0	0	1 (12.5)
Systemic mycosis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					
-Total	1 (12.5)	1 (12.5)	0	0	0
Procedural pain	1 (12.5)	1 (12.5)	0	0	0

Age: <10 years

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
C-reactive protein increased	1 (12.5)	0	0	1 (12.5)	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Tumour lysis syndrome	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hyperuricaemia	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Haemorrhage intracranial	1 (12.5)	0	0	0	1 (12.5)
Psychiatric disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Mental status changes	1 (12.5)	0	0	1 (12.5)	0
Renal and urinary disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0

Age: <10 years

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (12.5)	1 (12.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	0	1 (12.5)	0	0
Pulmonary haemorrhage	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Tachypnoea	1 (12.5)	0	1 (12.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Pain of skin	1 (12.5)	1 (12.5)	0	0	0
Skin ulcer	1 (12.5)	0	1 (12.5)	0	0
Vascular disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Hypertension	2 (25.0)	0	2 (25.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	2 (28.6)	4 (57.1)
Blood and lymphatic system disorders					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Anaemia	2 (28.6)	0	0	2 (28.6)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	0	0	3 (42.9)	0
Tachycardia	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal disorders					

Age: >=10 years to <18 years

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (57.1)	1 (14.3)	0	2 (28.6)	1 (14.3)
Abdominal compartment syndrome	1 (14.3)	0	0	0	1 (14.3)
Colitis	1 (14.3)	0	0	1 (14.3)	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Haematemesis	1 (14.3)	1 (14.3)	0	0	0
Haemoperitoneum	1 (14.3)	0	0	0	1 (14.3)
General disorders and administration site conditions					
-Total	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Pyrexia	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Pain	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	0	0	1 (14.3)	0
Immune system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Graft versus host disease	1 (14.3)	0	0	1 (14.3)	0

Age: >=10 years to <18 years

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	6 (85.7)	0	1 (14.3)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Disseminated trichosporonosis	1 (14.3)	0	0	0	1 (14.3)
Epstein-barr virus infection	1 (14.3)	0	1 (14.3)	0	0
Klebsiella bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Oral herpes	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Serratia sepsis	1 (14.3)	0	0	0	1 (14.3)
Staphylococcal infection	1 (14.3)	0	0	0	1 (14.3)
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	0	1 (14.3)	0
Post procedural haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Alanine aminotransferase increased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)

Age: >=10 years to <18 years

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (14.3)	1 (14.3)	0	0	0
Blood magnesium decreased	1 (14.3)	0	1 (14.3)	0	0
Blood potassium decreased	1 (14.3)	0	0	1 (14.3)	0
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0	0	0
Serum ferritin increased	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (42.9)	0	0	3 (42.9)	0
Hypocalcaemia	2 (28.6)	0	2 (28.6)	0	0
Metabolic acidosis	2 (28.6)	0	0	2 (28.6)	0
Hyperammonaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Hypokalaemia	1 (14.3)	0	1 (14.3)	0	0
Hypomagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0

Age: >=10 years to <18 years

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Cognitive disorder	1 (14.3)	0	0	1 (14.3)	0
Intraventricular haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Acute kidney injury	2 (28.6)	2 (28.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Respiratory failure	2 (28.6)	0	0	0	2 (28.6)
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Vascular disorders					

Age: >=10 years to <18 years

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (71.4)	1 (14.3)	0	3 (42.9)	1 (14.3)
Hypotension	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Hypertension	1 (14.3)	1 (14.3)	0	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Pancytopenia	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Bradycardia	1 (33.3)	1 (33.3)	0	0	0
Cardiac failure	1 (33.3)	0	0	1 (33.3)	0
Endocrine disorders					

Age: >=18

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	0	1 (33.3)	0	0
Adrenal insufficiency	1 (33.3)	0	1 (33.3)	0	0
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Eyelid oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Abdominal pain upper	1 (33.3)	1 (33.3)	0	0	0
Nausea	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Catheter site pain	1 (33.3)	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Bacterial sepsis	1 (33.3)	0	0	0	1 (33.3)
Clostridium difficile colitis	1 (33.3)	0	1 (33.3)	0	0

Age: >=18

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related sepsis	1 (33.3)	0	0	1 (33.3)	0
Fungal sepsis	1 (33.3)	0	0	0	1 (33.3)
Pneumonia	1 (33.3)	0	0	0	1 (33.3)
Investigations					
-Total	1 (33.3)	0	0	1 (33.3)	0
C-reactive protein increased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Decreased appetite	1 (33.3)	0	1 (33.3)	0	0
Hyperglycaemia	1 (33.3)	0	0	0	1 (33.3)
Musculoskeletal and connective tissue disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Arthralgia	1 (33.3)	0	1 (33.3)	0	0
Back pain	1 (33.3)	1 (33.3)	0	0	0
Nervous system disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Headache	1 (33.3)	1 (33.3)	0	0	0

Age: >=18

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paraesthesia	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Acute respiratory distress syndrome	1 (33.3)	0	0	0	1 (33.3)
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Rash	1 (33.3)	1 (33.3)	0	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	0	2 (22.2)	7 (77.8)
Blood and lymphatic system disorders					
-Total	4 (44.4)	0	0	4 (44.4)	0
Anaemia	2 (22.2)	0	0	2 (22.2)	0
Febrile neutropenia	2 (22.2)	0	0	2 (22.2)	0
Hyperleukocytosis	1 (11.1)	0	0	1 (11.1)	0
Cardiac disorders					
-Total	4 (44.4)	0	1 (11.1)	3 (33.3)	0
Tachycardia	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Left ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					

Gender: Male

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	0	0	0	1 (11.1)
Hypercalcaemia of malignancy	1 (11.1)	0	0	0	1 (11.1)
Gastrointestinal disorders					
-Total	6 (66.7)	1 (11.1)	0	4 (44.4)	1 (11.1)
Abdominal pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Diarrhoea	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Abdominal compartment syndrome	1 (11.1)	0	0	0	1 (11.1)
Duodenal perforation	1 (11.1)	0	0	1 (11.1)	0
Gastritis	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal haemorrhage	1 (11.1)	0	0	1 (11.1)	0
Haematemesis	1 (11.1)	1 (11.1)	0	0	0
Haemoperitoneum	1 (11.1)	0	0	0	1 (11.1)
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	6 (66.7)	0	2 (22.2)	4 (44.4)	0
Pyrexia	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Oedema peripheral	2 (22.2)	1 (11.1)	1 (11.1)	0	0

Gender: Male

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Catheter site pain	1 (11.1)	1 (11.1)	0	0	0
Generalised oedema	1 (11.1)	0	0	1 (11.1)	0
Hepatobiliary disorders					
-Total	2 (22.2)	0	0	2 (22.2)	0
Hyperbilirubinaemia	2 (22.2)	0	0	2 (22.2)	0
Infections and infestations					
-Total	7 (77.8)	0	0	3 (33.3)	4 (44.4)
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Disseminated trichosporonosis	1 (11.1)	0	0	0	1 (11.1)
Fungaemia	1 (11.1)	0	0	0	1 (11.1)
Klebsiella bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Oral herpes	1 (11.1)	0	0	1 (11.1)	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Serratia sepsis	1 (11.1)	0	0	0	1 (11.1)
Staphylococcal infection	1 (11.1)	0	0	0	1 (11.1)

Gender: Male

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	0	0	1 (11.1)	0
Procedural pain	1 (11.1)	1 (11.1)	0	0	0
Investigations					
-Total	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Alanine aminotransferase increased	1 (11.1)	1 (11.1)	0	0	0
Aspartate aminotransferase increased	1 (11.1)	0	0	0	1 (11.1)
Blood creatinine increased	1 (11.1)	1 (11.1)	0	0	0
C-reactive protein increased	1 (11.1)	0	0	1 (11.1)	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0	0	0
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Platelet count decreased	1 (11.1)	0	0	0	1 (11.1)
White blood cell count decreased	1 (11.1)	1 (11.1)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (55.6)	0	0	4 (44.4)	1 (11.1)
Hypocalcaemia	2 (22.2)	0	2 (22.2)	0	0

Gender: Male

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	2 (22.2)	0	0	2 (22.2)	0
Tumour lysis syndrome	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Hyperammonaemia	1 (11.1)	0	0	1 (11.1)	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)	0	0
Hypokalaemia	1 (11.1)	0	1 (11.1)	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Myositis	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	4 (44.4)	1 (11.1)	0	2 (22.2)	1 (11.1)
Cognitive disorder	1 (11.1)	0	0	1 (11.1)	0
Encephalopathy	1 (11.1)	0	0	1 (11.1)	0
Haemorrhage intracranial	1 (11.1)	0	0	0	1 (11.1)
Intraventricular haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Psychiatric disorders					

Gender: Male

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	0	0	1 (11.1)	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Renal and urinary disorders					
-Total	3 (33.3)	3 (33.3)	0	0	0
Acute kidney injury	3 (33.3)	3 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (55.6)	0	1 (11.1)	1 (11.1)	3 (33.3)
Respiratory failure	3 (33.3)	0	0	0	3 (33.3)
Tachypnoea	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hypoxia	1 (11.1)	0	1 (11.1)	0	0
Pulmonary haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	0	0	1 (11.1)
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Pain of skin	1 (11.1)	1 (11.1)	0	0	0
Skin ulcer	1 (11.1)	0	1 (11.1)	0	0
Vascular disorders					

Gender: Male

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (66.7)	0	2 (22.2)	3 (33.3)	1 (11.1)
Hypotension	4 (44.4)	0	0	3 (33.3)	1 (11.1)
Hypertension	2 (22.2)	0	2 (22.2)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Female

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	1 (11.1)	3 (33.3)	5 (55.6)
Blood and lymphatic system disorders					
-Total	5 (55.6)	0	0	2 (22.2)	3 (33.3)
Febrile neutropenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Anaemia	1 (11.1)	0	0	1 (11.1)	0
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Bradycardia	1 (11.1)	1 (11.1)	0	0	0
Cardiac failure	1 (11.1)	0	0	1 (11.1)	0

Gender: Female

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Eye disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Eyelid oedema	1 (11.1)	1 (11.1)	0	0	0
Gastrointestinal disorders					
-Total	3 (33.3)	1 (11.1)	1 (11.1)	1 (11.1)	0
Abdominal pain upper	1 (11.1)	1 (11.1)	0	0	0
Colitis	1 (11.1)	0	0	1 (11.1)	0
Diarrhoea	1 (11.1)	0	1 (11.1)	0	0
Nausea	1 (11.1)	0	1 (11.1)	0	0
General disorders and administration site conditions					
-Total	3 (33.3)	1 (11.1)	2 (22.2)	0	0
Catheter site pain	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Pyrexia	1 (11.1)	0	1 (11.1)	0	0
Immune system disorders					

Gender: Female

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Graft versus host disease	1 (11.1)	0	0	1 (11.1)	0
Hypersensitivity	1 (11.1)	0	1 (11.1)	0	0
Infections and infestations					
-Total	8 (88.9)	0	1 (11.1)	3 (33.3)	4 (44.4)
Acute sinusitis	1 (11.1)	0	0	1 (11.1)	0
Aspergillus infection	1 (11.1)	0	0	0	1 (11.1)
Bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Bacterial sepsis	1 (11.1)	0	0	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)	0	0
Device related sepsis	1 (11.1)	0	0	1 (11.1)	0
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Fungal sepsis	1 (11.1)	0	0	0	1 (11.1)
Fungal skin infection	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0	0	1 (11.1)
Systemic mycosis	1 (11.1)	0	0	1 (11.1)	0
Investigations					

Gender: Female

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	0	0	2 (22.2)	0
Alanine aminotransferase increased	1 (11.1)	0	0	1 (11.1)	0
Blood magnesium decreased	1 (11.1)	0	1 (11.1)	0	0
Blood potassium decreased	1 (11.1)	0	0	1 (11.1)	0
C-reactive protein increased	1 (11.1)	0	0	1 (11.1)	0
Serum ferritin increased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Decreased appetite	1 (11.1)	0	1 (11.1)	0	0
Hyperglycaemia	1 (11.1)	0	0	0	1 (11.1)
Hyperuricaemia	1 (11.1)	0	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Arthralgia	1 (11.1)	0	1 (11.1)	0	0
Back pain	1 (11.1)	1 (11.1)	0	0	0
Nervous system disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0

Gender: Female

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (11.1)	1 (11.1)	0	0	0
Paraesthesia	1 (11.1)	1 (11.1)	0	0	0
Psychiatric disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Acute respiratory distress syndrome	1 (11.1)	0	0	0	1 (11.1)
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Rash	1 (11.1)	1 (11.1)	0	0	0
Vascular disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Hypertension	1 (11.1)	1 (11.1)	0	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	1 (9.1)	4 (36.4)	5 (45.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	4 (36.4)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Pancytopenia	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Anaemia	1 (9.1)	0	0	1 (9.1)	0
Cardiac disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Tachycardia	2 (18.2)	0	0	2 (18.2)	0
Gastrointestinal disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Race: White

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Abdominal pain	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	1 (9.1)	2 (18.2)	3 (27.3)	0
Pyrexia	4 (36.4)	0	2 (18.2)	2 (18.2)	0
Catheter site pain	2 (18.2)	2 (18.2)	0	0	0
Oedema peripheral	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Hyperbilirubinaemia	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	3 (27.3)	1 (9.1)	0	2 (18.2)	0
C-reactive protein increased	2 (18.2)	0	0	2 (18.2)	0
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (36.4)	0	0	3 (27.3)	1 (9.1)

Race: White

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (18.2)	0	2 (18.2)	0	0
Metabolic acidosis	2 (18.2)	0	0	2 (18.2)	0
Tumour lysis syndrome	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Psychiatric disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Mental status changes	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0
Acute kidney injury	2 (18.2)	2 (18.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Respiratory failure	2 (18.2)	0	0	0	2 (18.2)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	5 (45.5)	1 (9.1)	1 (9.1)	2 (18.2)	1 (9.1)
Hypotension	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Hypertension	2 (18.2)	1 (9.1)	1 (9.1)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Anaemia	1 (20.0)	0	0	1 (20.0)	0
Thrombocytopenia	1 (20.0)	0	0	0	1 (20.0)
Cardiac disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Left ventricular dysfunction	1 (20.0)	0	0	1 (20.0)	0
Tachycardia	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0

Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Duodenal perforation	1 (20.0)	0	0	1 (20.0)	0
Gastritis	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	2 (40.0)	0	0
Catheter site pain	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	0	1 (20.0)	2 (40.0)	1 (20.0)
Epstein-barr virus infection	1 (20.0)	0	1 (20.0)	0	0
Klebsiella bacteraemia	1 (20.0)	0	0	1 (20.0)	0
Peritonitis	1 (20.0)	0	0	1 (20.0)	0
Pneumonia fungal	1 (20.0)	0	0	0	1 (20.0)
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	0	1 (20.0)	0
Post procedural haemorrhage	1 (20.0)	0	0	1 (20.0)	0
Investigations					
-Total	1 (20.0)	0	0	1 (20.0)	0

Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood magnesium decreased	1 (20.0)	0	1 (20.0)	0	0
Blood potassium decreased	1 (20.0)	0	0	1 (20.0)	0
Serum ferritin increased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Hyperuricaemia	1 (20.0)	0	1 (20.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Myositis	1 (20.0)	0	1 (20.0)	0	0
Nervous system disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Haemorrhage intracranial	1 (20.0)	0	0	0	1 (20.0)
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hypotension	1 (20.0)	0	0	1 (20.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Febrile neutropenia	2 (100)	0	0	1 (50.0)	1 (50.0)
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Tachycardia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Stomatitis	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Generalised oedema	1 (50.0)	0	0	1 (50.0)	0
Hepatobiliary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hyperbilirubinaemia	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	2 (100)	0	0	0	2 (100)
Fungaemia	1 (50.0)	0	0	0	1 (50.0)
Pneumonia	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Neutrophil count decreased	1 (50.0)	0	0	0	1 (50.0)
Platelet count decreased	1 (50.0)	0	0	0	1 (50.0)

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Acute kidney injury	1 (50.0)	1 (50.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Pulmonary haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Respiratory failure	1 (50.0)	0	0	0	1 (50.0)
Tachypnoea	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypertension	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Cardiac disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Colitis	1 (33.3)	0	0	1 (33.3)	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (33.3)	1 (33.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Pyrexia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Graft versus host disease	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Aspergillus infection	1 (33.3)	0	0	0	1 (33.3)
Bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Disseminated trichosporonosis	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hyperkalaemia	1 (33.3)	0	0	1 (33.3)	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Hypomagnesaemia	1 (33.3)	1 (33.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Psychiatric disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Mental status changes	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Acute kidney injury	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypertension	1 (33.3)	1 (33.3)	0	0	0
Hypotension	1 (33.3)	0	0	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (80.0)	0	1 (6.7)	5 (33.3)	6 (40.0)
Blood and lymphatic system disorders					
-Total	7 (46.7)	0	0	5 (33.3)	2 (13.3)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Febrile neutropenia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Pancytopenia	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Cardiac disorders					
-Total	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Tachycardia	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Gastrointestinal disorders					
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0

Ethnicity: Other

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Diarrhoea	2 (13.3)	0	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions					
-Total	7 (46.7)	1 (6.7)	4 (26.7)	2 (13.3)	0
Pyrexia	4 (26.7)	0	3 (20.0)	1 (6.7)	0
Catheter site pain	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Oedema peripheral	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Hepatobiliary disorders					
-Total	2 (13.3)	0	0	2 (13.3)	0
Hyperbilirubinaemia	2 (13.3)	0	0	2 (13.3)	0
Investigations					
-Total	4 (26.7)	1 (6.7)	0	3 (20.0)	0
Alanine aminotransferase increased	2 (13.3)	1 (6.7)	0	1 (6.7)	0
C-reactive protein increased	2 (13.3)	0	0	2 (13.3)	0
Metabolism and nutrition disorders					
-Total	3 (20.0)	0	0	2 (13.3)	1 (6.7)

Ethnicity: Other

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypocalcaemia	1 (6.7)	0	1 (6.7)	0	0
Metabolic acidosis	1 (6.7)	0	0	1 (6.7)	0
Psychiatric disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Mental status changes	1 (6.7)	0	0	1 (6.7)	0
Renal and urinary disorders					
-Total	2 (13.3)	2 (13.3)	0	0	0
Acute kidney injury	2 (13.3)	2 (13.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (20.0)	0	0	1 (6.7)	2 (13.3)
Respiratory failure	2 (13.3)	0	0	0	2 (13.3)
Tachypnoea	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Vascular disorders					
-Total	5 (33.3)	0	2 (13.3)	2 (13.3)	1 (6.7)
Hypotension	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Hypertension	2 (13.3)	0	2 (13.3)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	2 (100)	0	0	2 (100)	0
Tachycardia	2 (100)	0	0	2 (100)	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	0	0	1 (50.0)

Response status at study entry: Primary refractory

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (50.0)	1 (50.0)	0	0	0
Haemoperitoneum	1 (50.0)	0	0	0	1 (50.0)
General disorders and administration site conditions					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Pyrexia	2 (100)	0	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	0	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	0	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood creatinine increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0	0	0

Response status at study entry: Primary refractory

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypocalcaemia	2 (100)	0	2 (100)	0	0
Metabolic acidosis	2 (100)	0	0	2 (100)	0
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypomagnesaemia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	2 (100)	2 (100)	0	0	0
Acute kidney injury	2 (100)	2 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	0	0	2 (100)
Respiratory failure	2 (100)	0	0	0	2 (100)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Vascular disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypotension	2 (100)	0	0	2 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (81.3)	0	2 (12.5)	6 (37.5)	5 (31.3)
Blood and lymphatic system disorders					
-Total	6 (37.5)	0	0	4 (25.0)	2 (12.5)
Febrile neutropenia	3 (18.8)	0	0	2 (12.5)	1 (6.3)
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Pancytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Cardiac disorders					
-Total	2 (12.5)	0	2 (12.5)	0	0
Tachycardia	2 (12.5)	0	2 (12.5)	0	0
Gastrointestinal disorders					
-Total	3 (18.8)	0	2 (12.5)	1 (6.3)	0

Response status at study entry: Relapsed disease

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Abdominal pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions					
-Total	6 (37.5)	1 (6.3)	3 (18.8)	2 (12.5)	0
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Pyrexia	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain	1 (6.3)	0	0	1 (6.3)	0
Hepatobiliary disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	0	0	2 (12.5)	0
Investigations					
-Total	3 (18.8)	0	0	3 (18.8)	0
C-reactive protein increased	2 (12.5)	0	0	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	0	0	1 (6.3)	0
Metabolism and nutrition disorders					
-Total	2 (12.5)	0	0	1 (6.3)	1 (6.3)

Response status at study entry: Relapsed disease

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Psychiatric disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Mental status changes	2 (12.5)	0	0	2 (12.5)	0
Renal and urinary disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Acute kidney injury	1 (6.3)	1 (6.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Tachypnoea	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Respiratory failure	1 (6.3)	0	0	0	1 (6.3)
Vascular disorders					
-Total	5 (31.3)	1 (6.3)	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Hypotension	2 (12.5)	0	0	1 (6.3)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217f
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	2 (11.1)	6 (33.3)	7 (38.9)
Blood and lymphatic system disorders					
-Total	8 (44.4)	0	0	6 (33.3)	2 (11.1)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Cardiac disorders					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Gastrointestinal disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions					
-Total	8 (44.4)	1 (5.6)	4 (22.2)	3 (16.7)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Investigations					
-Total	4 (22.2)	1 (5.6)	0	3 (16.7)	0
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	0	0	3 (16.7)	1 (5.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217g
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	2 (11.1)	6 (33.3)	7 (38.9)
Blood and lymphatic system disorders					
-Total	8 (44.4)	0	0	6 (33.3)	2 (11.1)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Cardiac disorders					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Gastrointestinal disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions					
-Total	8 (44.4)	1 (5.6)	4 (22.2)	3 (16.7)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Investigations					
-Total	4 (22.2)	1 (5.6)	0	3 (16.7)	0
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	0	0	3 (16.7)	1 (5.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217h
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	2 (100)	0	0	2 (100)	0
Tachycardia	2 (100)	0	1 (50.0)	1 (50.0)	0
Left ventricular dysfunction	1 (50.0)	0	0	1 (50.0)	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	0	0	1 (50.0)

Hypodiploidy: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (50.0)	0	0	0	1 (50.0)
General disorders and administration site conditions					
-Total	2 (100)	0	2 (100)	0	0
Pyrexia	2 (100)	0	2 (100)	0	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Klebsiella bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Serratia sepsis	1 (50.0)	0	0	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Injury, poisoning and procedural complications					
-Total	1 (50.0)	0	0	1 (50.0)	0
Post procedural haemorrhage	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0

Hypodiploidy: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood creatinine increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypocalcaemia	1 (50.0)	0	1 (50.0)	0	0
Metabolic acidosis	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Myositis	1 (50.0)	0	1 (50.0)	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (50.0)	1 (50.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Respiratory failure	1 (50.0)	0	0	0	1 (50.0)
Vascular disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypotension	2 (100)	0	0	2 (100)	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217h
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (81.3)	0	2 (12.5)	5 (31.3)	6 (37.5)
Blood and lymphatic system disorders					
-Total	7 (43.8)	0	0	5 (31.3)	2 (12.5)
Febrile neutropenia	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Pancytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Cardiac disorders					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Tachycardia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders					
-Total	3 (18.8)	0	2 (12.5)	1 (6.3)	0

Hypodiploidy: No

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Abdominal pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions					
-Total	6 (37.5)	1 (6.3)	2 (12.5)	3 (18.8)	0
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Pyrexia	3 (18.8)	0	1 (6.3)	2 (12.5)	0
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain	1 (6.3)	0	0	1 (6.3)	0
Hepatobiliary disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	0	0	2 (12.5)	0
Investigations					
-Total	3 (18.8)	0	0	3 (18.8)	0
C-reactive protein increased	2 (12.5)	0	0	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	0	0	1 (6.3)	0
Metabolism and nutrition disorders					
-Total	3 (18.8)	0	0	2 (12.5)	1 (6.3)

Hypodiploidy: No

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Hypocalcaemia	1 (6.3)	0	1 (6.3)	0	0
Metabolic acidosis	1 (6.3)	0	0	1 (6.3)	0
Psychiatric disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Mental status changes	2 (12.5)	0	0	2 (12.5)	0
Renal and urinary disorders					
-Total	2 (12.5)	2 (12.5)	0	0	0
Acute kidney injury	2 (12.5)	2 (12.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (18.8)	0	0	1 (6.3)	2 (12.5)
Respiratory failure	2 (12.5)	0	0	0	2 (12.5)
Tachypnoea	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vascular disorders					
-Total	5 (31.3)	1 (6.3)	2 (12.5)	1 (6.3)	1 (6.3)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Hypotension	2 (12.5)	0	0	1 (6.3)	1 (6.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypersensitivity	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Acute sinusitis	1 (100)	0	0	1 (100)	0
Fungal skin infection	1 (100)	0	0	1 (100)	0

BCR-ABL1-like: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (100)	0	0	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (82.4)	0	2 (11.8)	5 (29.4)	7 (41.2)
Blood and lymphatic system disorders					
-Total	7 (41.2)	0	0	5 (29.4)	2 (11.8)
Anaemia	3 (17.6)	0	0	3 (17.6)	0
Febrile neutropenia	3 (17.6)	0	0	2 (11.8)	1 (5.9)
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Cardiac disorders					
-Total	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Tachycardia	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Gastrointestinal disorders					
-Total	3 (17.6)	0	2 (11.8)	1 (5.9)	0

BCR-ABL1-like: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Abdominal pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions					
-Total	8 (47.1)	1 (5.9)	4 (23.5)	3 (17.6)	0
Pyrexia	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Catheter site pain	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Oedema peripheral	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Hyperbilirubinaemia	2 (11.8)	0	0	2 (11.8)	0
Investigations					
-Total	4 (23.5)	1 (5.9)	0	3 (17.6)	0
Alanine aminotransferase increased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
C-reactive protein increased	2 (11.8)	0	0	2 (11.8)	0
Metabolism and nutrition disorders					
-Total	4 (23.5)	0	0	3 (17.6)	1 (5.9)

BCR-ABL1-like: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (11.8)	0	2 (11.8)	0	0
Metabolic acidosis	2 (11.8)	0	0	2 (11.8)	0
Tumour lysis syndrome	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Psychiatric disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Mental status changes	2 (11.8)	0	0	2 (11.8)	0
Renal and urinary disorders					
-Total	3 (17.6)	3 (17.6)	0	0	0
Acute kidney injury	3 (17.6)	3 (17.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (23.5)	0	0	1 (5.9)	3 (17.6)
Respiratory failure	3 (17.6)	0	0	0	3 (17.6)
Tachypnoea	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Vascular disorders					
-Total	7 (41.2)	1 (5.9)	2 (11.8)	3 (17.6)	1 (5.9)
Hypotension	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Hypertension	3 (17.6)	1 (5.9)	2 (11.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	0	3 (100)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Tachycardia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	0	0	1 (33.3)
Abdominal pain	1 (33.3)	0	1 (33.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Haemoperitoneum	1 (33.3)	0	0	0	1 (33.3)
Stomatitis	1 (33.3)	0	0	1 (33.3)	0
General disorders and administration site conditions					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Generalised oedema	1 (33.3)	0	0	1 (33.3)	0
Pain	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Hepatobiliary disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	3 (100)	0	0	0	3 (100)
Aspergillus infection	1 (33.3)	0	0	0	1 (33.3)
Fungaemia	1 (33.3)	0	0	0	1 (33.3)
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Investigations					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (66.7)	0	0	0	2 (66.7)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Aspartate aminotransferase increased	1 (33.3)	0	0	0	1 (33.3)
Blood creatinine increased	1 (33.3)	1 (33.3)	0	0	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	0	0	0	1 (33.3)
White blood cell count decreased	1 (33.3)	1 (33.3)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0
Psychiatric disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	2 (66.7)	2 (66.7)	0	0	0
Acute kidney injury	2 (66.7)	2 (66.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Respiratory failure	2 (66.7)	0	0	0	2 (66.7)
Pulmonary haemorrhage	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Tachypnoea	1 (33.3)	0	1 (33.3)	0	0
Vascular disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hypertension	1 (33.3)	0	1 (33.3)	0	0
Hypotension	1 (33.3)	0	0	1 (33.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (80.0)	0	2 (13.3)	5 (33.3)	5 (33.3)
Blood and lymphatic system disorders					
-Total	6 (40.0)	0	0	4 (26.7)	2 (13.3)
Febrile neutropenia	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Pancytopenia	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Anaemia	1 (6.7)	0	0	1 (6.7)	0
Cardiac disorders					
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Tachycardia	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders					
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Abdominal pain	1 (6.7)	0	0	1 (6.7)	0
General disorders and administration site conditions					
-Total	7 (46.7)	1 (6.7)	3 (20.0)	3 (20.0)	0
Pyrexia	4 (26.7)	0	2 (13.3)	2 (13.3)	0
Catheter site pain	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Oedema peripheral	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pain	1 (6.7)	0	0	1 (6.7)	0
Hepatobiliary disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Hyperbilirubinaemia	1 (6.7)	0	0	1 (6.7)	0
Investigations					
-Total	3 (20.0)	0	0	3 (20.0)	0
C-reactive protein increased	2 (13.3)	0	0	2 (13.3)	0
Alanine aminotransferase increased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	3 (20.0)	0	0	2 (13.3)	1 (6.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Hypocalcaemia	1 (6.7)	0	1 (6.7)	0	0
Metabolic acidosis	1 (6.7)	0	0	1 (6.7)	0
Psychiatric disorders					
-Total	1 (6.7)	0	0	1 (6.7)	0
Mental status changes	1 (6.7)	0	0	1 (6.7)	0
Renal and urinary disorders					
-Total	1 (6.7)	1 (6.7)	0	0	0
Acute kidney injury	1 (6.7)	1 (6.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (13.3)	0	0	1 (6.7)	1 (6.7)
Respiratory failure	1 (6.7)	0	0	0	1 (6.7)
Tachypnoea	1 (6.7)	0	0	1 (6.7)	0
Vascular disorders					
-Total	5 (33.3)	1 (6.7)	1 (6.7)	2 (13.3)	1 (6.7)
Hypotension	3 (20.0)	0	0	2 (13.3)	1 (6.7)
Hypertension	2 (13.3)	1 (6.7)	1 (6.7)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Europe

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	2 (50.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	0	1 (25.0)
Pancytopenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Bradycardia	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Eyelid oedema	1 (25.0)	1 (25.0)	0	0	0

Region: Europe

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Abdominal pain upper	1 (25.0)	1 (25.0)	0	0	0
Diarrhoea	1 (25.0)	0	0	1 (25.0)	0
General disorders and administration site conditions					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Catheter site pain	2 (50.0)	2 (50.0)	0	0	0
Oedema peripheral	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Pain	1 (25.0)	0	0	1 (25.0)	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Device related infection	1 (25.0)	0	0	1 (25.0)	0
Device related sepsis	1 (25.0)	0	0	1 (25.0)	0
Pneumonia	1 (25.0)	0	0	0	1 (25.0)
Injury, poisoning and procedural complications					

Region: Europe

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	1 (25.0)	0	0	0
Procedural pain	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	2 (50.0)	0	0	2 (50.0)	0
C-reactive protein increased	2 (50.0)	0	0	2 (50.0)	0
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Tumour lysis syndrome	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Back pain	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Encephalopathy	1 (25.0)	0	0	1 (25.0)	0
Headache	1 (25.0)	1 (25.0)	0	0	0
Paraesthesia	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					

Region: Europe

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pain of skin	1 (25.0)	1 (25.0)	0	0	0
Skin ulcer	1 (25.0)	0	1 (25.0)	0	0
Vascular disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypertension	1 (25.0)	0	1 (25.0)	0	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=12				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (91.7)	0	2 (16.7)	4 (33.3)	5 (41.7)
Blood and lymphatic system disorders					
-Total	6 (50.0)	0	0	5 (41.7)	1 (8.3)
Anaemia	3 (25.0)	0	0	3 (25.0)	0
Febrile neutropenia	3 (25.0)	0	0	3 (25.0)	0
Pancytopenia	1 (8.3)	0	0	0	1 (8.3)
Cardiac disorders					
-Total	4 (33.3)	0	2 (16.7)	2 (16.7)	0
Tachycardia	4 (33.3)	0	2 (16.7)	2 (16.7)	0
Gastrointestinal disorders					
-Total	2 (16.7)	0	2 (16.7)	0	0

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Diarrhoea	2 (16.7)	0	2 (16.7)	0	0
Abdominal pain	1 (8.3)	0	1 (8.3)	0	0
General disorders and administration site conditions					
-Total	5 (41.7)	0	4 (33.3)	1 (8.3)	0
Pyrexia	4 (33.3)	0	3 (25.0)	1 (8.3)	0
Catheter site pain	1 (8.3)	0	1 (8.3)	0	0
Pain	1 (8.3)	0	1 (8.3)	0	0
Hepatobiliary disorders					
-Total	2 (16.7)	0	0	2 (16.7)	0
Hyperbilirubinaemia	2 (16.7)	0	0	2 (16.7)	0
Investigations					
-Total	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Alanine aminotransferase increased	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Metabolism and nutrition disorders					
-Total	2 (16.7)	0	0	2 (16.7)	0
Hypocalcaemia	2 (16.7)	0	2 (16.7)	0	0
Metabolic acidosis	2 (16.7)	0	0	2 (16.7)	0

Region: US

Group term Preferred term	All patients N=12 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	2 (16.7)	0	0	2 (16.7)	0
Mental status changes	2 (16.7)	0	0	2 (16.7)	0
Renal and urinary disorders					
-Total	3 (25.0)	3 (25.0)	0	0	0
Acute kidney injury	3 (25.0)	3 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (33.3)	0	0	1 (8.3)	3 (25.0)
Respiratory failure	3 (25.0)	0	0	0	3 (25.0)
Tachypnoea	2 (16.7)	0	1 (8.3)	1 (8.3)	0
Vascular disorders					
-Total	6 (50.0)	1 (8.3)	1 (8.3)	3 (25.0)	1 (8.3)
Hypotension	4 (33.3)	0	0	3 (25.0)	1 (8.3)
Hypertension	2 (16.7)	1 (8.3)	1 (8.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: Rest of World

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Duodenal perforation	1 (50.0)	0	0	1 (50.0)	0
Gastritis	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Epstein-barr virus infection	1 (50.0)	0	1 (50.0)	0	0
Peritonitis	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					

Region: Rest of World

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (50.0)	0	0	0	1 (50.0)
Haemorrhage intracranial	1 (50.0)	0	0	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	1 (10.0)	4 (40.0)	5 (50.0)
Blood and lymphatic system disorders					
-Total	4 (40.0)	0	0	2 (20.0)	2 (20.0)
Febrile neutropenia	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Pancytopenia	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Anaemia	1 (10.0)	0	0	1 (10.0)	0
Cardiac disorders					
-Total	4 (40.0)	1 (10.0)	1 (10.0)	2 (20.0)	0
Tachycardia	2 (20.0)	0	2 (20.0)	0	0
Bradycardia	1 (10.0)	1 (10.0)	0	0	0
Cardiac failure	1 (10.0)	0	0	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Endocrine disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Adrenal insufficiency	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0
Eyelid oedema	1 (10.0)	1 (10.0)	0	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	1 (10.0)	1 (10.0)	4 (40.0)	0
Diarrhoea	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal pain	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Abdominal pain upper	1 (10.0)	1 (10.0)	0	0	0
Colitis	1 (10.0)	0	0	1 (10.0)	0
Duodenal perforation	1 (10.0)	0	0	1 (10.0)	0
Gastritis	1 (10.0)	0	1 (10.0)	0	0
Nausea	1 (10.0)	0	1 (10.0)	0	0
Stomatitis	1 (10.0)	0	0	1 (10.0)	0

Prior SCT therapy: Yes

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	6 (60.0)	1 (10.0)	2 (20.0)	3 (30.0)	0
Pyrexia	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Catheter site pain	2 (20.0)	2 (20.0)	0	0	0
Oedema peripheral	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Generalised oedema	1 (10.0)	0	0	1 (10.0)	0
Pain	1 (10.0)	0	0	1 (10.0)	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Hyperbilirubinaemia	1 (10.0)	0	0	1 (10.0)	0
Immune system disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Graft versus host disease	1 (10.0)	0	0	1 (10.0)	0
Infections and infestations					
-Total	9 (90.0)	0	1 (10.0)	5 (50.0)	3 (30.0)
Bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)

Prior SCT therapy: Yes

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (10.0)	0	1 (10.0)	0	0
Device related infection	1 (10.0)	0	0	1 (10.0)	0
Device related sepsis	1 (10.0)	0	0	1 (10.0)	0
Epstein-barr virus infection	1 (10.0)	0	1 (10.0)	0	0
Fungaemia	1 (10.0)	0	0	0	1 (10.0)
Fungal sepsis	1 (10.0)	0	0	0	1 (10.0)
Klebsiella bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Peritonitis	1 (10.0)	0	0	1 (10.0)	0
Pneumonia	1 (10.0)	0	0	0	1 (10.0)
Injury, poisoning and procedural complications					
-Total	2 (20.0)	1 (10.0)	0	1 (10.0)	0
Post procedural haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Procedural pain	1 (10.0)	1 (10.0)	0	0	0
Investigations					
-Total	3 (30.0)	0	0	2 (20.0)	1 (10.0)
C-reactive protein increased	2 (20.0)	0	0	2 (20.0)	0
Neutrophil count decreased	1 (10.0)	0	0	0	1 (10.0)

Prior SCT therapy: Yes

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Tumour lysis syndrome	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Decreased appetite	1 (10.0)	0	1 (10.0)	0	0
Hyperglycaemia	1 (10.0)	0	0	0	1 (10.0)
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	1 (10.0)	2 (20.0)	0	0
Arthralgia	1 (10.0)	0	1 (10.0)	0	0
Back pain	1 (10.0)	1 (10.0)	0	0	0
Myositis	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	3 (30.0)	1 (10.0)	0	1 (10.0)	1 (10.0)
Encephalopathy	1 (10.0)	0	0	1 (10.0)	0
Haemorrhage intracranial	1 (10.0)	0	0	0	1 (10.0)
Headache	1 (10.0)	1 (10.0)	0	0	0
Paraesthesia	1 (10.0)	1 (10.0)	0	0	0

Prior SCT therapy: Yes

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0
Acute kidney injury	1 (10.0)	1 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (30.0)	0	1 (10.0)	0	2 (20.0)
Acute respiratory distress syndrome	1 (10.0)	0	0	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)	0	0
Pulmonary haemorrhage	1 (10.0)	0	0	0	1 (10.0)
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Tachypnoea	1 (10.0)	0	1 (10.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Pain of skin	1 (10.0)	1 (10.0)	0	0	0
Rash	1 (10.0)	1 (10.0)	0	0	0
Skin ulcer	1 (10.0)	0	1 (10.0)	0	0
Vascular disorders					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	3 (30.0)	1 (10.0)	2 (20.0)	0	0
Hypotension	1 (10.0)	0	0	1 (10.0)	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders					
-Total	5 (62.5)	0	0	4 (50.0)	1 (12.5)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Hyperleukocytosis	1 (12.5)	0	0	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Tachycardia	2 (25.0)	0	0	2 (25.0)	0
Endocrine disorders					

Prior SCT therapy: No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	0	0	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	0	0	1 (12.5)
Gastrointestinal disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Gastrointestinal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)
General disorders and administration site conditions					
-Total	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Pyrexia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Catheter site pain	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					

Prior SCT therapy: No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypersensitivity	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	1 (12.5)	5 (62.5)
Acute sinusitis	1 (12.5)	0	0	1 (12.5)	0
Aspergillus infection	1 (12.5)	0	0	0	1 (12.5)
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Fungal skin infection	1 (12.5)	0	0	1 (12.5)	0
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	0	0	1 (12.5)
Sepsis	1 (12.5)	0	0	0	1 (12.5)
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Systemic mycosis	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Alanine aminotransferase increased	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Prior SCT therapy: No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood creatinine increased	1 (12.5)	1 (12.5)	0	0	0
Blood magnesium decreased	1 (12.5)	0	1 (12.5)	0	0
Blood potassium decreased	1 (12.5)	0	0	1 (12.5)	0
Lymphocyte count decreased	1 (12.5)	1 (12.5)	0	0	0
Serum ferritin increased	1 (12.5)	0	0	1 (12.5)	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Hypocalcaemia	2 (25.0)	0	2 (25.0)	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Hyperammonaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperuricaemia	1 (12.5)	0	1 (12.5)	0	0
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	1 (12.5)	0	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0

Prior SCT therapy: No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Intraventricular haemorrhage	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Mental status changes	2 (25.0)	0	0	2 (25.0)	0
Renal and urinary disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Acute kidney injury	2 (25.0)	2 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Tachypnoea	1 (12.5)	0	0	1 (12.5)	0
Vascular disorders					
-Total	3 (37.5)	0	0	2 (25.0)	1 (12.5)

Prior SCT therapy: No

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (37.5)	0	0	2 (25.0)	1 (12.5)

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Gastrointestinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Duodenal perforation	1 (25.0)	0	0	1 (25.0)	0
Gastritis	1 (25.0)	0	1 (25.0)	0	0
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypersensitivity	1 (25.0)	0	1 (25.0)	0	0

Eligibility for SCT: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	4 (100)	0	1 (25.0)	2 (50.0)	1 (25.0)
Acute sinusitis	1 (25.0)	0	0	1 (25.0)	0
Aspergillus infection	1 (25.0)	0	0	0	1 (25.0)
Epstein-barr virus infection	1 (25.0)	0	1 (25.0)	0	0
Fungal skin infection	1 (25.0)	0	0	1 (25.0)	0
Peritonitis	1 (25.0)	0	0	1 (25.0)	0
Systemic mycosis	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Haemorrhage intracranial	1 (25.0)	0	0	0	1 (25.0)
Psychiatric disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Mental status changes	1 (25.0)	0	0	1 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	2 (14.3)	4 (28.6)	7 (50.0)
Blood and lymphatic system disorders					
-Total	7 (50.0)	0	0	5 (35.7)	2 (14.3)
Anaemia	3 (21.4)	0	0	3 (21.4)	0
Febrile neutropenia	3 (21.4)	0	0	2 (14.3)	1 (7.1)
Pancytopenia	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Cardiac disorders					
-Total	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Tachycardia	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Gastrointestinal disorders					
-Total	3 (21.4)	0	2 (14.3)	1 (7.1)	0

Eligibility for SCT: No

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Abdominal pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions					
-Total	8 (57.1)	1 (7.1)	4 (28.6)	3 (21.4)	0
Pyrexia	5 (35.7)	0	3 (21.4)	2 (14.3)	0
Catheter site pain	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Oedema peripheral	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	0	0	2 (14.3)	0
Investigations					
-Total	4 (28.6)	1 (7.1)	0	3 (21.4)	0
Alanine aminotransferase increased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
C-reactive protein increased	2 (14.3)	0	0	2 (14.3)	0
Metabolism and nutrition disorders					
-Total	4 (28.6)	0	0	3 (21.4)	1 (7.1)

Eligibility for SCT: No

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (14.3)	0	2 (14.3)	0	0
Metabolic acidosis	2 (14.3)	0	0	2 (14.3)	0
Tumour lysis syndrome	2 (14.3)	0	0	1 (7.1)	1 (7.1)
Psychiatric disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Mental status changes	1 (7.1)	0	0	1 (7.1)	0
Renal and urinary disorders					
-Total	3 (21.4)	3 (21.4)	0	0	0
Acute kidney injury	3 (21.4)	3 (21.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	0	0	1 (7.1)	3 (21.4)
Respiratory failure	3 (21.4)	0	0	0	3 (21.4)
Tachypnoea	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Vascular disorders					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	3 (21.4)	1 (7.1)
Hypotension	4 (28.6)	0	0	3 (21.4)	1 (7.1)
Hypertension	3 (21.4)	1 (7.1)	2 (14.3)	0	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Thrombocytopenia	1 (50.0)	0	0	0	1 (50.0)
Infections and infestations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Epstein-barr virus infection	1 (50.0)	0	1 (50.0)	0	0
Investigations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood magnesium decreased	1 (50.0)	0	1 (50.0)	0	0
Blood potassium decreased	1 (50.0)	0	0	1 (50.0)	0
Serum ferritin increased	1 (50.0)	0	0	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (87.5)	0	2 (12.5)	5 (31.3)	7 (43.8)
Blood and lymphatic system disorders					
-Total	7 (43.8)	0	0	5 (31.3)	2 (12.5)
Febrile neutropenia	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Pancytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Cardiac disorders					
-Total	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Tachycardia	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Gastrointestinal disorders					
-Total	3 (18.8)	0	2 (12.5)	1 (6.3)	0

Baseline bone marrow tumor burden: High

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Abdominal pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions					
-Total	8 (50.0)	1 (6.3)	4 (25.0)	3 (18.8)	0
Pyrexia	5 (31.3)	0	3 (18.8)	2 (12.5)	0
Catheter site pain	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Oedema peripheral	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hepatobiliary disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hyperbilirubinaemia	2 (12.5)	0	0	2 (12.5)	0
Investigations					
-Total	3 (18.8)	1 (6.3)	0	2 (12.5)	0
C-reactive protein increased	2 (12.5)	0	0	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	1 (6.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (25.0)	0	0	3 (18.8)	1 (6.3)

Baseline bone marrow tumor burden: High

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (12.5)	0	2 (12.5)	0	0
Metabolic acidosis	2 (12.5)	0	0	2 (12.5)	0
Tumour lysis syndrome	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Psychiatric disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Mental status changes	2 (12.5)	0	0	2 (12.5)	0
Renal and urinary disorders					
-Total	3 (18.8)	3 (18.8)	0	0	0
Acute kidney injury	3 (18.8)	3 (18.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (25.0)	0	0	1 (6.3)	3 (18.8)
Respiratory failure	3 (18.8)	0	0	0	3 (18.8)
Tachypnoea	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vascular disorders					
-Total	7 (43.8)	1 (6.3)	2 (12.5)	3 (18.8)	1 (6.3)
Hypotension	4 (25.0)	0	0	3 (18.8)	1 (6.3)
Hypertension	3 (18.8)	1 (6.3)	2 (12.5)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	2 (11.1)	6 (33.3)	7 (38.9)
Blood and lymphatic system disorders					
-Total	8 (44.4)	0	0	6 (33.3)	2 (11.1)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Cardiac disorders					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Gastrointestinal disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0

Baseline extramedullary disease presence: No

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions					
-Total	8 (44.4)	1 (5.6)	4 (22.2)	3 (16.7)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Investigations					
-Total	4 (22.2)	1 (5.6)	0	3 (16.7)	0
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	0	0	3 (16.7)	1 (5.6)

Baseline extramedullary disease presence: No

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Gastrointestinal disorders					
-Total	1 (100)	0	0	1 (100)	0
Duodenal perforation	1 (100)	0	0	1 (100)	0
Gastritis	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Peritonitis	1 (100)	0	0	1 (100)	0
Nervous system disorders					
-Total	1 (100)	0	0	0	1 (100)
Haemorrhage intracranial	1 (100)	0	0	0	1 (100)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (88.2)	0	2 (11.8)	6 (35.3)	7 (41.2)
Blood and lymphatic system disorders					
-Total	8 (47.1)	0	0	6 (35.3)	2 (11.8)
Febrile neutropenia	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Anaemia	3 (17.6)	0	0	3 (17.6)	0
Pancytopenia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Cardiac disorders					
-Total	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Tachycardia	4 (23.5)	0	2 (11.8)	2 (11.8)	0
Gastrointestinal disorders					
-Total	3 (17.6)	0	2 (11.8)	1 (5.9)	0

Down syndrome: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Abdominal pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions					
-Total	8 (47.1)	1 (5.9)	4 (23.5)	3 (17.6)	0
Pyrexia	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Catheter site pain	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Oedema peripheral	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Hyperbilirubinaemia	2 (11.8)	0	0	2 (11.8)	0
Investigations					
-Total	4 (23.5)	1 (5.9)	0	3 (17.6)	0
Alanine aminotransferase increased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
C-reactive protein increased	2 (11.8)	0	0	2 (11.8)	0
Metabolism and nutrition disorders					
-Total	4 (23.5)	0	0	3 (17.6)	1 (5.9)

Down syndrome: No

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (11.8)	0	2 (11.8)	0	0
Metabolic acidosis	2 (11.8)	0	0	2 (11.8)	0
Tumour lysis syndrome	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Psychiatric disorders					
-Total	2 (11.8)	0	0	2 (11.8)	0
Mental status changes	2 (11.8)	0	0	2 (11.8)	0
Renal and urinary disorders					
-Total	3 (17.6)	3 (17.6)	0	0	0
Acute kidney injury	3 (17.6)	3 (17.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (23.5)	0	0	1 (5.9)	3 (17.6)
Respiratory failure	3 (17.6)	0	0	0	3 (17.6)
Tachypnoea	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Vascular disorders					
-Total	7 (41.2)	1 (5.9)	2 (11.8)	3 (17.6)	1 (5.9)
Hypotension	4 (23.5)	0	0	3 (17.6)	1 (5.9)
Hypertension	3 (17.6)	1 (5.9)	2 (11.8)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	2 (11.1)	6 (33.3)	7 (38.9)
Blood and lymphatic system disorders					
-Total	8 (44.4)	0	0	6 (33.3)	2 (11.1)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Cardiac disorders					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Gastrointestinal disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions					
-Total	8 (44.4)	1 (5.6)	4 (22.2)	3 (16.7)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Investigations					
-Total	4 (22.2)	1 (5.6)	0	3 (16.7)	0
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	0	0	3 (16.7)	1 (5.6)

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (22.2)	0	0	1 (5.6)	3 (16.7)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Anaemia	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	2 (100)	0	0	2 (100)	0
Tachycardia	2 (100)	0	0	2 (100)	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Abdominal compartment syndrome	1 (50.0)	0	0	0	1 (50.0)

Number of previous relapses: 0

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (50.0)	1 (50.0)	0	0	0
Haemoperitoneum	1 (50.0)	0	0	0	1 (50.0)
General disorders and administration site conditions					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Pyrexia	2 (100)	0	1 (50.0)	1 (50.0)	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	2 (100)	0	0	0	2 (100)
Disseminated trichosporonosis	1 (50.0)	0	0	0	1 (50.0)
Serratia sepsis	1 (50.0)	0	0	0	1 (50.0)
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood creatinine increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	1 (50.0)	0	0	0

Number of previous relapses: 0

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypocalcaemia	2 (100)	0	2 (100)	0	0
Metabolic acidosis	2 (100)	0	0	2 (100)	0
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypomagnesaemia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cognitive disorder	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	2 (100)	2 (100)	0	0	0
Acute kidney injury	2 (100)	2 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	0	0	2 (100)
Respiratory failure	2 (100)	0	0	0	2 (100)

Number of previous relapses: 0

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Vascular disorders					
-Total	2 (100)	0	0	2 (100)	0
Hypotension	2 (100)	0	0	2 (100)	0

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-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	4 (50.0)	4 (50.0)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Anaemia	1 (12.5)	0	0	1 (12.5)	0
Febrile neutropenia	1 (12.5)	0	0	1 (12.5)	0
Hyperleukocytosis	1 (12.5)	0	0	1 (12.5)	0
Pancytopenia	1 (12.5)	0	0	1 (12.5)	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Bradycardia	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 1

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (12.5)	0	0	1 (12.5)	0
Tachycardia	1 (12.5)	0	1 (12.5)	0	0
Endocrine disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hypercalcaemia of malignancy	1 (12.5)	0	0	0	1 (12.5)
Eye disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Eyelid oedema	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Abdominal pain upper	1 (12.5)	1 (12.5)	0	0	0
Diarrhoea	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	4 (50.0)	1 (12.5)	2 (25.0)	1 (12.5)	0
Catheter site pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Number of previous relapses: 1

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Oedema peripheral	1 (12.5)	0	1 (12.5)	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Hyperbilirubinaemia	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypersensitivity	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Acute sinusitis	1 (12.5)	0	0	1 (12.5)	0
Device related infection	1 (12.5)	0	0	1 (12.5)	0
Device related sepsis	1 (12.5)	0	0	1 (12.5)	0
Fungal skin infection	1 (12.5)	0	0	1 (12.5)	0
Klebsiella bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia fungal	1 (12.5)	0	0	0	1 (12.5)
Sepsis	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 1

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Systemic mycosis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					
-Total	1 (12.5)	0	0	1 (12.5)	0
Post procedural haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	3 (37.5)	0	0	3 (37.5)	0
C-reactive protein increased	2 (25.0)	0	0	2 (25.0)	0
Alanine aminotransferase increased	1 (12.5)	0	0	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	0	1 (12.5)	0	0
Blood potassium decreased	1 (12.5)	0	0	1 (12.5)	0
Serum ferritin increased	1 (12.5)	0	0	1 (12.5)	0
Metabolism and nutrition disorders					
-Total	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Hyperammonaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperuricaemia	1 (12.5)	0	1 (12.5)	0	0
Hypokalaemia	1 (12.5)	0	1 (12.5)	0	0
Tumour lysis syndrome	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 1

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Back pain	1 (12.5)	1 (12.5)	0	0	0
Myositis	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Headache	1 (12.5)	1 (12.5)	0	0	0
Intraventricular haemorrhage	1 (12.5)	1 (12.5)	0	0	0
Paraesthesia	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Mental status changes	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Hypoxia	1 (12.5)	0	1 (12.5)	0	0
Tachypnoea	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Pain of skin	1 (12.5)	1 (12.5)	0	0	0
Skin ulcer	1 (12.5)	0	1 (12.5)	0	0
Vascular disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	0	0	1 (12.5)	1 (12.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Aspergillus infection	1 (100)	0	0	0	1 (100)
Psychiatric disorders					
-Total	1 (100)	0	0	1 (100)	0
Mental status changes	1 (100)	0	0	1 (100)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 217r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Febrile neutropenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Pancytopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Cardiac failure	1 (14.3)	0	0	1 (14.3)	0
Tachycardia	1 (14.3)	0	1 (14.3)	0	0

Number of previous relapses: >=3

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	0	1 (14.3)	3 (42.9)	0
Diarrhoea	2 (28.6)	0	2 (28.6)	0	0
Abdominal pain	1 (14.3)	0	1 (14.3)	0	0
Colitis	1 (14.3)	0	0	1 (14.3)	0
Duodenal perforation	1 (14.3)	0	0	1 (14.3)	0
Gastritis	1 (14.3)	0	1 (14.3)	0	0
Nausea	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Catheter site pain	1 (14.3)	1 (14.3)	0	0	0
Generalised oedema	1 (14.3)	0	0	1 (14.3)	0
Oedema peripheral	1 (14.3)	1 (14.3)	0	0	0

Number of previous relapses: >=3

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (14.3)	0	0	1 (14.3)	0
Pyrexia	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	0	0	1 (14.3)	0
Immune system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Graft versus host disease	1 (14.3)	0	0	1 (14.3)	0
Infections and infestations					
-Total	6 (85.7)	0	1 (14.3)	2 (28.6)	3 (42.9)
Bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Bacterial sepsis	1 (14.3)	0	0	0	1 (14.3)
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Epstein-barr virus infection	1 (14.3)	0	1 (14.3)	0	0
Fungaemia	1 (14.3)	0	0	0	1 (14.3)
Fungal sepsis	1 (14.3)	0	0	0	1 (14.3)
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	0	1 (14.3)

Number of previous relapses: >=3

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	1 (14.3)	0	0	0
Investigations					
-Total	1 (14.3)	0	0	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
Platelet count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Decreased appetite	1 (14.3)	0	1 (14.3)	0	0
Hyperglycaemia	1 (14.3)	0	0	0	1 (14.3)
Tumour lysis syndrome	1 (14.3)	0	0	0	1 (14.3)
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthralgia	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Number of previous relapses: >=3

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (14.3)	0	0	1 (14.3)	0
Haemorrhage intracranial	1 (14.3)	0	0	0	1 (14.3)
Renal and urinary disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Acute kidney injury	1 (14.3)	1 (14.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Acute respiratory distress syndrome	1 (14.3)	0	0	0	1 (14.3)
Pulmonary haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Rash	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-Only AEs occured to non-infused patients are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (95.1)	0	3 (7.3)	10 (24.4)	26 (63.4)
Blood and lymphatic system disorders					
-Total	31 (75.6)	1 (2.4)	3 (7.3)	20 (48.8)	7 (17.1)
Anaemia	23 (56.1)	4 (9.8)	5 (12.2)	14 (34.1)	0
Febrile neutropenia	20 (48.8)	0	0	20 (48.8)	0
Thrombocytopenia	8 (19.5)	1 (2.4)	0	2 (4.9)	5 (12.2)
Neutropenia	7 (17.1)	0	1 (2.4)	1 (2.4)	5 (12.2)
Disseminated intravascular coagulation	4 (9.8)	0	3 (7.3)	1 (2.4)	0
Pancytopenia	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Coagulopathy	1 (2.4)	0	0	1 (2.4)	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	10 (24.4)	4 (9.8)	4 (9.8)	1 (2.4)	1 (2.4)
Tachycardia	10 (24.4)	4 (9.8)	4 (9.8)	1 (2.4)	1 (2.4)
Endocrine disorders					
-Total	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Adrenal insufficiency	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Gastrointestinal disorders					
-Total	32 (78.0)	10 (24.4)	11 (26.8)	11 (26.8)	0
Vomiting	18 (43.9)	13 (31.7)	5 (12.2)	0	0
Diarrhoea	17 (41.5)	9 (22.0)	5 (12.2)	3 (7.3)	0
Nausea	17 (41.5)	7 (17.1)	8 (19.5)	2 (4.9)	0
Abdominal pain	10 (24.4)	2 (4.9)	4 (9.8)	4 (9.8)	0
Constipation	7 (17.1)	4 (9.8)	3 (7.3)	0	0
Stomatitis	6 (14.6)	0	2 (4.9)	4 (9.8)	0
Abdominal pain upper	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Mouth haemorrhage	2 (4.9)	0	1 (2.4)	1 (2.4)	0
General disorders and administration site conditions					

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	28 (68.3)	15 (36.6)	8 (19.5)	4 (9.8)	1 (2.4)
Pyrexia	20 (48.8)	10 (24.4)	6 (14.6)	3 (7.3)	1 (2.4)
Fatigue	12 (29.3)	10 (24.4)	2 (4.9)	0	0
Chills	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Pain	4 (9.8)	0	0	4 (9.8)	0
Face oedema	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Catheter site pain	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Oedema peripheral	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Asthenia	1 (2.4)	1 (2.4)	0	0	0
Non-cardiac chest pain	1 (2.4)	1 (2.4)	0	0	0
Hepatobiliary disorders					
-Total	4 (9.8)	1 (2.4)	1 (2.4)	2 (4.9)	0
Hyperbilirubinaemia	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0
Hepatic function abnormal	1 (2.4)	0	0	1 (2.4)	0
Immune system disorders					
-Total	29 (70.7)	2 (4.9)	14 (34.1)	5 (12.2)	8 (19.5)
Cytokine release syndrome	24 (58.5)	3 (7.3)	10 (24.4)	3 (7.3)	8 (19.5)
Hypogammaglobulinaemia	17 (41.5)	1 (2.4)	13 (31.7)	3 (7.3)	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	21 (51.2)	4 (9.8)	8 (19.5)	6 (14.6)	3 (7.3)
Upper respiratory tract infection	7 (17.1)	4 (9.8)	3 (7.3)	0	0
Conjunctivitis	6 (14.6)	2 (4.9)	4 (9.8)	0	0
Nasopharyngitis	4 (9.8)	3 (7.3)	1 (2.4)	0	0
Pneumonia	4 (9.8)	1 (2.4)	0	1 (2.4)	2 (4.9)
Gastroenteritis	3 (7.3)	2 (4.9)	0	1 (2.4)	0
Parainfluenzae virus infection	3 (7.3)	0	0	2 (4.9)	1 (2.4)
Rhinovirus infection	3 (7.3)	0	2 (4.9)	1 (2.4)	0
Candida infection	2 (4.9)	0	2 (4.9)	0	0
Oral herpes	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Staphylococcal bacteraemia	2 (4.9)	0	0	2 (4.9)	0
Staphylococcal infection	2 (4.9)	0	1 (2.4)	1 (2.4)	0
Acute sinusitis	1 (2.4)	0	0	1 (2.4)	0
Herpes zoster	1 (2.4)	0	0	1 (2.4)	0
Sinusitis	1 (2.4)	0	0	1 (2.4)	0
Injury, poisoning and procedural complications					

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.4)	1 (2.4)	0	0	0
Procedural pain	1 (2.4)	1 (2.4)	0	0	0
Investigations					
-Total	29 (70.7)	1 (2.4)	0	8 (19.5)	20 (48.8)
White blood cell count decreased	20 (48.8)	2 (4.9)	1 (2.4)	1 (2.4)	16 (39.0)
Neutrophil count decreased	18 (43.9)	0	1 (2.4)	2 (4.9)	15 (36.6)
Platelet count decreased	16 (39.0)	4 (9.8)	1 (2.4)	4 (9.8)	7 (17.1)
Lymphocyte count decreased	14 (34.1)	0	0	6 (14.6)	8 (19.5)
Alanine aminotransferase increased	12 (29.3)	2 (4.9)	6 (14.6)	4 (9.8)	0
Aspartate aminotransferase increased	9 (22.0)	1 (2.4)	3 (7.3)	3 (7.3)	2 (4.9)
Blood immunoglobulin m decreased	6 (14.6)	4 (9.8)	1 (2.4)	1 (2.4)	0
Blood bilirubin increased	5 (12.2)	0	1 (2.4)	4 (9.8)	0
Blood immunoglobulin a decreased	5 (12.2)	4 (9.8)	1 (2.4)	0	0
C-reactive protein increased	5 (12.2)	2 (4.9)	0	3 (7.3)	0
Serum ferritin increased	5 (12.2)	2 (4.9)	3 (7.3)	0	0
International normalised ratio increased	4 (9.8)	3 (7.3)	1 (2.4)	0	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Blood fibrinogen decreased	3 (7.3)	2 (4.9)	0	0	1 (2.4)
Blood lactate dehydrogenase increased	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Blood creatinine increased	1 (2.4)	0	0	1 (2.4)	0
Electrocardiogram qt prolonged	1 (2.4)	0	1 (2.4)	0	0
Metabolism and nutrition disorders					
-Total	25 (61.0)	4 (9.8)	8 (19.5)	7 (17.1)	6 (14.6)
Decreased appetite	12 (29.3)	4 (9.8)	3 (7.3)	4 (9.8)	1 (2.4)
Hypophosphataemia	10 (24.4)	2 (4.9)	4 (9.8)	3 (7.3)	1 (2.4)
Hypokalaemia	9 (22.0)	3 (7.3)	1 (2.4)	3 (7.3)	2 (4.9)
Hypocalcaemia	7 (17.1)	1 (2.4)	4 (9.8)	2 (4.9)	0
Hypoalbuminaemia	5 (12.2)	0	5 (12.2)	0	0
Hyperglycaemia	4 (9.8)	0	0	4 (9.8)	0
Hyperuricaemia	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Metabolic acidosis	2 (4.9)	1 (2.4)	0	0	1 (2.4)
Tumour lysis syndrome	2 (4.9)	0	0	1 (2.4)	1 (2.4)
Hypervolaemia	1 (2.4)	0	1 (2.4)	0	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (43.9)	8 (19.5)	7 (17.1)	3 (7.3)	0
Pain in extremity	13 (31.7)	6 (14.6)	6 (14.6)	1 (2.4)	0
Arthralgia	5 (12.2)	2 (4.9)	3 (7.3)	0	0
Back pain	5 (12.2)	1 (2.4)	2 (4.9)	2 (4.9)	0
Myalgia	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Nervous system disorders					
-Total	17 (41.5)	8 (19.5)	3 (7.3)	6 (14.6)	0
Headache	11 (26.8)	8 (19.5)	1 (2.4)	2 (4.9)	0
Encephalopathy	5 (12.2)	0	2 (4.9)	3 (7.3)	0
Lethargy	2 (4.9)	2 (4.9)	0	0	0
Somnolence	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Tremor	2 (4.9)	2 (4.9)	0	0	0
Seizure	1 (2.4)	0	0	1 (2.4)	0
Psychiatric disorders					
-Total	9 (22.0)	3 (7.3)	4 (9.8)	2 (4.9)	0

Age: <10 years

	All patients N=41				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	5 (12.2)	2 (4.9)	3 (7.3)	0	0
Delirium	3 (7.3)	1 (2.4)	2 (4.9)	0	0
Agitation	2 (4.9)	2 (4.9)	0	0	0
Mental status changes	2 (4.9)	0	0	2 (4.9)	0
Renal and urinary disorders					
-Total	4 (9.8)	2 (4.9)	0	0	2 (4.9)
Acute kidney injury	4 (9.8)	2 (4.9)	0	0	2 (4.9)
Respiratory, thoracic and mediastinal disorders					
-Total	25 (61.0)	9 (22.0)	3 (7.3)	6 (14.6)	7 (17.1)
Cough	13 (31.7)	12 (29.3)	1 (2.4)	0	0
Hypoxia	9 (22.0)	0	3 (7.3)	4 (9.8)	2 (4.9)
Tachypnoea	6 (14.6)	2 (4.9)	1 (2.4)	2 (4.9)	1 (2.4)
Epistaxis	5 (12.2)	3 (7.3)	0	2 (4.9)	0
Nasal congestion	5 (12.2)	4 (9.8)	1 (2.4)	0	0
Pulmonary oedema	5 (12.2)	1 (2.4)	1 (2.4)	3 (7.3)	0
Dyspnoea	3 (7.3)	0	0	1 (2.4)	2 (4.9)
Pleural effusion	3 (7.3)	1 (2.4)	1 (2.4)	1 (2.4)	0

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	3 (7.3)	0	0	0	3 (7.3)
Oropharyngeal pain	2 (4.9)	1 (2.4)	1 (2.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (24.4)	6 (14.6)	4 (9.8)	0	0
Rash	5 (12.2)	3 (7.3)	2 (4.9)	0	0
Pruritus	4 (9.8)	1 (2.4)	3 (7.3)	0	0
Dry skin	3 (7.3)	2 (4.9)	1 (2.4)	0	0
Vascular disorders					
-Total	18 (43.9)	2 (4.9)	7 (17.1)	6 (14.6)	3 (7.3)
Hypotension	11 (26.8)	1 (2.4)	3 (7.3)	4 (9.8)	3 (7.3)
Hypertension	9 (22.0)	2 (4.9)	4 (9.8)	3 (7.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (97.5)	0	0	10 (25.0)	29 (72.5)
Blood and lymphatic system disorders					
-Total	27 (67.5)	0	1 (2.5)	14 (35.0)	12 (30.0)
Anaemia	16 (40.0)	2 (5.0)	4 (10.0)	9 (22.5)	1 (2.5)
Febrile neutropenia	16 (40.0)	0	0	14 (35.0)	2 (5.0)
Neutropenia	9 (22.5)	1 (2.5)	0	1 (2.5)	7 (17.5)
Thrombocytopenia	5 (12.5)	0	1 (2.5)	1 (2.5)	3 (7.5)
Disseminated intravascular coagulation	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Coagulopathy	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	12 (30.0)	3 (7.5)	4 (10.0)	4 (10.0)	1 (2.5)
Tachycardia	10 (25.0)	3 (7.5)	4 (10.0)	3 (7.5)	0
Cardiac failure	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Sinus tachycardia	1 (2.5)	1 (2.5)	0	0	0
Endocrine disorders					
-Total	2 (5.0)	0	2 (5.0)	0	0
Adrenal insufficiency	2 (5.0)	0	2 (5.0)	0	0
Gastrointestinal disorders					
-Total	25 (62.5)	4 (10.0)	16 (40.0)	5 (12.5)	0
Nausea	13 (32.5)	4 (10.0)	7 (17.5)	2 (5.0)	0
Diarrhoea	10 (25.0)	6 (15.0)	4 (10.0)	0	0
Abdominal pain	8 (20.0)	2 (5.0)	6 (15.0)	0	0
Constipation	8 (20.0)	4 (10.0)	4 (10.0)	0	0
Vomiting	7 (17.5)	4 (10.0)	1 (2.5)	2 (5.0)	0
Stomatitis	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Abdominal pain upper	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Mouth haemorrhage	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	25 (62.5)	8 (20.0)	9 (22.5)	7 (17.5)	1 (2.5)
Pyrexia	19 (47.5)	6 (15.0)	6 (15.0)	6 (15.0)	1 (2.5)
Fatigue	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Oedema peripheral	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Catheter site pain	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Face oedema	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Pain	4 (10.0)	0	4 (10.0)	0	0
Chills	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Asthenia	1 (2.5)	1 (2.5)	0	0	0
Non-cardiac chest pain	1 (2.5)	0	1 (2.5)	0	0
Hepatobiliary disorders					
-Total	5 (12.5)	0	2 (5.0)	2 (5.0)	1 (2.5)
Hyperbilirubinaemia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hepatic function abnormal	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Immune system disorders					
-Total	29 (72.5)	0	8 (20.0)	12 (30.0)	9 (22.5)

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	25 (62.5)	1 (2.5)	5 (12.5)	10 (25.0)	9 (22.5)
Hypogammaglobulinaemia	18 (45.0)	0	12 (30.0)	6 (15.0)	0
Seasonal allergy	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Infections and infestations					
-Total	28 (70.0)	2 (5.0)	8 (20.0)	17 (42.5)	1 (2.5)
Paronychia	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
Sinusitis	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Upper respiratory tract infection	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Bacteraemia	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Herpes zoster	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Pneumonia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Rhinovirus infection	4 (10.0)	0	4 (10.0)	0	0
Staphylococcal bacteraemia	4 (10.0)	0	0	4 (10.0)	0
Oral herpes	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Staphylococcal infection	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Conjunctivitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Gastroenteritis	2 (5.0)	2 (5.0)	0	0	0
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (5.0)	0	2 (5.0)	0	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Catheter site infection	1 (2.5)	0	0	1 (2.5)	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Procedural pain	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Investigations					
-Total	26 (65.0)	0	0	11 (27.5)	15 (37.5)
White blood cell count decreased	11 (27.5)	1 (2.5)	2 (5.0)	0	8 (20.0)
Alanine aminotransferase increased	10 (25.0)	3 (7.5)	1 (2.5)	6 (15.0)	0
Neutrophil count decreased	10 (25.0)	1 (2.5)	1 (2.5)	1 (2.5)	7 (17.5)
Aspartate aminotransferase increased	9 (22.5)	0	3 (7.5)	4 (10.0)	2 (5.0)
Platelet count decreased	9 (22.5)	1 (2.5)	1 (2.5)	1 (2.5)	6 (15.0)
Lymphocyte count decreased	8 (20.0)	1 (2.5)	1 (2.5)	3 (7.5)	3 (7.5)
Serum ferritin increased	7 (17.5)	0	3 (7.5)	4 (10.0)	0
Blood bilirubin increased	6 (15.0)	1 (2.5)	1 (2.5)	4 (10.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	5 (12.5)	2 (5.0)	1 (2.5)	1 (2.5)	1 (2.5)
Blood fibrinogen decreased	5 (12.5)	1 (2.5)	3 (7.5)	1 (2.5)	0
C-reactive protein increased	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Activated partial thromboplastin time prolonged	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Blood lactate dehydrogenase increased	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Electrocardiogram qt prolonged	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
International normalised ratio increased	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Weight decreased	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Blood immunoglobulin a decreased	1 (2.5)	0	0	1 (2.5)	0
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	28 (70.0)	2 (5.0)	6 (15.0)	15 (37.5)	5 (12.5)
Decreased appetite	16 (40.0)	5 (12.5)	5 (12.5)	5 (12.5)	1 (2.5)
Hypokalaemia	11 (27.5)	0	2 (5.0)	8 (20.0)	1 (2.5)
Hypocalcaemia	8 (20.0)	1 (2.5)	6 (15.0)	1 (2.5)	0
Hypophosphataemia	8 (20.0)	1 (2.5)	3 (7.5)	4 (10.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	6 (15.0)	5 (12.5)	0	1 (2.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hypomagnesaemia	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Hypervolaemia	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Metabolic acidosis	4 (10.0)	0	0	2 (5.0)	2 (5.0)
Tumour lysis syndrome	4 (10.0)	0	0	3 (7.5)	1 (2.5)
Hyperglycaemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	16 (40.0)	6 (15.0)	6 (15.0)	4 (10.0)	0
Pain in extremity	8 (20.0)	2 (5.0)	4 (10.0)	2 (5.0)	0
Arthralgia	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Back pain	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Myalgia	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Pain in jaw	1 (2.5)	1 (2.5)	0	0	0
Nervous system disorders					
-Total	21 (52.5)	5 (12.5)	11 (27.5)	5 (12.5)	0
Headache	17 (42.5)	6 (15.0)	9 (22.5)	2 (5.0)	0

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Encephalopathy	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Somnolence	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Tremor	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Neuropathy peripheral	1 (2.5)	0	1 (2.5)	0	0
Paraesthesia	1 (2.5)	1 (2.5)	0	0	0
Psychiatric disorders					
-Total	14 (35.0)	3 (7.5)	5 (12.5)	6 (15.0)	0
Anxiety	8 (20.0)	1 (2.5)	4 (10.0)	3 (7.5)	0
Mental status changes	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Agitation	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Delirium	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Renal and urinary disorders					
-Total	9 (22.5)	3 (7.5)	1 (2.5)	2 (5.0)	3 (7.5)
Acute kidney injury	9 (22.5)	3 (7.5)	1 (2.5)	2 (5.0)	3 (7.5)
Respiratory, thoracic and mediastinal disorders					
-Total	25 (62.5)	8 (20.0)	3 (7.5)	5 (12.5)	9 (22.5)

Age: >=10 years to <18 years

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	11 (27.5)	7 (17.5)	4 (10.0)	0	0
Hypoxia	9 (22.5)	0	2 (5.0)	3 (7.5)	4 (10.0)
Oropharyngeal pain	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Pleural effusion	6 (15.0)	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)
Nasal congestion	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Pulmonary oedema	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory failure	5 (12.5)	0	0	0	5 (12.5)
Dyspnoea	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Epistaxis	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Tachypnoea	4 (10.0)	1 (2.5)	0	3 (7.5)	0
Skin and subcutaneous tissue disorders					
-Total	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Dry skin	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Rash	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Ingrowing nail	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Hyperhidrosis	1 (2.5)	1 (2.5)	0	0	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	20 (50.0)	4 (10.0)	4 (10.0)	7 (17.5)	5 (12.5)
Hypotension	16 (40.0)	2 (5.0)	3 (7.5)	6 (15.0)	5 (12.5)
Hypertension	9 (22.5)	3 (7.5)	5 (12.5)	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (100)	0	0	5 (29.4)	12 (70.6)
Blood and lymphatic system disorders					
-Total	14 (82.4)	0	2 (11.8)	6 (35.3)	6 (35.3)
Febrile neutropenia	9 (52.9)	0	0	8 (47.1)	1 (5.9)
Anaemia	7 (41.2)	0	3 (17.6)	4 (23.5)	0
Neutropenia	6 (35.3)	0	1 (5.9)	1 (5.9)	4 (23.5)
Pancytopenia	3 (17.6)	0	0	1 (5.9)	2 (11.8)
Coagulopathy	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Thrombocytopenia	2 (11.8)	0	0	2 (11.8)	0
Cardiac disorders					

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (35.3)	2 (11.8)	1 (5.9)	2 (11.8)	1 (5.9)
Tachycardia	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Cardiac failure	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Sinus tachycardia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Endocrine disorders					
-Total	4 (23.5)	0	4 (23.5)	0	0
Adrenal insufficiency	4 (23.5)	0	4 (23.5)	0	0
Gastrointestinal disorders					
-Total	14 (82.4)	7 (41.2)	5 (29.4)	2 (11.8)	0
Nausea	7 (41.2)	3 (17.6)	4 (23.5)	0	0
Vomiting	6 (35.3)	4 (23.5)	2 (11.8)	0	0
Constipation	5 (29.4)	2 (11.8)	3 (17.6)	0	0
Diarrhoea	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Stomatitis	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Abdominal pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Abdominal pain upper	2 (11.8)	2 (11.8)	0	0	0
Mouth haemorrhage	2 (11.8)	1 (5.9)	0	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	14 (82.4)	6 (35.3)	6 (35.3)	2 (11.8)	0
Pyrexia	9 (52.9)	2 (11.8)	5 (29.4)	2 (11.8)	0
Fatigue	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Pain	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Asthenia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Catheter site pain	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Chills	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Face oedema	2 (11.8)	2 (11.8)	0	0	0
Non-cardiac chest pain	2 (11.8)	2 (11.8)	0	0	0
Oedema peripheral	2 (11.8)	2 (11.8)	0	0	0
Hepatobiliary disorders					
-Total	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Hepatic function abnormal	2 (11.8)	0	2 (11.8)	0	0
Hyperbilirubinaemia	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Immune system disorders					
-Total	12 (70.6)	0	4 (23.5)	4 (23.5)	4 (23.5)

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cytokine release syndrome	12 (70.6)	1 (5.9)	3 (17.6)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	6 (35.3)	1 (5.9)	5 (29.4)	0	0
Seasonal allergy	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	13 (76.5)	1 (5.9)	3 (17.6)	6 (35.3)	3 (17.6)
Parainfluenzae virus infection	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Sinusitis	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Urinary tract infection	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Acute sinusitis	2 (11.8)	0	2 (11.8)	0	0
Bacteraemia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Candida infection	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Catheter site infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Gastroenteritis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Nasopharyngitis	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Oral herpes	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Pneumonia	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Rhinovirus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Varicella zoster virus infection	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Conjunctivitis	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	11 (64.7)	0	1 (5.9)	3 (17.6)	7 (41.2)
Platelet count decreased	7 (41.2)	1 (5.9)	0	1 (5.9)	5 (29.4)
Aspartate aminotransferase increased	5 (29.4)	1 (5.9)	0	4 (23.5)	0
White blood cell count decreased	4 (23.5)	0	0	0	4 (23.5)
Alanine aminotransferase increased	3 (17.6)	0	2 (11.8)	1 (5.9)	0
Neutrophil count decreased	3 (17.6)	1 (5.9)	0	0	2 (11.8)
Blood bilirubin increased	2 (11.8)	0	0	2 (11.8)	0
C-reactive protein increased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
International normalised ratio increased	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Lymphocyte count decreased	2 (11.8)	0	0	0	2 (11.8)
Blood creatinine increased	1 (5.9)	0	0	1 (5.9)	0
Blood immunoglobulin a decreased	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (5.9)	0	0	1 (5.9)	0
Electrocardiogram qt prolonged	1 (5.9)	1 (5.9)	0	0	0
Serum ferritin increased	1 (5.9)	0	0	0	1 (5.9)
Metabolism and nutrition disorders					
-Total	8 (47.1)	2 (11.8)	0	5 (29.4)	1 (5.9)
Decreased appetite	7 (41.2)	3 (17.6)	1 (5.9)	3 (17.6)	0
Hypokalaemia	6 (35.3)	1 (5.9)	3 (17.6)	2 (11.8)	0
Hyperglycaemia	4 (23.5)	0	3 (17.6)	0	1 (5.9)
Hypocalcaemia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Hypervolaemia	3 (17.6)	0	0	3 (17.6)	0
Hypomagnesaemia	3 (17.6)	1 (5.9)	2 (11.8)	0	0
Hypophosphataemia	3 (17.6)	0	1 (5.9)	2 (11.8)	0
Hypoalbuminaemia	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Hyperuricaemia	1 (5.9)	1 (5.9)	0	0	0
Tumour lysis syndrome	1 (5.9)	0	0	1 (5.9)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (52.9)	4 (23.5)	3 (17.6)	2 (11.8)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Arthralgia	5 (29.4)	2 (11.8)	3 (17.6)	0	0
Back pain	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0
Joint effusion	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Myalgia	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Neck pain	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain in extremity	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Pain in jaw	2 (11.8)	0	0	2 (11.8)	0
Nervous system disorders					
-Total	9 (52.9)	4 (23.5)	2 (11.8)	3 (17.6)	0
Headache	7 (41.2)	4 (23.5)	2 (11.8)	1 (5.9)	0
Paraesthesia	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Lethargy	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Neuropathy peripheral	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Somnolence	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Tremor	2 (11.8)	2 (11.8)	0	0	0
Encephalopathy	1 (5.9)	0	0	1 (5.9)	0
Psychiatric disorders					
-Total	7 (41.2)	2 (11.8)	3 (17.6)	2 (11.8)	0

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (23.5)	1 (5.9)	3 (17.6)	0	0
Agitation	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Delirium	2 (11.8)	0	0	2 (11.8)	0
Mental status changes	1 (5.9)	0	1 (5.9)	0	0
Renal and urinary disorders					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Acute kidney injury	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (58.8)	3 (17.6)	2 (11.8)	3 (17.6)	2 (11.8)
Hypoxia	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Pulmonary oedema	4 (23.5)	1 (5.9)	0	2 (11.8)	1 (5.9)
Epistaxis	3 (17.6)	2 (11.8)	0	1 (5.9)	0
Cough	2 (11.8)	2 (11.8)	0	0	0
Dyspnoea	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Oropharyngeal pain	2 (11.8)	2 (11.8)	0	0	0
Respiratory failure	2 (11.8)	0	0	0	2 (11.8)
Nasal congestion	1 (5.9)	1 (5.9)	0	0	0

Age: >=18

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (5.9)	0	1 (5.9)	0	0
Tachypnoea	1 (5.9)	0	1 (5.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (47.1)	4 (23.5)	4 (23.5)	0	0
Pruritus	5 (29.4)	3 (17.6)	2 (11.8)	0	0
Hyperhidrosis	2 (11.8)	0	2 (11.8)	0	0
Dry skin	1 (5.9)	1 (5.9)	0	0	0
Rash	1 (5.9)	1 (5.9)	0	0	0
Vascular disorders					
-Total	6 (35.3)	1 (5.9)	1 (5.9)	2 (11.8)	2 (11.8)
Hypertension	6 (35.3)	1 (5.9)	4 (23.5)	1 (5.9)	0
Hypotension	4 (23.5)	0	0	2 (11.8)	2 (11.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (96.4)	0	2 (3.6)	14 (25.5)	37 (67.3)
Blood and lymphatic system disorders					
-Total	38 (69.1)	0	4 (7.3)	21 (38.2)	13 (23.6)
Anaemia	25 (45.5)	2 (3.6)	7 (12.7)	15 (27.3)	1 (1.8)
Febrile neutropenia	21 (38.2)	0	0	21 (38.2)	0
Neutropenia	12 (21.8)	0	1 (1.8)	1 (1.8)	10 (18.2)
Thrombocytopenia	10 (18.2)	1 (1.8)	1 (1.8)	2 (3.6)	6 (10.9)
Disseminated intravascular coagulation	6 (10.9)	0	5 (9.1)	1 (1.8)	0
Cardiac disorders					
-Total	14 (25.5)	4 (7.3)	6 (10.9)	4 (7.3)	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (25.5)	4 (7.3)	6 (10.9)	4 (7.3)	0
Endocrine disorders					
-Total	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Adrenal insufficiency	3 (5.5)	0	2 (3.6)	1 (1.8)	0
Gastrointestinal disorders					
-Total	41 (74.5)	14 (25.5)	17 (30.9)	10 (18.2)	0
Nausea	23 (41.8)	10 (18.2)	10 (18.2)	3 (5.5)	0
Vomiting	18 (32.7)	15 (27.3)	3 (5.5)	0	0
Diarrhoea	17 (30.9)	9 (16.4)	5 (9.1)	3 (5.5)	0
Abdominal pain	12 (21.8)	3 (5.5)	6 (10.9)	3 (5.5)	0
Constipation	11 (20.0)	6 (10.9)	5 (9.1)	0	0
Stomatitis	4 (7.3)	0	0	4 (7.3)	0
General disorders and administration site conditions					
-Total	36 (65.5)	14 (25.5)	12 (21.8)	8 (14.5)	2 (3.6)
Pyrexia	29 (52.7)	10 (18.2)	11 (20.0)	6 (10.9)	2 (3.6)
Fatigue	12 (21.8)	9 (16.4)	3 (5.5)	0	0
Pain	8 (14.5)	0	5 (9.1)	3 (5.5)	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	6 (10.9)	4 (7.3)	1 (1.8)	1 (1.8)	0
Chills	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Immune system disorders					
-Total	38 (69.1)	1 (1.8)	15 (27.3)	11 (20.0)	11 (20.0)
Cytokine release syndrome	31 (56.4)	3 (5.5)	9 (16.4)	8 (14.5)	11 (20.0)
Hypogammaglobulinaemia	22 (40.0)	1 (1.8)	17 (30.9)	4 (7.3)	0
Infections and infestations					
-Total	25 (45.5)	6 (10.9)	11 (20.0)	6 (10.9)	2 (3.6)
Upper respiratory tract infection	9 (16.4)	4 (7.3)	3 (5.5)	2 (3.6)	0
Conjunctivitis	7 (12.7)	3 (5.5)	4 (7.3)	0	0
Pneumonia	7 (12.7)	1 (1.8)	1 (1.8)	3 (5.5)	2 (3.6)
Nasopharyngitis	6 (10.9)	4 (7.3)	2 (3.6)	0	0
Rhinovirus infection	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Sinusitis	4 (7.3)	0	3 (5.5)	1 (1.8)	0
Gastroenteritis	2 (3.6)	2 (3.6)	0	0	0
Bacteraemia	1 (1.8)	0	1 (1.8)	0	0
Investigations					
-Total	34 (61.8)	0	0	12 (21.8)	22 (40.0)

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	19 (34.5)	5 (9.1)	7 (12.7)	7 (12.7)	0
Neutrophil count decreased	17 (30.9)	2 (3.6)	0	2 (3.6)	13 (23.6)
White blood cell count decreased	17 (30.9)	1 (1.8)	1 (1.8)	1 (1.8)	14 (25.5)
Aspartate aminotransferase increased	15 (27.3)	1 (1.8)	5 (9.1)	6 (10.9)	3 (5.5)
Platelet count decreased	15 (27.3)	2 (3.6)	1 (1.8)	4 (7.3)	8 (14.5)
Lymphocyte count decreased	12 (21.8)	1 (1.8)	0	4 (7.3)	7 (12.7)
Blood bilirubin increased	9 (16.4)	0	1 (1.8)	8 (14.5)	0
Serum ferritin increased	8 (14.5)	2 (3.6)	5 (9.1)	1 (1.8)	0
C-reactive protein increased	7 (12.7)	3 (5.5)	1 (1.8)	3 (5.5)	0
International normalised ratio increased	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	33 (60.0)	4 (7.3)	12 (21.8)	12 (21.8)	5 (9.1)
Decreased appetite	18 (32.7)	6 (10.9)	5 (9.1)	5 (9.1)	2 (3.6)
Hypokalaemia	14 (25.5)	2 (3.6)	3 (5.5)	7 (12.7)	2 (3.6)
Hypocalcaemia	11 (20.0)	2 (3.6)	6 (10.9)	3 (5.5)	0
Hypophosphataemia	9 (16.4)	3 (5.5)	3 (5.5)	2 (3.6)	1 (1.8)
Hypoalbuminaemia	6 (10.9)	0	6 (10.9)	0	0

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperuricaemia	5 (9.1)	4 (7.3)	1 (1.8)	0	0
Hypomagnesaemia	5 (9.1)	5 (9.1)	0	0	0
Hyperglycaemia	4 (7.3)	0	0	4 (7.3)	0
Hypervolaemia	4 (7.3)	1 (1.8)	1 (1.8)	2 (3.6)	0
Musculoskeletal and connective tissue disorders					
-Total	20 (36.4)	7 (12.7)	11 (20.0)	2 (3.6)	0
Pain in extremity	12 (21.8)	3 (5.5)	9 (16.4)	0	0
Arthralgia	11 (20.0)	6 (10.9)	5 (9.1)	0	0
Back pain	5 (9.1)	0	3 (5.5)	2 (3.6)	0
Myalgia	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Nervous system disorders					
-Total	16 (29.1)	9 (16.4)	3 (5.5)	4 (7.3)	0
Headache	16 (29.1)	9 (16.4)	3 (5.5)	4 (7.3)	0
Psychiatric disorders					
-Total	15 (27.3)	3 (5.5)	9 (16.4)	3 (5.5)	0
Anxiety	10 (18.2)	2 (3.6)	8 (14.5)	0	0
Delirium	6 (10.9)	2 (3.6)	2 (3.6)	2 (3.6)	0

Gender: Male

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Renal and urinary disorders					
-Total	8 (14.5)	5 (9.1)	1 (1.8)	0	2 (3.6)
Acute kidney injury	8 (14.5)	5 (9.1)	1 (1.8)	0	2 (3.6)
Respiratory, thoracic and mediastinal disorders					
-Total	35 (63.6)	9 (16.4)	8 (14.5)	5 (9.1)	13 (23.6)
Cough	14 (25.5)	12 (21.8)	2 (3.6)	0	0
Hypoxia	13 (23.6)	0	5 (9.1)	4 (7.3)	4 (7.3)
Pleural effusion	9 (16.4)	3 (5.5)	3 (5.5)	2 (3.6)	1 (1.8)
Pulmonary oedema	8 (14.5)	2 (3.6)	2 (3.6)	2 (3.6)	2 (3.6)
Respiratory failure	7 (12.7)	0	0	0	7 (12.7)
Epistaxis	6 (10.9)	3 (5.5)	1 (1.8)	2 (3.6)	0
Nasal congestion	6 (10.9)	5 (9.1)	1 (1.8)	0	0
Oropharyngeal pain	6 (10.9)	4 (7.3)	2 (3.6)	0	0
Tachypnoea	6 (10.9)	2 (3.6)	1 (1.8)	2 (3.6)	1 (1.8)
Dyspnoea	3 (5.5)	1 (1.8)	0	1 (1.8)	1 (1.8)
Skin and subcutaneous tissue disorders					

Gender: Male

Group term Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (20.0)	5 (9.1)	6 (10.9)	0	0
Pruritus	6 (10.9)	2 (3.6)	4 (7.3)	0	0
Rash	6 (10.9)	3 (5.5)	3 (5.5)	0	0
Dry skin	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Vascular disorders					
-Total	28 (50.9)	4 (7.3)	10 (18.2)	11 (20.0)	3 (5.5)
Hypotension	19 (34.5)	2 (3.6)	6 (10.9)	8 (14.5)	3 (5.5)
Hypertension	14 (25.5)	3 (5.5)	8 (14.5)	3 (5.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (97.7)	0	2 (4.7)	11 (25.6)	29 (67.4)
Blood and lymphatic system disorders					
-Total	31 (72.1)	1 (2.3)	1 (2.3)	18 (41.9)	11 (25.6)
Febrile neutropenia	24 (55.8)	0	0	21 (48.8)	3 (7.0)
Anaemia	21 (48.8)	4 (9.3)	5 (11.6)	12 (27.9)	0
Neutropenia	10 (23.3)	1 (2.3)	1 (2.3)	2 (4.7)	6 (14.0)
Thrombocytopenia	5 (11.6)	0	0	3 (7.0)	2 (4.7)
Disseminated intravascular coagulation	2 (4.7)	0	0	2 (4.7)	0
Cardiac disorders					
-Total	9 (20.9)	4 (9.3)	3 (7.0)	1 (2.3)	1 (2.3)

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	9 (20.9)	4 (9.3)	3 (7.0)	1 (2.3)	1 (2.3)
Endocrine disorders					
-Total	5 (11.6)	0	5 (11.6)	0	0
Adrenal insufficiency	5 (11.6)	0	5 (11.6)	0	0
Gastrointestinal disorders					
-Total	29 (67.4)	7 (16.3)	15 (34.9)	7 (16.3)	0
Nausea	14 (32.6)	4 (9.3)	9 (20.9)	1 (2.3)	0
Diarrhoea	13 (30.2)	8 (18.6)	5 (11.6)	0	0
Vomiting	13 (30.2)	6 (14.0)	5 (11.6)	2 (4.7)	0
Constipation	9 (20.9)	4 (9.3)	5 (11.6)	0	0
Stomatitis	9 (20.9)	1 (2.3)	4 (9.3)	4 (9.3)	0
Abdominal pain	8 (18.6)	2 (4.7)	5 (11.6)	1 (2.3)	0
General disorders and administration site conditions					
-Total	25 (58.1)	12 (27.9)	8 (18.6)	5 (11.6)	0
Pyrexia	19 (44.2)	8 (18.6)	6 (14.0)	5 (11.6)	0
Fatigue	10 (23.3)	7 (16.3)	3 (7.0)	0	0
Chills	5 (11.6)	2 (4.7)	3 (7.0)	0	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Pain	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Immune system disorders					
-Total	32 (74.4)	1 (2.3)	11 (25.6)	10 (23.3)	10 (23.3)
Cytokine release syndrome	30 (69.8)	2 (4.7)	9 (20.9)	9 (20.9)	10 (23.3)
Hypogammaglobulinaemia	19 (44.2)	1 (2.3)	13 (30.2)	5 (11.6)	0
Infections and infestations					
-Total	21 (48.8)	1 (2.3)	8 (18.6)	10 (23.3)	2 (4.7)
Bacteraemia	5 (11.6)	0	0	4 (9.3)	1 (2.3)
Gastroenteritis	5 (11.6)	2 (4.7)	1 (2.3)	2 (4.7)	0
Rhinovirus infection	5 (11.6)	0	4 (9.3)	1 (2.3)	0
Sinusitis	5 (11.6)	0	3 (7.0)	2 (4.7)	0
Upper respiratory tract infection	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Urinary tract infection	5 (11.6)	0	3 (7.0)	2 (4.7)	0
Pneumonia	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Conjunctivitis	2 (4.7)	0	2 (4.7)	0	0
Nasopharyngitis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Investigations					

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (67.4)	1 (2.3)	1 (2.3)	8 (18.6)	19 (44.2)
White blood cell count decreased	18 (41.9)	2 (4.7)	2 (4.7)	0	14 (32.6)
Platelet count decreased	17 (39.5)	4 (9.3)	1 (2.3)	2 (4.7)	10 (23.3)
Neutrophil count decreased	14 (32.6)	0	2 (4.7)	1 (2.3)	11 (25.6)
Lymphocyte count decreased	12 (27.9)	0	1 (2.3)	5 (11.6)	6 (14.0)
Aspartate aminotransferase increased	8 (18.6)	1 (2.3)	1 (2.3)	5 (11.6)	1 (2.3)
International normalised ratio increased	7 (16.3)	4 (9.3)	3 (7.0)	0	0
Alanine aminotransferase increased	6 (14.0)	0	2 (4.7)	4 (9.3)	0
C-reactive protein increased	5 (11.6)	0	1 (2.3)	3 (7.0)	1 (2.3)
Serum ferritin increased	5 (11.6)	0	1 (2.3)	3 (7.0)	1 (2.3)
Blood bilirubin increased	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Metabolism and nutrition disorders					
-Total	24 (55.8)	4 (9.3)	5 (11.6)	13 (30.2)	2 (4.7)
Decreased appetite	17 (39.5)	6 (14.0)	4 (9.3)	7 (16.3)	0
Hypokalaemia	12 (27.9)	2 (4.7)	3 (7.0)	6 (14.0)	1 (2.3)
Hypophosphataemia	12 (27.9)	0	5 (11.6)	7 (16.3)	0
Hypocalcaemia	8 (18.6)	0	5 (11.6)	3 (7.0)	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	7 (16.3)	0	6 (14.0)	1 (2.3)	0
Hyperglycaemia	6 (14.0)	0	4 (9.3)	1 (2.3)	1 (2.3)
Hyperuricaemia	5 (11.6)	3 (7.0)	1 (2.3)	1 (2.3)	0
Hypervolaemia	5 (11.6)	0	1 (2.3)	4 (9.3)	0
Hypomagnesaemia	5 (11.6)	2 (4.7)	3 (7.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	23 (53.5)	11 (25.6)	6 (14.0)	6 (14.0)	0
Pain in extremity	11 (25.6)	6 (14.0)	2 (4.7)	3 (7.0)	0
Back pain	8 (18.6)	2 (4.7)	4 (9.3)	2 (4.7)	0
Myalgia	7 (16.3)	4 (9.3)	3 (7.0)	0	0
Arthralgia	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0
Nervous system disorders					
-Total	20 (46.5)	10 (23.3)	9 (20.9)	1 (2.3)	0
Headache	19 (44.2)	9 (20.9)	9 (20.9)	1 (2.3)	0
Tremor	6 (14.0)	5 (11.6)	1 (2.3)	0	0
Psychiatric disorders					
-Total	13 (30.2)	3 (7.0)	3 (7.0)	7 (16.3)	0

Gender: Female

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	7 (16.3)	2 (4.7)	2 (4.7)	3 (7.0)	0
Mental status changes	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Delirium	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Renal and urinary disorders					
-Total	7 (16.3)	0	1 (2.3)	3 (7.0)	3 (7.0)
Acute kidney injury	7 (16.3)	0	1 (2.3)	3 (7.0)	3 (7.0)
Respiratory, thoracic and mediastinal disorders					
-Total	25 (58.1)	11 (25.6)	0	9 (20.9)	5 (11.6)
Cough	12 (27.9)	9 (20.9)	3 (7.0)	0	0
Hypoxia	9 (20.9)	0	1 (2.3)	6 (14.0)	2 (4.7)
Dyspnoea	6 (14.0)	1 (2.3)	2 (4.7)	2 (4.7)	1 (2.3)
Epistaxis	6 (14.0)	4 (9.3)	1 (2.3)	1 (2.3)	0
Pulmonary oedema	6 (14.0)	1 (2.3)	1 (2.3)	4 (9.3)	0
Nasal congestion	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Tachypnoea	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Oropharyngeal pain	4 (9.3)	4 (9.3)	0	0	0
Respiratory failure	3 (7.0)	0	0	0	3 (7.0)

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	1 (2.3)	1 (2.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (34.9)	11 (25.6)	4 (9.3)	0	0
Dry skin	7 (16.3)	6 (14.0)	1 (2.3)	0	0
Pruritus	6 (14.0)	4 (9.3)	2 (4.7)	0	0
Rash	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Vascular disorders					
-Total	16 (37.2)	3 (7.0)	2 (4.7)	4 (9.3)	7 (16.3)
Hypotension	12 (27.9)	1 (2.3)	0	4 (9.3)	7 (16.3)
Hypertension	10 (23.3)	3 (7.0)	5 (11.6)	2 (4.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (97.1)	0	4 (5.7)	17 (24.3)	47 (67.1)
Blood and lymphatic system disorders					
-Total	47 (67.1)	1 (1.4)	4 (5.7)	27 (38.6)	15 (21.4)
Anaemia	34 (48.6)	5 (7.1)	10 (14.3)	18 (25.7)	1 (1.4)
Febrile neutropenia	30 (42.9)	0	0	29 (41.4)	1 (1.4)
Neutropenia	15 (21.4)	1 (1.4)	2 (2.9)	3 (4.3)	9 (12.9)
Thrombocytopenia	10 (14.3)	1 (1.4)	1 (1.4)	3 (4.3)	5 (7.1)
Disseminated intravascular coagulation	5 (7.1)	0	3 (4.3)	2 (2.9)	0
Leukopenia	4 (5.7)	0	0	1 (1.4)	3 (4.3)
Cardiac disorders					

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (27.1)	7 (10.0)	6 (8.6)	5 (7.1)	1 (1.4)
Tachycardia	19 (27.1)	7 (10.0)	6 (8.6)	5 (7.1)	1 (1.4)
Endocrine disorders					
-Total	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Adrenal insufficiency	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Gastrointestinal disorders					
-Total	51 (72.9)	14 (20.0)	25 (35.7)	12 (17.1)	0
Nausea	27 (38.6)	9 (12.9)	15 (21.4)	3 (4.3)	0
Vomiting	23 (32.9)	16 (22.9)	7 (10.0)	0	0
Diarrhoea	21 (30.0)	12 (17.1)	6 (8.6)	3 (4.3)	0
Abdominal pain	16 (22.9)	4 (5.7)	8 (11.4)	4 (5.7)	0
Constipation	13 (18.6)	6 (8.6)	7 (10.0)	0	0
Stomatitis	9 (12.9)	0	4 (5.7)	5 (7.1)	0
Pancreatitis	2 (2.9)	1 (1.4)	0	1 (1.4)	0
General disorders and administration site conditions					
-Total	49 (70.0)	20 (28.6)	17 (24.3)	9 (12.9)	3 (4.3)
Pyrexia	37 (52.9)	15 (21.4)	13 (18.6)	7 (10.0)	2 (2.9)

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fatigue	19 (27.1)	14 (20.0)	5 (7.1)	0	0
Pain	10 (14.3)	1 (1.4)	6 (8.6)	3 (4.3)	0
Face oedema	9 (12.9)	6 (8.6)	2 (2.9)	1 (1.4)	0
Oedema peripheral	9 (12.9)	6 (8.6)	2 (2.9)	1 (1.4)	0
Catheter site pain	7 (10.0)	3 (4.3)	3 (4.3)	1 (1.4)	0
Chills	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Generalised oedema	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Multiple organ dysfunction syndrome	1 (1.4)	0	0	0	1 (1.4)
Hepatobiliary disorders					
-Total	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Hyperbilirubinaemia	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Hepatic function abnormal	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	51 (72.9)	1 (1.4)	20 (28.6)	18 (25.7)	12 (17.1)
Cytokine release syndrome	43 (61.4)	3 (4.3)	14 (20.0)	14 (20.0)	12 (17.1)
Hypogammaglobulinaemia	31 (44.3)	1 (1.4)	21 (30.0)	9 (12.9)	0
Seasonal allergy	2 (2.9)	0	2 (2.9)	0	0
Infections and infestations					

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	40 (57.1)	7 (10.0)	18 (25.7)	12 (17.1)	3 (4.3)
Upper respiratory tract infection	10 (14.3)	4 (5.7)	5 (7.1)	1 (1.4)	0
Conjunctivitis	8 (11.4)	3 (4.3)	5 (7.1)	0	0
Sinusitis	8 (11.4)	0	5 (7.1)	3 (4.3)	0
Pneumonia	7 (10.0)	1 (1.4)	2 (2.9)	3 (4.3)	1 (1.4)
Rhinovirus infection	7 (10.0)	0	6 (8.6)	1 (1.4)	0
Staphylococcal infection	7 (10.0)	0	3 (4.3)	3 (4.3)	1 (1.4)
Nasopharyngitis	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Parainfluenzae virus infection	5 (7.1)	1 (1.4)	0	3 (4.3)	1 (1.4)
Staphylococcal bacteraemia	5 (7.1)	0	0	5 (7.1)	0
Otitis media	2 (2.9)	0	2 (2.9)	0	0
Investigations					
-Total	45 (64.3)	2 (2.9)	0	16 (22.9)	27 (38.6)
Platelet count decreased	24 (34.3)	5 (7.1)	2 (2.9)	4 (5.7)	13 (18.6)
White blood cell count decreased	24 (34.3)	3 (4.3)	3 (4.3)	1 (1.4)	17 (24.3)
Neutrophil count decreased	23 (32.9)	2 (2.9)	2 (2.9)	3 (4.3)	16 (22.9)
Lymphocyte count decreased	19 (27.1)	1 (1.4)	1 (1.4)	8 (11.4)	9 (12.9)
Alanine aminotransferase increased	17 (24.3)	5 (7.1)	7 (10.0)	5 (7.1)	0

Race: White

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	17 (24.3)	1 (1.4)	6 (8.6)	8 (11.4)	2 (2.9)
Blood bilirubin increased	9 (12.9)	1 (1.4)	1 (1.4)	7 (10.0)	0
C-reactive protein increased	8 (11.4)	2 (2.9)	1 (1.4)	5 (7.1)	0
International normalised ratio increased	7 (10.0)	5 (7.1)	2 (2.9)	0	0
Activated partial thromboplastin time prolonged	5 (7.1)	4 (5.7)	1 (1.4)	0	0
Blood lactate dehydrogenase increased	5 (7.1)	3 (4.3)	2 (2.9)	0	0
Blood fibrinogen decreased	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Serum ferritin increased	4 (5.7)	0	3 (4.3)	1 (1.4)	0
Fibrin d dimer increased	2 (2.9)	2 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	45 (64.3)	6 (8.6)	11 (15.7)	19 (27.1)	9 (12.9)
Decreased appetite	27 (38.6)	10 (14.3)	8 (11.4)	7 (10.0)	2 (2.9)
Hypokalaemia	19 (27.1)	3 (4.3)	5 (7.1)	8 (11.4)	3 (4.3)
Hypophosphataemia	14 (20.0)	3 (4.3)	5 (7.1)	6 (8.6)	0
Hypocalcaemia	13 (18.6)	2 (2.9)	8 (11.4)	3 (4.3)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoalbuminaemia	8 (11.4)	0	8 (11.4)	0	0
Hypervolaemia	7 (10.0)	1 (1.4)	2 (2.9)	4 (5.7)	0
Hyperglycaemia	6 (8.6)	0	2 (2.9)	3 (4.3)	1 (1.4)
Hyperuricaemia	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	5 (7.1)	5 (7.1)	0	0	0
Metabolic acidosis	4 (5.7)	1 (1.4)	0	2 (2.9)	1 (1.4)
Tumour lysis syndrome	4 (5.7)	0	0	2 (2.9)	2 (2.9)
Musculoskeletal and connective tissue disorders					
-Total	32 (45.7)	15 (21.4)	13 (18.6)	4 (5.7)	0
Pain in extremity	19 (27.1)	8 (11.4)	10 (14.3)	1 (1.4)	0
Arthralgia	11 (15.7)	6 (8.6)	5 (7.1)	0	0
Back pain	9 (12.9)	2 (2.9)	4 (5.7)	3 (4.3)	0
Myalgia	8 (11.4)	4 (5.7)	4 (5.7)	0	0
Nervous system disorders					
-Total	38 (54.3)	14 (20.0)	10 (14.3)	14 (20.0)	0
Headache	29 (41.4)	15 (21.4)	9 (12.9)	5 (7.1)	0
Encephalopathy	9 (12.9)	1 (1.4)	3 (4.3)	5 (7.1)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	4 (5.7)	0	1 (1.4)	3 (4.3)	0
Paraesthesia	2 (2.9)	2 (2.9)	0	0	0
Cognitive disorder	1 (1.4)	0	0	1 (1.4)	0
Psychiatric disorders					
-Total	18 (25.7)	7 (10.0)	7 (10.0)	4 (5.7)	0
Anxiety	10 (14.3)	4 (5.7)	5 (7.1)	1 (1.4)	0
Delirium	7 (10.0)	2 (2.9)	2 (2.9)	3 (4.3)	0
Confusional state	5 (7.1)	5 (7.1)	0	0	0
Renal and urinary disorders					
-Total	12 (17.1)	4 (5.7)	2 (2.9)	3 (4.3)	3 (4.3)
Acute kidney injury	12 (17.1)	4 (5.7)	2 (2.9)	3 (4.3)	3 (4.3)
Respiratory, thoracic and mediastinal disorders					
-Total	46 (65.7)	17 (24.3)	7 (10.0)	11 (15.7)	11 (15.7)
Cough	21 (30.0)	17 (24.3)	4 (5.7)	0	0
Hypoxia	16 (22.9)	0	6 (8.6)	8 (11.4)	2 (2.9)
Pulmonary oedema	12 (17.1)	3 (4.3)	3 (4.3)	4 (5.7)	2 (2.9)
Epistaxis	11 (15.7)	7 (10.0)	2 (2.9)	2 (2.9)	0

Race: White

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasal congestion	9 (12.9)	7 (10.0)	2 (2.9)	0	0
Oropharyngeal pain	9 (12.9)	7 (10.0)	2 (2.9)	0	0
Respiratory failure	8 (11.4)	0	0	0	8 (11.4)
Tachypnoea	8 (11.4)	2 (2.9)	1 (1.4)	5 (7.1)	0
Dyspnoea	7 (10.0)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.4)
Pleural effusion	6 (8.6)	3 (4.3)	1 (1.4)	2 (2.9)	0
Rhinorrhoea	4 (5.7)	3 (4.3)	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	22 (31.4)	12 (17.1)	10 (14.3)	0	0
Rash	10 (14.3)	5 (7.1)	5 (7.1)	0	0
Dry skin	8 (11.4)	6 (8.6)	2 (2.9)	0	0
Pruritus	8 (11.4)	3 (4.3)	5 (7.1)	0	0
Rash maculo-papular	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Vascular disorders					
-Total	32 (45.7)	6 (8.6)	8 (11.4)	11 (15.7)	7 (10.0)
Hypotension	27 (38.6)	3 (4.3)	6 (8.6)	11 (15.7)	7 (10.0)
Hypertension	15 (21.4)	5 (7.1)	9 (12.9)	1 (1.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (86.7)	0	1 (6.7)	4 (26.7)	8 (53.3)
Blood and lymphatic system disorders					
-Total	9 (60.0)	0	1 (6.7)	2 (13.3)	6 (40.0)
Febrile neutropenia	4 (26.7)	0	0	4 (26.7)	0
Neutropenia	4 (26.7)	0	0	0	4 (26.7)
Anaemia	3 (20.0)	0	0	3 (20.0)	0
Disseminated intravascular coagulation	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Thrombocytopenia	3 (20.0)	0	0	0	3 (20.0)
Leukopenia	2 (13.3)	0	0	0	2 (13.3)
Cardiac disorders					

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Cardiac dysfunction	2 (13.3)	2 (13.3)	0	0	0
Tachycardia	2 (13.3)	0	2 (13.3)	0	0
Gastrointestinal disorders					
-Total	9 (60.0)	5 (33.3)	3 (20.0)	1 (6.7)	0
Nausea	4 (26.7)	3 (20.0)	1 (6.7)	0	0
Constipation	3 (20.0)	3 (20.0)	0	0	0
Diarrhoea	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Abdominal pain	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Pancreatitis	2 (13.3)	0	2 (13.3)	0	0
Stomatitis	2 (13.3)	1 (6.7)	0	1 (6.7)	0
Vomiting	2 (13.3)	1 (6.7)	0	1 (6.7)	0
General disorders and administration site conditions					
-Total	5 (33.3)	1 (6.7)	3 (20.0)	1 (6.7)	0
Pyrexia	4 (26.7)	1 (6.7)	2 (13.3)	1 (6.7)	0
Catheter site pain	1 (6.7)	0	1 (6.7)	0	0
Fatigue	1 (6.7)	1 (6.7)	0	0	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	5 (33.3)	0	2 (13.3)	2 (13.3)	1 (6.7)
Hepatic function abnormal	4 (26.7)	0	1 (6.7)	2 (13.3)	1 (6.7)
Hyperbilirubinaemia	1 (6.7)	0	1 (6.7)	0	0
Immune system disorders					
-Total	9 (60.0)	0	4 (26.7)	2 (13.3)	3 (20.0)
Cytokine release syndrome	8 (53.3)	1 (6.7)	2 (13.3)	2 (13.3)	3 (20.0)
Hypogammaglobulinaemia	5 (33.3)	0	5 (33.3)	0	0
Seasonal allergy	1 (6.7)	0	1 (6.7)	0	0
Infections and infestations					
-Total	4 (26.7)	0	1 (6.7)	3 (20.0)	0
Nasopharyngitis	1 (6.7)	1 (6.7)	0	0	0
Otitis media	1 (6.7)	0	1 (6.7)	0	0
Pneumonia	1 (6.7)	0	0	1 (6.7)	0
Sinusitis	1 (6.7)	0	1 (6.7)	0	0
Staphylococcal bacteraemia	1 (6.7)	0	0	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	0	0	1 (6.7)	0
Investigations					

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (60.0)	0	1 (6.7)	4 (26.7)	4 (26.7)
Serum ferritin increased	6 (40.0)	1 (6.7)	3 (20.0)	2 (13.3)	0
Alanine aminotransferase increased	4 (26.7)	0	1 (6.7)	3 (20.0)	0
White blood cell count decreased	4 (26.7)	0	0	0	4 (26.7)
Blood fibrinogen decreased	3 (20.0)	0	2 (13.3)	1 (6.7)	0
Aspartate aminotransferase increased	2 (13.3)	1 (6.7)	0	1 (6.7)	0
C-reactive protein increased	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Neutrophil count decreased	2 (13.3)	0	0	0	2 (13.3)
Blood bilirubin increased	1 (6.7)	0	0	1 (6.7)	0
Blood lactate dehydrogenase increased	1 (6.7)	0	0	1 (6.7)	0
Fibrin d dimer increased	1 (6.7)	1 (6.7)	0	0	0
International normalised ratio increased	1 (6.7)	0	1 (6.7)	0	0
Platelet count decreased	1 (6.7)	0	0	1 (6.7)	0
Metabolism and nutrition disorders					
-Total	6 (40.0)	2 (13.3)	1 (6.7)	1 (6.7)	2 (13.3)
Decreased appetite	2 (13.3)	2 (13.3)	0	0	0

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Metabolic acidosis	2 (13.3)	0	0	0	2 (13.3)
Tumour lysis syndrome	2 (13.3)	0	0	2 (13.3)	0
Hypoalbuminaemia	1 (6.7)	0	1 (6.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (40.0)	2 (13.3)	2 (13.3)	2 (13.3)	0
Arthralgia	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Pain in extremity	3 (20.0)	1 (6.7)	1 (6.7)	1 (6.7)	0
Back pain	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Nervous system disorders					
-Total	4 (26.7)	2 (13.3)	2 (13.3)	0	0
Headache	3 (20.0)	2 (13.3)	1 (6.7)	0	0
Seizure	2 (13.3)	0	2 (13.3)	0	0
Psychiatric disorders					
-Total	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Anxiety	2 (13.3)	0	1 (6.7)	1 (6.7)	0
Delirium	1 (6.7)	0	1 (6.7)	0	0

Race: Asian

	All patients N=15				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	2 (13.3)	0	0	0	2 (13.3)
Acute kidney injury	2 (13.3)	0	0	0	2 (13.3)
Respiratory, thoracic and mediastinal disorders					
-Total	7 (46.7)	2 (13.3)	1 (6.7)	0	4 (26.7)
Hypoxia	4 (26.7)	0	0	0	4 (26.7)
Pleural effusion	2 (13.3)	1 (6.7)	1 (6.7)	0	0
Cough	1 (6.7)	1 (6.7)	0	0	0
Dyspnoea	1 (6.7)	0	0	1 (6.7)	0
Nasal congestion	1 (6.7)	1 (6.7)	0	0	0
Oropharyngeal pain	1 (6.7)	1 (6.7)	0	0	0
Respiratory failure	1 (6.7)	0	0	0	1 (6.7)
Skin and subcutaneous tissue disorders					
-Total	3 (20.0)	3 (20.0)	0	0	0
Pruritus	3 (20.0)	3 (20.0)	0	0	0
Dry skin	1 (6.7)	1 (6.7)	0	0	0
Vascular disorders					

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (33.3)	0	3 (20.0)	1 (6.7)	1 (6.7)
Hypertension	3 (20.0)	0	3 (20.0)	0	0
Hypotension	2 (13.3)	0	0	1 (6.7)	1 (6.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (100)	0	0	0	13 (100)
Blood and lymphatic system disorders					
-Total	13 (100)	0	0	8 (61.5)	5 (38.5)
Febrile neutropenia	11 (84.6)	0	0	9 (69.2)	2 (15.4)
Anaemia	9 (69.2)	1 (7.7)	2 (15.4)	6 (46.2)	0
Neutropenia	3 (23.1)	0	0	0	3 (23.1)
Thrombocytopenia	2 (15.4)	0	0	2 (15.4)	0
Cardiac disorders					
-Total	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Tachycardia	2 (15.4)	1 (7.7)	1 (7.7)	0	0

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	3 (23.1)	0	3 (23.1)	0	0
Adrenal insufficiency	3 (23.1)	0	3 (23.1)	0	0
Gastrointestinal disorders					
-Total	11 (84.6)	2 (15.4)	4 (30.8)	5 (38.5)	0
Diarrhoea	6 (46.2)	3 (23.1)	3 (23.1)	0	0
Nausea	6 (46.2)	2 (15.4)	3 (23.1)	1 (7.7)	0
Vomiting	6 (46.2)	4 (30.8)	1 (7.7)	1 (7.7)	0
Constipation	4 (30.8)	1 (7.7)	3 (23.1)	0	0
Abdominal pain	2 (15.4)	0	2 (15.4)	0	0
Pancreatitis	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Stomatitis	2 (15.4)	0	0	2 (15.4)	0
General disorders and administration site conditions					
-Total	11 (84.6)	3 (23.1)	2 (15.4)	4 (30.8)	2 (15.4)
Pyrexia	7 (53.8)	2 (15.4)	2 (15.4)	3 (23.1)	0
Chills	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Fatigue	2 (15.4)	1 (7.7)	1 (7.7)	0	0

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Multiple organ dysfunction syndrome	2 (15.4)	0	0	0	2 (15.4)
Oedema peripheral	1 (7.7)	1 (7.7)	0	0	0
Pain	1 (7.7)	0	0	1 (7.7)	0
Hepatobiliary disorders					
-Total	3 (23.1)	1 (7.7)	0	2 (15.4)	0
Hyperbilirubinaemia	3 (23.1)	1 (7.7)	0	2 (15.4)	0
Immune system disorders					
-Total	10 (76.9)	1 (7.7)	2 (15.4)	1 (7.7)	6 (46.2)
Cytokine release syndrome	10 (76.9)	1 (7.7)	2 (15.4)	1 (7.7)	6 (46.2)
Hypogammaglobulinaemia	5 (38.5)	1 (7.7)	4 (30.8)	0	0
Seasonal allergy	2 (15.4)	2 (15.4)	0	0	0
Infections and infestations					
-Total	7 (53.8)	1 (7.7)	1 (7.7)	3 (23.1)	2 (15.4)
Upper respiratory tract infection	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Nasopharyngitis	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Otitis media	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Parainfluenzae virus infection	2 (15.4)	0	1 (7.7)	1 (7.7)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	2 (15.4)	0	0	0	2 (15.4)
Rhinovirus infection	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Staphylococcal bacteraemia	2 (15.4)	0	0	2 (15.4)	0
Conjunctivitis	1 (7.7)	0	1 (7.7)	0	0
Investigations					
-Total	10 (76.9)	0	0	0	10 (76.9)
Platelet count decreased	7 (53.8)	1 (7.7)	0	1 (7.7)	5 (38.5)
White blood cell count decreased	7 (53.8)	0	0	0	7 (53.8)
Neutrophil count decreased	6 (46.2)	0	0	0	6 (46.2)
Lymphocyte count decreased	5 (38.5)	0	0	1 (7.7)	4 (30.8)
Alanine aminotransferase increased	4 (30.8)	0	1 (7.7)	3 (23.1)	0
Aspartate aminotransferase increased	4 (30.8)	0	0	2 (15.4)	2 (15.4)
Blood bilirubin increased	3 (23.1)	0	1 (7.7)	2 (15.4)	0
Serum ferritin increased	3 (23.1)	1 (7.7)	0	1 (7.7)	1 (7.7)
Activated partial thromboplastin time prolonged	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Blood lactate dehydrogenase increased	2 (15.4)	0	0	2 (15.4)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
C-reactive protein increased	2 (15.4)	0	0	1 (7.7)	1 (7.7)
Fibrin d dimer increased	2 (15.4)	0	0	1 (7.7)	1 (7.7)
International normalised ratio increased	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Blood fibrinogen decreased	1 (7.7)	0	0	0	1 (7.7)
Metabolism and nutrition disorders					
-Total	10 (76.9)	0	2 (15.4)	7 (53.8)	1 (7.7)
Hypokalaemia	7 (53.8)	1 (7.7)	1 (7.7)	5 (38.5)	0
Hypophosphataemia	7 (53.8)	0	3 (23.1)	3 (23.1)	1 (7.7)
Decreased appetite	6 (46.2)	0	1 (7.7)	5 (38.5)	0
Hypocalcaemia	6 (46.2)	0	3 (23.1)	3 (23.1)	0
Hypomagnesaemia	5 (38.5)	2 (15.4)	3 (23.1)	0	0
Hyperglycaemia	4 (30.8)	0	2 (15.4)	2 (15.4)	0
Hypoalbuminaemia	4 (30.8)	0	3 (23.1)	1 (7.7)	0
Hyperuricaemia	2 (15.4)	2 (15.4)	0	0	0
Hypervolaemia	2 (15.4)	0	0	2 (15.4)	0
Tumour lysis syndrome	1 (7.7)	0	0	1 (7.7)	0
Musculoskeletal and connective tissue disorders					

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (53.8)	3 (23.1)	2 (15.4)	2 (15.4)	0
Arthralgia	2 (15.4)	0	1 (7.7)	1 (7.7)	0
Back pain	2 (15.4)	0	2 (15.4)	0	0
Myalgia	2 (15.4)	2 (15.4)	0	0	0
Osteopenia	2 (15.4)	2 (15.4)	0	0	0
Pain in extremity	1 (7.7)	0	0	1 (7.7)	0
Nervous system disorders					
-Total	7 (53.8)	0	6 (46.2)	1 (7.7)	0
Cognitive disorder	3 (23.1)	0	2 (15.4)	1 (7.7)	0
Headache	3 (23.1)	1 (7.7)	2 (15.4)	0	0
Neuralgia	2 (15.4)	0	2 (15.4)	0	0
Paraesthesia	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Psychiatric disorders					
-Total	7 (53.8)	2 (15.4)	4 (30.8)	1 (7.7)	0
Anxiety	5 (38.5)	0	4 (30.8)	1 (7.7)	0
Confusional state	2 (15.4)	2 (15.4)	0	0	0
Renal and urinary disorders					
-Total	1 (7.7)	1 (7.7)	0	0	0

Race: Other

	All patients N=13				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (7.7)	1 (7.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (53.8)	1 (7.7)	0	3 (23.1)	3 (23.1)
Cough	4 (30.8)	3 (23.1)	1 (7.7)	0	0
Tachypnoea	3 (23.1)	1 (7.7)	1 (7.7)	0	1 (7.7)
Hypoxia	2 (15.4)	0	0	2 (15.4)	0
Pleural effusion	2 (15.4)	0	1 (7.7)	0	1 (7.7)
Pulmonary oedema	2 (15.4)	0	0	2 (15.4)	0
Rhinorrhoea	2 (15.4)	1 (7.7)	1 (7.7)	0	0
Dyspnoea	1 (7.7)	0	0	0	1 (7.7)
Epistaxis	1 (7.7)	0	0	1 (7.7)	0
Nasal congestion	1 (7.7)	1 (7.7)	0	0	0
Respiratory failure	1 (7.7)	0	0	0	1 (7.7)
Skin and subcutaneous tissue disorders					
-Total	3 (23.1)	1 (7.7)	1 (7.7)	1 (7.7)	0
Rash maculo-papular	2 (15.4)	1 (7.7)	0	1 (7.7)	0
Pruritus	1 (7.7)	0	1 (7.7)	0	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	1 (7.7)	1 (7.7)	0	0	0
Vascular disorders					
-Total	7 (53.8)	1 (7.7)	1 (7.7)	3 (23.1)	2 (15.4)
Hypertension	6 (46.2)	1 (7.7)	1 (7.7)	4 (30.8)	0
Hypotension	2 (15.4)	0	0	0	2 (15.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	0	3 (16.7)	15 (83.3)
Blood and lymphatic system disorders					
-Total	13 (72.2)	0	1 (5.6)	8 (44.4)	4 (22.2)
Febrile neutropenia	11 (61.1)	0	0	9 (50.0)	2 (11.1)
Anaemia	7 (38.9)	0	1 (5.6)	5 (27.8)	1 (5.6)
Thrombocytopenia	3 (16.7)	0	0	3 (16.7)	0
Coagulopathy	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	5 (27.8)	1 (5.6)	3 (16.7)	1 (5.6)	0
Tachycardia	4 (22.2)	0	3 (16.7)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (11.1)	2 (11.1)	0	0	0
Endocrine disorders					
-Total	6 (33.3)	0	6 (33.3)	0	0
Adrenal insufficiency	4 (22.2)	0	4 (22.2)	0	0
Hypothyroidism	2 (11.1)	0	2 (11.1)	0	0
Gastrointestinal disorders					
-Total	15 (83.3)	4 (22.2)	7 (38.9)	4 (22.2)	0
Diarrhoea	7 (38.9)	3 (16.7)	4 (22.2)	0	0
Nausea	6 (33.3)	2 (11.1)	4 (22.2)	0	0
Vomiting	6 (33.3)	5 (27.8)	0	1 (5.6)	0
Constipation	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Mouth haemorrhage	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Stomatitis	2 (11.1)	0	0	2 (11.1)	0
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					
-Total	14 (77.8)	4 (22.2)	6 (33.3)	4 (22.2)	0
Pyrexia	10 (55.6)	2 (11.1)	4 (22.2)	4 (22.2)	0

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Chills	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Oedema peripheral	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Face oedema	2 (11.1)	2 (11.1)	0	0	0
Generalised oedema	2 (11.1)	0	2 (11.1)	0	0
Pain	1 (5.6)	0	1 (5.6)	0	0
Hepatobiliary disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Hypertransaminasaemia	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Immune system disorders					
-Total	14 (77.8)	0	5 (27.8)	1 (5.6)	8 (44.4)
Cytokine release syndrome	13 (72.2)	0	4 (22.2)	1 (5.6)	8 (44.4)
Hypogammaglobulinaemia	8 (44.4)	1 (5.6)	6 (33.3)	1 (5.6)	0
Seasonal allergy	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Infections and infestations					
-Total	12 (66.7)	0	3 (16.7)	8 (44.4)	1 (5.6)
Upper respiratory tract infection	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Bacteraemia	4 (22.2)	0	1 (5.6)	2 (11.1)	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	2 (11.1)	0	0	2 (11.1)	0
Conjunctivitis	2 (11.1)	2 (11.1)	0	0	0
Escherichia bacteraemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	2 (11.1)	0	0	2 (11.1)	0
Urinary tract infection	2 (11.1)	0	0	2 (11.1)	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0
Sinusitis	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Procedural pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Transfusion reaction	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Investigations					
-Total	11 (61.1)	0	0	1 (5.6)	10 (55.6)
Aspartate aminotransferase increased	8 (44.4)	0	1 (5.6)	5 (27.8)	2 (11.1)

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	6 (33.3)	0	0	0	6 (33.3)
Alanine aminotransferase increased	5 (27.8)	0	1 (5.6)	4 (22.2)	0
White blood cell count decreased	5 (27.8)	0	0	0	5 (27.8)
Blood bilirubin increased	4 (22.2)	0	0	4 (22.2)	0
Neutrophil count decreased	4 (22.2)	0	0	0	4 (22.2)
Blood creatinine increased	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Blood lactate dehydrogenase increased	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Activated partial thromboplastin time prolonged	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Blood uric acid increased	2 (11.1)	1 (5.6)	0	0	1 (5.6)
C-reactive protein increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Electrocardiogram qt prolonged	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Fibrin d dimer increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
International normalised ratio increased	2 (11.1)	0	2 (11.1)	0	0
Lymphocyte count decreased	2 (11.1)	0	0	0	2 (11.1)
Serum ferritin increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Metabolism and nutrition disorders					

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (77.8)	0	4 (22.2)	6 (33.3)	4 (22.2)
Decreased appetite	10 (55.6)	0	4 (22.2)	6 (33.3)	0
Hypocalcaemia	10 (55.6)	0	6 (33.3)	4 (22.2)	0
Hypokalaemia	8 (44.4)	1 (5.6)	3 (16.7)	3 (16.7)	1 (5.6)
Hypomagnesaemia	6 (33.3)	3 (16.7)	3 (16.7)	0	0
Hypophosphataemia	6 (33.3)	0	2 (11.1)	4 (22.2)	0
Hyperglycaemia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Hypoalbuminaemia	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Hyperuricaemia	4 (22.2)	3 (16.7)	0	1 (5.6)	0
Hyperkalaemia	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Hypervolaemia	3 (16.7)	0	0	3 (16.7)	0
Tumour lysis syndrome	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Acidosis	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hypercalcaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Malnutrition	2 (11.1)	0	0	2 (11.1)	0
Metabolic acidosis	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Musculoskeletal and connective tissue disorders					

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (50.0)	3 (16.7)	3 (16.7)	3 (16.7)	0
Arthralgia	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0
Pain in extremity	4 (22.2)	1 (5.6)	2 (11.1)	1 (5.6)	0
Myalgia	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Back pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Nervous system disorders					
-Total	8 (44.4)	0	5 (27.8)	3 (16.7)	0
Headache	5 (27.8)	2 (11.1)	2 (11.1)	1 (5.6)	0
Cognitive disorder	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Paraesthesia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Somnolence	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Psychiatric disorders					
-Total	9 (50.0)	1 (5.6)	6 (33.3)	2 (11.1)	0
Anxiety	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Mental status changes	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Insomnia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Renal and urinary disorders					

Ethnicity: Hispanic or Latino

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (33.3)	1 (5.6)	1 (5.6)	2 (11.1)	2 (11.1)
Acute kidney injury	5 (27.8)	1 (5.6)	1 (5.6)	1 (5.6)	2 (11.1)
Haematuria	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (72.2)	2 (11.1)	2 (11.1)	3 (16.7)	6 (33.3)
Pulmonary oedema	5 (27.8)	1 (5.6)	1 (5.6)	2 (11.1)	1 (5.6)
Cough	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Hypoxia	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Nasal congestion	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oropharyngeal pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Acute respiratory distress syndrome	2 (11.1)	0	0	0	2 (11.1)
Pleural effusion	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Respiratory failure	2 (11.1)	0	0	0	2 (11.1)
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Dyspnoea	1 (5.6)	1 (5.6)	0	0	0
Epistaxis	1 (5.6)	0	0	1 (5.6)	0
Tachypnoea	1 (5.6)	0	0	1 (5.6)	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Pruritus	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Dry skin	2 (11.1)	2 (11.1)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					
-Total	12 (66.7)	2 (11.1)	1 (5.6)	6 (33.3)	3 (16.7)
Hypotension	9 (50.0)	0	1 (5.6)	5 (27.8)	3 (16.7)
Hypertension	7 (38.9)	4 (22.2)	1 (5.6)	2 (11.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	77 (96.3)	0	4 (5.0)	21 (26.3)	52 (65.0)
Blood and lymphatic system disorders					
-Total	56 (70.0)	1 (1.3)	4 (5.0)	31 (38.8)	20 (25.0)
Anaemia	39 (48.8)	6 (7.5)	11 (13.8)	22 (27.5)	0
Febrile neutropenia	34 (42.5)	0	0	33 (41.3)	1 (1.3)
Neutropenia	21 (26.3)	1 (1.3)	2 (2.5)	3 (3.8)	15 (18.8)
Thrombocytopenia	12 (15.0)	1 (1.3)	1 (1.3)	2 (2.5)	8 (10.0)
Coagulopathy	3 (3.8)	1 (1.3)	1 (1.3)	1 (1.3)	0
Cardiac disorders					
-Total	20 (25.0)	8 (10.0)	7 (8.8)	4 (5.0)	1 (1.3)
Tachycardia	19 (23.8)	8 (10.0)	6 (7.5)	4 (5.0)	1 (1.3)

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (1.3)	0	1 (1.3)	0	0
Endocrine disorders					
-Total	7 (8.8)	0	6 (7.5)	1 (1.3)	0
Adrenal insufficiency	4 (5.0)	0	3 (3.8)	1 (1.3)	0
Hypothyroidism	3 (3.8)	0	3 (3.8)	0	0
Gastrointestinal disorders					
-Total	55 (68.8)	16 (20.0)	25 (31.3)	14 (17.5)	0
Nausea	31 (38.8)	12 (15.0)	15 (18.8)	4 (5.0)	0
Vomiting	25 (31.3)	16 (20.0)	8 (10.0)	1 (1.3)	0
Diarrhoea	23 (28.8)	14 (17.5)	6 (7.5)	3 (3.8)	0
Abdominal pain	19 (23.8)	5 (6.3)	10 (12.5)	4 (5.0)	0
Constipation	16 (20.0)	9 (11.3)	7 (8.8)	0	0
Stomatitis	11 (13.8)	1 (1.3)	4 (5.0)	6 (7.5)	0
Mouth haemorrhage	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions					
-Total	51 (63.8)	21 (26.3)	18 (22.5)	10 (12.5)	2 (2.5)
Pyrexia	38 (47.5)	16 (20.0)	13 (16.3)	7 (8.8)	2 (2.5)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fatigue	17 (21.3)	13 (16.3)	4 (5.0)	0	0
Pain	10 (12.5)	1 (1.3)	5 (6.3)	4 (5.0)	0
Catheter site pain	8 (10.0)	3 (3.8)	4 (5.0)	1 (1.3)	0
Face oedema	7 (8.8)	4 (5.0)	2 (2.5)	1 (1.3)	0
Oedema peripheral	7 (8.8)	5 (6.3)	1 (1.3)	1 (1.3)	0
Chills	5 (6.3)	3 (3.8)	2 (2.5)	0	0
Generalised oedema	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders					
-Total	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Hypertransaminasaemia	2 (2.5)	1 (1.3)	1 (1.3)	0	0
Immune system disorders					
-Total	56 (70.0)	2 (2.5)	21 (26.3)	20 (25.0)	13 (16.3)
Cytokine release syndrome	48 (60.0)	5 (6.3)	14 (17.5)	16 (20.0)	13 (16.3)
Hypogammaglobulinaemia	33 (41.3)	1 (1.3)	24 (30.0)	8 (10.0)	0
Seasonal allergy	2 (2.5)	0	2 (2.5)	0	0
Infections and infestations					
-Total	41 (51.3)	6 (7.5)	14 (17.5)	18 (22.5)	3 (3.8)
Pneumonia	10 (12.5)	1 (1.3)	2 (2.5)	4 (5.0)	3 (3.8)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Upper respiratory tract infection	9 (11.3)	5 (6.3)	2 (2.5)	2 (2.5)	0
Nasopharyngitis	8 (10.0)	5 (6.3)	3 (3.8)	0	0
Rhinovirus infection	8 (10.0)	0	6 (7.5)	2 (2.5)	0
Sinusitis	8 (10.0)	0	6 (7.5)	2 (2.5)	0
Conjunctivitis	7 (8.8)	1 (1.3)	6 (7.5)	0	0
Staphylococcal bacteraemia	6 (7.5)	0	0	6 (7.5)	0
Gastroenteritis	5 (6.3)	3 (3.8)	0	2 (2.5)	0
Oral herpes	5 (6.3)	1 (1.3)	2 (2.5)	2 (2.5)	0
Urinary tract infection	3 (3.8)	0	3 (3.8)	0	0
Bacteraemia	2 (2.5)	0	0	2 (2.5)	0
Escherichia bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	5 (6.3)	3 (3.8)	2 (2.5)	0	0
Procedural pain	3 (3.8)	2 (2.5)	1 (1.3)	0	0
Transfusion reaction	3 (3.8)	1 (1.3)	2 (2.5)	0	0
Investigations					

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	53 (66.3)	1 (1.3)	1 (1.3)	19 (23.8)	32 (40.0)
White blood cell count decreased	30 (37.5)	3 (3.8)	3 (3.8)	1 (1.3)	23 (28.8)
Neutrophil count decreased	27 (33.8)	2 (2.5)	2 (2.5)	3 (3.8)	20 (25.0)
Platelet count decreased	26 (32.5)	6 (7.5)	2 (2.5)	6 (7.5)	12 (15.0)
Lymphocyte count decreased	22 (27.5)	1 (1.3)	1 (1.3)	9 (11.3)	11 (13.8)
Alanine aminotransferase increased	20 (25.0)	5 (6.3)	8 (10.0)	7 (8.8)	0
Aspartate aminotransferase increased	15 (18.8)	2 (2.5)	5 (6.3)	6 (7.5)	2 (2.5)
Serum ferritin increased	11 (13.8)	2 (2.5)	6 (7.5)	3 (3.8)	0
C-reactive protein increased	10 (12.5)	3 (3.8)	2 (2.5)	5 (6.3)	0
Blood bilirubin increased	9 (11.3)	1 (1.3)	2 (2.5)	6 (7.5)	0
Blood fibrinogen decreased	8 (10.0)	3 (3.8)	3 (3.8)	1 (1.3)	1 (1.3)
International normalised ratio increased	8 (10.0)	6 (7.5)	2 (2.5)	0	0
Activated partial thromboplastin time prolonged	5 (6.3)	4 (5.0)	1 (1.3)	0	0
Blood lactate dehydrogenase increased	5 (6.3)	3 (3.8)	1 (1.3)	1 (1.3)	0
Blood creatinine increased	4 (5.0)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	4 (5.0)	1 (1.3)	2 (2.5)	1 (1.3)	0
Fibrin d dimer increased	3 (3.8)	3 (3.8)	0	0	0
Blood uric acid increased	2 (2.5)	1 (1.3)	0	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	48 (60.0)	7 (8.8)	11 (13.8)	21 (26.3)	9 (11.3)
Decreased appetite	25 (31.3)	12 (15.0)	5 (6.3)	6 (7.5)	2 (2.5)
Hypokalaemia	18 (22.5)	3 (3.8)	3 (3.8)	10 (12.5)	2 (2.5)
Hypophosphataemia	15 (18.8)	3 (3.8)	6 (7.5)	5 (6.3)	1 (1.3)
Hypocalcaemia	9 (11.3)	2 (2.5)	5 (6.3)	2 (2.5)	0
Hypoalbuminaemia	8 (10.0)	0	8 (10.0)	0	0
Hyperuricaemia	6 (7.5)	4 (5.0)	2 (2.5)	0	0
Hypervolaemia	6 (7.5)	1 (1.3)	2 (2.5)	3 (3.8)	0
Hyperglycaemia	5 (6.3)	0	1 (1.3)	3 (3.8)	1 (1.3)
Hypomagnesaemia	4 (5.0)	4 (5.0)	0	0	0
Metabolic acidosis	4 (5.0)	1 (1.3)	0	1 (1.3)	2 (2.5)
Tumour lysis syndrome	4 (5.0)	0	0	3 (3.8)	1 (1.3)
Malnutrition	2 (2.5)	0	1 (1.3)	1 (1.3)	0
Hypercalcaemia	1 (1.3)	0	0	0	1 (1.3)

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (1.3)	0	0	0	1 (1.3)
Musculoskeletal and connective tissue disorders					
-Total	34 (42.5)	15 (18.8)	14 (17.5)	5 (6.3)	0
Pain in extremity	19 (23.8)	8 (10.0)	9 (11.3)	2 (2.5)	0
Arthralgia	12 (15.0)	7 (8.8)	5 (6.3)	0	0
Back pain	11 (13.8)	2 (2.5)	6 (7.5)	3 (3.8)	0
Myalgia	7 (8.8)	4 (5.0)	3 (3.8)	0	0
Nervous system disorders					
-Total	37 (46.3)	16 (20.0)	12 (15.0)	9 (11.3)	0
Headache	30 (37.5)	16 (20.0)	10 (12.5)	4 (5.0)	0
Encephalopathy	8 (10.0)	1 (1.3)	3 (3.8)	4 (5.0)	0
Somnolence	4 (5.0)	2 (2.5)	1 (1.3)	1 (1.3)	0
Paraesthesia	2 (2.5)	2 (2.5)	0	0	0
Cognitive disorder	1 (1.3)	0	0	1 (1.3)	0
Psychiatric disorders					
-Total	17 (21.3)	6 (7.5)	6 (7.5)	5 (6.3)	0
Anxiety	12 (15.0)	4 (5.0)	6 (7.5)	2 (2.5)	0

Ethnicity: Other

	All patients N=80				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	4 (5.0)	1 (1.3)	3 (3.8)	0	0
Mental status changes	4 (5.0)	1 (1.3)	0	3 (3.8)	0
Renal and urinary disorders					
-Total	11 (13.8)	5 (6.3)	1 (1.3)	2 (2.5)	3 (3.8)
Acute kidney injury	10 (12.5)	4 (5.0)	1 (1.3)	2 (2.5)	3 (3.8)
Haematuria	2 (2.5)	2 (2.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	50 (62.5)	17 (21.3)	7 (8.8)	11 (13.8)	15 (18.8)
Cough	23 (28.8)	19 (23.8)	4 (5.0)	0	0
Hypoxia	19 (23.8)	0	6 (7.5)	8 (10.0)	5 (6.3)
Epistaxis	11 (13.8)	7 (8.8)	2 (2.5)	2 (2.5)	0
Tachypnoea	10 (12.5)	3 (3.8)	2 (2.5)	4 (5.0)	1 (1.3)
Pulmonary oedema	9 (11.3)	2 (2.5)	2 (2.5)	4 (5.0)	1 (1.3)
Dyspnoea	8 (10.0)	1 (1.3)	2 (2.5)	3 (3.8)	2 (2.5)
Nasal congestion	8 (10.0)	7 (8.8)	1 (1.3)	0	0
Pleural effusion	8 (10.0)	4 (5.0)	3 (3.8)	1 (1.3)	0
Respiratory failure	8 (10.0)	0	0	0	8 (10.0)

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	7 (8.8)	6 (7.5)	1 (1.3)	0	0
Acute respiratory distress syndrome	2 (2.5)	0	0	0	2 (2.5)
Skin and subcutaneous tissue disorders					
-Total	20 (25.0)	12 (15.0)	8 (10.0)	0	0
Rash	10 (12.5)	5 (6.3)	5 (6.3)	0	0
Pruritus	9 (11.3)	5 (6.3)	4 (5.0)	0	0
Dry skin	7 (8.8)	5 (6.3)	2 (2.5)	0	0
Vascular disorders					
-Total	32 (40.0)	5 (6.3)	11 (13.8)	9 (11.3)	7 (8.8)
Hypotension	22 (27.5)	3 (3.8)	5 (6.3)	7 (8.8)	7 (8.8)
Hypertension	17 (21.3)	2 (2.5)	12 (15.0)	3 (3.8)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	3 (37.5)	5 (62.5)
Blood and lymphatic system disorders					
-Total	7 (87.5)	0	1 (12.5)	4 (50.0)	2 (25.0)
Anaemia	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Febrile neutropenia	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Coagulopathy	1 (12.5)	0	0	1 (12.5)	0
Disseminated intravascular coagulation	1 (12.5)	0	0	1 (12.5)	0
Lymphocytosis	1 (12.5)	0	1 (12.5)	0	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Tachycardia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Sinus tachycardia	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Eyelid oedema	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	6 (75.0)	2 (25.0)	1 (12.5)	2 (25.0)	1 (12.5)
Abdominal pain	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Nausea	2 (25.0)	2 (25.0)	0	0	0
Stomatitis	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Abdominal distension	1 (12.5)	0	1 (12.5)	0	0
Ascites	1 (12.5)	1 (12.5)	0	0	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (12.5)	0	1 (12.5)	0	0
Melaena	1 (12.5)	0	0	1 (12.5)	0
Mouth haemorrhage	1 (12.5)	0	1 (12.5)	0	0
Tooth pulp haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	2 (25.0)	2 (25.0)	1 (12.5)
Pyrexia	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Fatigue	2 (25.0)	2 (25.0)	0	0	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Face oedema	1 (12.5)	0	1 (12.5)	0	0
Generalised oedema	1 (12.5)	0	1 (12.5)	0	0
Multiple organ dysfunction syndrome	1 (12.5)	0	0	0	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Systemic inflammatory response syndrome	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	0	0	0	1 (12.5)
Cholelithiasis	1 (12.5)	1 (12.5)	0	0	0
Cholestasis	1 (12.5)	0	0	0	1 (12.5)
Gallbladder enlargement	1 (12.5)	1 (12.5)	0	0	0
Immune system disorders					
-Total	6 (75.0)	0	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Hypogammaglobulinaemia	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Seasonal allergy	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0	0	0
Otitis externa	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)	0	0
Vulval cellulitis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	0	2 (25.0)	0	1 (12.5)
Fibula fracture	1 (12.5)	0	1 (12.5)	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Skin injury	1 (12.5)	0	1 (12.5)	0	0
Skin wound	1 (12.5)	1 (12.5)	0	0	0
Vasoplegia syndrome	1 (12.5)	0	0	0	1 (12.5)
Wound	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Alanine aminotransferase increased	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Neutrophil count decreased	3 (37.5)	0	0	1 (12.5)	2 (25.0)
White blood cell count decreased	3 (37.5)	1 (12.5)	1 (12.5)	0	1 (12.5)
Aspartate aminotransferase increased	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Blood creatinine increased	2 (25.0)	2 (25.0)	0	0	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (12.5)	1 (12.5)	0	0	0
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0
Blood creatine phosphokinase increased	1 (12.5)	0	0	0	1 (12.5)
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Electrocardiogram qt prolonged	1 (12.5)	0	1 (12.5)	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Lipase increased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	0	1 (12.5)	0	0
Metabolism and nutrition disorders					
-Total	7 (87.5)	1 (12.5)	1 (12.5)	4 (50.0)	1 (12.5)
Hypocalcaemia	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Decreased appetite	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Hypophosphataemia	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Hyperuricaemia	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (25.0)	0	2 (25.0)	0	0
Hypomagnesaemia	2 (25.0)	2 (25.0)	0	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Acidosis	1 (12.5)	0	0	1 (12.5)	0
Haemosiderosis	1 (12.5)	0	1 (12.5)	0	0
Hyperglycaemia	1 (12.5)	0	1 (12.5)	0	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperlactacidaemia	1 (12.5)	1 (12.5)	0	0	0
Hypermagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypernatraemia	1 (12.5)	0	0	0	1 (12.5)
Hypokalaemia	1 (12.5)	0	0	0	1 (12.5)
Hyponatraemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Myalgia	1 (12.5)	1 (12.5)	0	0	0
Myositis	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (12.5)	0	0	0	1 (12.5)
Nervous system disorders					
-Total	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Headache	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Monoparesis	1 (12.5)	0	1 (12.5)	0	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Tremor	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Confusional state	1 (12.5)	1 (12.5)	0	0	0
Irritability	1 (12.5)	0	0	1 (12.5)	0
Persistent depressive disorder	1 (12.5)	0	1 (12.5)	0	0
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Bladder dilatation	1 (12.5)	0	1 (12.5)	0	0
Dysuria	1 (12.5)	1 (12.5)	0	0	0
Renal tubular necrosis	1 (12.5)	0	0	0	1 (12.5)
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Reproductive system and breast disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Vaginal ulceration	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (75.0)	2 (25.0)	0	1 (12.5)	3 (37.5)
Nasal congestion	2 (25.0)	2 (25.0)	0	0	0
Oropharyngeal pain	2 (25.0)	2 (25.0)	0	0	0
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Tachypnoea	2 (25.0)	0	0	2 (25.0)	0
Acute respiratory distress syndrome	1 (12.5)	0	0	0	1 (12.5)
Acute respiratory failure	1 (12.5)	0	0	1 (12.5)	0
Atelectasis	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)
Hypoxia	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory acidosis	1 (12.5)	0	0	1 (12.5)	0
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	0	1 (12.5)	0
Dry skin	2 (25.0)	2 (25.0)	0	0	0
Rash	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Decubitus ulcer	1 (12.5)	0	1 (12.5)	0	0
Erythema	1 (12.5)	1 (12.5)	0	0	0
Hyperhidrosis	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Petechiae	1 (12.5)	0	0	1 (12.5)	0
Pruritus	1 (12.5)	0	1 (12.5)	0	0
Skin hypopigmentation	1 (12.5)	1 (12.5)	0	0	0
Skin necrosis	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Hypotension	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Hypertension	1 (12.5)	0	0	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	86 (95.6)	0	5 (5.6)	20 (22.2)	61 (67.8)
Blood and lymphatic system disorders					
-Total	64 (71.1)	1 (1.1)	6 (6.7)	35 (38.9)	22 (24.4)
Anaemia	42 (46.7)	5 (5.6)	11 (12.2)	25 (27.8)	1 (1.1)
Febrile neutropenia	41 (45.6)	0	0	39 (43.3)	2 (2.2)
Neutropenia	22 (24.4)	1 (1.1)	2 (2.2)	3 (3.3)	16 (17.8)
Thrombocytopenia	14 (15.6)	1 (1.1)	1 (1.1)	5 (5.6)	7 (7.8)
Disseminated intravascular coagulation	7 (7.8)	0	5 (5.6)	2 (2.2)	0
Coagulopathy	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Cardiac disorders					

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (22.2)	8 (8.9)	9 (10.0)	3 (3.3)	0
Tachycardia	18 (20.0)	7 (7.8)	8 (8.9)	3 (3.3)	0
Sinus tachycardia	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Eye disorders					
-Total	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Eyelid oedema	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Gastrointestinal disorders					
-Total	66 (73.3)	18 (20.0)	31 (34.4)	16 (17.8)	1 (1.1)
Nausea	35 (38.9)	12 (13.3)	19 (21.1)	4 (4.4)	0
Vomiting	31 (34.4)	21 (23.3)	8 (8.9)	2 (2.2)	0
Diarrhoea	30 (33.3)	17 (18.9)	10 (11.1)	3 (3.3)	0
Constipation	19 (21.1)	9 (10.0)	10 (11.1)	0	0
Abdominal pain	18 (20.0)	4 (4.4)	11 (12.2)	3 (3.3)	0
Stomatitis	11 (12.2)	1 (1.1)	3 (3.3)	7 (7.8)	0
Mouth haemorrhage	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Haematemesis	3 (3.3)	3 (3.3)	0	0	0
Abdominal distension	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Ascites	2 (2.2)	1 (1.1)	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
General disorders and administration site conditions					
-Total	59 (65.6)	23 (25.6)	20 (22.2)	12 (13.3)	4 (4.4)
Pyrexia	43 (47.8)	18 (20.0)	14 (15.6)	9 (10.0)	2 (2.2)
Fatigue	20 (22.2)	14 (15.6)	6 (6.7)	0	0
Pain	10 (11.1)	1 (1.1)	5 (5.6)	4 (4.4)	0
Oedema peripheral	9 (10.0)	7 (7.8)	1 (1.1)	1 (1.1)	0
Chills	8 (8.9)	5 (5.6)	3 (3.3)	0	0
Face oedema	8 (8.9)	6 (6.7)	1 (1.1)	1 (1.1)	0
Catheter site pain	7 (7.8)	2 (2.2)	4 (4.4)	1 (1.1)	0
Generalised oedema	5 (5.6)	2 (2.2)	2 (2.2)	1 (1.1)	0
Multiple organ dysfunction syndrome	2 (2.2)	0	0	0	2 (2.2)
Hepatobiliary disorders					
-Total	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Cholelithiasis	1 (1.1)	0	1 (1.1)	0	0
Gallbladder enlargement	1 (1.1)	1 (1.1)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	64 (71.1)	2 (2.2)	21 (23.3)	21 (23.3)	20 (22.2)
Cytokine release syndrome	56 (62.2)	4 (4.4)	16 (17.8)	17 (18.9)	19 (21.1)
Hypogammaglobulinaemia	37 (41.1)	2 (2.2)	27 (30.0)	8 (8.9)	0
Haemophagocytic lymphohistiocytosis	5 (5.6)	1 (1.1)	1 (1.1)	2 (2.2)	1 (1.1)
Seasonal allergy	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Infections and infestations					
-Total	47 (52.2)	5 (5.6)	19 (21.1)	19 (21.1)	4 (4.4)
Upper respiratory tract infection	13 (14.4)	5 (5.6)	5 (5.6)	3 (3.3)	0
Pneumonia	9 (10.0)	1 (1.1)	2 (2.2)	3 (3.3)	3 (3.3)
Conjunctivitis	8 (8.9)	3 (3.3)	5 (5.6)	0	0
Rhinovirus infection	8 (8.9)	0	6 (6.7)	2 (2.2)	0
Sinusitis	8 (8.9)	0	5 (5.6)	3 (3.3)	0
Staphylococcal bacteraemia	7 (7.8)	0	0	7 (7.8)	0
Gastroenteritis	6 (6.7)	3 (3.3)	1 (1.1)	2 (2.2)	0
Staphylococcal infection	6 (6.7)	0	3 (3.3)	3 (3.3)	0
Gastroenteritis viral	2 (2.2)	1 (1.1)	1 (1.1)	0	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Clostridium difficile colitis	1 (1.1)	0	1 (1.1)	0	0
Encephalitis	1 (1.1)	0	0	0	1 (1.1)
Localised infection	1 (1.1)	0	0	1 (1.1)	0
Sialoadenitis	1 (1.1)	0	0	1 (1.1)	0
Injury, poisoning and procedural complications					
-Total	11 (12.2)	5 (5.6)	3 (3.3)	3 (3.3)	0
Infusion related reaction	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Procedural pain	4 (4.4)	2 (2.2)	1 (1.1)	1 (1.1)	0
Wound	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Investigations					
-Total	60 (66.7)	1 (1.1)	2 (2.2)	18 (20.0)	39 (43.3)
White blood cell count decreased	32 (35.6)	2 (2.2)	2 (2.2)	1 (1.1)	27 (30.0)
Platelet count decreased	31 (34.4)	6 (6.7)	2 (2.2)	6 (6.7)	17 (18.9)
Neutrophil count decreased	28 (31.1)	2 (2.2)	2 (2.2)	2 (2.2)	22 (24.4)
Alanine aminotransferase increased	22 (24.4)	4 (4.4)	9 (10.0)	9 (10.0)	0
Lymphocyte count decreased	22 (24.4)	0	1 (1.1)	8 (8.9)	13 (14.4)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	21 (23.3)	2 (2.2)	6 (6.7)	10 (11.1)	3 (3.3)
Serum ferritin increased	13 (14.4)	2 (2.2)	6 (6.7)	4 (4.4)	1 (1.1)
Blood bilirubin increased	12 (13.3)	1 (1.1)	2 (2.2)	9 (10.0)	0
C-reactive protein increased	12 (13.3)	3 (3.3)	2 (2.2)	6 (6.7)	1 (1.1)
International normalised ratio increased	9 (10.0)	5 (5.6)	4 (4.4)	0	0
Blood immunoglobulin m decreased	6 (6.7)	4 (4.4)	0	2 (2.2)	0
Blood creatinine increased	5 (5.6)	0	1 (1.1)	3 (3.3)	1 (1.1)
Electrocardiogram qt prolonged	5 (5.6)	2 (2.2)	1 (1.1)	1 (1.1)	1 (1.1)
Weight increased	5 (5.6)	2 (2.2)	1 (1.1)	2 (2.2)	0
Blood immunoglobulin g decreased	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Blood creatine phosphokinase increased	1 (1.1)	0	0	1 (1.1)	0
Lipase increased	1 (1.1)	1 (1.1)	0	0	0
Metabolism and nutrition disorders					
-Total	53 (58.9)	8 (8.9)	13 (14.4)	21 (23.3)	11 (12.2)
Decreased appetite	32 (35.6)	10 (11.1)	8 (8.9)	12 (13.3)	2 (2.2)
Hypokalaemia	25 (27.8)	4 (4.4)	6 (6.7)	13 (14.4)	2 (2.2)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	18 (20.0)	3 (3.3)	7 (7.8)	7 (7.8)	1 (1.1)
Hypocalcaemia	15 (16.7)	2 (2.2)	8 (8.9)	5 (5.6)	0
Hypoalbuminaemia	11 (12.2)	0	10 (11.1)	1 (1.1)	0
Hyperglycaemia	9 (10.0)	0	3 (3.3)	5 (5.6)	1 (1.1)
Hypervolaemia	9 (10.0)	1 (1.1)	2 (2.2)	6 (6.7)	0
Hyperuricaemia	8 (8.9)	6 (6.7)	2 (2.2)	0	0
Hypomagnesaemia	8 (8.9)	5 (5.6)	3 (3.3)	0	0
Hyponatraemia	4 (4.4)	3 (3.3)	0	0	1 (1.1)
Metabolic acidosis	4 (4.4)	1 (1.1)	0	0	3 (3.3)
Hyperkalaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hypernatraemia	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Acidosis	1 (1.1)	0	0	0	1 (1.1)
Hypermagnesaemia	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	42 (46.7)	17 (18.9)	18 (20.0)	7 (7.8)	0
Pain in extremity	21 (23.3)	8 (8.9)	11 (12.2)	2 (2.2)	0
Arthralgia	16 (17.8)	8 (8.9)	7 (7.8)	1 (1.1)	0

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	13 (14.4)	2 (2.2)	7 (7.8)	4 (4.4)	0
Myalgia	9 (10.0)	5 (5.6)	4 (4.4)	0	0
Myositis	1 (1.1)	0	1 (1.1)	0	0
Nervous system disorders					
-Total	41 (45.6)	16 (17.8)	14 (15.6)	11 (12.2)	0
Headache	31 (34.4)	15 (16.7)	11 (12.2)	5 (5.6)	0
Encephalopathy	8 (8.9)	1 (1.1)	3 (3.3)	4 (4.4)	0
Tremor	5 (5.6)	4 (4.4)	1 (1.1)	0	0
Somnolence	4 (4.4)	1 (1.1)	1 (1.1)	2 (2.2)	0
Cognitive disorder	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Neuropathy peripheral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Psychiatric disorders					
-Total	25 (27.8)	10 (11.1)	12 (13.3)	3 (3.3)	0
Anxiety	17 (18.9)	4 (4.4)	10 (11.1)	3 (3.3)	0
Confusional state	6 (6.7)	6 (6.7)	0	0	0
Irritability	3 (3.3)	3 (3.3)	0	0	0
Sleep disorder	2 (2.2)	0	2 (2.2)	0	0
Renal and urinary disorders					

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (17.8)	6 (6.7)	3 (3.3)	3 (3.3)	4 (4.4)
Acute kidney injury	11 (12.2)	3 (3.3)	2 (2.2)	2 (2.2)	4 (4.4)
Dysuria	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Renal tubular necrosis	1 (1.1)	0	0	1 (1.1)	0
Urinary retention	1 (1.1)	0	1 (1.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	56 (62.2)	17 (18.9)	8 (8.9)	13 (14.4)	18 (20.0)
Cough	25 (27.8)	20 (22.2)	5 (5.6)	0	0
Hypoxia	21 (23.3)	0	6 (6.7)	9 (10.0)	6 (6.7)
Pulmonary oedema	13 (14.4)	3 (3.3)	3 (3.3)	6 (6.7)	1 (1.1)
Epistaxis	12 (13.3)	7 (7.8)	2 (2.2)	3 (3.3)	0
Pleural effusion	10 (11.1)	4 (4.4)	3 (3.3)	2 (2.2)	1 (1.1)
Nasal congestion	9 (10.0)	7 (7.8)	2 (2.2)	0	0
Tachypnoea	9 (10.0)	3 (3.3)	2 (2.2)	3 (3.3)	1 (1.1)
Dyspnoea	8 (8.9)	2 (2.2)	2 (2.2)	3 (3.3)	1 (1.1)
Oropharyngeal pain	8 (8.9)	6 (6.7)	2 (2.2)	0	0
Respiratory failure	8 (8.9)	0	0	0	8 (8.9)

Response status at study entry: Relapsed disease

	All patients N=90				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory distress syndrome	3 (3.3)	0	0	0	3 (3.3)
Atelectasis	3 (3.3)	0	1 (1.1)	2 (2.2)	0
Skin and subcutaneous tissue disorders					
-Total	33 (36.7)	15 (16.7)	16 (17.8)	2 (2.2)	0
Pruritus	11 (12.2)	6 (6.7)	5 (5.6)	0	0
Rash	9 (10.0)	5 (5.6)	4 (4.4)	0	0
Dry skin	7 (7.8)	5 (5.6)	2 (2.2)	0	0
Erythema	5 (5.6)	4 (4.4)	1 (1.1)	0	0
Skin ulcer	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Ingrowing nail	3 (3.3)	0	3 (3.3)	0	0
Hyperhidrosis	2 (2.2)	0	2 (2.2)	0	0
Petechiae	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Decubitus ulcer	1 (1.1)	0	0	1 (1.1)	0
Vascular disorders					
-Total	40 (44.4)	7 (7.8)	12 (13.3)	12 (13.3)	9 (10.0)
Hypotension	27 (30.0)	3 (3.3)	6 (6.7)	9 (10.0)	9 (10.0)
Hypertension	23 (25.6)	6 (6.7)	13 (14.4)	4 (4.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218f
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Pancytopenia	1 (50.0)	0	0	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Left ventricular dysfunction	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Delayed puberty	1 (50.0)	0	1 (50.0)	0	0
Hypothyroidism	1 (50.0)	0	1 (50.0)	0	0
Eye disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Dry eye	1 (50.0)	1 (50.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Nausea	1 (50.0)	1 (50.0)	0	0	0
Peritoneal haematoma	1 (50.0)	1 (50.0)	0	0	0
Vomiting	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	0	1 (50.0)	0
Fatigue	1 (50.0)	0	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hepatic cytolysis	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypogammaglobulinaemia	2 (100)	0	1 (50.0)	1 (50.0)	0
Seasonal allergy	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Abscess limb	1 (50.0)	0	0	1 (50.0)	0
Device related bacteraemia	1 (50.0)	0	1 (50.0)	0	0
Encephalitis	1 (50.0)	0	0	0	1 (50.0)
Fungal infection	1 (50.0)	0	1 (50.0)	0	0
Paronychia	1 (50.0)	0	1 (50.0)	0	0
Respiratory syncytial virus infection	1 (50.0)	0	0	1 (50.0)	0
Sepsis	1 (50.0)	0	0	1 (50.0)	0
Tonsillitis	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (50.0)	0	0	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	0	0	1 (50.0)	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	0	1 (50.0)	0	0
Transfusion reaction	1 (50.0)	0	1 (50.0)	0	0
Investigations					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	0	0	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	0	0	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	1 (50.0)	0
Blood creatinine increased	1 (50.0)	0	0	1 (50.0)	0
Weight decreased	1 (50.0)	0	0	1 (50.0)	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	0	0	1 (50.0)

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemochromatosis	1 (50.0)	0	0	1 (50.0)	0
Hypocalcaemia	1 (50.0)	0	0	1 (50.0)	0
Hypokalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypophosphataemia	1 (50.0)	0	1 (50.0)	0	0
Tumour lysis syndrome	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Growth retardation	1 (50.0)	0	1 (50.0)	0	0
Osteopenia	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	0	0	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Cognitive disorder	1 (50.0)	0	1 (50.0)	0	0
Dysarthria	1 (50.0)	0	1 (50.0)	0	0
Memory impairment	1 (50.0)	0	1 (50.0)	0	0
Seizure	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	2 (100)	0	2 (100)	0	0
Anxiety	1 (50.0)	0	1 (50.0)	0	0
Sleep disorder	1 (50.0)	0	1 (50.0)	0	0
Renal and urinary disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Renal tubular disorder	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Pleural effusion	2 (100)	0	1 (50.0)	0	1 (50.0)
Cough	1 (50.0)	0	1 (50.0)	0	0
Lung disorder	1 (50.0)	1 (50.0)	0	0	0
Rhinorrhoea	1 (50.0)	0	1 (50.0)	0	0
Wheezing	1 (50.0)	0	1 (50.0)	0	0
Vascular disorders					
-Total	2 (100)	1 (50.0)	0	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (50.0)	1 (50.0)	0	0	0

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Table 218f
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	92 (95.8)	0	4 (4.2)	22 (22.9)	66 (68.8)
Blood and lymphatic system disorders					
-Total	69 (71.9)	1 (1.0)	5 (5.2)	39 (40.6)	24 (25.0)
Anaemia	46 (47.9)	6 (6.3)	12 (12.5)	27 (28.1)	1 (1.0)
Febrile neutropenia	44 (45.8)	0	0	41 (42.7)	3 (3.1)
Neutropenia	21 (21.9)	1 (1.0)	2 (2.1)	3 (3.1)	15 (15.6)
Thrombocytopenia	15 (15.6)	1 (1.0)	1 (1.0)	5 (5.2)	8 (8.3)
Disseminated intravascular coagulation	7 (7.3)	0	5 (5.2)	2 (2.1)	0
Pancytopenia	5 (5.2)	0	1 (1.0)	2 (2.1)	2 (2.1)
Cardiac disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (25.0)	7 (7.3)	7 (7.3)	9 (9.4)	1 (1.0)
Tachycardia	23 (24.0)	8 (8.3)	9 (9.4)	5 (5.2)	1 (1.0)
Left ventricular dysfunction	4 (4.2)	0	0	4 (4.2)	0
Endocrine disorders					
-Total	4 (4.2)	0	4 (4.2)	0	0
Hypothyroidism	4 (4.2)	0	4 (4.2)	0	0
Eye disorders					
-Total	1 (1.0)	1 (1.0)	0	0	0
Dry eye	1 (1.0)	1 (1.0)	0	0	0
Gastrointestinal disorders					
-Total	69 (71.9)	21 (21.9)	31 (32.3)	17 (17.7)	0
Nausea	36 (37.5)	13 (13.5)	19 (19.8)	4 (4.2)	0
Vomiting	30 (31.3)	20 (20.8)	8 (8.3)	2 (2.1)	0
Diarrhoea	29 (30.2)	17 (17.7)	9 (9.4)	3 (3.1)	0
Abdominal pain	20 (20.8)	5 (5.2)	11 (11.5)	4 (4.2)	0
Constipation	20 (20.8)	10 (10.4)	10 (10.4)	0	0
Stomatitis	13 (13.5)	1 (1.0)	4 (4.2)	8 (8.3)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	59 (61.5)	26 (27.1)	19 (19.8)	12 (12.5)	2 (2.1)
Pyrexia	47 (49.0)	18 (18.8)	17 (17.7)	10 (10.4)	2 (2.1)
Fatigue	21 (21.9)	16 (16.7)	5 (5.2)	0	0
Pain	11 (11.5)	1 (1.0)	6 (6.3)	4 (4.2)	0
Oedema peripheral	10 (10.4)	7 (7.3)	2 (2.1)	1 (1.0)	0
Hepatobiliary disorders					
-Total	1 (1.0)	0	0	1 (1.0)	0
Hepatic cytolysis	1 (1.0)	0	0	1 (1.0)	0
Immune system disorders					
-Total	68 (70.8)	2 (2.1)	26 (27.1)	20 (20.8)	20 (20.8)
Cytokine release syndrome	59 (61.5)	5 (5.2)	18 (18.8)	16 (16.7)	20 (20.8)
Hypogammaglobulinaemia	39 (40.6)	2 (2.1)	29 (30.2)	8 (8.3)	0
Seasonal allergy	4 (4.2)	1 (1.0)	3 (3.1)	0	0
Infections and infestations					
-Total	29 (30.2)	4 (4.2)	11 (11.5)	7 (7.3)	7 (7.3)
Upper respiratory tract infection	13 (13.5)	5 (5.2)	6 (6.3)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	10 (10.4)	1 (1.0)	2 (2.1)	4 (4.2)	3 (3.1)
Paronychia	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Sepsis	3 (3.1)	0	0	0	3 (3.1)
Fungal infection	2 (2.1)	0	2 (2.1)	0	0
Respiratory syncytial virus infection	2 (2.1)	0	1 (1.0)	1 (1.0)	0
Encephalitis	1 (1.0)	0	0	0	1 (1.0)
Injury, poisoning and procedural complications					
-Total	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Transfusion reaction	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)	0
Investigations					
-Total	64 (66.7)	1 (1.0)	1 (1.0)	21 (21.9)	41 (42.7)
White blood cell count decreased	35 (36.5)	3 (3.1)	3 (3.1)	1 (1.0)	28 (29.2)
Platelet count decreased	32 (33.3)	6 (6.3)	2 (2.1)	6 (6.3)	18 (18.8)
Neutrophil count decreased	31 (32.3)	2 (2.1)	2 (2.1)	3 (3.1)	24 (25.0)
Alanine aminotransferase increased	24 (25.0)	5 (5.2)	9 (9.4)	10 (10.4)	0
Lymphocyte count decreased	24 (25.0)	1 (1.0)	1 (1.0)	9 (9.4)	13 (13.5)
Aspartate aminotransferase increased	22 (22.9)	2 (2.1)	6 (6.3)	11 (11.5)	3 (3.1)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	13 (13.5)	2 (2.1)	6 (6.3)	4 (4.2)	1 (1.0)
Blood bilirubin increased	12 (12.5)	1 (1.0)	2 (2.1)	9 (9.4)	0
C-reactive protein increased	12 (12.5)	3 (3.1)	2 (2.1)	6 (6.3)	1 (1.0)
International normalised ratio increased	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Activated partial thromboplastin time prolonged	6 (6.3)	4 (4.2)	2 (2.1)	0	0
Blood creatinine increased	6 (6.3)	2 (2.1)	1 (1.0)	2 (2.1)	1 (1.0)
Weight decreased	3 (3.1)	0	2 (2.1)	1 (1.0)	0
Metabolism and nutrition disorders					
-Total	58 (60.4)	8 (8.3)	17 (17.7)	25 (26.0)	8 (8.3)
Decreased appetite	34 (35.4)	12 (12.5)	9 (9.4)	12 (12.5)	1 (1.0)
Hypokalaemia	25 (26.0)	4 (4.2)	6 (6.3)	12 (12.5)	3 (3.1)
Hypophosphataemia	20 (20.8)	3 (3.1)	7 (7.3)	9 (9.4)	1 (1.0)
Hypocalcaemia	18 (18.8)	2 (2.1)	11 (11.5)	5 (5.2)	0
Hypoalbuminaemia	13 (13.5)	0	12 (12.5)	1 (1.0)	0
Hyperglycaemia	10 (10.4)	0	4 (4.2)	5 (5.2)	1 (1.0)
Hyperuricaemia	10 (10.4)	7 (7.3)	2 (2.1)	1 (1.0)	0
Hypomagnesaemia	10 (10.4)	7 (7.3)	3 (3.1)	0	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	6 (6.3)	0	0	4 (4.2)	2 (2.1)
Musculoskeletal and connective tissue disorders					
-Total	44 (45.8)	18 (18.8)	18 (18.8)	8 (8.3)	0
Pain in extremity	23 (24.0)	9 (9.4)	11 (11.5)	3 (3.1)	0
Arthralgia	16 (16.7)	8 (8.3)	7 (7.3)	1 (1.0)	0
Back pain	13 (13.5)	2 (2.1)	7 (7.3)	4 (4.2)	0
Myalgia	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Growth retardation	1 (1.0)	0	1 (1.0)	0	0
Osteopenia	1 (1.0)	1 (1.0)	0	0	0
Nervous system disorders					
-Total	40 (41.7)	17 (17.7)	12 (12.5)	10 (10.4)	1 (1.0)
Headache	35 (36.5)	18 (18.8)	12 (12.5)	5 (5.2)	0
Seizure	5 (5.2)	0	3 (3.1)	2 (2.1)	0
Cognitive disorder	3 (3.1)	0	1 (1.0)	2 (2.1)	0
Cerebral haemorrhage	1 (1.0)	0	0	0	1 (1.0)
Dysarthria	1 (1.0)	0	0	1 (1.0)	0
Psychiatric disorders					

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (17.7)	3 (3.1)	11 (11.5)	3 (3.1)	0
Anxiety	16 (16.7)	4 (4.2)	9 (9.4)	3 (3.1)	0
Sleep disorder	2 (2.1)	0	2 (2.1)	0	0
Renal and urinary disorders					
-Total	15 (15.6)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Acute kidney injury	15 (15.6)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Respiratory, thoracic and mediastinal disorders					
-Total	57 (59.4)	19 (19.8)	7 (7.3)	15 (15.6)	16 (16.7)
Cough	25 (26.0)	21 (21.9)	4 (4.2)	0	0
Hypoxia	22 (22.9)	0	6 (6.3)	10 (10.4)	6 (6.3)
Pulmonary oedema	14 (14.6)	3 (3.1)	3 (3.1)	6 (6.3)	2 (2.1)
Epistaxis	12 (12.5)	7 (7.3)	2 (2.1)	3 (3.1)	0
Nasal congestion	11 (11.5)	9 (9.4)	2 (2.1)	0	0
Tachypnoea	11 (11.5)	3 (3.1)	2 (2.1)	5 (5.2)	1 (1.0)
Oropharyngeal pain	10 (10.4)	8 (8.3)	2 (2.1)	0	0
Respiratory failure	10 (10.4)	0	0	0	10 (10.4)
Pleural effusion	8 (8.3)	4 (4.2)	2 (2.1)	2 (2.1)	0

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	5 (5.2)	4 (4.2)	1 (1.0)	0	0
Wheezing	2 (2.1)	1 (1.0)	1 (1.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (20.8)	11 (11.5)	9 (9.4)	0	0
Pruritus	12 (12.5)	6 (6.3)	6 (6.3)	0	0
Rash	11 (11.5)	6 (6.3)	5 (5.2)	0	0
Vascular disorders					
-Total	43 (44.8)	6 (6.3)	12 (12.5)	15 (15.6)	10 (10.4)
Hypotension	30 (31.3)	2 (2.1)	6 (6.3)	12 (12.5)	10 (10.4)
Hypertension	24 (25.0)	6 (6.3)	13 (13.5)	5 (5.2)	0
Capillary leak syndrome	1 (1.0)	0	1 (1.0)	0	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218g
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)	0	0
Blood and lymphatic system disorders					
-Total	1 (100)	1 (100)	0	0	0
Anaemia	1 (100)	1 (100)	0	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Abdominal pain	1 (100)	1 (100)	0	0	0
Anal fissure	1 (100)	0	1 (100)	0	0
Anal haemorrhage	1 (100)	1 (100)	0	0	0
Diarrhoea	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	1 (100)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (100)	1 (100)	0	0	0
Vomiting	1 (100)	1 (100)	0	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Hypogammaglobulinaemia	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	1 (100)	0	0	0
Blood fibrinogen decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin a decreased	1 (100)	1 (100)	0	0	0
Blood immunoglobulin m decreased	1 (100)	1 (100)	0	0	0
Blood uric acid increased	1 (100)	1 (100)	0	0	0
Platelet count decreased	1 (100)	1 (100)	0	0	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	1 (100)	0	0	0
Decreased appetite	1 (100)	1 (100)	0	0	0
Musculoskeletal and connective tissue disorders					

Mixed-lineage leukemia rearrangement: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (100)	1 (100)	0	0	0
Pain in extremity	1 (100)	1 (100)	0	0	0
Psychiatric disorders					
-Total	1 (100)	1 (100)	0	0	0
Irritability	1 (100)	1 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	1 (100)	0	0	0
Cough	1 (100)	1 (100)	0	0	0
Rhinorrhoea	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	1 (100)	0	0	0
Dry skin	1 (100)	1 (100)	0	0	0
Rash papular	1 (100)	1 (100)	0	0	0
Rash pruritic	1 (100)	1 (100)	0	0	0

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218g
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	93 (95.9)	0	4 (4.1)	23 (23.7)	66 (68.0)
Blood and lymphatic system disorders					
-Total	67 (69.1)	0	4 (4.1)	39 (40.2)	24 (24.7)
Anaemia	45 (46.4)	5 (5.2)	12 (12.4)	27 (27.8)	1 (1.0)
Febrile neutropenia	45 (46.4)	0	0	42 (43.3)	3 (3.1)
Neutropenia	22 (22.7)	1 (1.0)	2 (2.1)	3 (3.1)	16 (16.5)
Thrombocytopenia	15 (15.5)	1 (1.0)	1 (1.0)	5 (5.2)	8 (8.2)
Cardiac disorders					
-Total	23 (23.7)	8 (8.2)	9 (9.3)	5 (5.2)	1 (1.0)
Tachycardia	23 (23.7)	8 (8.2)	9 (9.3)	5 (5.2)	1 (1.0)
Gastrointestinal disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	69 (71.1)	19 (19.6)	32 (33.0)	18 (18.6)	0
Nausea	36 (37.1)	13 (13.4)	19 (19.6)	4 (4.1)	0
Vomiting	30 (30.9)	20 (20.6)	8 (8.2)	2 (2.1)	0
Diarrhoea	29 (29.9)	16 (16.5)	10 (10.3)	3 (3.1)	0
Constipation	20 (20.6)	10 (10.3)	10 (10.3)	0	0
Abdominal pain	19 (19.6)	4 (4.1)	11 (11.3)	4 (4.1)	0
Stomatitis	13 (13.4)	1 (1.0)	4 (4.1)	8 (8.2)	0
Anal fissure	1 (1.0)	0	1 (1.0)	0	0
Proctalgia	1 (1.0)	0	0	1 (1.0)	0
General disorders and administration site conditions					
-Total	60 (61.9)	26 (26.8)	19 (19.6)	13 (13.4)	2 (2.1)
Pyrexia	48 (49.5)	18 (18.6)	17 (17.5)	11 (11.3)	2 (2.1)
Fatigue	22 (22.7)	16 (16.5)	6 (6.2)	0	0
Pain	11 (11.3)	1 (1.0)	6 (6.2)	4 (4.1)	0
Oedema peripheral	10 (10.3)	7 (7.2)	2 (2.1)	1 (1.0)	0
Immune system disorders					
-Total	69 (71.1)	2 (2.1)	25 (25.8)	21 (21.6)	21 (21.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	61 (62.9)	5 (5.2)	18 (18.6)	17 (17.5)	21 (21.6)
Hypogammaglobulinaemia	40 (41.2)	2 (2.1)	29 (29.9)	9 (9.3)	0
Infections and infestations					
-Total	22 (22.7)	5 (5.2)	7 (7.2)	7 (7.2)	3 (3.1)
Upper respiratory tract infection	14 (14.4)	5 (5.2)	6 (6.2)	3 (3.1)	0
Pneumonia	10 (10.3)	1 (1.0)	2 (2.1)	4 (4.1)	3 (3.1)
Investigations					
-Total	62 (63.9)	0	1 (1.0)	20 (20.6)	41 (42.3)
White blood cell count decreased	34 (35.1)	2 (2.1)	3 (3.1)	1 (1.0)	28 (28.9)
Neutrophil count decreased	31 (32.0)	2 (2.1)	2 (2.1)	3 (3.1)	24 (24.7)
Platelet count decreased	31 (32.0)	5 (5.2)	2 (2.1)	6 (6.2)	18 (18.6)
Alanine aminotransferase increased	25 (25.8)	5 (5.2)	9 (9.3)	11 (11.3)	0
Lymphocyte count decreased	24 (24.7)	1 (1.0)	1 (1.0)	9 (9.3)	13 (13.4)
Aspartate aminotransferase increased	23 (23.7)	2 (2.1)	6 (6.2)	11 (11.3)	4 (4.1)
Blood bilirubin increased	13 (13.4)	1 (1.0)	2 (2.1)	10 (10.3)	0
Serum ferritin increased	13 (13.4)	2 (2.1)	6 (6.2)	4 (4.1)	1 (1.0)
C-reactive protein increased	12 (12.4)	3 (3.1)	2 (2.1)	6 (6.2)	1 (1.0)

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	10 (10.3)	6 (6.2)	4 (4.1)	0	0
Blood fibrinogen decreased	7 (7.2)	2 (2.1)	3 (3.1)	1 (1.0)	1 (1.0)
Blood immunoglobulin a decreased	6 (6.2)	4 (4.1)	1 (1.0)	1 (1.0)	0
Blood immunoglobulin m decreased	6 (6.2)	3 (3.1)	1 (1.0)	2 (2.1)	0
Blood uric acid increased	3 (3.1)	1 (1.0)	0	1 (1.0)	1 (1.0)
Metabolism and nutrition disorders					
-Total	56 (57.7)	7 (7.2)	18 (18.6)	24 (24.7)	7 (7.2)
Decreased appetite	34 (35.1)	11 (11.3)	9 (9.3)	12 (12.4)	2 (2.1)
Hypokalaemia	26 (26.8)	4 (4.1)	6 (6.2)	13 (13.4)	3 (3.1)
Hypophosphataemia	21 (21.6)	3 (3.1)	8 (8.2)	9 (9.3)	1 (1.0)
Hypocalcaemia	19 (19.6)	2 (2.1)	11 (11.3)	6 (6.2)	0
Hypoalbuminaemia	13 (13.4)	0	12 (12.4)	1 (1.0)	0
Hyperglycaemia	10 (10.3)	0	4 (4.1)	5 (5.2)	1 (1.0)
Hyperuricaemia	10 (10.3)	7 (7.2)	2 (2.1)	1 (1.0)	0
Hypomagnesaemia	10 (10.3)	7 (7.2)	3 (3.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	42 (43.3)	17 (17.5)	17 (17.5)	8 (8.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	22 (22.7)	8 (8.2)	11 (11.3)	3 (3.1)	0
Arthralgia	16 (16.5)	8 (8.2)	7 (7.2)	1 (1.0)	0
Back pain	13 (13.4)	2 (2.1)	7 (7.2)	4 (4.1)	0
Myalgia	10 (10.3)	6 (6.2)	4 (4.1)	0	0
Nervous system disorders					
-Total	35 (36.1)	18 (18.6)	12 (12.4)	5 (5.2)	0
Headache	35 (36.1)	18 (18.6)	12 (12.4)	5 (5.2)	0
Psychiatric disorders					
-Total	20 (20.6)	6 (6.2)	10 (10.3)	4 (4.1)	0
Anxiety	17 (17.5)	4 (4.1)	10 (10.3)	3 (3.1)	0
Irritability	3 (3.1)	2 (2.1)	0	1 (1.0)	0
Renal and urinary disorders					
-Total	15 (15.5)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Acute kidney injury	15 (15.5)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Respiratory, thoracic and mediastinal disorders					
-Total	58 (59.8)	18 (18.6)	8 (8.2)	15 (15.5)	17 (17.5)
Cough	25 (25.8)	20 (20.6)	5 (5.2)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=97				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	22 (22.7)	0	6 (6.2)	10 (10.3)	6 (6.2)
Pulmonary oedema	14 (14.4)	3 (3.1)	3 (3.1)	6 (6.2)	2 (2.1)
Epistaxis	12 (12.4)	7 (7.2)	2 (2.1)	3 (3.1)	0
Nasal congestion	11 (11.3)	9 (9.3)	2 (2.1)	0	0
Tachypnoea	11 (11.3)	3 (3.1)	2 (2.1)	5 (5.2)	1 (1.0)
Oropharyngeal pain	10 (10.3)	8 (8.2)	2 (2.1)	0	0
Pleural effusion	10 (10.3)	4 (4.1)	3 (3.1)	2 (2.1)	1 (1.0)
Respiratory failure	10 (10.3)	0	0	0	10 (10.3)
Rhinorrhoea	5 (5.2)	3 (3.1)	2 (2.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	26 (26.8)	15 (15.5)	11 (11.3)	0	0
Pruritus	12 (12.4)	6 (6.2)	6 (6.2)	0	0
Rash	11 (11.3)	6 (6.2)	5 (5.2)	0	0
Dry skin	8 (8.2)	6 (6.2)	2 (2.1)	0	0
Rash papular	3 (3.1)	2 (2.1)	1 (1.0)	0	0
Vascular disorders					
-Total	44 (45.4)	7 (7.2)	12 (12.4)	15 (15.5)	10 (10.3)

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=97 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	31 (32.0)	3 (3.1)	6 (6.2)	12 (12.4)	10 (10.3)
Hypertension	24 (24.7)	6 (6.2)	13 (13.4)	5 (5.2)	0

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Table 218h
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Lymphadenopathy	1 (33.3)	0	1 (33.3)	0	0
Cardiac disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Tachycardia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (33.3)	0	0	0	1 (33.3)
Constipation	1 (33.3)	0	1 (33.3)	0	0
Haemoperitoneum	1 (33.3)	0	0	0	1 (33.3)
General disorders and administration site conditions					
-Total	2 (66.7)	0	2 (66.7)	0	0
Pyrexia	2 (66.7)	0	2 (66.7)	0	0
Pain	1 (33.3)	0	1 (33.3)	0	0
Immune system disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Hypogammaglobulinaemia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Bronchitis	1 (33.3)	0	1 (33.3)	0	0
Cystitis	1 (33.3)	0	1 (33.3)	0	0
Gastroenteritis	1 (33.3)	1 (33.3)	0	0	0
Gastroenteritis adenovirus	1 (33.3)	0	0	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	0	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Nasopharyngitis	1 (33.3)	1 (33.3)	0	0	0
Serratia sepsis	1 (33.3)	0	0	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	0	0	1 (33.3)
Injury, poisoning and procedural complications					
-Total	1 (33.3)	0	0	1 (33.3)	0
Post procedural haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	2 (66.7)	0	0	0	2 (66.7)
Lymphocyte count decreased	2 (66.7)	1 (33.3)	0	0	1 (33.3)
White blood cell count decreased	2 (66.7)	1 (33.3)	0	0	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Aspartate aminotransferase increased	1 (33.3)	0	0	0	1 (33.3)
Blood creatinine increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	1 (33.3)	0	0	0
Metabolism and nutrition disorders					

Hypodiploidy: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Hypocalcaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic acidosis	1 (33.3)	0	0	1 (33.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Myositis	1 (33.3)	0	1 (33.3)	0	0
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cognitive disorder	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Acute kidney injury	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	1 (33.3)	0	0	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)

Hypodiploidy: Yes

Group term Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Dermatitis atopic	1 (33.3)	1 (33.3)	0	0	0
Rash vesicular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypotension	2 (66.7)	0	0	2 (66.7)	0

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Enrolled set

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	91 (95.8)	0	5 (5.3)	22 (23.2)	64 (67.4)
Blood and lymphatic system disorders					
-Total	67 (70.5)	1 (1.1)	4 (4.2)	38 (40.0)	24 (25.3)
Anaemia	45 (47.4)	6 (6.3)	12 (12.6)	26 (27.4)	1 (1.1)
Febrile neutropenia	45 (47.4)	0	0	42 (44.2)	3 (3.2)
Neutropenia	22 (23.2)	1 (1.1)	2 (2.1)	3 (3.2)	16 (16.8)
Thrombocytopenia	15 (15.8)	1 (1.1)	1 (1.1)	5 (5.3)	8 (8.4)
Lymphadenopathy	1 (1.1)	1 (1.1)	0	0	0
Cardiac disorders					
-Total	23 (24.2)	7 (7.4)	8 (8.4)	7 (7.4)	1 (1.1)
Tachycardia	21 (22.1)	8 (8.4)	8 (8.4)	4 (4.2)	1 (1.1)

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	4 (4.2)	0	1 (1.1)	3 (3.2)	0
Gastrointestinal disorders					
-Total	69 (72.6)	21 (22.1)	30 (31.6)	17 (17.9)	1 (1.1)
Nausea	37 (38.9)	14 (14.7)	19 (20.0)	4 (4.2)	0
Vomiting	31 (32.6)	21 (22.1)	8 (8.4)	2 (2.1)	0
Diarrhoea	30 (31.6)	17 (17.9)	10 (10.5)	3 (3.2)	0
Abdominal pain	20 (21.1)	5 (5.3)	11 (11.6)	4 (4.2)	0
Constipation	19 (20.0)	10 (10.5)	9 (9.5)	0	0
Stomatitis	13 (13.7)	1 (1.1)	4 (4.2)	8 (8.4)	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)
General disorders and administration site conditions					
-Total	58 (61.1)	26 (27.4)	17 (17.9)	13 (13.7)	2 (2.1)
Pyrexia	46 (48.4)	18 (18.9)	15 (15.8)	11 (11.6)	2 (2.1)
Fatigue	22 (23.2)	16 (16.8)	6 (6.3)	0	0
Oedema peripheral	10 (10.5)	7 (7.4)	2 (2.1)	1 (1.1)	0
Pain	10 (10.5)	1 (1.1)	5 (5.3)	4 (4.2)	0
Immune system disorders					

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	69 (72.6)	2 (2.1)	25 (26.3)	21 (22.1)	21 (22.1)
Cytokine release syndrome	61 (64.2)	5 (5.3)	18 (18.9)	17 (17.9)	21 (22.1)
Hypogammaglobulinaemia	40 (42.1)	2 (2.1)	29 (30.5)	9 (9.5)	0
Infections and infestations					
-Total	34 (35.8)	8 (8.4)	11 (11.6)	12 (12.6)	3 (3.2)
Upper respiratory tract infection	14 (14.7)	5 (5.3)	6 (6.3)	3 (3.2)	0
Pneumonia	10 (10.5)	1 (1.1)	2 (2.1)	4 (4.2)	3 (3.2)
Nasopharyngitis	7 (7.4)	4 (4.2)	3 (3.2)	0	0
Gastroenteritis	6 (6.3)	3 (3.2)	1 (1.1)	2 (2.1)	0
Staphylococcal infection	6 (6.3)	0	3 (3.2)	3 (3.2)	0
Bronchitis	2 (2.1)	0	2 (2.1)	0	0
Klebsiella bacteraemia	1 (1.1)	0	1 (1.1)	0	0
Investigations					
-Total	62 (65.3)	1 (1.1)	1 (1.1)	20 (21.1)	40 (42.1)
White blood cell count decreased	33 (34.7)	2 (2.1)	3 (3.2)	1 (1.1)	27 (28.4)
Platelet count decreased	31 (32.6)	5 (5.3)	2 (2.1)	6 (6.3)	18 (18.9)
Neutrophil count decreased	30 (31.6)	2 (2.1)	2 (2.1)	3 (3.2)	23 (24.2)
Alanine aminotransferase increased	24 (25.3)	4 (4.2)	9 (9.5)	11 (11.6)	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	22 (23.2)	2 (2.1)	6 (6.3)	11 (11.6)	3 (3.2)
Lymphocyte count decreased	22 (23.2)	0	1 (1.1)	9 (9.5)	12 (12.6)
Blood bilirubin increased	13 (13.7)	1 (1.1)	2 (2.1)	10 (10.5)	0
Serum ferritin increased	13 (13.7)	2 (2.1)	6 (6.3)	4 (4.2)	1 (1.1)
C-reactive protein increased	12 (12.6)	3 (3.2)	2 (2.1)	6 (6.3)	1 (1.1)
International normalised ratio increased	10 (10.5)	6 (6.3)	4 (4.2)	0	0
Blood creatinine increased	6 (6.3)	1 (1.1)	1 (1.1)	3 (3.2)	1 (1.1)
Metabolism and nutrition disorders					
-Total	57 (60.0)	8 (8.4)	15 (15.8)	24 (25.3)	10 (10.5)
Decreased appetite	35 (36.8)	12 (12.6)	9 (9.5)	12 (12.6)	2 (2.1)
Hypokalaemia	26 (27.4)	4 (4.2)	6 (6.3)	13 (13.7)	3 (3.2)
Hypophosphataemia	21 (22.1)	3 (3.2)	8 (8.4)	9 (9.5)	1 (1.1)
Hypocalcaemia	18 (18.9)	2 (2.1)	10 (10.5)	6 (6.3)	0
Hypoalbuminaemia	12 (12.6)	0	11 (11.6)	1 (1.1)	0
Hyperglycaemia	10 (10.5)	0	4 (4.2)	5 (5.3)	1 (1.1)
Hyperuricaemia	10 (10.5)	7 (7.4)	2 (2.1)	1 (1.1)	0
Hypomagnesaemia	10 (10.5)	7 (7.4)	3 (3.2)	0	0

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	5 (5.3)	1 (1.1)	0	1 (1.1)	3 (3.2)
Musculoskeletal and connective tissue disorders					
-Total	43 (45.3)	17 (17.9)	18 (18.9)	8 (8.4)	0
Pain in extremity	23 (24.2)	9 (9.5)	11 (11.6)	3 (3.2)	0
Arthralgia	16 (16.8)	8 (8.4)	7 (7.4)	1 (1.1)	0
Back pain	13 (13.7)	2 (2.1)	7 (7.4)	4 (4.2)	0
Myalgia	10 (10.5)	6 (6.3)	4 (4.2)	0	0
Myositis	1 (1.1)	0	1 (1.1)	0	0
Nervous system disorders					
-Total	37 (38.9)	18 (18.9)	13 (13.7)	6 (6.3)	0
Headache	35 (36.8)	18 (18.9)	12 (12.6)	5 (5.3)	0
Cognitive disorder	3 (3.2)	0	2 (2.1)	1 (1.1)	0
Psychiatric disorders					
-Total	17 (17.9)	4 (4.2)	10 (10.5)	3 (3.2)	0
Anxiety	17 (17.9)	4 (4.2)	10 (10.5)	3 (3.2)	0
Renal and urinary disorders					
-Total	14 (14.7)	4 (4.2)	2 (2.1)	3 (3.2)	5 (5.3)

Hypodiploidy: No

	All patients N=95				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	14 (14.7)	4 (4.2)	2 (2.1)	3 (3.2)	5 (5.3)
Respiratory, thoracic and mediastinal disorders					
-Total	57 (60.0)	18 (18.9)	8 (8.4)	15 (15.8)	16 (16.8)
Cough	25 (26.3)	20 (21.1)	5 (5.3)	0	0
Hypoxia	22 (23.2)	0	6 (6.3)	10 (10.5)	6 (6.3)
Pulmonary oedema	13 (13.7)	3 (3.2)	3 (3.2)	6 (6.3)	1 (1.1)
Epistaxis	12 (12.6)	7 (7.4)	2 (2.1)	3 (3.2)	0
Nasal congestion	11 (11.6)	9 (9.5)	2 (2.1)	0	0
Tachypnoea	11 (11.6)	3 (3.2)	2 (2.1)	5 (5.3)	1 (1.1)
Oropharyngeal pain	10 (10.5)	8 (8.4)	2 (2.1)	0	0
Pleural effusion	10 (10.5)	4 (4.2)	3 (3.2)	2 (2.1)	1 (1.1)
Respiratory failure	9 (9.5)	0	0	0	9 (9.5)
Skin and subcutaneous tissue disorders					
-Total	21 (22.1)	12 (12.6)	8 (8.4)	1 (1.1)	0
Pruritus	12 (12.6)	6 (6.3)	6 (6.3)	0	0
Rash	11 (11.6)	6 (6.3)	5 (5.3)	0	0
Dermatitis atopic	2 (2.1)	1 (1.1)	0	1 (1.1)	0

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	42 (44.2)	7 (7.4)	12 (12.6)	13 (13.7)	10 (10.5)
Hypotension	29 (30.5)	3 (3.2)	6 (6.3)	10 (10.5)	10 (10.5)
Hypertension	24 (25.3)	6 (6.3)	13 (13.7)	5 (5.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	2 (100)	0
Febrile neutropenia	2 (100)	0	0	2 (100)	0
General disorders and administration site conditions					
-Total	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Hypersensitivity	1 (50.0)	0	1 (50.0)	0	0

BCR-ABL1-like: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Acute sinusitis	1 (50.0)	0	0	1 (50.0)	0
Fungal skin infection	1 (50.0)	0	0	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	1 (50.0)	0	0
Systemic mycosis	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Gamma-glutamyltransferase increased	1 (50.0)	0	0	1 (50.0)	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Photosensitivity reaction	1 (50.0)	0	1 (50.0)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	92 (95.8)	0	5 (5.2)	22 (22.9)	65 (67.7)
Blood and lymphatic system disorders					
-Total	66 (68.8)	1 (1.0)	4 (4.2)	37 (38.5)	24 (25.0)
Anaemia	46 (47.9)	6 (6.3)	12 (12.5)	27 (28.1)	1 (1.0)
Febrile neutropenia	43 (44.8)	0	0	40 (41.7)	3 (3.1)
Neutropenia	22 (22.9)	1 (1.0)	2 (2.1)	3 (3.1)	16 (16.7)
Thrombocytopenia	15 (15.6)	1 (1.0)	1 (1.0)	5 (5.2)	8 (8.3)
Cardiac disorders					
-Total	23 (24.0)	8 (8.3)	9 (9.4)	5 (5.2)	1 (1.0)
Tachycardia	23 (24.0)	8 (8.3)	9 (9.4)	5 (5.2)	1 (1.0)
Gastrointestinal disorders					

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	70 (72.9)	21 (21.9)	32 (33.3)	17 (17.7)	0
Nausea	37 (38.5)	14 (14.6)	19 (19.8)	4 (4.2)	0
Vomiting	31 (32.3)	21 (21.9)	8 (8.3)	2 (2.1)	0
Diarrhoea	30 (31.3)	17 (17.7)	10 (10.4)	3 (3.1)	0
Abdominal pain	20 (20.8)	5 (5.2)	11 (11.5)	4 (4.2)	0
Constipation	20 (20.8)	10 (10.4)	10 (10.4)	0	0
Stomatitis	13 (13.5)	1 (1.0)	4 (4.2)	8 (8.3)	0
General disorders and administration site conditions					
-Total	59 (61.5)	25 (26.0)	19 (19.8)	13 (13.5)	2 (2.1)
Pyrexia	47 (49.0)	17 (17.7)	17 (17.7)	11 (11.5)	2 (2.1)
Fatigue	22 (22.9)	16 (16.7)	6 (6.3)	0	0
Pain	11 (11.5)	1 (1.0)	6 (6.3)	4 (4.2)	0
Oedema peripheral	10 (10.4)	7 (7.3)	2 (2.1)	1 (1.0)	0
Immune system disorders					
-Total	70 (72.9)	2 (2.1)	26 (27.1)	21 (21.9)	21 (21.9)
Cytokine release syndrome	61 (63.5)	5 (5.2)	18 (18.8)	17 (17.7)	21 (21.9)
Hypogammaglobulinaemia	41 (42.7)	2 (2.1)	30 (31.3)	9 (9.4)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypersensitivity	1 (1.0)	1 (1.0)	0	0	0
Infections and infestations					
-Total	29 (30.2)	4 (4.2)	11 (11.5)	10 (10.4)	4 (4.2)
Upper respiratory tract infection	14 (14.6)	5 (5.2)	6 (6.3)	3 (3.1)	0
Pneumonia	10 (10.4)	1 (1.0)	2 (2.1)	4 (4.2)	3 (3.1)
Staphylococcal infection	6 (6.3)	0	2 (2.1)	3 (3.1)	1 (1.0)
Acute sinusitis	3 (3.1)	0	3 (3.1)	0	0
Fungal skin infection	1 (1.0)	0	1 (1.0)	0	0
Investigations					
-Total	62 (64.6)	1 (1.0)	1 (1.0)	20 (20.8)	40 (41.7)
White blood cell count decreased	34 (35.4)	3 (3.1)	3 (3.1)	1 (1.0)	27 (28.1)
Platelet count decreased	32 (33.3)	6 (6.3)	2 (2.1)	6 (6.3)	18 (18.8)
Neutrophil count decreased	31 (32.3)	2 (2.1)	2 (2.1)	3 (3.1)	24 (25.0)
Alanine aminotransferase increased	24 (25.0)	4 (4.2)	9 (9.4)	11 (11.5)	0
Lymphocyte count decreased	24 (25.0)	1 (1.0)	1 (1.0)	9 (9.4)	13 (13.5)
Aspartate aminotransferase increased	23 (24.0)	2 (2.1)	6 (6.3)	11 (11.5)	4 (4.2)
Blood bilirubin increased	13 (13.5)	1 (1.0)	2 (2.1)	10 (10.4)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	13 (13.5)	2 (2.1)	6 (6.3)	4 (4.2)	1 (1.0)
C-reactive protein increased	12 (12.5)	3 (3.1)	2 (2.1)	6 (6.3)	1 (1.0)
International normalised ratio increased	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Gamma-glutamyltransferase increased	1 (1.0)	0	0	1 (1.0)	0
Metabolism and nutrition disorders					
-Total	57 (59.4)	8 (8.3)	18 (18.8)	24 (25.0)	7 (7.3)
Decreased appetite	35 (36.5)	12 (12.5)	9 (9.4)	12 (12.5)	2 (2.1)
Hypokalaemia	26 (27.1)	4 (4.2)	6 (6.3)	13 (13.5)	3 (3.1)
Hypophosphataemia	21 (21.9)	3 (3.1)	8 (8.3)	9 (9.4)	1 (1.0)
Hypocalcaemia	19 (19.8)	2 (2.1)	11 (11.5)	6 (6.3)	0
Hypoalbuminaemia	13 (13.5)	0	12 (12.5)	1 (1.0)	0
Hyperglycaemia	10 (10.4)	0	4 (4.2)	5 (5.2)	1 (1.0)
Hyperuricaemia	10 (10.4)	7 (7.3)	2 (2.1)	1 (1.0)	0
Hypomagnesaemia	10 (10.4)	7 (7.3)	3 (3.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	43 (44.8)	18 (18.8)	17 (17.7)	8 (8.3)	0

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	23 (24.0)	9 (9.4)	11 (11.5)	3 (3.1)	0
Arthralgia	16 (16.7)	8 (8.3)	7 (7.3)	1 (1.0)	0
Back pain	13 (13.5)	2 (2.1)	7 (7.3)	4 (4.2)	0
Myalgia	10 (10.4)	6 (6.3)	4 (4.2)	0	0
Nervous system disorders					
-Total	35 (36.5)	18 (18.8)	12 (12.5)	5 (5.2)	0
Headache	35 (36.5)	18 (18.8)	12 (12.5)	5 (5.2)	0
Psychiatric disorders					
-Total	17 (17.7)	4 (4.2)	10 (10.4)	3 (3.1)	0
Anxiety	17 (17.7)	4 (4.2)	10 (10.4)	3 (3.1)	0
Renal and urinary disorders					
-Total	15 (15.6)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Acute kidney injury	15 (15.6)	5 (5.2)	2 (2.1)	3 (3.1)	5 (5.2)
Respiratory, thoracic and mediastinal disorders					
-Total	59 (61.5)	19 (19.8)	8 (8.3)	15 (15.6)	17 (17.7)
Cough	26 (27.1)	21 (21.9)	5 (5.2)	0	0
Hypoxia	22 (22.9)	0	6 (6.3)	10 (10.4)	6 (6.3)

BCR-ABL1-like: No

	All patients N=96				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	14 (14.6)	3 (3.1)	3 (3.1)	6 (6.3)	2 (2.1)
Epistaxis	12 (12.5)	7 (7.3)	2 (2.1)	3 (3.1)	0
Nasal congestion	11 (11.5)	9 (9.4)	2 (2.1)	0	0
Tachypnoea	11 (11.5)	3 (3.1)	2 (2.1)	5 (5.2)	1 (1.0)
Oropharyngeal pain	10 (10.4)	8 (8.3)	2 (2.1)	0	0
Pleural effusion	10 (10.4)	4 (4.2)	3 (3.1)	2 (2.1)	1 (1.0)
Respiratory failure	10 (10.4)	0	0	0	10 (10.4)
Skin and subcutaneous tissue disorders					
-Total	20 (20.8)	11 (11.5)	9 (9.4)	0	0
Pruritus	12 (12.5)	6 (6.3)	6 (6.3)	0	0
Rash	11 (11.5)	6 (6.3)	5 (5.2)	0	0
Vascular disorders					
-Total	44 (45.8)	7 (7.3)	12 (12.5)	15 (15.6)	10 (10.4)
Hypotension	31 (32.3)	3 (3.1)	6 (6.3)	12 (12.5)	10 (10.4)
Hypertension	24 (25.0)	6 (6.3)	13 (13.5)	5 (5.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (100)	0	2 (6.7)	6 (20.0)	22 (73.3)
Blood and lymphatic system disorders					
-Total	21 (70.0)	1 (3.3)	3 (10.0)	10 (33.3)	7 (23.3)
Anaemia	14 (46.7)	3 (10.0)	5 (16.7)	6 (20.0)	0
Febrile neutropenia	10 (33.3)	0	0	10 (33.3)	0
Neutropenia	8 (26.7)	1 (3.3)	1 (3.3)	1 (3.3)	5 (16.7)
Thrombocytopenia	5 (16.7)	1 (3.3)	0	1 (3.3)	3 (10.0)
Disseminated intravascular coagulation	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Cardiac disorders					
-Total	6 (20.0)	2 (6.7)	1 (3.3)	2 (6.7)	1 (3.3)
Tachycardia	6 (20.0)	2 (6.7)	1 (3.3)	2 (6.7)	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Eyelid oedema	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Gastrointestinal disorders					
-Total	24 (80.0)	7 (23.3)	11 (36.7)	6 (20.0)	0
Diarrhoea	12 (40.0)	7 (23.3)	3 (10.0)	2 (6.7)	0
Nausea	11 (36.7)	5 (16.7)	5 (16.7)	1 (3.3)	0
Abdominal pain	10 (33.3)	2 (6.7)	7 (23.3)	1 (3.3)	0
Vomiting	8 (26.7)	7 (23.3)	1 (3.3)	0	0
Constipation	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Pancreatitis	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Stomatitis	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Abdominal pain upper	3 (10.0)	2 (6.7)	1 (3.3)	0	0
General disorders and administration site conditions					
-Total	18 (60.0)	8 (26.7)	7 (23.3)	2 (6.7)	1 (3.3)
Pyrexia	16 (53.3)	6 (20.0)	7 (23.3)	2 (6.7)	1 (3.3)
Fatigue	8 (26.7)	6 (20.0)	2 (6.7)	0	0
Oedema peripheral	4 (13.3)	4 (13.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Pain	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Hepatobiliary disorders					
-Total	8 (26.7)	1 (3.3)	2 (6.7)	4 (13.3)	1 (3.3)
Hepatic function abnormal	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hyperbilirubinaemia	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Hypertransaminasaemia	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Immune system disorders					
-Total	23 (76.7)	0	5 (16.7)	9 (30.0)	9 (30.0)
Cytokine release syndrome	20 (66.7)	0	3 (10.0)	8 (26.7)	9 (30.0)
Hypogammaglobulinaemia	12 (40.0)	1 (3.3)	8 (26.7)	3 (10.0)	0
Haemophagocytic lymphohistiocytosis	4 (13.3)	1 (3.3)	1 (3.3)	1 (3.3)	1 (3.3)
Infections and infestations					
-Total	20 (66.7)	1 (3.3)	6 (20.0)	9 (30.0)	4 (13.3)
Conjunctivitis	5 (16.7)	1 (3.3)	4 (13.3)	0	0
Pneumonia	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Nasopharyngitis	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Staphylococcal infection	4 (13.3)	0	1 (3.3)	2 (6.7)	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	3 (10.0)	0	0	3 (10.0)	0
Nail infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Paronychia	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	3 (10.0)	0	3 (10.0)	0	0
Sinusitis	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Staphylococcal sepsis	3 (10.0)	0	0	0	3 (10.0)
Upper respiratory tract infection	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications					
-Total	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Procedural pain	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Investigations					
-Total	22 (73.3)	1 (3.3)	0	6 (20.0)	15 (50.0)
Neutrophil count decreased	11 (36.7)	1 (3.3)	1 (3.3)	0	9 (30.0)
Platelet count decreased	11 (36.7)	2 (6.7)	1 (3.3)	2 (6.7)	6 (20.0)
White blood cell count decreased	11 (36.7)	2 (6.7)	1 (3.3)	1 (3.3)	7 (23.3)
Alanine aminotransferase increased	8 (26.7)	2 (6.7)	3 (10.0)	3 (10.0)	0
Aspartate aminotransferase increased	8 (26.7)	0	5 (16.7)	2 (6.7)	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (26.7)	1 (3.3)	1 (3.3)	3 (10.0)	3 (10.0)
Blood fibrinogen decreased	6 (20.0)	2 (6.7)	3 (10.0)	0	1 (3.3)
Serum ferritin increased	5 (16.7)	0	5 (16.7)	0	0
Blood bilirubin increased	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Electrocardiogram qt prolonged	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Activated partial thromboplastin time prolonged	3 (10.0)	3 (10.0)	0	0	0
Blood creatinine increased	3 (10.0)	1 (3.3)	1 (3.3)	0	1 (3.3)
Blood immunoglobulin m decreased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Blood lactate dehydrogenase increased	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Blood uric acid increased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
C-reactive protein increased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
International normalised ratio increased	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Metabolism and nutrition disorders					
-Total	20 (66.7)	4 (13.3)	3 (10.0)	10 (33.3)	3 (10.0)
Hypokalaemia	13 (43.3)	2 (6.7)	2 (6.7)	8 (26.7)	1 (3.3)
Decreased appetite	9 (30.0)	5 (16.7)	0	4 (13.3)	0
Hypophosphataemia	7 (23.3)	2 (6.7)	2 (6.7)	2 (6.7)	1 (3.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	5 (16.7)	0	5 (16.7)	0	0
Hypocalcaemia	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hyperuricaemia	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Tumour lysis syndrome	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hypervolaemia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Hypomagnesaemia	2 (6.7)	2 (6.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (46.7)	8 (26.7)	6 (20.0)	0	0
Pain in extremity	10 (33.3)	5 (16.7)	5 (16.7)	0	0
Arthralgia	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Myalgia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Back pain	1 (3.3)	0	1 (3.3)	0	0
Nervous system disorders					
-Total	12 (40.0)	6 (20.0)	3 (10.0)	3 (10.0)	0
Headache	10 (33.3)	5 (16.7)	4 (13.3)	1 (3.3)	0
Dizziness	3 (10.0)	3 (10.0)	0	0	0
Encephalopathy	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Tremor	3 (10.0)	2 (6.7)	1 (3.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	11 (36.7)	4 (13.3)	4 (13.3)	3 (10.0)	0
Anxiety	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Mental status changes	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Delirium	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Insomnia	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Renal and urinary disorders					
-Total	8 (26.7)	3 (10.0)	0	1 (3.3)	4 (13.3)
Acute kidney injury	8 (26.7)	3 (10.0)	0	1 (3.3)	4 (13.3)
Respiratory, thoracic and mediastinal disorders					
-Total	22 (73.3)	9 (30.0)	2 (6.7)	3 (10.0)	8 (26.7)
Hypoxia	9 (30.0)	0	1 (3.3)	4 (13.3)	4 (13.3)
Cough	7 (23.3)	6 (20.0)	1 (3.3)	0	0
Pleural effusion	5 (16.7)	3 (10.0)	1 (3.3)	1 (3.3)	0
Pulmonary oedema	5 (16.7)	2 (6.7)	1 (3.3)	1 (3.3)	1 (3.3)
Oropharyngeal pain	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Tachypnoea	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Atelectasis	3 (10.0)	0	0	3 (10.0)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	3 (10.0)	1 (3.3)	1 (3.3)	0	1 (3.3)
Epistaxis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Respiratory failure	3 (10.0)	0	0	0	3 (10.0)
Nasal congestion	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (40.0)	5 (16.7)	6 (20.0)	1 (3.3)	0
Pruritus	5 (16.7)	2 (6.7)	3 (10.0)	0	0
Dry skin	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Rash	4 (13.3)	0	4 (13.3)	0	0
Skin ulcer	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Vascular disorders					
-Total	15 (50.0)	2 (6.7)	5 (16.7)	3 (10.0)	5 (16.7)
Hypotension	10 (33.3)	1 (3.3)	2 (6.7)	2 (6.7)	5 (16.7)
Hypertension	9 (30.0)	2 (6.7)	5 (16.7)	2 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=68			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (95.6)	0	1 (1.5)	18 (26.5)	46 (67.6)
Blood and lymphatic system disorders					
-Total	48 (70.6)	0	2 (2.9)	29 (42.6)	17 (25.0)
Febrile neutropenia	35 (51.5)	0	0	32 (47.1)	3 (4.4)
Anaemia	32 (47.1)	3 (4.4)	7 (10.3)	21 (30.9)	1 (1.5)
Neutropenia	14 (20.6)	0	1 (1.5)	2 (2.9)	11 (16.2)
Thrombocytopenia	10 (14.7)	0	1 (1.5)	4 (5.9)	5 (7.4)
Disseminated intravascular coagulation	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Cardiac disorders					
-Total	17 (25.0)	6 (8.8)	8 (11.8)	3 (4.4)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	17 (25.0)	6 (8.8)	8 (11.8)	3 (4.4)	0
Endocrine disorders					
-Total	8 (11.8)	0	7 (10.3)	1 (1.5)	0
Adrenal insufficiency	8 (11.8)	0	7 (10.3)	1 (1.5)	0
Eye disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Eyelid oedema	1 (1.5)	1 (1.5)	0	0	0
Gastrointestinal disorders					
-Total	48 (70.6)	15 (22.1)	21 (30.9)	12 (17.6)	0
Nausea	26 (38.2)	9 (13.2)	14 (20.6)	3 (4.4)	0
Vomiting	23 (33.8)	14 (20.6)	7 (10.3)	2 (2.9)	0
Diarrhoea	18 (26.5)	10 (14.7)	7 (10.3)	1 (1.5)	0
Constipation	14 (20.6)	6 (8.8)	8 (11.8)	0	0
Abdominal pain	10 (14.7)	3 (4.4)	4 (5.9)	3 (4.4)	0
Stomatitis	9 (13.2)	1 (1.5)	2 (2.9)	6 (8.8)	0
Abdominal pain upper	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Pancreatitis	2 (2.9)	1 (1.5)	1 (1.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	44 (64.7)	18 (26.5)	14 (20.6)	11 (16.2)	1 (1.5)
Pyrexia	32 (47.1)	12 (17.6)	10 (14.7)	9 (13.2)	1 (1.5)
Fatigue	14 (20.6)	10 (14.7)	4 (5.9)	0	0
Chills	9 (13.2)	5 (7.4)	4 (5.9)	0	0
Pain	8 (11.8)	1 (1.5)	4 (5.9)	3 (4.4)	0
Face oedema	6 (8.8)	4 (5.9)	1 (1.5)	1 (1.5)	0
Oedema peripheral	6 (8.8)	3 (4.4)	2 (2.9)	1 (1.5)	0
Hepatobiliary disorders					
-Total	8 (11.8)	2 (2.9)	4 (5.9)	2 (2.9)	0
Hyperbilirubinaemia	5 (7.4)	1 (1.5)	2 (2.9)	2 (2.9)	0
Hepatic function abnormal	2 (2.9)	0	2 (2.9)	0	0
Hypertransaminasaemia	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	47 (69.1)	2 (2.9)	20 (29.4)	12 (17.6)	13 (19.1)
Cytokine release syndrome	41 (60.3)	5 (7.4)	15 (22.1)	9 (13.2)	12 (17.6)
Hypogammaglobulinaemia	29 (42.6)	1 (1.5)	22 (32.4)	6 (8.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Infections and infestations					
-Total	32 (47.1)	6 (8.8)	16 (23.5)	6 (8.8)	4 (5.9)
Upper respiratory tract infection	12 (17.6)	5 (7.4)	5 (7.4)	2 (2.9)	0
Rhinovirus infection	6 (8.8)	0	4 (5.9)	2 (2.9)	0
Sinusitis	6 (8.8)	0	4 (5.9)	2 (2.9)	0
Pneumonia	5 (7.4)	0	1 (1.5)	1 (1.5)	3 (4.4)
Conjunctivitis	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Nasopharyngitis	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Bacteraemia	3 (4.4)	0	1 (1.5)	1 (1.5)	1 (1.5)
Staphylococcal infection	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Paronychia	2 (2.9)	0	2 (2.9)	0	0
Nail infection	1 (1.5)	1 (1.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Procedural pain	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Investigations					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	42 (61.8)	0	1 (1.5)	14 (20.6)	27 (39.7)
White blood cell count decreased	24 (35.3)	1 (1.5)	2 (2.9)	0	21 (30.9)
Platelet count decreased	21 (30.9)	4 (5.9)	1 (1.5)	4 (5.9)	12 (17.6)
Neutrophil count decreased	20 (29.4)	1 (1.5)	1 (1.5)	3 (4.4)	15 (22.1)
Alanine aminotransferase increased	17 (25.0)	3 (4.4)	6 (8.8)	8 (11.8)	0
Lymphocyte count decreased	16 (23.5)	0	0	6 (8.8)	10 (14.7)
Aspartate aminotransferase increased	15 (22.1)	2 (2.9)	1 (1.5)	9 (13.2)	3 (4.4)
C-reactive protein increased	10 (14.7)	2 (2.9)	2 (2.9)	5 (7.4)	1 (1.5)
Blood bilirubin increased	9 (13.2)	0	1 (1.5)	8 (11.8)	0
International normalised ratio increased	8 (11.8)	5 (7.4)	3 (4.4)	0	0
Serum ferritin increased	8 (11.8)	2 (2.9)	1 (1.5)	4 (5.9)	1 (1.5)
Blood lactate dehydrogenase increased	5 (7.4)	2 (2.9)	0	3 (4.4)	0
Activated partial thromboplastin time prolonged	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Blood creatinine increased	4 (5.9)	1 (1.5)	0	3 (4.4)	0
Blood immunoglobulin m decreased	4 (5.9)	3 (4.4)	0	1 (1.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Electrocardiogram qt prolonged	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Metabolism and nutrition disorders					
-Total	40 (58.8)	4 (5.9)	13 (19.1)	17 (25.0)	6 (8.8)
Decreased appetite	26 (38.2)	7 (10.3)	9 (13.2)	8 (11.8)	2 (2.9)
Hypocalcaemia	14 (20.6)	1 (1.5)	9 (13.2)	4 (5.9)	0
Hypophosphataemia	14 (20.6)	1 (1.5)	6 (8.8)	7 (10.3)	0
Hypokalaemia	13 (19.1)	2 (2.9)	4 (5.9)	5 (7.4)	2 (2.9)
Hyperglycaemia	10 (14.7)	0	4 (5.9)	5 (7.4)	1 (1.5)
Hypoalbuminaemia	8 (11.8)	0	7 (10.3)	1 (1.5)	0
Hypomagnesaemia	8 (11.8)	5 (7.4)	3 (4.4)	0	0
Hyperuricaemia	7 (10.3)	5 (7.4)	1 (1.5)	1 (1.5)	0
Hypervolaemia	7 (10.3)	1 (1.5)	1 (1.5)	5 (7.4)	0
Tumour lysis syndrome	4 (5.9)	0	0	3 (4.4)	1 (1.5)
Musculoskeletal and connective tissue disorders					
-Total	29 (42.6)	10 (14.7)	11 (16.2)	8 (11.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	13 (19.1)	4 (5.9)	6 (8.8)	3 (4.4)	0
Arthralgia	12 (17.6)	6 (8.8)	5 (7.4)	1 (1.5)	0
Back pain	12 (17.6)	2 (2.9)	6 (8.8)	4 (5.9)	0
Myalgia	8 (11.8)	5 (7.4)	3 (4.4)	0	0
Nervous system disorders					
-Total	31 (45.6)	13 (19.1)	11 (16.2)	7 (10.3)	0
Headache	25 (36.8)	13 (19.1)	8 (11.8)	4 (5.9)	0
Encephalopathy	6 (8.8)	0	3 (4.4)	3 (4.4)	0
Tremor	3 (4.4)	3 (4.4)	0	0	0
Dizziness	2 (2.9)	2 (2.9)	0	0	0
Psychiatric disorders					
-Total	19 (27.9)	4 (5.9)	8 (11.8)	7 (10.3)	0
Anxiety	13 (19.1)	4 (5.9)	7 (10.3)	2 (2.9)	0
Delirium	5 (7.4)	0	2 (2.9)	3 (4.4)	0
Insomnia	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Mental status changes	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Renal and urinary disorders					
-Total	7 (10.3)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	7 (10.3)	2 (2.9)	2 (2.9)	2 (2.9)	1 (1.5)
Respiratory, thoracic and mediastinal disorders					
-Total	38 (55.9)	11 (16.2)	6 (8.8)	11 (16.2)	10 (14.7)
Cough	19 (27.9)	15 (22.1)	4 (5.9)	0	0
Hypoxia	13 (19.1)	0	5 (7.4)	6 (8.8)	2 (2.9)
Epistaxis	9 (13.2)	6 (8.8)	0	3 (4.4)	0
Nasal congestion	9 (13.2)	8 (11.8)	1 (1.5)	0	0
Pulmonary oedema	9 (13.2)	1 (1.5)	2 (2.9)	5 (7.4)	1 (1.5)
Respiratory failure	7 (10.3)	0	0	0	7 (10.3)
Tachypnoea	7 (10.3)	2 (2.9)	1 (1.5)	3 (4.4)	1 (1.5)
Dyspnoea	6 (8.8)	1 (1.5)	1 (1.5)	3 (4.4)	1 (1.5)
Oropharyngeal pain	6 (8.8)	5 (7.4)	1 (1.5)	0	0
Pleural effusion	5 (7.4)	1 (1.5)	2 (2.9)	1 (1.5)	1 (1.5)
Atelectasis	1 (1.5)	0	1 (1.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	18 (26.5)	12 (17.6)	6 (8.8)	0	0
Pruritus	7 (10.3)	4 (5.9)	3 (4.4)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	7 (10.3)	6 (8.8)	1 (1.5)	0	0
Dry skin	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Skin ulcer	1 (1.5)	0	1 (1.5)	0	0
Vascular disorders					
-Total	29 (42.6)	5 (7.4)	7 (10.3)	12 (17.6)	5 (7.4)
Hypotension	21 (30.9)	2 (2.9)	4 (5.9)	10 (14.7)	5 (7.4)
Hypertension	15 (22.1)	4 (5.9)	8 (11.8)	3 (4.4)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	1 (3.1)	8 (25.0)	23 (71.9)
Blood and lymphatic system disorders					
-Total	24 (75.0)	0	0	13 (40.6)	11 (34.4)
Febrile neutropenia	15 (46.9)	0	0	14 (43.8)	1 (3.1)
Anaemia	14 (43.8)	1 (3.1)	2 (6.3)	11 (34.4)	0
Neutropenia	12 (37.5)	0	1 (3.1)	2 (6.3)	9 (28.1)
Thrombocytopenia	4 (12.5)	0	0	2 (6.3)	2 (6.3)
Disseminated intravascular coagulation	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Leukopenia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Cardiac disorders					

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	1 (3.1)	0	0	0
Tachycardia	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	23 (71.9)	6 (18.8)	9 (28.1)	8 (25.0)	0
Abdominal pain	9 (28.1)	2 (6.3)	6 (18.8)	1 (3.1)	0
Diarrhoea	9 (28.1)	3 (9.4)	4 (12.5)	2 (6.3)	0
Vomiting	9 (28.1)	7 (21.9)	2 (6.3)	0	0
Nausea	8 (25.0)	1 (3.1)	5 (15.6)	2 (6.3)	0
Constipation	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Abdominal pain upper	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Stomatitis	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Pancreatitis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
General disorders and administration site conditions					
-Total	19 (59.4)	9 (28.1)	6 (18.8)	4 (12.5)	0
Pyrexia	14 (43.8)	7 (21.9)	5 (15.6)	2 (6.3)	0
Oedema peripheral	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Face oedema	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Catheter site pain	2 (6.3)	2 (6.3)	0	0	0
Fatigue	2 (6.3)	2 (6.3)	0	0	0
Influenza like illness	1 (3.1)	0	1 (3.1)	0	0
Hepatobiliary disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Hyperbilirubinaemia	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	22 (68.8)	0	5 (15.6)	9 (28.1)	8 (25.0)
Cytokine release syndrome	19 (59.4)	0	6 (18.8)	5 (15.6)	8 (25.0)
Hypogammaglobulinaemia	15 (46.9)	1 (3.1)	8 (25.0)	6 (18.8)	0
Immunodeficiency	4 (12.5)	0	0	4 (12.5)	0
Infections and infestations					
-Total	23 (71.9)	4 (12.5)	5 (15.6)	10 (31.3)	4 (12.5)
Nasopharyngitis	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Pneumonia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Conjunctivitis	5 (15.6)	1 (3.1)	4 (12.5)	0	0
Gastroenteritis	5 (15.6)	2 (6.3)	1 (3.1)	2 (6.3)	0

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Herpes zoster	4 (12.5)	0	0	4 (12.5)	0
Respiratory tract infection	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Parainfluenzae virus infection	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Upper respiratory tract infection	3 (9.4)	3 (9.4)	0	0	0
Bacteraemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Rhinovirus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Encephalitis viral	1 (3.1)	0	0	1 (3.1)	0
Otitis media	1 (3.1)	0	1 (3.1)	0	0
Sinusitis	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal skin infection	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	19 (59.4)	0	0	5 (15.6)	14 (43.8)
White blood cell count decreased	12 (37.5)	0	0	0	12 (37.5)
Lymphocyte count decreased	11 (34.4)	0	0	1 (3.1)	10 (31.3)
Neutrophil count decreased	10 (31.3)	1 (3.1)	0	0	9 (28.1)

Region: Europe

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (31.3)	2 (6.3)	0	1 (3.1)	7 (21.9)
C-reactive protein increased	5 (15.6)	0	1 (3.1)	4 (12.5)	0
Alanine aminotransferase increased	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Aspartate aminotransferase increased	1 (3.1)	0	0	1 (3.1)	0
Blood bilirubin increased	1 (3.1)	0	0	1 (3.1)	0
Blood fibrinogen decreased	1 (3.1)	0	0	0	1 (3.1)
Blood lactate dehydrogenase increased	1 (3.1)	0	1 (3.1)	0	0
Serum ferritin increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	15 (46.9)	2 (6.3)	2 (6.3)	7 (21.9)	4 (12.5)
Hypokalaemia	8 (25.0)	1 (3.1)	1 (3.1)	5 (15.6)	1 (3.1)
Decreased appetite	5 (15.6)	2 (6.3)	1 (3.1)	1 (3.1)	1 (3.1)
Hypophosphataemia	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Hyperglycaemia	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Hypomagnesaemia	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Hypocalcaemia	2 (6.3)	0	0	2 (6.3)	0
Tumour lysis syndrome	2 (6.3)	0	0	1 (3.1)	1 (3.1)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperuricaemia	1 (3.1)	0	1 (3.1)	0	0
Hypoalbuminaemia	1 (3.1)	0	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (37.5)	5 (15.6)	6 (18.8)	1 (3.1)	0
Back pain	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Pain in extremity	6 (18.8)	1 (3.1)	5 (15.6)	0	0
Arthralgia	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Myalgia	1 (3.1)	1 (3.1)	0	0	0
Nervous system disorders					
-Total	18 (56.3)	7 (21.9)	6 (18.8)	5 (15.6)	0
Headache	13 (40.6)	8 (25.0)	4 (12.5)	1 (3.1)	0
Encephalopathy	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Seizure	2 (6.3)	0	0	2 (6.3)	0
Psychiatric disorders					
-Total	6 (18.8)	1 (3.1)	4 (12.5)	1 (3.1)	0
Anxiety	6 (18.8)	1 (3.1)	4 (12.5)	1 (3.1)	0
Agitation	1 (3.1)	1 (3.1)	0	0	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	18 (56.3)	8 (25.0)	5 (15.6)	3 (9.4)	2 (6.3)
Cough	10 (31.3)	8 (25.0)	2 (6.3)	0	0
Hypoxia	4 (12.5)	0	4 (12.5)	0	0
Pulmonary oedema	4 (12.5)	1 (3.1)	0	3 (9.4)	0
Oropharyngeal pain	3 (9.4)	3 (9.4)	0	0	0
Epistaxis	2 (6.3)	2 (6.3)	0	0	0
Pleural effusion	2 (6.3)	0	2 (6.3)	0	0
Dyspnoea	1 (3.1)	0	0	0	1 (3.1)
Respiratory failure	1 (3.1)	0	0	0	1 (3.1)
Tachypnoea	1 (3.1)	0	0	0	1 (3.1)
Skin and subcutaneous tissue disorders					
-Total	7 (21.9)	1 (3.1)	6 (18.8)	0	0
Pruritus	3 (9.4)	0	3 (9.4)	0	0
Rash	3 (9.4)	0	3 (9.4)	0	0
Dry skin	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Skin ulcer	1 (3.1)	0	1 (3.1)	0	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	9 (28.1)	3 (9.4)	3 (9.4)	3 (9.4)	0
Hypotension	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Hypertension	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	0	3 (5.3)	14 (24.6)	39 (68.4)
Blood and lymphatic system disorders					
-Total	39 (68.4)	1 (1.8)	3 (5.3)	24 (42.1)	11 (19.3)
Anaemia	31 (54.4)	5 (8.8)	9 (15.8)	16 (28.1)	1 (1.8)
Febrile neutropenia	29 (50.9)	0	0	27 (47.4)	2 (3.5)
Thrombocytopenia	10 (17.5)	1 (1.8)	1 (1.8)	3 (5.3)	5 (8.8)
Neutropenia	7 (12.3)	1 (1.8)	1 (1.8)	1 (1.8)	4 (7.0)
Disseminated intravascular coagulation	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Leukopenia	2 (3.5)	0	0	0	2 (3.5)
Cardiac disorders					

Region: US

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (42.1)	7 (12.3)	8 (14.0)	7 (12.3)	2 (3.5)
Tachycardia	22 (38.6)	7 (12.3)	9 (15.8)	5 (8.8)	1 (1.8)
Cardiac failure	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Gastrointestinal disorders					
-Total	43 (75.4)	12 (21.1)	21 (36.8)	10 (17.5)	0
Nausea	27 (47.4)	11 (19.3)	14 (24.6)	2 (3.5)	0
Vomiting	22 (38.6)	14 (24.6)	6 (10.5)	2 (3.5)	0
Diarrhoea	20 (35.1)	14 (24.6)	5 (8.8)	1 (1.8)	0
Constipation	12 (21.1)	6 (10.5)	6 (10.5)	0	0
Abdominal pain	10 (17.5)	2 (3.5)	5 (8.8)	3 (5.3)	0
Stomatitis	8 (14.0)	0	3 (5.3)	5 (8.8)	0
Pancreatitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Abdominal pain upper	1 (1.8)	1 (1.8)	0	0	0
Trichoglossia	1 (1.8)	0	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	44 (77.2)	17 (29.8)	16 (28.1)	9 (15.8)	2 (3.5)
Pyrexia	33 (57.9)	10 (17.5)	12 (21.1)	9 (15.8)	2 (3.5)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fatigue	19 (33.3)	14 (24.6)	5 (8.8)	0	0
Chills	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Pain	7 (12.3)	0	5 (8.8)	2 (3.5)	0
Catheter site pain	6 (10.5)	1 (1.8)	4 (7.0)	1 (1.8)	0
Oedema peripheral	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Face oedema	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Hepatobiliary disorders					
-Total	8 (14.0)	1 (1.8)	4 (7.0)	3 (5.3)	0
Hyperbilirubinaemia	7 (12.3)	1 (1.8)	3 (5.3)	3 (5.3)	0
Hepatic function abnormal	1 (1.8)	0	1 (1.8)	0	0
Immune system disorders					
-Total	42 (73.7)	2 (3.5)	18 (31.6)	12 (21.1)	10 (17.5)
Cytokine release syndrome	36 (63.2)	4 (7.0)	12 (21.1)	10 (17.5)	10 (17.5)
Hypogammaglobulinaemia	22 (38.6)	1 (1.8)	18 (31.6)	3 (5.3)	0
Infections and infestations					
-Total	28 (49.1)	1 (1.8)	11 (19.3)	15 (26.3)	1 (1.8)
Upper respiratory tract infection	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0
Sinusitis	7 (12.3)	0	5 (8.8)	2 (3.5)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	7 (12.3)	0	0	7 (12.3)	0
Rhinovirus infection	6 (10.5)	0	6 (10.5)	0	0
Conjunctivitis	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Bacteraemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Otitis media	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Parainfluenzae virus infection	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Pneumonia	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Gastroenteritis	2 (3.5)	2 (3.5)	0	0	0
Otitis externa	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Urinary tract infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bk virus infection	1 (1.8)	0	0	1 (1.8)	0
Herpes zoster	1 (1.8)	0	1 (1.8)	0	0
Tinea pedis	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	40 (70.2)	1 (1.8)	1 (1.8)	15 (26.3)	23 (40.4)
Alanine aminotransferase increased	22 (38.6)	4 (7.0)	9 (15.8)	9 (15.8)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	22 (38.6)	2 (3.5)	6 (10.5)	10 (17.5)	4 (7.0)
Platelet count decreased	20 (35.1)	4 (7.0)	2 (3.5)	4 (7.0)	10 (17.5)
White blood cell count decreased	19 (33.3)	3 (5.3)	3 (5.3)	1 (1.8)	12 (21.1)
Neutrophil count decreased	18 (31.6)	1 (1.8)	2 (3.5)	3 (5.3)	12 (21.1)
Lymphocyte count decreased	13 (22.8)	1 (1.8)	1 (1.8)	8 (14.0)	3 (5.3)
Blood bilirubin increased	12 (21.1)	1 (1.8)	2 (3.5)	9 (15.8)	0
International normalised ratio increased	10 (17.5)	6 (10.5)	4 (7.0)	0	0
Serum ferritin increased	9 (15.8)	1 (1.8)	3 (5.3)	4 (7.0)	1 (1.8)
Activated partial thromboplastin time prolonged	7 (12.3)	4 (7.0)	2 (3.5)	1 (1.8)	0
Blood creatinine increased	7 (12.3)	2 (3.5)	1 (1.8)	3 (5.3)	1 (1.8)
Blood immunoglobulin a decreased	7 (12.3)	5 (8.8)	1 (1.8)	1 (1.8)	0
Blood immunoglobulin m decreased	7 (12.3)	4 (7.0)	1 (1.8)	2 (3.5)	0
Blood lactate dehydrogenase increased	7 (12.3)	3 (5.3)	1 (1.8)	3 (5.3)	0
C-reactive protein increased	7 (12.3)	3 (5.3)	1 (1.8)	2 (3.5)	1 (1.8)
Electrocardiogram qt prolonged	6 (10.5)	2 (3.5)	2 (3.5)	1 (1.8)	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Weight increased	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Blood fibrinogen decreased	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)	0
Blood creatine phosphokinase increased	1 (1.8)	0	0	0	1 (1.8)
Metabolism and nutrition disorders					
-Total	44 (77.2)	6 (10.5)	12 (21.1)	19 (33.3)	7 (12.3)
Decreased appetite	30 (52.6)	10 (17.5)	8 (14.0)	11 (19.3)	1 (1.8)
Hypokalaemia	18 (31.6)	3 (5.3)	5 (8.8)	8 (14.0)	2 (3.5)
Hypocalcaemia	17 (29.8)	2 (3.5)	11 (19.3)	4 (7.0)	0
Hypophosphataemia	17 (29.8)	3 (5.3)	7 (12.3)	7 (12.3)	0
Hypoalbuminaemia	11 (19.3)	0	10 (17.5)	1 (1.8)	0
Hyperuricaemia	9 (15.8)	7 (12.3)	1 (1.8)	1 (1.8)	0
Hypervolaemia	9 (15.8)	1 (1.8)	2 (3.5)	6 (10.5)	0
Hyperglycaemia	7 (12.3)	0	3 (5.3)	3 (5.3)	1 (1.8)
Hypomagnesaemia	7 (12.3)	5 (8.8)	2 (3.5)	0	0
Hyperphosphataemia	6 (10.5)	5 (8.8)	0	0	1 (1.8)
Metabolic acidosis	5 (8.8)	1 (1.8)	0	2 (3.5)	2 (3.5)
Tumour lysis syndrome	3 (5.3)	0	0	2 (3.5)	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	28 (49.1)	11 (19.3)	10 (17.5)	7 (12.3)	0
Pain in extremity	15 (26.3)	7 (12.3)	5 (8.8)	3 (5.3)	0
Arthralgia	10 (17.5)	4 (7.0)	5 (8.8)	1 (1.8)	0
Myalgia	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Back pain	7 (12.3)	0	4 (7.0)	3 (5.3)	0
Nervous system disorders					
-Total	23 (40.4)	7 (12.3)	8 (14.0)	8 (14.0)	0
Headache	20 (35.1)	8 (14.0)	8 (14.0)	4 (7.0)	0
Somnolence	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Encephalopathy	5 (8.8)	1 (1.8)	1 (1.8)	3 (5.3)	0
Seizure	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Psychiatric disorders					
-Total	23 (40.4)	6 (10.5)	8 (14.0)	9 (15.8)	0
Anxiety	10 (17.5)	2 (3.5)	6 (10.5)	2 (3.5)	0
Delirium	8 (14.0)	2 (3.5)	3 (5.3)	3 (5.3)	0
Mental status changes	7 (12.3)	1 (1.8)	2 (3.5)	4 (7.0)	0

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Renal and urinary disorders					
-Total	14 (24.6)	5 (8.8)	2 (3.5)	4 (7.0)	3 (5.3)
Acute kidney injury	13 (22.8)	5 (8.8)	2 (3.5)	3 (5.3)	3 (5.3)
Haematuria	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (63.2)	10 (17.5)	2 (3.5)	11 (19.3)	13 (22.8)
Cough	16 (28.1)	13 (22.8)	3 (5.3)	0	0
Hypoxia	15 (26.3)	0	2 (3.5)	10 (17.5)	3 (5.3)
Nasal congestion	11 (19.3)	9 (15.8)	2 (3.5)	0	0
Pulmonary oedema	10 (17.5)	2 (3.5)	3 (5.3)	3 (5.3)	2 (3.5)
Tachypnoea	10 (17.5)	3 (5.3)	2 (3.5)	5 (8.8)	0
Epistaxis	9 (15.8)	4 (7.0)	2 (3.5)	3 (5.3)	0
Respiratory failure	9 (15.8)	0	0	0	9 (15.8)
Dyspnoea	8 (14.0)	2 (3.5)	2 (3.5)	3 (5.3)	1 (1.8)
Oropharyngeal pain	6 (10.5)	4 (7.0)	2 (3.5)	0	0
Pleural effusion	6 (10.5)	3 (5.3)	0	2 (3.5)	1 (1.8)

Region: US

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinorrhoea	6 (10.5)	4 (7.0)	2 (3.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (35.1)	14 (24.6)	5 (8.8)	1 (1.8)	0
Rash	8 (14.0)	6 (10.5)	2 (3.5)	0	0
Pruritus	7 (12.3)	4 (7.0)	3 (5.3)	0	0
Dry skin	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Skin ulcer	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Vascular disorders					
-Total	33 (57.9)	4 (7.0)	8 (14.0)	12 (21.1)	9 (15.8)
Hypotension	25 (43.9)	1 (1.8)	4 (7.0)	11 (19.3)	9 (15.8)
Hypertension	19 (33.3)	5 (8.8)	11 (19.3)	3 (5.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	1 (11.1)	1 (11.1)	7 (77.8)
Blood and lymphatic system disorders					
-Total	6 (66.7)	0	2 (22.2)	0	4 (44.4)
Neutropenia	3 (33.3)	0	0	0	3 (33.3)
Disseminated intravascular coagulation	2 (22.2)	0	2 (22.2)	0	0
Anaemia	1 (11.1)	0	1 (11.1)	0	0
B-cell aplasia	1 (11.1)	0	1 (11.1)	0	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Hypofibrinogenaemia	1 (11.1)	0	1 (11.1)	0	0
Leukopenia	1 (11.1)	0	0	0	1 (11.1)

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	3 (33.3)	2 (22.2)	0	0	1 (11.1)
Cardiac dysfunction	2 (22.2)	2 (22.2)	0	0	0
Cardiac failure	1 (11.1)	0	0	0	1 (11.1)
Gastrointestinal disorders					
-Total	7 (77.8)	2 (22.2)	4 (44.4)	1 (11.1)	0
Constipation	2 (22.2)	2 (22.2)	0	0	0
Nausea	2 (22.2)	2 (22.2)	0	0	0
Pancreatitis	2 (22.2)	0	2 (22.2)	0	0
Abdominal pain	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	0	1 (11.1)	0	0
Duodenal perforation	1 (11.1)	0	0	1 (11.1)	0
Enteritis	1 (11.1)	0	1 (11.1)	0	0
Enterocolitis	1 (11.1)	0	1 (11.1)	0	0
Gastritis	1 (11.1)	0	1 (11.1)	0	0
Haemorrhoids	1 (11.1)	0	1 (11.1)	0	0
Stomatitis	1 (11.1)	1 (11.1)	0	0	0

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Trichoglossia	1 (11.1)	1 (11.1)	0	0	0
General disorders and administration site conditions					
-Total	1 (11.1)	0	1 (11.1)	0	0
Face oedema	1 (11.1)	1 (11.1)	0	0	0
Fatigue	1 (11.1)	0	1 (11.1)	0	0
Influenza like illness	1 (11.1)	1 (11.1)	0	0	0
Pain	1 (11.1)	1 (11.1)	0	0	0
Pyrexia	1 (11.1)	1 (11.1)	0	0	0
Hepatobiliary disorders					
-Total	4 (44.4)	0	1 (11.1)	2 (22.2)	1 (11.1)
Hepatic function abnormal	4 (44.4)	0	1 (11.1)	2 (22.2)	1 (11.1)
Immune system disorders					
-Total	7 (77.8)	0	2 (22.2)	2 (22.2)	3 (33.3)
Cytokine release syndrome	6 (66.7)	1 (11.1)	0	2 (22.2)	3 (33.3)
Hypogammaglobulinaemia	4 (44.4)	0	4 (44.4)	0	0
Infections and infestations					
-Total	9 (100)	3 (33.3)	1 (11.1)	4 (44.4)	1 (11.1)

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (22.2)	0	0	2 (22.2)	0
Bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Bk virus infection	1 (11.1)	1 (11.1)	0	0	0
Encephalitis viral	1 (11.1)	0	0	0	1 (11.1)
Epstein-barr virus infection	1 (11.1)	0	1 (11.1)	0	0
Meningitis bacterial	1 (11.1)	0	0	1 (11.1)	0
Nasopharyngitis	1 (11.1)	1 (11.1)	0	0	0
Otitis externa	1 (11.1)	0	1 (11.1)	0	0
Otitis media	1 (11.1)	0	1 (11.1)	0	0
Parainfluenzae virus infection	1 (11.1)	0	0	1 (11.1)	0
Peritonitis	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	1 (11.1)	0
Respiratory syncytial virus infection	1 (11.1)	0	0	1 (11.1)	0
Rhinovirus infection	1 (11.1)	0	0	1 (11.1)	0
Sinusitis	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal skin infection	1 (11.1)	0	0	1 (11.1)	0
Tinea pedis	1 (11.1)	1 (11.1)	0	0	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection viral	1 (11.1)	1 (11.1)	0	0	0
Investigations					
-Total	5 (55.6)	0	0	0	5 (55.6)
White blood cell count decreased	4 (44.4)	0	0	0	4 (44.4)
Neutrophil count decreased	3 (33.3)	0	0	0	3 (33.3)
Serum ferritin increased	3 (33.3)	0	3 (33.3)	0	0
Blood fibrinogen decreased	2 (22.2)	0	2 (22.2)	0	0
Platelet count decreased	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Blood creatine phosphokinase increased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Tumour lysis syndrome	2 (22.2)	0	0	2 (22.2)	0
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)	0	0
Metabolic acidosis	1 (11.1)	0	0	0	1 (11.1)
Musculoskeletal and connective tissue disorders					
-Total	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Pain in extremity	2 (22.2)	1 (11.1)	1 (11.1)	0	0

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (11.1)	1 (11.1)	0	0	0
Nervous system disorders					
-Total	4 (44.4)	2 (22.2)	1 (11.1)	0	1 (11.1)
Headache	2 (22.2)	2 (22.2)	0	0	0
Haemorrhage intracranial	1 (11.1)	0	0	0	1 (11.1)
Seizure	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Anxiety	1 (11.1)	1 (11.1)	0	0	0
Renal and urinary disorders					
-Total	4 (44.4)	1 (11.1)	1 (11.1)	0	2 (22.2)
Acute kidney injury	2 (22.2)	0	0	0	2 (22.2)
Cystitis haemorrhagic	1 (11.1)	0	1 (11.1)	0	0
Haematuria	1 (11.1)	1 (11.1)	0	0	0
Proteinuria	1 (11.1)	1 (11.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0

Region: Rest of World

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Heavy menstrual bleeding	1 (11.1)	0	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (66.7)	1 (11.1)	2 (22.2)	0	3 (33.3)
Hypoxia	3 (33.3)	0	0	0	3 (33.3)
Pleural effusion	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Epistaxis	1 (11.1)	1 (11.1)	0	0	0
Oropharyngeal pain	1 (11.1)	1 (11.1)	0	0	0
Upper respiratory tract inflammation	1 (11.1)	0	1 (11.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (55.6)	4 (44.4)	1 (11.1)	0	0
Pruritus	2 (22.2)	2 (22.2)	0	0	0
Dry skin	1 (11.1)	1 (11.1)	0	0	0
Erythema nodosum	1 (11.1)	1 (11.1)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome	1 (11.1)	1 (11.1)	0	0	0
Skin swelling	1 (11.1)	1 (11.1)	0	0	0
Skin ulcer	1 (11.1)	0	1 (11.1)	0	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Hypertension	1 (11.1)	0	1 (11.1)	0	0
Hypotension	1 (11.1)	0	0	0	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (96.6)	0	3 (5.2)	16 (27.6)	37 (63.8)
Blood and lymphatic system disorders					
-Total	40 (69.0)	1 (1.7)	3 (5.2)	24 (41.4)	12 (20.7)
Febrile neutropenia	26 (44.8)	0	0	25 (43.1)	1 (1.7)
Anaemia	25 (43.1)	2 (3.4)	6 (10.3)	17 (29.3)	0
Neutropenia	13 (22.4)	0	1 (1.7)	2 (3.4)	10 (17.2)
Thrombocytopenia	8 (13.8)	0	1 (1.7)	3 (5.2)	4 (6.9)
Disseminated intravascular coagulation	4 (6.9)	0	3 (5.2)	1 (1.7)	0
Cardiac disorders					
-Total	11 (19.0)	5 (8.6)	4 (6.9)	2 (3.4)	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	11 (19.0)	5 (8.6)	4 (6.9)	2 (3.4)	0
Gastrointestinal disorders					
-Total	44 (75.9)	14 (24.1)	20 (34.5)	10 (17.2)	0
Nausea	23 (39.7)	10 (17.2)	11 (19.0)	2 (3.4)	0
Diarrhoea	22 (37.9)	11 (19.0)	8 (13.8)	3 (5.2)	0
Vomiting	20 (34.5)	13 (22.4)	7 (12.1)	0	0
Abdominal pain	14 (24.1)	4 (6.9)	7 (12.1)	3 (5.2)	0
Constipation	11 (19.0)	6 (10.3)	5 (8.6)	0	0
Abdominal pain upper	6 (10.3)	4 (6.9)	2 (3.4)	0	0
Stomatitis	6 (10.3)	0	2 (3.4)	4 (6.9)	0
General disorders and administration site conditions					
-Total	34 (58.6)	16 (27.6)	10 (17.2)	7 (12.1)	1 (1.7)
Pyrexia	26 (44.8)	12 (20.7)	7 (12.1)	6 (10.3)	1 (1.7)
Fatigue	13 (22.4)	10 (17.2)	3 (5.2)	0	0
Pain	7 (12.1)	1 (1.7)	2 (3.4)	4 (6.9)	0
Chills	6 (10.3)	4 (6.9)	2 (3.4)	0	0
Face oedema	4 (6.9)	3 (5.2)	1 (1.7)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Hepatobiliary disorders					
-Total	4 (6.9)	1 (1.7)	2 (3.4)	1 (1.7)	0
Hyperbilirubinaemia	4 (6.9)	1 (1.7)	2 (3.4)	1 (1.7)	0
Immune system disorders					
-Total	44 (75.9)	1 (1.7)	17 (29.3)	15 (25.9)	11 (19.0)
Cytokine release syndrome	37 (63.8)	3 (5.2)	11 (19.0)	12 (20.7)	11 (19.0)
Hypogammaglobulinaemia	28 (48.3)	0	21 (36.2)	7 (12.1)	0
Haemophagocytic lymphohistiocytosis	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Infections and infestations					
-Total	32 (55.2)	4 (6.9)	14 (24.1)	13 (22.4)	1 (1.7)
Upper respiratory tract infection	8 (13.8)	3 (5.2)	2 (3.4)	3 (5.2)	0
Conjunctivitis	7 (12.1)	3 (5.2)	4 (6.9)	0	0
Sinusitis	7 (12.1)	0	4 (6.9)	3 (5.2)	0
Gastroenteritis	6 (10.3)	3 (5.2)	1 (1.7)	2 (3.4)	0
Nasopharyngitis	6 (10.3)	4 (6.9)	2 (3.4)	0	0
Pneumonia	6 (10.3)	1 (1.7)	1 (1.7)	3 (5.2)	1 (1.7)

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	5 (8.6)	0	4 (6.9)	1 (1.7)	0
Staphylococcal bacteraemia	2 (3.4)	0	0	2 (3.4)	0
Staphylococcal infection	2 (3.4)	0	0	2 (3.4)	0
Investigations					
-Total	38 (65.5)	1 (1.7)	1 (1.7)	11 (19.0)	25 (43.1)
Neutrophil count decreased	22 (37.9)	2 (3.4)	1 (1.7)	1 (1.7)	18 (31.0)
Platelet count decreased	22 (37.9)	4 (6.9)	0	5 (8.6)	13 (22.4)
White blood cell count decreased	21 (36.2)	2 (3.4)	0	0	19 (32.8)
Alanine aminotransferase increased	15 (25.9)	2 (3.4)	6 (10.3)	7 (12.1)	0
Lymphocyte count decreased	15 (25.9)	0	0	4 (6.9)	11 (19.0)
Aspartate aminotransferase increased	12 (20.7)	2 (3.4)	3 (5.2)	5 (8.6)	2 (3.4)
C-reactive protein increased	8 (13.8)	2 (3.4)	1 (1.7)	5 (8.6)	0
Blood bilirubin increased	6 (10.3)	0	1 (1.7)	5 (8.6)	0
Blood immunoglobulin a decreased	6 (10.3)	5 (8.6)	0	1 (1.7)	0
Serum ferritin increased	5 (8.6)	1 (1.7)	3 (5.2)	1 (1.7)	0
Blood fibrinogen decreased	4 (6.9)	2 (3.4)	1 (1.7)	0	1 (1.7)
Blood lactate dehydrogenase increased	4 (6.9)	2 (3.4)	2 (3.4)	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (5.2)	1 (1.7)	1 (1.7)	1 (1.7)	0
Blood creatinine increased	3 (5.2)	0	1 (1.7)	2 (3.4)	0
International normalised ratio increased	3 (5.2)	3 (5.2)	0	0	0
Electrocardiogram qt prolonged	1 (1.7)	0	0	1 (1.7)	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	31 (53.4)	6 (10.3)	5 (8.6)	14 (24.1)	6 (10.3)
Decreased appetite	20 (34.5)	7 (12.1)	5 (8.6)	6 (10.3)	2 (3.4)
Hypokalaemia	16 (27.6)	3 (5.2)	2 (3.4)	9 (15.5)	2 (3.4)
Hypophosphataemia	12 (20.7)	3 (5.2)	4 (6.9)	4 (6.9)	1 (1.7)
Hypocalcaemia	7 (12.1)	2 (3.4)	2 (3.4)	3 (5.2)	0
Hypoalbuminaemia	5 (8.6)	0	5 (8.6)	0	0
Hyperglycaemia	4 (6.9)	0	1 (1.7)	2 (3.4)	1 (1.7)
Hypervolaemia	4 (6.9)	1 (1.7)	1 (1.7)	2 (3.4)	0
Hypomagnesaemia	4 (6.9)	3 (5.2)	1 (1.7)	0	0
Hyperuricaemia	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Hyperphosphataemia	1 (1.7)	1 (1.7)	0	0	0

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	27 (46.6)	11 (19.0)	12 (20.7)	4 (6.9)	0
Pain in extremity	13 (22.4)	5 (8.6)	7 (12.1)	1 (1.7)	0
Arthralgia	12 (20.7)	7 (12.1)	5 (8.6)	0	0
Back pain	10 (17.2)	2 (3.4)	5 (8.6)	3 (5.2)	0
Myalgia	5 (8.6)	3 (5.2)	2 (3.4)	0	0
Nervous system disorders					
-Total	25 (43.1)	12 (20.7)	7 (12.1)	6 (10.3)	0
Headache	20 (34.5)	11 (19.0)	5 (8.6)	4 (6.9)	0
Encephalopathy	5 (8.6)	1 (1.7)	2 (3.4)	2 (3.4)	0
Somnolence	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Psychiatric disorders					
-Total	15 (25.9)	4 (6.9)	9 (15.5)	2 (3.4)	0
Anxiety	12 (20.7)	4 (6.9)	7 (12.1)	1 (1.7)	0
Delirium	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Mental status changes	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Renal and urinary disorders					

Prior SCT therapy: Yes

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (10.3)	3 (5.2)	1 (1.7)	0	2 (3.4)
Acute kidney injury	6 (10.3)	3 (5.2)	1 (1.7)	0	2 (3.4)
Respiratory, thoracic and mediastinal disorders					
-Total	39 (67.2)	16 (27.6)	8 (13.8)	8 (13.8)	7 (12.1)
Cough	20 (34.5)	16 (27.6)	4 (6.9)	0	0
Hypoxia	12 (20.7)	0	5 (8.6)	4 (6.9)	3 (5.2)
Epistaxis	9 (15.5)	7 (12.1)	0	2 (3.4)	0
Nasal congestion	8 (13.8)	7 (12.1)	1 (1.7)	0	0
Pulmonary oedema	7 (12.1)	3 (5.2)	0	4 (6.9)	0
Pleural effusion	6 (10.3)	3 (5.2)	2 (3.4)	0	1 (1.7)
Tachypnoea	6 (10.3)	3 (5.2)	2 (3.4)	1 (1.7)	0
Dyspnoea	5 (8.6)	2 (3.4)	1 (1.7)	2 (3.4)	0
Oropharyngeal pain	4 (6.9)	4 (6.9)	0	0	0
Respiratory failure	3 (5.2)	0	0	0	3 (5.2)
Skin and subcutaneous tissue disorders					
-Total	16 (27.6)	10 (17.2)	6 (10.3)	0	0
Rash	7 (12.1)	4 (6.9)	3 (5.2)	0	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	6 (10.3)	3 (5.2)	3 (5.2)	0	0
Dry skin	5 (8.6)	3 (5.2)	2 (3.4)	0	0
Erythema	2 (3.4)	2 (3.4)	0	0	0
Vascular disorders					
-Total	23 (39.7)	7 (12.1)	7 (12.1)	5 (8.6)	4 (6.9)
Hypotension	14 (24.1)	3 (5.2)	3 (5.2)	4 (6.9)	4 (6.9)
Hypertension	13 (22.4)	5 (8.6)	7 (12.1)	1 (1.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (97.5)	0	2 (5.0)	8 (20.0)	29 (72.5)
Blood and lymphatic system disorders					
-Total	29 (72.5)	0	2 (5.0)	15 (37.5)	12 (30.0)
Anaemia	21 (52.5)	4 (10.0)	6 (15.0)	10 (25.0)	1 (2.5)
Febrile neutropenia	19 (47.5)	0	0	17 (42.5)	2 (5.0)
Neutropenia	9 (22.5)	1 (2.5)	1 (2.5)	1 (2.5)	6 (15.0)
Thrombocytopenia	7 (17.5)	1 (2.5)	0	2 (5.0)	4 (10.0)
Disseminated intravascular coagulation	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Cardiac disorders					
-Total	12 (30.0)	3 (7.5)	5 (12.5)	3 (7.5)	1 (2.5)

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	12 (30.0)	3 (7.5)	5 (12.5)	3 (7.5)	1 (2.5)
Gastrointestinal disorders					
-Total	27 (67.5)	8 (20.0)	12 (30.0)	7 (17.5)	0
Nausea	14 (35.0)	4 (10.0)	8 (20.0)	2 (5.0)	0
Vomiting	11 (27.5)	8 (20.0)	1 (2.5)	2 (5.0)	0
Constipation	9 (22.5)	4 (10.0)	5 (12.5)	0	0
Diarrhoea	8 (20.0)	6 (15.0)	2 (5.0)	0	0
Stomatitis	7 (17.5)	1 (2.5)	2 (5.0)	4 (10.0)	0
Abdominal pain	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
General disorders and administration site conditions					
-Total	28 (70.0)	10 (25.0)	11 (27.5)	6 (15.0)	1 (2.5)
Pyrexia	22 (55.0)	6 (15.0)	10 (25.0)	5 (12.5)	1 (2.5)
Fatigue	9 (22.5)	6 (15.0)	3 (7.5)	0	0
Oedema peripheral	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Face oedema	5 (12.5)	3 (7.5)	1 (2.5)	1 (2.5)	0
Pain	4 (10.0)	0	4 (10.0)	0	0
Chills	3 (7.5)	1 (2.5)	2 (5.0)	0	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hyperbilirubinaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Immune system disorders					
-Total	26 (65.0)	1 (2.5)	8 (20.0)	6 (15.0)	11 (27.5)
Cytokine release syndrome	24 (60.0)	2 (5.0)	7 (17.5)	5 (12.5)	10 (25.0)
Hypogammaglobulinaemia	13 (32.5)	2 (5.0)	9 (22.5)	2 (5.0)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Infections and infestations					
-Total	18 (45.0)	2 (5.0)	7 (17.5)	6 (15.0)	3 (7.5)
Staphylococcal bacteraemia	6 (15.0)	0	0	6 (15.0)	0
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Staphylococcal infection	5 (12.5)	0	3 (7.5)	1 (2.5)	1 (2.5)
Pneumonia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Rhinovirus infection	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Conjunctivitis	2 (5.0)	0	2 (5.0)	0	0
Nasopharyngitis	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (5.0)	0	2 (5.0)	0	0
Gastroenteritis	1 (2.5)	1 (2.5)	0	0	0
Investigations					
-Total	27 (67.5)	0	1 (2.5)	9 (22.5)	17 (42.5)
White blood cell count decreased	14 (35.0)	1 (2.5)	3 (7.5)	1 (2.5)	9 (22.5)
Aspartate aminotransferase increased	11 (27.5)	0	3 (7.5)	6 (15.0)	2 (5.0)
Alanine aminotransferase increased	10 (25.0)	3 (7.5)	3 (7.5)	4 (10.0)	0
Platelet count decreased	10 (25.0)	2 (5.0)	2 (5.0)	1 (2.5)	5 (12.5)
Lymphocyte count decreased	9 (22.5)	1 (2.5)	1 (2.5)	5 (12.5)	2 (5.0)
Neutrophil count decreased	9 (22.5)	0	1 (2.5)	2 (5.0)	6 (15.0)
Serum ferritin increased	8 (20.0)	1 (2.5)	3 (7.5)	3 (7.5)	1 (2.5)
Blood bilirubin increased	7 (17.5)	1 (2.5)	1 (2.5)	5 (12.5)	0
International normalised ratio increased	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Electrocardiogram qt prolonged	5 (12.5)	2 (5.0)	2 (5.0)	0	1 (2.5)
Activated partial thromboplastin time prolonged	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Blood creatinine increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Blood immunoglobulin g decreased	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Blood lactate dehydrogenase increased	4 (10.0)	1 (2.5)	0	3 (7.5)	0
C-reactive protein increased	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
Fibrin d dimer increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)
Blood immunoglobulin a decreased	1 (2.5)	0	1 (2.5)	0	0
Metabolism and nutrition disorders					
-Total	27 (67.5)	2 (5.0)	9 (22.5)	12 (30.0)	4 (10.0)
Decreased appetite	15 (37.5)	5 (12.5)	4 (10.0)	6 (15.0)	0
Hypocalcaemia	12 (30.0)	0	9 (22.5)	3 (7.5)	0
Hypokalaemia	10 (25.0)	1 (2.5)	4 (10.0)	4 (10.0)	1 (2.5)
Hypophosphataemia	9 (22.5)	0	4 (10.0)	5 (12.5)	0
Hypoalbuminaemia	8 (20.0)	0	7 (17.5)	1 (2.5)	0
Hyperuricaemia	7 (17.5)	5 (12.5)	1 (2.5)	1 (2.5)	0
Hyperglycaemia	6 (15.0)	0	3 (7.5)	3 (7.5)	0
Hypomagnesaemia	6 (15.0)	4 (10.0)	2 (5.0)	0	0
Metabolic acidosis	6 (15.0)	1 (2.5)	0	2 (5.0)	3 (7.5)

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	5 (12.5)	4 (10.0)	0	0	1 (2.5)
Hypervolaemia	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Musculoskeletal and connective tissue disorders					
-Total	16 (40.0)	7 (17.5)	5 (12.5)	4 (10.0)	0
Pain in extremity	10 (25.0)	4 (10.0)	4 (10.0)	2 (5.0)	0
Myalgia	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Arthralgia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Back pain	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Nervous system disorders					
-Total	17 (42.5)	5 (12.5)	8 (20.0)	4 (10.0)	0
Headache	15 (37.5)	7 (17.5)	7 (17.5)	1 (2.5)	0
Encephalopathy	4 (10.0)	0	1 (2.5)	3 (7.5)	0
Somnolence	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Psychiatric disorders					
-Total	13 (32.5)	2 (5.0)	3 (7.5)	8 (20.0)	0
Anxiety	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Delirium	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0

Prior SCT therapy: No

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Renal and urinary disorders					
-Total	9 (22.5)	2 (5.0)	1 (2.5)	3 (7.5)	3 (7.5)
Acute kidney injury	9 (22.5)	2 (5.0)	1 (2.5)	3 (7.5)	3 (7.5)
Respiratory, thoracic and mediastinal disorders					
-Total	21 (52.5)	4 (10.0)	0	6 (15.0)	11 (27.5)
Hypoxia	10 (25.0)	0	1 (2.5)	6 (15.0)	3 (7.5)
Pulmonary oedema	7 (17.5)	0	3 (7.5)	2 (5.0)	2 (5.0)
Respiratory failure	7 (17.5)	0	0	0	7 (17.5)
Cough	6 (15.0)	5 (12.5)	1 (2.5)	0	0
Oropharyngeal pain	6 (15.0)	4 (10.0)	2 (5.0)	0	0
Tachypnoea	5 (12.5)	0	0	4 (10.0)	1 (2.5)
Dyspnoea	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Pleural effusion	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Epistaxis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Nasal congestion	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Skin and subcutaneous tissue disorders					

Prior SCT therapy: No

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	13 (32.5)	8 (20.0)	5 (12.5)	0	0
Pruritus	6 (15.0)	3 (7.5)	3 (7.5)	0	0
Dry skin	4 (10.0)	4 (10.0)	0	0	0
Erythema	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Rash	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Vascular disorders					
-Total	21 (52.5)	0	5 (12.5)	10 (25.0)	6 (15.0)
Hypotension	17 (42.5)	0	3 (7.5)	8 (20.0)	6 (15.0)
Hypertension	11 (27.5)	1 (2.5)	6 (15.0)	4 (10.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (88.2)	0	1 (5.9)	7 (41.2)	7 (41.2)
Blood and lymphatic system disorders					
-Total	12 (70.6)	1 (5.9)	1 (5.9)	8 (47.1)	2 (11.8)
Febrile neutropenia	9 (52.9)	0	0	9 (52.9)	0
Anaemia	8 (47.1)	3 (17.6)	5 (29.4)	0	0
Neutropenia	2 (11.8)	0	0	0	2 (11.8)
Cardiac disorders					
-Total	6 (35.3)	6 (35.3)	0	0	0
Tachycardia	6 (35.3)	6 (35.3)	0	0	0
Eye disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	2 (11.8)	2 (11.8)	0	0	0
Gastrointestinal disorders					
-Total	11 (64.7)	5 (29.4)	3 (17.6)	3 (17.6)	0
Nausea	9 (52.9)	6 (35.3)	3 (17.6)	0	0
Vomiting	7 (41.2)	4 (23.5)	3 (17.6)	0	0
Diarrhoea	5 (29.4)	5 (29.4)	0	0	0
Abdominal pain	4 (23.5)	1 (5.9)	2 (11.8)	1 (5.9)	0
Constipation	3 (17.6)	3 (17.6)	0	0	0
Haematemesis	2 (11.8)	2 (11.8)	0	0	0
Neutropenic colitis	2 (11.8)	0	0	2 (11.8)	0
Proctalgia	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Stomatitis	2 (11.8)	1 (5.9)	0	1 (5.9)	0
General disorders and administration site conditions					
-Total	7 (41.2)	6 (35.3)	1 (5.9)	0	0
Fatigue	7 (41.2)	6 (35.3)	1 (5.9)	0	0
Pyrexia	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Oedema peripheral	1 (5.9)	1 (5.9)	0	0	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Hepatic function abnormal	2 (11.8)	0	1 (5.9)	0	1 (5.9)
Immune system disorders					
-Total	13 (76.5)	0	7 (41.2)	5 (29.4)	1 (5.9)
Cytokine release syndrome	11 (64.7)	0	5 (29.4)	5 (29.4)	1 (5.9)
Hypogammaglobulinaemia	6 (35.3)	0	6 (35.3)	0	0
Infections and infestations					
-Total	7 (41.2)	1 (5.9)	0	6 (35.3)	0
Acute sinusitis	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Catheter site infection	2 (11.8)	0	0	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	0	0	2 (11.8)	0
Tinea pedis	2 (11.8)	2 (11.8)	0	0	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Pneumonia	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	2 (11.8)	1 (5.9)	1 (5.9)	0	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Investigations					
-Total	11 (64.7)	1 (5.9)	0	4 (23.5)	6 (35.3)
Neutrophil count decreased	9 (52.9)	1 (5.9)	2 (11.8)	1 (5.9)	5 (29.4)
Platelet count decreased	9 (52.9)	4 (23.5)	1 (5.9)	4 (23.5)	0
White blood cell count decreased	9 (52.9)	2 (11.8)	2 (11.8)	0	5 (29.4)
Lymphocyte count decreased	7 (41.2)	0	1 (5.9)	4 (23.5)	2 (11.8)
Blood immunoglobulin a decreased	6 (35.3)	5 (29.4)	0	1 (5.9)	0
International normalised ratio increased	6 (35.3)	5 (29.4)	1 (5.9)	0	0
Alanine aminotransferase increased	5 (29.4)	0	3 (17.6)	2 (11.8)	0
Aspartate aminotransferase increased	5 (29.4)	0	1 (5.9)	4 (23.5)	0
Blood immunoglobulin m decreased	5 (29.4)	4 (23.5)	0	1 (5.9)	0
Blood bilirubin increased	4 (23.5)	1 (5.9)	0	3 (17.6)	0
Blood fibrinogen decreased	4 (23.5)	3 (17.6)	1 (5.9)	0	0
Activated partial thromboplastin time prolonged	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Serum ferritin increased	2 (11.8)	0	2 (11.8)	0	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	2 (11.8)	0	1 (5.9)	1 (5.9)	0
C-reactive protein increased	1 (5.9)	1 (5.9)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (52.9)	2 (11.8)	2 (11.8)	5 (29.4)	0
Decreased appetite	8 (47.1)	4 (23.5)	2 (11.8)	2 (11.8)	0
Hyperphosphataemia	3 (17.6)	3 (17.6)	0	0	0
Hypokalaemia	3 (17.6)	0	0	3 (17.6)	0
Hyperuricaemia	2 (11.8)	2 (11.8)	0	0	0
Hypophosphataemia	2 (11.8)	0	0	2 (11.8)	0
Hypoalbuminaemia	1 (5.9)	0	1 (5.9)	0	0
Hypomagnesaemia	1 (5.9)	1 (5.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (52.9)	7 (41.2)	2 (11.8)	0	0
Pain in extremity	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Myalgia	4 (23.5)	2 (11.8)	2 (11.8)	0	0
Arthralgia	3 (17.6)	3 (17.6)	0	0	0
Nervous system disorders					

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Headache	5 (29.4)	4 (23.5)	1 (5.9)	0	0
Psychiatric disorders					
-Total	5 (29.4)	3 (17.6)	1 (5.9)	1 (5.9)	0
Anxiety	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Confusional state	2 (11.8)	2 (11.8)	0	0	0
Mental status changes	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Renal and urinary disorders					
-Total	1 (5.9)	0	0	0	1 (5.9)
Acute kidney injury	1 (5.9)	0	0	0	1 (5.9)
Respiratory, thoracic and mediastinal disorders					
-Total	10 (58.8)	5 (29.4)	2 (11.8)	2 (11.8)	1 (5.9)
Cough	5 (29.4)	5 (29.4)	0	0	0
Rhinorrhoea	4 (23.5)	4 (23.5)	0	0	0
Hypoxia	3 (17.6)	0	1 (5.9)	1 (5.9)	1 (5.9)
Nasal congestion	3 (17.6)	3 (17.6)	0	0	0
Oropharyngeal pain	3 (17.6)	3 (17.6)	0	0	0

Eligibility for SCT: Yes

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Pleural effusion	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Tachypnoea	2 (11.8)	2 (11.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (35.3)	3 (17.6)	2 (11.8)	1 (5.9)	0
Dry skin	3 (17.6)	2 (11.8)	1 (5.9)	0	0
Rash papular	3 (17.6)	3 (17.6)	0	0	0
Eczema	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Pruritus	2 (11.8)	2 (11.8)	0	0	0
Skin ulcer	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Vascular disorders					
-Total	4 (23.5)	2 (11.8)	0	1 (5.9)	1 (5.9)
Hypotension	3 (17.6)	1 (5.9)	0	1 (5.9)	1 (5.9)
Hypertension	1 (5.9)	1 (5.9)	0	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	80 (98.8)	0	4 (4.9)	17 (21.0)	59 (72.8)
Blood and lymphatic system disorders					
-Total	56 (69.1)	0	3 (3.7)	31 (38.3)	22 (27.2)
Anaemia	38 (46.9)	3 (3.7)	7 (8.6)	27 (33.3)	1 (1.2)
Febrile neutropenia	36 (44.4)	0	0	33 (40.7)	3 (3.7)
Neutropenia	20 (24.7)	1 (1.2)	2 (2.5)	3 (3.7)	14 (17.3)
Thrombocytopenia	15 (18.5)	1 (1.2)	1 (1.2)	5 (6.2)	8 (9.9)
Cardiac disorders					
-Total	17 (21.0)	2 (2.5)	9 (11.1)	5 (6.2)	1 (1.2)
Tachycardia	17 (21.0)	2 (2.5)	9 (11.1)	5 (6.2)	1 (1.2)
Eye disorders					

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.2)	1 (1.2)	0	0	0
Ocular hyperaemia	1 (1.2)	1 (1.2)	0	0	0
Gastrointestinal disorders					
-Total	61 (75.3)	17 (21.0)	26 (32.1)	18 (22.2)	0
Nausea	28 (34.6)	8 (9.9)	16 (19.8)	4 (4.9)	0
Diarrhoea	25 (30.9)	12 (14.8)	10 (12.3)	3 (3.7)	0
Vomiting	24 (29.6)	17 (21.0)	5 (6.2)	2 (2.5)	0
Constipation	17 (21.0)	7 (8.6)	10 (12.3)	0	0
Abdominal pain	16 (19.8)	4 (4.9)	9 (11.1)	3 (3.7)	0
Stomatitis	11 (13.6)	0	4 (4.9)	7 (8.6)	0
Haematemesis	2 (2.5)	2 (2.5)	0	0	0
Neutropenic colitis	2 (2.5)	0	0	2 (2.5)	0
General disorders and administration site conditions					
-Total	54 (66.7)	20 (24.7)	19 (23.5)	13 (16.0)	2 (2.5)
Pyrexia	45 (55.6)	16 (19.8)	16 (19.8)	11 (13.6)	2 (2.5)
Fatigue	15 (18.5)	10 (12.3)	5 (6.2)	0	0
Pain	11 (13.6)	1 (1.2)	6 (7.4)	4 (4.9)	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	9 (11.1)	6 (7.4)	2 (2.5)	1 (1.2)	0
Oedema peripheral	9 (11.1)	6 (7.4)	2 (2.5)	1 (1.2)	0
Hepatobiliary disorders					
-Total	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Hepatic function abnormal	3 (3.7)	0	1 (1.2)	2 (2.5)	0
Immune system disorders					
-Total	57 (70.4)	2 (2.5)	19 (23.5)	16 (19.8)	20 (24.7)
Cytokine release syndrome	50 (61.7)	5 (6.2)	13 (16.0)	12 (14.8)	20 (24.7)
Hypogammaglobulinaemia	35 (43.2)	2 (2.5)	24 (29.6)	9 (11.1)	0
Infections and infestations					
-Total	29 (35.8)	3 (3.7)	13 (16.0)	10 (12.3)	3 (3.7)
Upper respiratory tract infection	12 (14.8)	4 (4.9)	6 (7.4)	2 (2.5)	0
Pneumonia	9 (11.1)	1 (1.2)	2 (2.5)	3 (3.7)	3 (3.7)
Rhinovirus infection	9 (11.1)	0	7 (8.6)	2 (2.5)	0
Staphylococcal bacteraemia	6 (7.4)	0	0	6 (7.4)	0
Acute sinusitis	2 (2.5)	0	2 (2.5)	0	0
Catheter site infection	1 (1.2)	0	1 (1.2)	0	0

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Transfusion reaction	3 (3.7)	0	2 (2.5)	1 (1.2)	0
Investigations					
-Total	53 (65.4)	0	1 (1.2)	17 (21.0)	35 (43.2)
White blood cell count decreased	26 (32.1)	1 (1.2)	1 (1.2)	1 (1.2)	23 (28.4)
Platelet count decreased	23 (28.4)	2 (2.5)	1 (1.2)	2 (2.5)	18 (22.2)
Neutrophil count decreased	22 (27.2)	1 (1.2)	0	2 (2.5)	19 (23.5)
Alanine aminotransferase increased	20 (24.7)	5 (6.2)	6 (7.4)	9 (11.1)	0
Aspartate aminotransferase increased	18 (22.2)	2 (2.5)	5 (6.2)	7 (8.6)	4 (4.9)
Lymphocyte count decreased	17 (21.0)	1 (1.2)	0	5 (6.2)	11 (13.6)
C-reactive protein increased	11 (13.6)	2 (2.5)	2 (2.5)	6 (7.4)	1 (1.2)
Serum ferritin increased	11 (13.6)	2 (2.5)	4 (4.9)	4 (4.9)	1 (1.2)
Blood bilirubin increased	9 (11.1)	0	2 (2.5)	7 (8.6)	0
Activated partial thromboplastin time prolonged	4 (4.9)	2 (2.5)	1 (1.2)	1 (1.2)	0
Blood fibrinogen decreased	4 (4.9)	0	2 (2.5)	1 (1.2)	1 (1.2)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	4 (4.9)	1 (1.2)	3 (3.7)	0	0
Weight increased	4 (4.9)	2 (2.5)	1 (1.2)	1 (1.2)	0
Blood immunoglobulin m decreased	2 (2.5)	0	1 (1.2)	1 (1.2)	0
Blood immunoglobulin a decreased	1 (1.2)	0	1 (1.2)	0	0
Metabolism and nutrition disorders					
-Total	49 (60.5)	6 (7.4)	15 (18.5)	20 (24.7)	8 (9.9)
Decreased appetite	27 (33.3)	8 (9.9)	7 (8.6)	10 (12.3)	2 (2.5)
Hypokalaemia	23 (28.4)	4 (4.9)	6 (7.4)	10 (12.3)	3 (3.7)
Hypocalcaemia	19 (23.5)	2 (2.5)	11 (13.6)	6 (7.4)	0
Hypophosphataemia	19 (23.5)	3 (3.7)	8 (9.9)	7 (8.6)	1 (1.2)
Hypoalbuminaemia	12 (14.8)	0	11 (13.6)	1 (1.2)	0
Hyperglycaemia	10 (12.3)	0	4 (4.9)	5 (6.2)	1 (1.2)
Hypervolaemia	9 (11.1)	1 (1.2)	2 (2.5)	6 (7.4)	0
Hypomagnesaemia	9 (11.1)	6 (7.4)	3 (3.7)	0	0
Hyperuricaemia	8 (9.9)	5 (6.2)	2 (2.5)	1 (1.2)	0
Hyperphosphataemia	3 (3.7)	2 (2.5)	0	0	1 (1.2)
Musculoskeletal and connective tissue disorders					

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	34 (42.0)	11 (13.6)	15 (18.5)	8 (9.9)	0
Pain in extremity	18 (22.2)	5 (6.2)	10 (12.3)	3 (3.7)	0
Arthralgia	13 (16.0)	5 (6.2)	7 (8.6)	1 (1.2)	0
Back pain	13 (16.0)	2 (2.5)	7 (8.6)	4 (4.9)	0
Myalgia	6 (7.4)	4 (4.9)	2 (2.5)	0	0
Nervous system disorders					
-Total	37 (45.7)	14 (17.3)	13 (16.0)	10 (12.3)	0
Headache	30 (37.0)	14 (17.3)	11 (13.6)	5 (6.2)	0
Encephalopathy	9 (11.1)	1 (1.2)	3 (3.7)	5 (6.2)	0
Psychiatric disorders					
-Total	23 (28.4)	6 (7.4)	11 (13.6)	6 (7.4)	0
Anxiety	15 (18.5)	3 (3.7)	9 (11.1)	3 (3.7)	0
Confusional state	5 (6.2)	5 (6.2)	0	0	0
Mental status changes	5 (6.2)	0	2 (2.5)	3 (3.7)	0
Renal and urinary disorders					
-Total	14 (17.3)	5 (6.2)	2 (2.5)	3 (3.7)	4 (4.9)
Acute kidney injury	14 (17.3)	5 (6.2)	2 (2.5)	3 (3.7)	4 (4.9)

Eligibility for SCT: No

	All patients N=81				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	49 (60.5)	14 (17.3)	6 (7.4)	13 (16.0)	16 (19.8)
Cough	21 (25.9)	16 (19.8)	5 (6.2)	0	0
Hypoxia	19 (23.5)	0	5 (6.2)	9 (11.1)	5 (6.2)
Pulmonary oedema	14 (17.3)	3 (3.7)	3 (3.7)	6 (7.4)	2 (2.5)
Epistaxis	10 (12.3)	6 (7.4)	2 (2.5)	2 (2.5)	0
Respiratory failure	10 (12.3)	0	0	0	10 (12.3)
Tachypnoea	9 (11.1)	1 (1.2)	2 (2.5)	5 (6.2)	1 (1.2)
Nasal congestion	8 (9.9)	6 (7.4)	2 (2.5)	0	0
Pleural effusion	8 (9.9)	3 (3.7)	2 (2.5)	2 (2.5)	1 (1.2)
Oropharyngeal pain	7 (8.6)	5 (6.2)	2 (2.5)	0	0
Rhinorrhoea	2 (2.5)	0	2 (2.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	25 (30.9)	13 (16.0)	11 (13.6)	1 (1.2)	0
Rash	11 (13.6)	6 (7.4)	5 (6.2)	0	0
Pruritus	10 (12.3)	4 (4.9)	6 (7.4)	0	0
Dry skin	6 (7.4)	5 (6.2)	1 (1.2)	0	0

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	3 (3.7)	1 (1.2)	1 (1.2)	1 (1.2)	0
Eczema	1 (1.2)	1 (1.2)	0	0	0
Rash papular	1 (1.2)	0	1 (1.2)	0	0
Vascular disorders					
-Total	40 (49.4)	5 (6.2)	12 (14.8)	14 (17.3)	9 (11.1)
Hypotension	28 (34.6)	2 (2.5)	6 (7.4)	11 (13.6)	9 (11.1)
Hypertension	23 (28.4)	5 (6.2)	13 (16.0)	5 (6.2)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	0	0	12 (42.9)	15 (53.6)
Blood and lymphatic system disorders					
-Total	21 (75.0)	0	2 (7.1)	10 (35.7)	9 (32.1)
Anaemia	14 (50.0)	3 (10.7)	2 (7.1)	9 (32.1)	0
Febrile neutropenia	13 (46.4)	0	0	12 (42.9)	1 (3.6)
Neutropenia	7 (25.0)	0	1 (3.6)	1 (3.6)	5 (17.9)
Thrombocytopenia	7 (25.0)	0	1 (3.6)	3 (10.7)	3 (10.7)
Disseminated intravascular coagulation	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Leukopenia	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Cardiac disorders					

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (21.4)	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)
Tachycardia	6 (21.4)	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)
Eye disorders					
-Total	3 (10.7)	3 (10.7)	0	0	0
Ocular hyperaemia	3 (10.7)	3 (10.7)	0	0	0
Gastrointestinal disorders					
-Total	21 (75.0)	9 (32.1)	6 (21.4)	6 (21.4)	0
Nausea	12 (42.9)	3 (10.7)	6 (21.4)	3 (10.7)	0
Diarrhoea	11 (39.3)	8 (28.6)	3 (10.7)	0	0
Vomiting	10 (35.7)	7 (25.0)	2 (7.1)	1 (3.6)	0
Constipation	7 (25.0)	7 (25.0)	0	0	0
Abdominal pain	5 (17.9)	2 (7.1)	2 (7.1)	1 (3.6)	0
Stomatitis	4 (14.3)	0	2 (7.1)	2 (7.1)	0
General disorders and administration site conditions					
-Total	20 (71.4)	7 (25.0)	10 (35.7)	2 (7.1)	1 (3.6)
Pyrexia	14 (50.0)	6 (21.4)	6 (21.4)	1 (3.6)	1 (3.6)
Fatigue	6 (21.4)	3 (10.7)	3 (10.7)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Pain	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Chills	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Oedema peripheral	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Hepatobiliary disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Hyperbilirubinaemia	1 (3.6)	0	1 (3.6)	0	0
Immune system disorders					
-Total	24 (85.7)	1 (3.6)	14 (50.0)	5 (17.9)	4 (14.3)
Cytokine release syndrome	18 (64.3)	3 (10.7)	8 (28.6)	3 (10.7)	4 (14.3)
Hypogammaglobulinaemia	17 (60.7)	1 (3.6)	12 (42.9)	4 (14.3)	0
Infections and infestations					
-Total	18 (64.3)	3 (10.7)	8 (28.6)	6 (21.4)	1 (3.6)
Upper respiratory tract infection	7 (25.0)	3 (10.7)	2 (7.1)	2 (7.1)	0
Conjunctivitis	5 (17.9)	2 (7.1)	3 (10.7)	0	0
Sinusitis	5 (17.9)	0	4 (14.3)	1 (3.6)	0
Rhinovirus infection	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Staphylococcal bacteraemia	4 (14.3)	0	0	4 (14.3)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Pneumonia	3 (10.7)	0	1 (3.6)	1 (3.6)	1 (3.6)
Respiratory syncytial virus infection	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Nasopharyngitis	1 (3.6)	0	1 (3.6)	0	0
Injury, poisoning and procedural complications					
-Total	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Infusion related reaction	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Investigations					
-Total	19 (67.9)	0	2 (7.1)	8 (28.6)	9 (32.1)
Alanine aminotransferase increased	9 (32.1)	2 (7.1)	3 (10.7)	4 (14.3)	0
Neutrophil count decreased	9 (32.1)	0	1 (3.6)	2 (7.1)	6 (21.4)
White blood cell count decreased	9 (32.1)	1 (3.6)	2 (7.1)	1 (3.6)	5 (17.9)
Lymphocyte count decreased	7 (25.0)	0	0	5 (17.9)	2 (7.1)
Platelet count decreased	7 (25.0)	2 (7.1)	1 (3.6)	0	4 (14.3)
Aspartate aminotransferase increased	6 (21.4)	1 (3.6)	3 (10.7)	1 (3.6)	1 (3.6)
Serum ferritin increased	6 (21.4)	1 (3.6)	2 (7.1)	3 (10.7)	0
C-reactive protein increased	4 (14.3)	1 (3.6)	0	3 (10.7)	0

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Blood immunoglobulin g decreased	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Blood immunoglobulin m decreased	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
International normalised ratio increased	3 (10.7)	3 (10.7)	0	0	0
Blood fibrinogen decreased	1 (3.6)	0	1 (3.6)	0	0
Metabolism and nutrition disorders					
-Total	15 (53.6)	1 (3.6)	6 (21.4)	5 (17.9)	3 (10.7)
Decreased appetite	10 (35.7)	4 (14.3)	3 (10.7)	2 (7.1)	1 (3.6)
Hypophosphataemia	7 (25.0)	0	4 (14.3)	3 (10.7)	0
Hypocalcaemia	6 (21.4)	0	4 (14.3)	2 (7.1)	0
Hypokalaemia	6 (21.4)	1 (3.6)	0	3 (10.7)	2 (7.1)
Hyperuricaemia	3 (10.7)	3 (10.7)	0	0	0
Hypoalbuminaemia	3 (10.7)	0	3 (10.7)	0	0
Hypomagnesaemia	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Hyperglycaemia	2 (7.1)	0	0	2 (7.1)	0
Hypervolaemia	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Musculoskeletal and connective tissue disorders					

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (42.9)	6 (21.4)	4 (14.3)	2 (7.1)	0
Pain in extremity	6 (21.4)	4 (14.3)	2 (7.1)	0	0
Arthralgia	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Back pain	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Myalgia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Nervous system disorders					
-Total	11 (39.3)	4 (14.3)	2 (7.1)	5 (17.9)	0
Headache	9 (32.1)	6 (21.4)	2 (7.1)	1 (3.6)	0
Seizure	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Encephalopathy	2 (7.1)	0	0	2 (7.1)	0
Psychiatric disorders					
-Total	5 (17.9)	2 (7.1)	2 (7.1)	1 (3.6)	0
Anxiety	5 (17.9)	2 (7.1)	2 (7.1)	1 (3.6)	0
Renal and urinary disorders					
-Total	3 (10.7)	2 (7.1)	0	0	1 (3.6)
Dysuria	3 (10.7)	3 (10.7)	0	0	0
Acute kidney injury	1 (3.6)	0	0	0	1 (3.6)

Baseline bone marrow tumor burden: Low

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	14 (50.0)	6 (21.4)	3 (10.7)	2 (7.1)	3 (10.7)
Cough	7 (25.0)	4 (14.3)	3 (10.7)	0	0
Nasal congestion	5 (17.9)	4 (14.3)	1 (3.6)	0	0
Pleural effusion	4 (14.3)	0	2 (7.1)	1 (3.6)	1 (3.6)
Epistaxis	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Hypoxia	3 (10.7)	0	1 (3.6)	2 (7.1)	0
Pulmonary oedema	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Dyspnoea	2 (7.1)	0	0	0	2 (7.1)
Tachypnoea	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Oropharyngeal pain	1 (3.6)	0	1 (3.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (32.1)	6 (21.4)	3 (10.7)	0	0
Rash	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Erythema	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Pruritus	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Dry skin	2 (7.1)	1 (3.6)	1 (3.6)	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	12 (42.9)	2 (7.1)	5 (17.9)	4 (14.3)	1 (3.6)
Hypotension	9 (32.1)	2 (7.1)	3 (10.7)	3 (10.7)	1 (3.6)
Hypertension	5 (17.9)	0	3 (10.7)	2 (7.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (97.1)	0	5 (7.1)	11 (15.7)	52 (74.3)
Blood and lymphatic system disorders					
-Total	48 (68.6)	1 (1.4)	3 (4.3)	27 (38.6)	17 (24.3)
Anaemia	32 (45.7)	3 (4.3)	10 (14.3)	18 (25.7)	1 (1.4)
Febrile neutropenia	32 (45.7)	0	0	30 (42.9)	2 (2.9)
Neutropenia	15 (21.4)	1 (1.4)	1 (1.4)	2 (2.9)	11 (15.7)
Thrombocytopenia	8 (11.4)	1 (1.4)	0	2 (2.9)	5 (7.1)
Disseminated intravascular coagulation	5 (7.1)	0	4 (5.7)	1 (1.4)	0
Leukopenia	3 (4.3)	0	0	0	3 (4.3)
Cardiac disorders					

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (24.3)	5 (7.1)	8 (11.4)	4 (5.7)	0
Tachycardia	17 (24.3)	5 (7.1)	8 (11.4)	4 (5.7)	0
Gastrointestinal disorders					
-Total	49 (70.0)	12 (17.1)	26 (37.1)	11 (15.7)	0
Nausea	25 (35.7)	11 (15.7)	13 (18.6)	1 (1.4)	0
Vomiting	21 (30.0)	14 (20.0)	6 (8.6)	1 (1.4)	0
Diarrhoea	19 (27.1)	9 (12.9)	7 (10.0)	3 (4.3)	0
Abdominal pain	15 (21.4)	3 (4.3)	9 (12.9)	3 (4.3)	0
Constipation	13 (18.6)	3 (4.3)	10 (14.3)	0	0
Stomatitis	9 (12.9)	1 (1.4)	2 (2.9)	6 (8.6)	0
General disorders and administration site conditions					
-Total	42 (60.0)	19 (27.1)	11 (15.7)	11 (15.7)	1 (1.4)
Pyrexia	34 (48.6)	12 (17.1)	11 (15.7)	10 (14.3)	1 (1.4)
Fatigue	16 (22.9)	13 (18.6)	3 (4.3)	0	0
Oedema peripheral	8 (11.4)	6 (8.6)	2 (2.9)	0	0
Pain	8 (11.4)	0	4 (5.7)	4 (5.7)	0
Chills	7 (10.0)	4 (5.7)	3 (4.3)	0	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	5 (7.1)	5 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Hyperbilirubinaemia	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Immune system disorders					
-Total	46 (65.7)	1 (1.4)	12 (17.1)	16 (22.9)	17 (24.3)
Cytokine release syndrome	43 (61.4)	2 (2.9)	10 (14.3)	14 (20.0)	17 (24.3)
Hypogammaglobulinaemia	24 (34.3)	1 (1.4)	18 (25.7)	5 (7.1)	0
Infections and infestations					
-Total	35 (50.0)	5 (7.1)	12 (17.1)	14 (20.0)	4 (5.7)
Nasopharyngitis	7 (10.0)	5 (7.1)	2 (2.9)	0	0
Oral herpes	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Pneumonia	7 (10.0)	1 (1.4)	1 (1.4)	3 (4.3)	2 (2.9)
Staphylococcal infection	7 (10.0)	0	3 (4.3)	3 (4.3)	1 (1.4)
Upper respiratory tract infection	7 (10.0)	2 (2.9)	4 (5.7)	1 (1.4)	0
Rhinovirus infection	5 (7.1)	0	5 (7.1)	0	0
Conjunctivitis	4 (5.7)	1 (1.4)	3 (4.3)	0	0
Parainfluenzae virus infection	4 (5.7)	0	1 (1.4)	2 (2.9)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	4 (5.7)	0	2 (2.9)	2 (2.9)	0
Staphylococcal bacteraemia	4 (5.7)	0	0	4 (5.7)	0
Injury, poisoning and procedural complications					
-Total	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Infusion related reaction	3 (4.3)	1 (1.4)	1 (1.4)	1 (1.4)	0
Investigations					
-Total	45 (64.3)	1 (1.4)	0	12 (17.1)	32 (45.7)
White blood cell count decreased	26 (37.1)	2 (2.9)	1 (1.4)	0	23 (32.9)
Platelet count decreased	25 (35.7)	4 (5.7)	1 (1.4)	6 (8.6)	14 (20.0)
Neutrophil count decreased	22 (31.4)	2 (2.9)	1 (1.4)	1 (1.4)	18 (25.7)
Aspartate aminotransferase increased	17 (24.3)	1 (1.4)	3 (4.3)	10 (14.3)	3 (4.3)
Lymphocyte count decreased	17 (24.3)	1 (1.4)	1 (1.4)	4 (5.7)	11 (15.7)
Alanine aminotransferase increased	16 (22.9)	3 (4.3)	6 (8.6)	7 (10.0)	0
Blood bilirubin increased	10 (14.3)	1 (1.4)	1 (1.4)	8 (11.4)	0
C-reactive protein increased	8 (11.4)	2 (2.9)	2 (2.9)	3 (4.3)	1 (1.4)
Blood fibrinogen decreased	7 (10.0)	3 (4.3)	2 (2.9)	1 (1.4)	1 (1.4)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	7 (10.0)	3 (4.3)	4 (5.7)	0	0
Serum ferritin increased	7 (10.0)	1 (1.4)	4 (5.7)	1 (1.4)	1 (1.4)
Blood immunoglobulin m decreased	4 (5.7)	3 (4.3)	0	1 (1.4)	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	42 (60.0)	7 (10.0)	11 (15.7)	20 (28.6)	4 (5.7)
Decreased appetite	25 (35.7)	8 (11.4)	6 (8.6)	10 (14.3)	1 (1.4)
Hypokalaemia	20 (28.6)	3 (4.3)	6 (8.6)	10 (14.3)	1 (1.4)
Hypophosphataemia	14 (20.0)	3 (4.3)	4 (5.7)	6 (8.6)	1 (1.4)
Hypocalcaemia	13 (18.6)	2 (2.9)	7 (10.0)	4 (5.7)	0
Hypoalbuminaemia	10 (14.3)	0	9 (12.9)	1 (1.4)	0
Hyperglycaemia	8 (11.4)	0	4 (5.7)	3 (4.3)	1 (1.4)
Hyperuricaemia	7 (10.0)	4 (5.7)	2 (2.9)	1 (1.4)	0
Hypervolaemia	7 (10.0)	0	2 (2.9)	5 (7.1)	0
Hypomagnesaemia	7 (10.0)	5 (7.1)	2 (2.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	31 (44.3)	12 (17.1)	13 (18.6)	6 (8.6)	0

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	17 (24.3)	5 (7.1)	9 (12.9)	3 (4.3)	0
Arthralgia	13 (18.6)	7 (10.0)	6 (8.6)	0	0
Back pain	10 (14.3)	1 (1.4)	6 (8.6)	3 (4.3)	0
Myalgia	8 (11.4)	5 (7.1)	3 (4.3)	0	0
Nervous system disorders					
-Total	33 (47.1)	13 (18.6)	12 (17.1)	8 (11.4)	0
Headache	26 (37.1)	12 (17.1)	10 (14.3)	4 (5.7)	0
Encephalopathy	7 (10.0)	1 (1.4)	3 (4.3)	3 (4.3)	0
Seizure	3 (4.3)	0	2 (2.9)	1 (1.4)	0
Psychiatric disorders					
-Total	25 (35.7)	6 (8.6)	10 (14.3)	9 (12.9)	0
Anxiety	12 (17.1)	2 (2.9)	8 (11.4)	2 (2.9)	0
Delirium	8 (11.4)	2 (2.9)	3 (4.3)	3 (4.3)	0
Agitation	7 (10.0)	4 (5.7)	3 (4.3)	0	0
Mental status changes	7 (10.0)	1 (1.4)	2 (2.9)	4 (5.7)	0
Renal and urinary disorders					
-Total	15 (21.4)	6 (8.6)	2 (2.9)	3 (4.3)	4 (5.7)
Acute kidney injury	14 (20.0)	5 (7.1)	2 (2.9)	3 (4.3)	4 (5.7)

Baseline bone marrow tumor burden: High

	All patients N=70				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	2 (2.9)	1 (1.4)	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	46 (65.7)	14 (20.0)	5 (7.1)	12 (17.1)	15 (21.4)
Cough	19 (27.1)	17 (24.3)	2 (2.9)	0	0
Hypoxia	19 (27.1)	0	5 (7.1)	8 (11.4)	6 (8.6)
Pulmonary oedema	11 (15.7)	2 (2.9)	3 (4.3)	4 (5.7)	2 (2.9)
Respiratory failure	10 (14.3)	0	0	0	10 (14.3)
Epistaxis	9 (12.9)	5 (7.1)	1 (1.4)	3 (4.3)	0
Oropharyngeal pain	9 (12.9)	8 (11.4)	1 (1.4)	0	0
Tachypnoea	9 (12.9)	3 (4.3)	2 (2.9)	4 (5.7)	0
Dyspnoea	7 (10.0)	2 (2.9)	2 (2.9)	3 (4.3)	0
Nasal congestion	6 (8.6)	5 (7.1)	1 (1.4)	0	0
Pleural effusion	6 (8.6)	4 (5.7)	1 (1.4)	1 (1.4)	0
Skin and subcutaneous tissue disorders					
-Total	20 (28.6)	12 (17.1)	8 (11.4)	0	0
Pruritus	9 (12.9)	4 (5.7)	5 (7.1)	0	0
Dry skin	7 (10.0)	6 (8.6)	1 (1.4)	0	0

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=70 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	7 (10.0)	3 (4.3)	4 (5.7)	0	0
Erythema	3 (4.3)	3 (4.3)	0	0	0
Vascular disorders					
-Total	32 (45.7)	5 (7.1)	7 (10.0)	11 (15.7)	9 (12.9)
Hypotension	22 (31.4)	1 (1.4)	3 (4.3)	9 (12.9)	9 (12.9)
Hypertension	19 (27.1)	6 (8.6)	10 (14.3)	3 (4.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	0	5 (45.5)	6 (54.5)
Blood and lymphatic system disorders					
-Total	8 (72.7)	0	1 (9.1)	5 (45.5)	2 (18.2)
Febrile neutropenia	4 (36.4)	0	0	4 (36.4)	0
Anaemia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Thrombocytopenia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	7 (63.6)	2 (18.2)	4 (36.4)	1 (9.1)	0
Constipation	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Nausea	4 (36.4)	0	3 (27.3)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	1 (9.1)	0	0	0
Vomiting	1 (9.1)	1 (9.1)	0	0	0
General disorders and administration site conditions					
-Total	8 (72.7)	4 (36.4)	4 (36.4)	0	0
Pyrexia	7 (63.6)	5 (45.5)	2 (18.2)	0	0
Pain	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Fatigue	1 (9.1)	0	1 (9.1)	0	0
Hepatobiliary disorders					
-Total	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Hepatic cytolysis	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Immune system disorders					
-Total	8 (72.7)	0	4 (36.4)	3 (27.3)	1 (9.1)
Hypogammaglobulinaemia	7 (63.6)	1 (9.1)	3 (27.3)	3 (27.3)	0
Cytokine release syndrome	6 (54.5)	1 (9.1)	3 (27.3)	1 (9.1)	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	4 (36.4)	3 (27.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	3 (27.3)	0	3 (27.3)	0	0
Paronychia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Urinary tract infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	7 (63.6)	0	1 (9.1)	1 (9.1)	5 (45.5)
Alanine aminotransferase increased	4 (36.4)	2 (18.2)	1 (9.1)	1 (9.1)	0
Platelet count decreased	4 (36.4)	0	0	0	4 (36.4)
White blood cell count decreased	3 (27.3)	0	0	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Aspartate aminotransferase increased	1 (9.1)	1 (9.1)	0	0	0
Blood bilirubin increased	1 (9.1)	0	0	1 (9.1)	0
C-reactive protein increased	1 (9.1)	0	0	1 (9.1)	0
Serum ferritin increased	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (27.3)	0	1 (9.1)	0	2 (18.2)
Hypophosphataemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Decreased appetite	2 (18.2)	1 (9.1)	0	0	1 (9.1)
Hypokalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	3 (27.3)	0	0
Back pain	2 (18.2)	0	2 (18.2)	0	0
Arthralgia	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	4 (36.4)	1 (9.1)	1 (9.1)	2 (18.2)	0
Headache	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Seizure	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Psychiatric disorders					
-Total	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Anxiety	3 (27.3)	1 (9.1)	2 (18.2)	0	0
Respiratory, thoracic and mediastinal disorders					

Baseline extramedullary disease presence: Yes

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (36.4)	2 (18.2)	2 (18.2)	0	0
Cough	1 (9.1)	0	1 (9.1)	0	0
Epistaxis	1 (9.1)	1 (9.1)	0	0	0
Nasal congestion	1 (9.1)	1 (9.1)	0	0	0
Pleural effusion	1 (9.1)	0	1 (9.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (27.3)	3 (27.3)	0	0	0
Pruritus	3 (27.3)	3 (27.3)	0	0	0
Rash	1 (9.1)	1 (9.1)	0	0	0
Vascular disorders					
-Total	4 (36.4)	1 (9.1)	2 (18.2)	1 (9.1)	0
Hypertension	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Hypotension	2 (18.2)	1 (9.1)	1 (9.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	83 (95.4)	0	4 (4.6)	19 (21.8)	60 (69.0)
Blood and lymphatic system disorders					
-Total	60 (69.0)	1 (1.1)	3 (3.4)	34 (39.1)	22 (25.3)
Anaemia	44 (50.6)	6 (6.9)	11 (12.6)	26 (29.9)	1 (1.1)
Febrile neutropenia	41 (47.1)	0	0	38 (43.7)	3 (3.4)
Neutropenia	20 (23.0)	1 (1.1)	2 (2.3)	3 (3.4)	14 (16.1)
Thrombocytopenia	14 (16.1)	1 (1.1)	0	5 (5.7)	8 (9.2)
Cardiac disorders					
-Total	23 (26.4)	8 (9.2)	9 (10.3)	5 (5.7)	1 (1.1)
Tachycardia	23 (26.4)	8 (9.2)	9 (10.3)	5 (5.7)	1 (1.1)
Gastrointestinal disorders					

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	63 (72.4)	19 (21.8)	28 (32.2)	16 (18.4)	0
Nausea	33 (37.9)	14 (16.1)	16 (18.4)	3 (3.4)	0
Vomiting	30 (34.5)	20 (23.0)	8 (9.2)	2 (2.3)	0
Diarrhoea	29 (33.3)	16 (18.4)	10 (11.5)	3 (3.4)	0
Abdominal pain	19 (21.8)	4 (4.6)	11 (12.6)	4 (4.6)	0
Constipation	16 (18.4)	8 (9.2)	8 (9.2)	0	0
Stomatitis	13 (14.9)	1 (1.1)	4 (4.6)	8 (9.2)	0
General disorders and administration site conditions					
-Total	53 (60.9)	22 (25.3)	16 (18.4)	13 (14.9)	2 (2.3)
Pyrexia	41 (47.1)	13 (14.9)	15 (17.2)	11 (12.6)	2 (2.3)
Fatigue	21 (24.1)	16 (18.4)	5 (5.7)	0	0
Oedema peripheral	10 (11.5)	7 (8.0)	2 (2.3)	1 (1.1)	0
Chills	9 (10.3)	5 (5.7)	4 (4.6)	0	0
Pain	9 (10.3)	0	5 (5.7)	4 (4.6)	0
Immune system disorders					
-Total	62 (71.3)	2 (2.3)	22 (25.3)	18 (20.7)	20 (23.0)
Cytokine release syndrome	55 (63.2)	4 (4.6)	15 (17.2)	16 (18.4)	20 (23.0)

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	34 (39.1)	1 (1.1)	27 (31.0)	6 (6.9)	0
Infections and infestations					
-Total	26 (29.9)	5 (5.7)	8 (9.2)	10 (11.5)	3 (3.4)
Upper respiratory tract infection	13 (14.9)	5 (5.7)	6 (6.9)	2 (2.3)	0
Pneumonia	9 (10.3)	1 (1.1)	1 (1.1)	4 (4.6)	3 (3.4)
Sinusitis	6 (6.9)	0	3 (3.4)	3 (3.4)	0
Paronychia	3 (3.4)	1 (1.1)	2 (2.3)	0	0
Urinary tract infection	3 (3.4)	0	2 (2.3)	1 (1.1)	0
Investigations					
-Total	56 (64.4)	1 (1.1)	0	19 (21.8)	36 (41.4)
White blood cell count decreased	32 (36.8)	3 (3.4)	3 (3.4)	1 (1.1)	25 (28.7)
Neutrophil count decreased	29 (33.3)	2 (2.3)	2 (2.3)	3 (3.4)	22 (25.3)
Platelet count decreased	28 (32.2)	6 (6.9)	2 (2.3)	6 (6.9)	14 (16.1)
Aspartate aminotransferase increased	22 (25.3)	1 (1.1)	6 (6.9)	11 (12.6)	4 (4.6)
Lymphocyte count decreased	22 (25.3)	1 (1.1)	1 (1.1)	9 (10.3)	11 (12.6)
Alanine aminotransferase increased	21 (24.1)	3 (3.4)	8 (9.2)	10 (11.5)	0
Blood bilirubin increased	12 (13.8)	1 (1.1)	2 (2.3)	9 (10.3)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	12 (13.8)	2 (2.3)	6 (6.9)	3 (3.4)	1 (1.1)
C-reactive protein increased	11 (12.6)	3 (3.4)	2 (2.3)	5 (5.7)	1 (1.1)
International normalised ratio increased	10 (11.5)	6 (6.9)	4 (4.6)	0	0
Metabolism and nutrition disorders					
-Total	54 (62.1)	8 (9.2)	17 (19.5)	24 (27.6)	5 (5.7)
Decreased appetite	33 (37.9)	11 (12.6)	9 (10.3)	12 (13.8)	1 (1.1)
Hypokalaemia	25 (28.7)	4 (4.6)	6 (6.9)	12 (13.8)	3 (3.4)
Hypocalcaemia	19 (21.8)	2 (2.3)	11 (12.6)	6 (6.9)	0
Hypophosphataemia	18 (20.7)	3 (3.4)	6 (6.9)	9 (10.3)	0
Hypoalbuminaemia	13 (14.9)	0	12 (13.8)	1 (1.1)	0
Hyperglycaemia	10 (11.5)	0	4 (4.6)	5 (5.7)	1 (1.1)
Hyperuricaemia	10 (11.5)	7 (8.0)	2 (2.3)	1 (1.1)	0
Hypomagnesaemia	9 (10.3)	6 (6.9)	3 (3.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	40 (46.0)	18 (20.7)	14 (16.1)	8 (9.2)	0
Pain in extremity	23 (26.4)	9 (10.3)	11 (12.6)	3 (3.4)	0
Arthralgia	15 (17.2)	8 (9.2)	6 (6.9)	1 (1.1)	0

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	11 (12.6)	2 (2.3)	5 (5.7)	4 (4.6)	0
Myalgia	10 (11.5)	6 (6.9)	4 (4.6)	0	0
Nervous system disorders					
-Total	40 (46.0)	16 (18.4)	13 (14.9)	11 (12.6)	0
Headache	32 (36.8)	17 (19.5)	11 (12.6)	4 (4.6)	0
Encephalopathy	9 (10.3)	1 (1.1)	3 (3.4)	5 (5.7)	0
Seizure	4 (4.6)	0	2 (2.3)	2 (2.3)	0
Psychiatric disorders					
-Total	14 (16.1)	3 (3.4)	8 (9.2)	3 (3.4)	0
Anxiety	14 (16.1)	3 (3.4)	8 (9.2)	3 (3.4)	0
Renal and urinary disorders					
-Total	15 (17.2)	5 (5.7)	2 (2.3)	3 (3.4)	5 (5.7)
Acute kidney injury	15 (17.2)	5 (5.7)	2 (2.3)	3 (3.4)	5 (5.7)
Respiratory, thoracic and mediastinal disorders					
-Total	56 (64.4)	18 (20.7)	6 (6.9)	14 (16.1)	18 (20.7)
Cough	25 (28.7)	21 (24.1)	4 (4.6)	0	0
Hypoxia	22 (25.3)	0	6 (6.9)	10 (11.5)	6 (6.9)

Baseline extramedullary disease presence: No

	All patients N=87				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	14 (16.1)	3 (3.4)	3 (3.4)	6 (6.9)	2 (2.3)
Epistaxis	11 (12.6)	6 (6.9)	2 (2.3)	3 (3.4)	0
Tachypnoea	11 (12.6)	3 (3.4)	2 (2.3)	5 (5.7)	1 (1.1)
Nasal congestion	10 (11.5)	8 (9.2)	2 (2.3)	0	0
Oropharyngeal pain	10 (11.5)	8 (9.2)	2 (2.3)	0	0
Respiratory failure	10 (11.5)	0	0	0	10 (11.5)
Dyspnoea	9 (10.3)	2 (2.3)	2 (2.3)	3 (3.4)	2 (2.3)
Pleural effusion	9 (10.3)	4 (4.6)	2 (2.3)	2 (2.3)	1 (1.1)
Skin and subcutaneous tissue disorders					
-Total	23 (26.4)	13 (14.9)	10 (11.5)	0	0
Rash	10 (11.5)	5 (5.7)	5 (5.7)	0	0
Dry skin	9 (10.3)	7 (8.0)	2 (2.3)	0	0
Pruritus	9 (10.3)	3 (3.4)	6 (6.9)	0	0
Vascular disorders					
-Total	40 (46.0)	6 (6.9)	10 (11.5)	14 (16.1)	10 (11.5)
Hypotension	29 (33.3)	2 (2.3)	5 (5.7)	12 (13.8)	10 (11.5)
Hypertension	21 (24.1)	6 (6.9)	11 (12.6)	4 (4.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	0	7 (100)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	1 (14.3)	4 (57.1)	0
Anaemia	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Febrile neutropenia	3 (42.9)	0	0	3 (42.9)	0
Disseminated intravascular coagulation	2 (28.6)	0	2 (28.6)	0	0
Neutropenia	1 (14.3)	1 (14.3)	0	0	0
Splenomegaly	1 (14.3)	1 (14.3)	0	0	0
Cardiac disorders					
-Total	3 (42.9)	0	2 (28.6)	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Bradycardia	1 (14.3)	0	1 (14.3)	0	0
Ear and labyrinth disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Ear pruritus	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Hypothyroidism	2 (28.6)	0	2 (28.6)	0	0
Eye disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Conjunctival haemorrhage	2 (28.6)	2 (28.6)	0	0	0
Ocular hyperaemia	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	1 (14.3)	2 (28.6)	2 (28.6)	1 (14.3)
Constipation	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Diarrhoea	3 (42.9)	3 (42.9)	0	0	0
Vomiting	2 (28.6)	2 (28.6)	0	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (14.3)	0	0	0	1 (14.3)
Anal fissure	1 (14.3)	0	1 (14.3)	0	0
Duodenal perforation	1 (14.3)	0	0	1 (14.3)	0
Dysphagia	1 (14.3)	0	0	1 (14.3)	0
Enterocolitis	1 (14.3)	0	1 (14.3)	0	0
Gastritis	1 (14.3)	0	1 (14.3)	0	0
Gingival erythema	1 (14.3)	1 (14.3)	0	0	0
Hypoaesthesia oral	1 (14.3)	0	1 (14.3)	0	0
Nausea	1 (14.3)	0	1 (14.3)	0	0
Oral pain	1 (14.3)	0	1 (14.3)	0	0
Stomatitis	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	4 (57.1)	2 (28.6)	2 (28.6)	0	0
Pyrexia	3 (42.9)	3 (42.9)	0	0	0
Face oedema	2 (28.6)	2 (28.6)	0	0	0
Fatigue	2 (28.6)	2 (28.6)	0	0	0
Generalised oedema	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (14.3)	0	1 (14.3)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Complication associated with device	1 (14.3)	1 (14.3)	0	0	0
Localised oedema	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Hepatic function abnormal	1 (14.3)	0	0	0	1 (14.3)
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)	0	0
Hypertransaminasaemia	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	6 (85.7)	1 (14.3)	1 (14.3)	1 (14.3)	3 (42.9)
Cytokine release syndrome	6 (85.7)	2 (28.6)	1 (14.3)	0	3 (42.9)
Hypogammaglobulinaemia	3 (42.9)	0	2 (28.6)	1 (14.3)	0
Haemophagocytic lymphohistiocytosis	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	7 (100)	0	2 (28.6)	5 (71.4)	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Otitis media	2 (28.6)	0	2 (28.6)	0	0
Bronchiolitis	1 (14.3)	0	0	1 (14.3)	0
Bronchitis	1 (14.3)	0	1 (14.3)	0	0
Cellulitis	1 (14.3)	0	1 (14.3)	0	0
Ear infection	1 (14.3)	0	1 (14.3)	0	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Folliculitis	1 (14.3)	0	1 (14.3)	0	0
Gastroenteritis viral	1 (14.3)	0	1 (14.3)	0	0
Metapneumovirus infection	1 (14.3)	0	0	1 (14.3)	0
Nail infection	1 (14.3)	0	1 (14.3)	0	0
Nasopharyngitis	1 (14.3)	1 (14.3)	0	0	0
Otitis externa	1 (14.3)	0	1 (14.3)	0	0
Paronychia	1 (14.3)	1 (14.3)	0	0	0
Peritonitis	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)	0	0
Pneumonia respiratory syncytial viral	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	0	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (14.3)	0	1 (14.3)	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Staphylococcal infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Abdominal injury	1 (14.3)	1 (14.3)	0	0	0
Contusion	1 (14.3)	1 (14.3)	0	0	0
Skin abrasion	1 (14.3)	1 (14.3)	0	0	0
Transfusion reaction	1 (14.3)	0	1 (14.3)	0	0
Wound	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	6 (85.7)	0	0	0	6 (85.7)
Neutrophil count decreased	4 (57.1)	0	0	1 (14.3)	3 (42.9)
White blood cell count decreased	4 (57.1)	0	0	0	4 (57.1)
Lymphocyte count decreased	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Platelet count decreased	3 (42.9)	0	1 (14.3)	0	2 (28.6)
Activated partial thromboplastin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Blood creatinine increased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Serum ferritin increased	2 (28.6)	0	2 (28.6)	0	0
Urine output decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Weight increased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bicarbonate decreased	1 (14.3)	0	1 (14.3)	0	0
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatine phosphokinase increased	1 (14.3)	0	0	1 (14.3)	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin a decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin g decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	0	0	1 (14.3)	0
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0	0	0
Blood thyroid stimulating hormone increased	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
C-reactive protein increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	0	1 (14.3)	0	0
Oxygen saturation decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (85.7)	0	2 (28.6)	3 (42.9)	1 (14.3)
Hypocalcaemia	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Hypokalaemia	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Hypophosphataemia	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Decreased appetite	2 (28.6)	0	0	2 (28.6)	0
Hyperphosphataemia	2 (28.6)	2 (28.6)	0	0	0
Hypoalbuminaemia	2 (28.6)	0	2 (28.6)	0	0
Hypercalcaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperchloraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperglycaemia	1 (14.3)	0	0	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperlipidaemia	1 (14.3)	0	1 (14.3)	0	0
Hypermagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypervolaemia	1 (14.3)	0	1 (14.3)	0	0
Hyponatraemia	1 (14.3)	1 (14.3)	0	0	0
Metabolic acidosis	1 (14.3)	0	0	0	1 (14.3)
Metabolic syndrome	1 (14.3)	0	1 (14.3)	0	0
Obesity	1 (14.3)	0	0	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	3 (42.9)	0	0	0
Bone pain	1 (14.3)	1 (14.3)	0	0	0
Muscle rigidity	1 (14.3)	1 (14.3)	0	0	0
Myalgia	1 (14.3)	1 (14.3)	0	0	0
Pain in extremity	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cerebral haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Encephalopathy	1 (14.3)	0	0	1 (14.3)	0
Generalised tonic-clonic seizure	1 (14.3)	0	1 (14.3)	0	0
Haemorrhage intracranial	1 (14.3)	0	0	0	1 (14.3)
Headache	1 (14.3)	0	1 (14.3)	0	0
Somnolence	1 (14.3)	0	0	1 (14.3)	0
Tremor	1 (14.3)	0	1 (14.3)	0	0
Psychiatric disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Automatism	1 (14.3)	1 (14.3)	0	0	0
Confusional state	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Insomnia	1 (14.3)	0	1 (14.3)	0	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Acute kidney injury	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Anuria	1 (14.3)	1 (14.3)	0	0	0
Azotaemia	1 (14.3)	0	1 (14.3)	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Dysmenorrhoea	1 (14.3)	0	1 (14.3)	0	0
Perineal rash	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	1 (14.3)	1 (14.3)	2 (28.6)	2 (28.6)
Hypoxia	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Cough	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Pleural effusion	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Epistaxis	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Nasal congestion	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Pulmonary oedema	2 (28.6)	0	2 (28.6)	0	0
Atelectasis	1 (14.3)	0	0	1 (14.3)	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (14.3)	0	1 (14.3)	0	0
Nasal discomfort	1 (14.3)	0	1 (14.3)	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pharyngeal haemorrhage	1 (14.3)	0	1 (14.3)	0	0
Respiratory distress	1 (14.3)	0	1 (14.3)	0	0
Rhinitis allergic	1 (14.3)	0	1 (14.3)	0	0
Rhinorrhoea	1 (14.3)	0	1 (14.3)	0	0
Sleep apnoea syndrome	1 (14.3)	0	1 (14.3)	0	0
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Wheezing	1 (14.3)	0	1 (14.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (85.7)	3 (42.9)	3 (42.9)	0	0
Rash	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Blister	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Erythema	2 (28.6)	2 (28.6)	0	0	0
Dermatitis diaper	1 (14.3)	0	1 (14.3)	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0

Down syndrome: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	1 (14.3)	1 (14.3)	0	0	0
Ingrowing nail	1 (14.3)	0	1 (14.3)	0	0
Miliaria	1 (14.3)	1 (14.3)	0	0	0
Petechiae	1 (14.3)	0	1 (14.3)	0	0
Rash erythematous	1 (14.3)	1 (14.3)	0	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Scab	1 (14.3)	1 (14.3)	0	0	0
Skin discolouration	1 (14.3)	1 (14.3)	0	0	0
Skin swelling	1 (14.3)	1 (14.3)	0	0	0
Skin ulcer	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	4 (57.1)	1 (14.3)	0	1 (14.3)	2 (28.6)
Hypertension	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Hypotension	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Thrombosis	1 (14.3)	0	1 (14.3)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	89 (97.8)	0	4 (4.4)	24 (26.4)	61 (67.0)
Blood and lymphatic system disorders					
-Total	64 (70.3)	1 (1.1)	4 (4.4)	35 (38.5)	24 (26.4)
Anaemia	43 (47.3)	6 (6.6)	11 (12.1)	25 (27.5)	1 (1.1)
Febrile neutropenia	42 (46.2)	0	0	39 (42.9)	3 (3.3)
Neutropenia	21 (23.1)	0	2 (2.2)	3 (3.3)	16 (17.6)
Thrombocytopenia	15 (16.5)	1 (1.1)	1 (1.1)	5 (5.5)	8 (8.8)
Disseminated intravascular coagulation	6 (6.6)	0	3 (3.3)	3 (3.3)	0
Splenomegaly	3 (3.3)	2 (2.2)	1 (1.1)	0	0
Cardiac disorders					

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (24.2)	9 (9.9)	8 (8.8)	4 (4.4)	1 (1.1)
Tachycardia	21 (23.1)	8 (8.8)	8 (8.8)	4 (4.4)	1 (1.1)
Bradycardia	3 (3.3)	3 (3.3)	0	0	0
Endocrine disorders					
-Total	3 (3.3)	0	3 (3.3)	0	0
Hypothyroidism	3 (3.3)	0	3 (3.3)	0	0
Eye disorders					
-Total	2 (2.2)	2 (2.2)	0	0	0
Ocular hyperaemia	2 (2.2)	2 (2.2)	0	0	0
Gastrointestinal disorders					
-Total	66 (72.5)	17 (18.7)	31 (34.1)	17 (18.7)	1 (1.1)
Nausea	36 (39.6)	14 (15.4)	18 (19.8)	4 (4.4)	0
Vomiting	29 (31.9)	19 (20.9)	8 (8.8)	2 (2.2)	0
Diarrhoea	27 (29.7)	14 (15.4)	10 (11.0)	3 (3.3)	0
Abdominal pain	20 (22.0)	5 (5.5)	11 (12.1)	4 (4.4)	0
Constipation	17 (18.7)	8 (8.8)	9 (9.9)	0	0
Stomatitis	12 (13.2)	1 (1.1)	3 (3.3)	8 (8.8)	0
Abdominal compartment syndrome	1 (1.1)	0	0	0	1 (1.1)

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (1.1)	0	1 (1.1)	0	0
Gingival erythema	1 (1.1)	1 (1.1)	0	0	0
Oral pain	1 (1.1)	0	0	1 (1.1)	0
General disorders and administration site conditions					
-Total	61 (67.0)	23 (25.3)	22 (24.2)	14 (15.4)	2 (2.2)
Pyrexia	45 (49.5)	15 (16.5)	17 (18.7)	11 (12.1)	2 (2.2)
Fatigue	20 (22.0)	14 (15.4)	6 (6.6)	0	0
Pain	11 (12.1)	1 (1.1)	6 (6.6)	4 (4.4)	0
Oedema peripheral	10 (11.0)	7 (7.7)	2 (2.2)	1 (1.1)	0
Chills	8 (8.8)	4 (4.4)	4 (4.4)	0	0
Catheter site pain	7 (7.7)	3 (3.3)	3 (3.3)	1 (1.1)	0
Face oedema	7 (7.7)	4 (4.4)	2 (2.2)	1 (1.1)	0
Generalised oedema	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Localised oedema	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Hepatobiliary disorders					
-Total	14 (15.4)	3 (3.3)	5 (5.5)	6 (6.6)	0
Hyperbilirubinaemia	7 (7.7)	1 (1.1)	3 (3.3)	3 (3.3)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	4 (4.4)	0	2 (2.2)	2 (2.2)	0
Hypertransaminasaemia	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Immune system disorders					
-Total	64 (70.3)	1 (1.1)	24 (26.4)	20 (22.0)	19 (20.9)
Cytokine release syndrome	55 (60.4)	3 (3.3)	17 (18.7)	17 (18.7)	18 (19.8)
Hypogammaglobulinaemia	38 (41.8)	2 (2.2)	28 (30.8)	8 (8.8)	0
Haemophagocytic lymphohistiocytosis	5 (5.5)	1 (1.1)	0	2 (2.2)	2 (2.2)
Seasonal allergy	4 (4.4)	2 (2.2)	2 (2.2)	0	0
Infections and infestations					
-Total	45 (49.5)	6 (6.6)	17 (18.7)	17 (18.7)	5 (5.5)
Upper respiratory tract infection	10 (11.0)	4 (4.4)	4 (4.4)	2 (2.2)	0
Pneumonia	9 (9.9)	1 (1.1)	1 (1.1)	4 (4.4)	3 (3.3)
Rhinovirus infection	8 (8.8)	0	6 (6.6)	2 (2.2)	0
Sinusitis	8 (8.8)	0	5 (5.5)	3 (3.3)	0
Nasopharyngitis	7 (7.7)	4 (4.4)	3 (3.3)	0	0
Staphylococcal infection	6 (6.6)	0	2 (2.2)	3 (3.3)	1 (1.1)
Paronychia	4 (4.4)	0	3 (3.3)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nail infection	3 (3.3)	3 (3.3)	0	0	0
Otitis media	3 (3.3)	0	2 (2.2)	1 (1.1)	0
Bronchitis	2 (2.2)	0	2 (2.2)	0	0
Ear infection	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Escherichia bacteraemia	2 (2.2)	0	0	1 (1.1)	1 (1.1)
Gastroenteritis viral	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Metapneumovirus infection	2 (2.2)	0	0	2 (2.2)	0
Otitis externa	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Skin infection	2 (2.2)	0	2 (2.2)	0	0
Bronchiolitis	1 (1.1)	0	0	1 (1.1)	0
Cellulitis	1 (1.1)	0	1 (1.1)	0	0
Injury, poisoning and procedural complications					
-Total	7 (7.7)	3 (3.3)	2 (2.2)	2 (2.2)	0
Transfusion reaction	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Wound	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Contusion	1 (1.1)	1 (1.1)	0	0	0
Skin abrasion	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	59 (64.8)	1 (1.1)	2 (2.2)	20 (22.0)	36 (39.6)
White blood cell count decreased	31 (34.1)	3 (3.3)	3 (3.3)	1 (1.1)	24 (26.4)
Platelet count decreased	29 (31.9)	6 (6.6)	1 (1.1)	6 (6.6)	16 (17.6)
Neutrophil count decreased	27 (29.7)	2 (2.2)	2 (2.2)	2 (2.2)	21 (23.1)
Alanine aminotransferase increased	23 (25.3)	5 (5.5)	8 (8.8)	10 (11.0)	0
Aspartate aminotransferase increased	22 (24.2)	2 (2.2)	6 (6.6)	11 (12.1)	3 (3.3)
Lymphocyte count decreased	21 (23.1)	1 (1.1)	1 (1.1)	7 (7.7)	12 (13.2)
Blood bilirubin increased	12 (13.2)	1 (1.1)	2 (2.2)	9 (9.9)	0
C-reactive protein increased	11 (12.1)	2 (2.2)	2 (2.2)	6 (6.6)	1 (1.1)
Serum ferritin increased	11 (12.1)	2 (2.2)	4 (4.4)	4 (4.4)	1 (1.1)
International normalised ratio increased	9 (9.9)	6 (6.6)	3 (3.3)	0	0
Blood fibrinogen decreased	7 (7.7)	3 (3.3)	2 (2.2)	1 (1.1)	1 (1.1)
Blood lactate dehydrogenase increased	7 (7.7)	2 (2.2)	2 (2.2)	3 (3.3)	0
Blood immunoglobulin a decreased	6 (6.6)	5 (5.5)	0	1 (1.1)	0
Blood immunoglobulin m decreased	6 (6.6)	4 (4.4)	1 (1.1)	1 (1.1)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	5 (5.5)	3 (3.3)	1 (1.1)	1 (1.1)	0
Blood creatinine increased	5 (5.5)	2 (2.2)	1 (1.1)	2 (2.2)	0
Fibrin d dimer increased	4 (4.4)	2 (2.2)	0	1 (1.1)	1 (1.1)
Weight increased	4 (4.4)	1 (1.1)	2 (2.2)	1 (1.1)	0
Blood immunoglobulin g decreased	3 (3.3)	0	3 (3.3)	0	0
Blood uric acid increased	3 (3.3)	1 (1.1)	0	1 (1.1)	1 (1.1)
Oxygen saturation decreased	2 (2.2)	0	1 (1.1)	1 (1.1)	0
Blood creatine phosphokinase increased	1 (1.1)	0	0	0	1 (1.1)
Metabolism and nutrition disorders					
-Total	57 (62.6)	9 (9.9)	11 (12.1)	25 (27.5)	12 (13.2)
Decreased appetite	33 (36.3)	12 (13.2)	9 (9.9)	10 (11.0)	2 (2.2)
Hypokalaemia	23 (25.3)	2 (2.2)	6 (6.6)	12 (13.2)	3 (3.3)
Hypophosphataemia	18 (19.8)	2 (2.2)	6 (6.6)	9 (9.9)	1 (1.1)
Hypocalcaemia	15 (16.5)	1 (1.1)	8 (8.8)	6 (6.6)	0
Hypoalbuminaemia	11 (12.1)	0	10 (11.0)	1 (1.1)	0
Hyperuricaemia	10 (11.0)	7 (7.7)	2 (2.2)	1 (1.1)	0
Hypomagnesaemia	10 (11.0)	7 (7.7)	3 (3.3)	0	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	9 (9.9)	0	4 (4.4)	4 (4.4)	1 (1.1)
Hypervolaemia	8 (8.8)	1 (1.1)	1 (1.1)	6 (6.6)	0
Tumour lysis syndrome	6 (6.6)	0	0	4 (4.4)	2 (2.2)
Metabolic acidosis	5 (5.5)	1 (1.1)	0	2 (2.2)	2 (2.2)
Hyperphosphataemia	4 (4.4)	3 (3.3)	0	0	1 (1.1)
Hyponatraemia	4 (4.4)	3 (3.3)	0	0	1 (1.1)
Hyperkalaemia	3 (3.3)	0	1 (1.1)	1 (1.1)	1 (1.1)
Hypercalcaemia	2 (2.2)	0	1 (1.1)	0	1 (1.1)
Hyperchloraemia	1 (1.1)	1 (1.1)	0	0	0
Hypermagnesaemia	1 (1.1)	1 (1.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	43 (47.3)	16 (17.6)	19 (20.9)	8 (8.8)	0
Pain in extremity	22 (24.2)	8 (8.8)	11 (12.1)	3 (3.3)	0
Arthralgia	16 (17.6)	8 (8.8)	7 (7.7)	1 (1.1)	0
Back pain	13 (14.3)	2 (2.2)	7 (7.7)	4 (4.4)	0
Myalgia	9 (9.9)	5 (5.5)	4 (4.4)	0	0
Bone pain	3 (3.3)	0	3 (3.3)	0	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	43 (47.3)	18 (19.8)	15 (16.5)	9 (9.9)	1 (1.1)
Headache	34 (37.4)	18 (19.8)	11 (12.1)	5 (5.5)	0
Encephalopathy	8 (8.8)	1 (1.1)	3 (3.3)	4 (4.4)	0
Somnolence	5 (5.5)	2 (2.2)	2 (2.2)	1 (1.1)	0
Tremor	5 (5.5)	5 (5.5)	0	0	0
Dizziness	4 (4.4)	4 (4.4)	0	0	0
Cerebral haemorrhage	1 (1.1)	0	0	0	1 (1.1)
Psychiatric disorders					
-Total	36 (39.6)	14 (15.4)	12 (13.2)	10 (11.0)	0
Anxiety	17 (18.7)	4 (4.4)	10 (11.0)	3 (3.3)	0
Delirium	7 (7.7)	2 (2.2)	2 (2.2)	3 (3.3)	0
Agitation	6 (6.6)	4 (4.4)	2 (2.2)	0	0
Confusional state	6 (6.6)	6 (6.6)	0	0	0
Mental status changes	6 (6.6)	1 (1.1)	2 (2.2)	3 (3.3)	0
Insomnia	5 (5.5)	2 (2.2)	3 (3.3)	0	0
Irritability	3 (3.3)	2 (2.2)	0	1 (1.1)	0
Renal and urinary disorders					

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (14.3)	5 (5.5)	2 (2.2)	2 (2.2)	4 (4.4)
Acute kidney injury	12 (13.2)	5 (5.5)	2 (2.2)	2 (2.2)	3 (3.3)
Anuria	1 (1.1)	0	0	0	1 (1.1)
Respiratory, thoracic and mediastinal disorders					
-Total	55 (60.4)	19 (20.9)	8 (8.8)	12 (13.2)	16 (17.6)
Cough	23 (25.3)	19 (20.9)	4 (4.4)	0	0
Hypoxia	18 (19.8)	0	6 (6.6)	8 (8.8)	4 (4.4)
Pulmonary oedema	12 (13.2)	3 (3.3)	1 (1.1)	6 (6.6)	2 (2.2)
Epistaxis	10 (11.0)	6 (6.6)	1 (1.1)	3 (3.3)	0
Respiratory failure	10 (11.0)	0	0	0	10 (11.0)
Tachypnoea	10 (11.0)	3 (3.3)	2 (2.2)	4 (4.4)	1 (1.1)
Nasal congestion	9 (9.9)	8 (8.8)	1 (1.1)	0	0
Oropharyngeal pain	9 (9.9)	8 (8.8)	1 (1.1)	0	0
Dyspnoea	8 (8.8)	2 (2.2)	1 (1.1)	3 (3.3)	2 (2.2)
Pleural effusion	7 (7.7)	2 (2.2)	3 (3.3)	1 (1.1)	1 (1.1)
Rhinorrhoea	5 (5.5)	4 (4.4)	1 (1.1)	0	0
Atelectasis	3 (3.3)	0	1 (1.1)	2 (2.2)	0

Down syndrome: No

	All patients N=91				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	3 (3.3)	0	1 (1.1)	0	2 (2.2)
Wheezing	2 (2.2)	1 (1.1)	1 (1.1)	0	0
Rhinitis allergic	1 (1.1)	1 (1.1)	0	0	0
Sleep apnoea syndrome	1 (1.1)	1 (1.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	32 (35.2)	15 (16.5)	13 (14.3)	4 (4.4)	0
Pruritus	12 (13.2)	6 (6.6)	6 (6.6)	0	0
Dry skin	8 (8.8)	6 (6.6)	2 (2.2)	0	0
Rash	8 (8.8)	4 (4.4)	4 (4.4)	0	0
Erythema	4 (4.4)	3 (3.3)	1 (1.1)	0	0
Skin ulcer	4 (4.4)	2 (2.2)	1 (1.1)	1 (1.1)	0
Ingrowing nail	3 (3.3)	1 (1.1)	2 (2.2)	0	0
Rash maculo-papular	3 (3.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Blister	2 (2.2)	2 (2.2)	0	0	0
Eczema	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Petechiae	2 (2.2)	1 (1.1)	0	1 (1.1)	0
Skin discolouration	1 (1.1)	1 (1.1)	0	0	0

Down syndrome: No

Group term Preferred term	All patients N=91 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	40 (44.0)	6 (6.6)	12 (13.2)	14 (15.4)	8 (8.8)
Hypotension	28 (30.8)	3 (3.3)	6 (6.6)	11 (12.1)	8 (8.8)
Hypertension	21 (23.1)	4 (4.4)	12 (13.2)	5 (5.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	1 (2.5)	7 (17.5)	32 (80.0)
Blood and lymphatic system disorders					
-Total	35 (87.5)	0	2 (5.0)	15 (37.5)	18 (45.0)
Anaemia	21 (52.5)	1 (2.5)	4 (10.0)	16 (40.0)	0
Febrile neutropenia	20 (50.0)	0	0	19 (47.5)	1 (2.5)
Neutropenia	18 (45.0)	0	1 (2.5)	2 (5.0)	15 (37.5)
Thrombocytopenia	6 (15.0)	0	0	1 (2.5)	5 (12.5)
Disseminated intravascular coagulation	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Leukopenia	5 (12.5)	0	0	1 (2.5)	4 (10.0)
Pancytopenia	3 (7.5)	0	0	2 (5.0)	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Tachycardia	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Endocrine disorders					
-Total	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Adrenal insufficiency	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Gastrointestinal disorders					
-Total	29 (72.5)	11 (27.5)	10 (25.0)	8 (20.0)	0
Nausea	13 (32.5)	6 (15.0)	4 (10.0)	3 (7.5)	0
Vomiting	13 (32.5)	8 (20.0)	5 (12.5)	0	0
Diarrhoea	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Abdominal pain	8 (20.0)	2 (5.0)	5 (12.5)	1 (2.5)	0
Constipation	8 (20.0)	4 (10.0)	4 (10.0)	0	0
Stomatitis	7 (17.5)	1 (2.5)	2 (5.0)	4 (10.0)	0
General disorders and administration site conditions					
-Total	23 (57.5)	12 (30.0)	6 (15.0)	4 (10.0)	1 (2.5)
Pyrexia	17 (42.5)	9 (22.5)	4 (10.0)	3 (7.5)	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Fatigue	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Asthenia	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Face oedema	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Pain	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Oedema peripheral	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Catheter site pain	1 (2.5)	0	0	1 (2.5)	0
Hepatobiliary disorders					
-Total	6 (15.0)	1 (2.5)	2 (5.0)	2 (5.0)	1 (2.5)
Hepatic function abnormal	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Hyperbilirubinaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Immune system disorders					
-Total	35 (87.5)	1 (2.5)	8 (20.0)	15 (37.5)	11 (27.5)
Cytokine release syndrome	31 (77.5)	3 (7.5)	8 (20.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	22 (55.0)	1 (2.5)	13 (32.5)	8 (20.0)	0
Immunodeficiency	4 (10.0)	0	0	4 (10.0)	0
Haemophagocytic lymphohistiocytosis	2 (5.0)	1 (2.5)	0	0	1 (2.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	26 (65.0)	3 (7.5)	5 (12.5)	15 (37.5)	3 (7.5)
Upper respiratory tract infection	8 (20.0)	4 (10.0)	2 (5.0)	2 (5.0)	0
Gastroenteritis	7 (17.5)	4 (10.0)	1 (2.5)	2 (5.0)	0
Nasopharyngitis	7 (17.5)	4 (10.0)	3 (7.5)	0	0
Herpes zoster	5 (12.5)	0	1 (2.5)	4 (10.0)	0
Parainfluenzae virus infection	5 (12.5)	1 (2.5)	0	3 (7.5)	1 (2.5)
Pneumonia	5 (12.5)	0	1 (2.5)	2 (5.0)	2 (5.0)
Conjunctivitis	4 (10.0)	0	4 (10.0)	0	0
Oral herpes	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Respiratory tract infection	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Sinusitis	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Rhinovirus infection	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	0	0	2 (5.0)	0
Injury, poisoning and procedural complications					
-Total	3 (7.5)	0	3 (7.5)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	2 (5.0)	0	2 (5.0)	0	0
Transfusion reaction	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	27 (67.5)	0	0	4 (10.0)	23 (57.5)
White blood cell count decreased	19 (47.5)	0	0	0	19 (47.5)
Platelet count decreased	17 (42.5)	3 (7.5)	0	3 (7.5)	11 (27.5)
Neutrophil count decreased	16 (40.0)	1 (2.5)	0	1 (2.5)	14 (35.0)
Lymphocyte count decreased	12 (30.0)	0	0	2 (5.0)	10 (25.0)
Alanine aminotransferase increased	9 (22.5)	2 (5.0)	2 (5.0)	5 (12.5)	0
Aspartate aminotransferase increased	6 (15.0)	1 (2.5)	0	4 (10.0)	1 (2.5)
Serum ferritin increased	6 (15.0)	2 (5.0)	4 (10.0)	0	0
C-reactive protein increased	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Blood bilirubin increased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Blood creatinine increased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood fibrinogen decreased	2 (5.0)	0	2 (5.0)	0	0
Blood immunoglobulin a decreased	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (2.5)	0	0	1 (2.5)	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0	0	0
International normalised ratio increased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					
-Total	21 (52.5)	4 (10.0)	3 (7.5)	10 (25.0)	4 (10.0)
Decreased appetite	11 (27.5)	5 (12.5)	2 (5.0)	2 (5.0)	2 (5.0)
Hypokalaemia	9 (22.5)	2 (5.0)	0	6 (15.0)	1 (2.5)
Hypophosphataemia	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Hypoalbuminaemia	6 (15.0)	0	6 (15.0)	0	0
Hyperglycaemia	5 (12.5)	0	2 (5.0)	3 (7.5)	0
Hypocalcaemia	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Hypomagnesaemia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Hyperuricaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Hypervolaemia	1 (2.5)	0	1 (2.5)	0	0
Metabolic acidosis	1 (2.5)	0	0	0	1 (2.5)
Musculoskeletal and connective tissue disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (47.5)	8 (20.0)	6 (15.0)	5 (12.5)	0
Pain in extremity	10 (25.0)	2 (5.0)	6 (15.0)	2 (5.0)	0
Arthralgia	9 (22.5)	7 (17.5)	2 (5.0)	0	0
Back pain	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Myalgia	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Nervous system disorders					
-Total	18 (45.0)	9 (22.5)	6 (15.0)	3 (7.5)	0
Headache	15 (37.5)	9 (22.5)	4 (10.0)	2 (5.0)	0
Encephalopathy	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Psychiatric disorders					
-Total	11 (27.5)	4 (10.0)	5 (12.5)	2 (5.0)	0
Anxiety	8 (20.0)	3 (7.5)	4 (10.0)	1 (2.5)	0
Agitation	3 (7.5)	3 (7.5)	0	0	0
Confusional state	2 (5.0)	2 (5.0)	0	0	0
Delirium	2 (5.0)	0	2 (5.0)	0	0
Mental status changes	1 (2.5)	0	0	1 (2.5)	0
Renal and urinary disorders					
-Total	6 (15.0)	2 (5.0)	1 (2.5)	1 (2.5)	2 (5.0)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	5 (12.5)	1 (2.5)	1 (2.5)	1 (2.5)	2 (5.0)
Dysuria	1 (2.5)	1 (2.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (70.0)	10 (25.0)	5 (12.5)	8 (20.0)	5 (12.5)
Cough	15 (37.5)	13 (32.5)	2 (5.0)	0	0
Hypoxia	10 (25.0)	0	3 (7.5)	4 (10.0)	3 (7.5)
Epistaxis	7 (17.5)	6 (15.0)	0	1 (2.5)	0
Oropharyngeal pain	5 (12.5)	5 (12.5)	0	0	0
Pleural effusion	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Pulmonary oedema	5 (12.5)	1 (2.5)	0	4 (10.0)	0
Dyspnoea	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Nasal congestion	4 (10.0)	4 (10.0)	0	0	0
Tachypnoea	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Rhinorrhoea	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (27.5)	8 (20.0)	3 (7.5)	0	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	4 (10.0)	4 (10.0)	0	0	0
Pruritus	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rash	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Erythema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Vascular disorders					
-Total	12 (30.0)	4 (10.0)	2 (5.0)	4 (10.0)	2 (5.0)
Hypotension	7 (17.5)	1 (2.5)	1 (2.5)	3 (7.5)	2 (5.0)
Hypertension	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (100)	0	2 (5.0)	10 (25.0)	28 (70.0)
Blood and lymphatic system disorders					
-Total	28 (70.0)	1 (2.5)	3 (7.5)	18 (45.0)	6 (15.0)
Anaemia	22 (55.0)	5 (12.5)	8 (20.0)	8 (20.0)	1 (2.5)
Febrile neutropenia	21 (52.5)	0	0	20 (50.0)	1 (2.5)
Thrombocytopenia	8 (20.0)	1 (2.5)	1 (2.5)	4 (10.0)	2 (5.0)
Neutropenia	4 (10.0)	1 (2.5)	1 (2.5)	1 (2.5)	1 (2.5)
Disseminated intravascular coagulation	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	15 (37.5)	7 (17.5)	5 (12.5)	2 (5.0)	1 (2.5)
Tachycardia	15 (37.5)	7 (17.5)	5 (12.5)	2 (5.0)	1 (2.5)
Endocrine disorders					
-Total	4 (10.0)	0	4 (10.0)	0	0
Adrenal insufficiency	4 (10.0)	0	4 (10.0)	0	0
Gastrointestinal disorders					
-Total	37 (92.5)	10 (25.0)	20 (50.0)	7 (17.5)	0
Nausea	23 (57.5)	8 (20.0)	14 (35.0)	1 (2.5)	0
Vomiting	18 (45.0)	13 (32.5)	3 (7.5)	2 (5.0)	0
Diarrhoea	15 (37.5)	11 (27.5)	2 (5.0)	2 (5.0)	0
Constipation	12 (30.0)	6 (15.0)	6 (15.0)	0	0
Abdominal pain	10 (25.0)	3 (7.5)	5 (12.5)	2 (5.0)	0
Stomatitis	5 (12.5)	0	2 (5.0)	3 (7.5)	0
General disorders and administration site conditions					
-Total	35 (87.5)	15 (37.5)	13 (32.5)	6 (15.0)	1 (2.5)
Pyrexia	26 (65.0)	9 (22.5)	10 (25.0)	6 (15.0)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	17 (42.5)	12 (30.0)	5 (12.5)	0	0
Face oedema	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Oedema peripheral	5 (12.5)	5 (12.5)	0	0	0
Pain	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Catheter site pain	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Chills	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Hepatobiliary disorders					
-Total	8 (20.0)	2 (5.0)	4 (10.0)	2 (5.0)	0
Hyperbilirubinaemia	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Hypertransaminasaemia	4 (10.0)	2 (5.0)	1 (2.5)	1 (2.5)	0
Hepatic function abnormal	1 (2.5)	0	1 (2.5)	0	0
Immune system disorders					
-Total	36 (90.0)	1 (2.5)	16 (40.0)	8 (20.0)	11 (27.5)
Cytokine release syndrome	30 (75.0)	2 (5.0)	10 (25.0)	7 (17.5)	11 (27.5)
Hypogammaglobulinaemia	19 (47.5)	1 (2.5)	17 (42.5)	1 (2.5)	0
Haemophagocytic lymphohistiocytosis	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Seasonal allergy	4 (10.0)	2 (5.0)	2 (5.0)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	22 (55.0)	2 (5.0)	11 (27.5)	9 (22.5)	0
Rhinovirus infection	6 (15.0)	0	6 (15.0)	0	0
Staphylococcal bacteraemia	6 (15.0)	0	0	6 (15.0)	0
Upper respiratory tract infection	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Conjunctivitis	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Sinusitis	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Pneumonia	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Oral herpes	2 (5.0)	0	2 (5.0)	0	0
Parainfluenzae virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Nasopharyngitis	1 (2.5)	1 (2.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	8 (20.0)	3 (7.5)	2 (5.0)	3 (7.5)	0
Infusion related reaction	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Transfusion reaction	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Investigations					
-Total	32 (80.0)	1 (2.5)	1 (2.5)	13 (32.5)	17 (42.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	16 (40.0)	1 (2.5)	6 (15.0)	7 (17.5)	2 (5.0)
White blood cell count decreased	15 (37.5)	2 (5.0)	3 (7.5)	1 (2.5)	9 (22.5)
Alanine aminotransferase increased	14 (35.0)	2 (5.0)	7 (17.5)	5 (12.5)	0
Neutrophil count decreased	14 (35.0)	1 (2.5)	2 (5.0)	2 (5.0)	9 (22.5)
Platelet count decreased	14 (35.0)	3 (7.5)	2 (5.0)	3 (7.5)	6 (15.0)
Lymphocyte count decreased	11 (27.5)	0	1 (2.5)	7 (17.5)	3 (7.5)
Blood bilirubin increased	10 (25.0)	1 (2.5)	1 (2.5)	8 (20.0)	0
International normalised ratio increased	9 (22.5)	5 (12.5)	4 (10.0)	0	0
Activated partial thromboplastin time prolonged	7 (17.5)	4 (10.0)	2 (5.0)	1 (2.5)	0
Blood fibrinogen decreased	6 (15.0)	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)
Blood immunoglobulin m decreased	6 (15.0)	4 (10.0)	1 (2.5)	1 (2.5)	0
Blood lactate dehydrogenase increased	6 (15.0)	1 (2.5)	2 (5.0)	3 (7.5)	0
C-reactive protein increased	6 (15.0)	1 (2.5)	1 (2.5)	3 (7.5)	1 (2.5)
Electrocardiogram qt prolonged	6 (15.0)	2 (5.0)	2 (5.0)	1 (2.5)	1 (2.5)
Serum ferritin increased	6 (15.0)	0	2 (5.0)	3 (7.5)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Blood creatinine increased	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Blood uric acid increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)
Fibrin d dimer increased	4 (10.0)	2 (5.0)	0	1 (2.5)	1 (2.5)
Metabolism and nutrition disorders					
-Total	33 (82.5)	4 (10.0)	9 (22.5)	14 (35.0)	6 (15.0)
Decreased appetite	23 (57.5)	7 (17.5)	6 (15.0)	10 (25.0)	0
Hypokalaemia	16 (40.0)	2 (5.0)	5 (12.5)	7 (17.5)	2 (5.0)
Hypophosphataemia	14 (35.0)	2 (5.0)	5 (12.5)	6 (15.0)	1 (2.5)
Hypocalcaemia	12 (30.0)	1 (2.5)	7 (17.5)	4 (10.0)	0
Hypervolaemia	8 (20.0)	1 (2.5)	1 (2.5)	6 (15.0)	0
Hyperuricaemia	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Hyperphosphataemia	6 (15.0)	5 (12.5)	0	0	1 (2.5)
Hypoalbuminaemia	6 (15.0)	0	5 (12.5)	1 (2.5)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hypomagnesaemia	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Metabolic acidosis	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Tumour lysis syndrome	3 (7.5)	0	0	2 (5.0)	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	22 (55.0)	9 (22.5)	10 (25.0)	3 (7.5)	0
Pain in extremity	13 (32.5)	7 (17.5)	5 (12.5)	1 (2.5)	0
Arthralgia	6 (15.0)	1 (2.5)	4 (10.0)	1 (2.5)	0
Back pain	5 (12.5)	0	4 (10.0)	1 (2.5)	0
Myalgia	5 (12.5)	2 (5.0)	3 (7.5)	0	0
Nervous system disorders					
-Total	22 (55.0)	8 (20.0)	8 (20.0)	6 (15.0)	0
Headache	19 (47.5)	8 (20.0)	8 (20.0)	3 (7.5)	0
Encephalopathy	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Psychiatric disorders					
-Total	22 (55.0)	9 (22.5)	7 (17.5)	6 (15.0)	0
Anxiety	9 (22.5)	1 (2.5)	6 (15.0)	2 (5.0)	0
Delirium	6 (15.0)	2 (5.0)	1 (2.5)	3 (7.5)	0
Insomnia	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Confusional state	5 (12.5)	5 (12.5)	0	0	0
Agitation	4 (10.0)	1 (2.5)	3 (7.5)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	4 (10.0)	1 (2.5)	2 (5.0)	1 (2.5)	0
Renal and urinary disorders					
-Total	9 (22.5)	3 (7.5)	1 (2.5)	2 (5.0)	3 (7.5)
Acute kidney injury	7 (17.5)	1 (2.5)	1 (2.5)	2 (5.0)	3 (7.5)
Dysuria	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (67.5)	10 (25.0)	2 (5.0)	5 (12.5)	10 (25.0)
Cough	11 (27.5)	8 (20.0)	3 (7.5)	0	0
Hypoxia	11 (27.5)	0	2 (5.0)	6 (15.0)	3 (7.5)
Pulmonary oedema	8 (20.0)	2 (5.0)	3 (7.5)	2 (5.0)	1 (2.5)
Nasal congestion	7 (17.5)	5 (12.5)	2 (5.0)	0	0
Respiratory failure	6 (15.0)	0	0	0	6 (15.0)
Dyspnoea	5 (12.5)	1 (2.5)	2 (5.0)	1 (2.5)	1 (2.5)
Epistaxis	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Oropharyngeal pain	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Pleural effusion	5 (12.5)	2 (5.0)	0	2 (5.0)	1 (2.5)
Rhinorrhoea	5 (12.5)	3 (7.5)	2 (5.0)	0	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	5 (12.5)	3 (7.5)	0	2 (5.0)	0
Respiratory distress	4 (10.0)	0	2 (5.0)	0	2 (5.0)
Skin and subcutaneous tissue disorders					
-Total	17 (42.5)	9 (22.5)	8 (20.0)	0	0
Pruritus	9 (22.5)	4 (10.0)	5 (12.5)	0	0
Rash	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Dry skin	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Erythema	4 (10.0)	4 (10.0)	0	0	0
Vascular disorders					
-Total	25 (62.5)	2 (5.0)	8 (20.0)	8 (20.0)	7 (17.5)
Hypotension	20 (50.0)	2 (5.0)	5 (12.5)	6 (15.0)	7 (17.5)
Hypertension	15 (37.5)	2 (5.0)	9 (22.5)	4 (10.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	2 (11.1)	5 (27.8)	8 (44.4)
Blood and lymphatic system disorders					
-Total	8 (44.4)	0	0	5 (27.8)	3 (16.7)
Febrile neutropenia	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	0	0	3 (16.7)	0
Pancytopenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Tachycardia	4 (22.2)	0	2 (11.1)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Adrenal insufficiency	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal disorders					
-Total	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Diarrhoea	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Nausea	1 (5.6)	0	1 (5.6)	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	8 (44.4)	1 (5.6)	4 (22.2)	3 (16.7)	0
Pyrexia	5 (27.8)	0	3 (16.7)	2 (11.1)	0
Catheter site pain	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Oedema peripheral	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	2 (11.1)	0	0	2 (11.1)	0
Infections and infestations					
-Total	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Oral herpes	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Investigations					
-Total	5 (27.8)	0	0	3 (16.7)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
C-reactive protein increased	2 (11.1)	0	0	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	0	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	0	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (38.9)	0	2 (11.1)	3 (16.7)	2 (11.1)
Hypocalcaemia	2 (11.1)	0	2 (11.1)	0	0
Metabolic acidosis	2 (11.1)	0	0	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Hyperglycaemia	1 (5.6)	0	0	0	1 (5.6)
Hyperuricaemia	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	1 (5.6)	0	0
Hypokalaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	2 (11.1)	0	0	2 (11.1)	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acute kidney injury	3 (16.7)	3 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (27.8)	0	1 (5.6)	1 (5.6)	3 (16.7)
Respiratory failure	3 (16.7)	0	0	0	3 (16.7)
Tachypnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hypoxia	1 (5.6)	0	1 (5.6)	0	0
Pulmonary oedema	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (38.9)	1 (5.6)	2 (11.1)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	3 (37.5)	5 (62.5)
Blood and lymphatic system disorders					
-Total	7 (87.5)	0	1 (12.5)	4 (50.0)	2 (25.0)
Anaemia	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Febrile neutropenia	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Coagulopathy	1 (12.5)	0	0	1 (12.5)	0
Disseminated intravascular coagulation	1 (12.5)	0	0	1 (12.5)	0
Lymphocytosis	1 (12.5)	0	1 (12.5)	0	0
Thrombocytopenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Tachycardia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Sinus tachycardia	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Eyelid oedema	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	6 (75.0)	2 (25.0)	1 (12.5)	2 (25.0)	1 (12.5)
Abdominal pain	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Nausea	2 (25.0)	2 (25.0)	0	0	0
Stomatitis	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Abdominal compartment syndrome	1 (12.5)	0	0	0	1 (12.5)
Abdominal distension	1 (12.5)	0	1 (12.5)	0	0
Ascites	1 (12.5)	1 (12.5)	0	0	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Gingival erythema	1 (12.5)	1 (12.5)	0	0	0
Haematemesis	1 (12.5)	1 (12.5)	0	0	0
Haemoperitoneum	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritable bowel syndrome	1 (12.5)	0	1 (12.5)	0	0
Melaena	1 (12.5)	0	0	1 (12.5)	0
Mouth haemorrhage	1 (12.5)	0	1 (12.5)	0	0
Tooth pulp haemorrhage	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	2 (25.0)	2 (25.0)	1 (12.5)
Pyrexia	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Fatigue	2 (25.0)	2 (25.0)	0	0	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	0	1 (12.5)	0	0
Face oedema	1 (12.5)	0	1 (12.5)	0	0
Generalised oedema	1 (12.5)	0	1 (12.5)	0	0
Multiple organ dysfunction syndrome	1 (12.5)	0	0	0	1 (12.5)
Oedema peripheral	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Systemic inflammatory response syndrome	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	0	0	0	1 (12.5)
Cholelithiasis	1 (12.5)	1 (12.5)	0	0	0
Cholestasis	1 (12.5)	0	0	0	1 (12.5)
Gallbladder enlargement	1 (12.5)	1 (12.5)	0	0	0
Immune system disorders					
-Total	6 (75.0)	0	4 (50.0)	0	2 (25.0)
Cytokine release syndrome	5 (62.5)	1 (12.5)	2 (25.0)	0	2 (25.0)
Hypogammaglobulinaemia	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Haemophagocytic lymphohistiocytosis	1 (12.5)	0	0	0	1 (12.5)
Seasonal allergy	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	6 (75.0)	0	0	3 (37.5)	3 (37.5)
Localised infection	2 (25.0)	2 (25.0)	0	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Conjunctivitis	1 (12.5)	0	1 (12.5)	0	0
Disseminated trichosporonosis	1 (12.5)	0	0	0	1 (12.5)
Encephalitis	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis escherichia coli	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis salmonella	1 (12.5)	0	0	1 (12.5)	0
Gastroenteritis viral	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal infection	1 (12.5)	1 (12.5)	0	0	0
Otitis externa	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	1 (12.5)	0
Pseudomonal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	0	1 (12.5)	0	0
Serratia sepsis	1 (12.5)	0	0	0	1 (12.5)
Sialoadenitis	1 (12.5)	0	0	1 (12.5)	0
Sinusitis	1 (12.5)	0	1 (12.5)	0	0
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Upper respiratory tract infection	1 (12.5)	0	1 (12.5)	0	0
Vulval cellulitis	1 (12.5)	0	0	1 (12.5)	0
Injury, poisoning and procedural complications					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	0	2 (25.0)	0	1 (12.5)
Fibula fracture	1 (12.5)	0	1 (12.5)	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	1 (12.5)	0	0
Radius fracture	1 (12.5)	0	1 (12.5)	0	0
Skin injury	1 (12.5)	0	1 (12.5)	0	0
Skin wound	1 (12.5)	1 (12.5)	0	0	0
Vasoplegia syndrome	1 (12.5)	0	0	0	1 (12.5)
Wound	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Alanine aminotransferase increased	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Neutrophil count decreased	3 (37.5)	0	0	1 (12.5)	2 (25.0)
White blood cell count decreased	3 (37.5)	1 (12.5)	1 (12.5)	0	1 (12.5)
Aspartate aminotransferase increased	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Blood creatinine increased	2 (25.0)	2 (25.0)	0	0	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (12.5)	1 (12.5)	0	0	0
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0
Blood creatine phosphokinase increased	1 (12.5)	0	0	0	1 (12.5)
Blood immunoglobulin g decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	0	1 (12.5)	0	0
Electrocardiogram qt prolonged	1 (12.5)	0	1 (12.5)	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Lipase increased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	0	1 (12.5)	0	0
Metabolism and nutrition disorders					
-Total	7 (87.5)	1 (12.5)	1 (12.5)	4 (50.0)	1 (12.5)
Hypocalcaemia	4 (50.0)	0	3 (37.5)	1 (12.5)	0
Decreased appetite	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Hypophosphataemia	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Hyperuricaemia	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (25.0)	0	2 (25.0)	0	0
Hypomagnesaemia	2 (25.0)	2 (25.0)	0	0	0
Metabolic acidosis	2 (25.0)	0	0	2 (25.0)	0
Acidosis	1 (12.5)	0	0	1 (12.5)	0
Haemosiderosis	1 (12.5)	0	1 (12.5)	0	0
Hyperglycaemia	1 (12.5)	0	1 (12.5)	0	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hyperlactacidaemia	1 (12.5)	1 (12.5)	0	0	0
Hypermagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypernatraemia	1 (12.5)	0	0	0	1 (12.5)
Hypokalaemia	1 (12.5)	0	0	0	1 (12.5)
Hyponatraemia	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Myalgia	1 (12.5)	1 (12.5)	0	0	0
Myositis	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhabdomyolysis	1 (12.5)	0	0	0	1 (12.5)
Nervous system disorders					
-Total	5 (62.5)	0	3 (37.5)	2 (25.0)	0
Headache	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Somnolence	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cognitive disorder	1 (12.5)	0	0	1 (12.5)	0
Encephalopathy	1 (12.5)	0	0	1 (12.5)	0
Monoparesis	1 (12.5)	0	1 (12.5)	0	0
Neuropathy peripheral	1 (12.5)	0	1 (12.5)	0	0
Tremor	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Confusional state	1 (12.5)	1 (12.5)	0	0	0
Irritability	1 (12.5)	0	0	1 (12.5)	0
Persistent depressive disorder	1 (12.5)	0	1 (12.5)	0	0
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Bladder dilatation	1 (12.5)	0	1 (12.5)	0	0
Dysuria	1 (12.5)	1 (12.5)	0	0	0
Renal tubular necrosis	1 (12.5)	0	0	0	1 (12.5)
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Reproductive system and breast disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Vaginal ulceration	1 (12.5)	0	0	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (75.0)	2 (25.0)	0	1 (12.5)	3 (37.5)
Nasal congestion	2 (25.0)	2 (25.0)	0	0	0
Oropharyngeal pain	2 (25.0)	2 (25.0)	0	0	0
Respiratory failure	2 (25.0)	0	0	0	2 (25.0)
Tachypnoea	2 (25.0)	0	0	2 (25.0)	0
Acute respiratory distress syndrome	1 (12.5)	0	0	0	1 (12.5)
Acute respiratory failure	1 (12.5)	0	0	1 (12.5)	0
Atelectasis	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (12.5)	1 (12.5)	0	0	0
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)
Hypoxia	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory acidosis	1 (12.5)	0	0	1 (12.5)	0
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	0	1 (12.5)	0
Dry skin	2 (25.0)	2 (25.0)	0	0	0
Rash	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Decubitus ulcer	1 (12.5)	0	1 (12.5)	0	0
Erythema	1 (12.5)	1 (12.5)	0	0	0
Hyperhidrosis	1 (12.5)	1 (12.5)	0	0	0
Ingrowing nail	1 (12.5)	1 (12.5)	0	0	0
Petechiae	1 (12.5)	0	0	1 (12.5)	0
Pruritus	1 (12.5)	0	1 (12.5)	0	0
Skin hypopigmentation	1 (12.5)	1 (12.5)	0	0	0
Skin necrosis	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Hypotension	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Hypertension	1 (12.5)	0	0	1 (12.5)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (96.7)	0	2 (6.7)	8 (26.7)	19 (63.3)
Blood and lymphatic system disorders					
-Total	18 (60.0)	1 (3.3)	2 (6.7)	7 (23.3)	8 (26.7)
Anaemia	12 (40.0)	2 (6.7)	3 (10.0)	7 (23.3)	0
Febrile neutropenia	10 (33.3)	0	0	9 (30.0)	1 (3.3)
Neutropenia	6 (20.0)	0	0	1 (3.3)	5 (16.7)
Thrombocytopenia	5 (16.7)	0	0	2 (6.7)	3 (10.0)
Coagulopathy	2 (6.7)	0	2 (6.7)	0	0
Disseminated intravascular coagulation	2 (6.7)	0	2 (6.7)	0	0
Splenomegaly	1 (3.3)	1 (3.3)	0	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	10 (33.3)	2 (6.7)	3 (10.0)	5 (16.7)	0
Tachycardia	8 (26.7)	2 (6.7)	4 (13.3)	2 (6.7)	0
Bradycardia	3 (10.0)	3 (10.0)	0	0	0
Left ventricular dysfunction	3 (10.0)	0	0	3 (10.0)	0
Endocrine disorders					
-Total	5 (16.7)	0	5 (16.7)	0	0
Adrenal insufficiency	3 (10.0)	0	3 (10.0)	0	0
Hypothyroidism	2 (6.7)	0	2 (6.7)	0	0
Eye disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Eyelid oedema	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	22 (73.3)	6 (20.0)	7 (23.3)	8 (26.7)	1 (3.3)
Nausea	12 (40.0)	3 (10.0)	6 (20.0)	3 (10.0)	0
Vomiting	12 (40.0)	9 (30.0)	2 (6.7)	1 (3.3)	0
Diarrhoea	8 (26.7)	6 (20.0)	1 (3.3)	1 (3.3)	0
Constipation	7 (23.3)	3 (10.0)	4 (13.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Stomatitis	3 (10.0)	0	0	3 (10.0)	0
Pancreatitis	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Abdominal compartment syndrome	1 (3.3)	0	0	0	1 (3.3)
Haematemesis	1 (3.3)	1 (3.3)	0	0	0
Mouth haemorrhage	1 (3.3)	0	0	1 (3.3)	0
General disorders and administration site conditions					
-Total	20 (66.7)	7 (23.3)	6 (20.0)	4 (13.3)	3 (10.0)
Pyrexia	13 (43.3)	5 (16.7)	4 (13.3)	3 (10.0)	1 (3.3)
Oedema peripheral	6 (20.0)	4 (13.3)	1 (3.3)	1 (3.3)	0
Face oedema	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Fatigue	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Catheter site pain	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Chills	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Pain	3 (10.0)	0	3 (10.0)	0	0
Multiple organ dysfunction syndrome	2 (6.7)	0	0	0	2 (6.7)
Generalised oedema	1 (3.3)	0	1 (3.3)	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Hyperbilirubinaemia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Gallbladder enlargement	1 (3.3)	1 (3.3)	0	0	0
Hypertransaminasaemia	1 (3.3)	1 (3.3)	0	0	0
Immune system disorders					
-Total	20 (66.7)	1 (3.3)	7 (23.3)	5 (16.7)	7 (23.3)
Cytokine release syndrome	15 (50.0)	1 (3.3)	4 (13.3)	4 (13.3)	6 (20.0)
Hypogammaglobulinaemia	10 (33.3)	1 (3.3)	8 (26.7)	1 (3.3)	0
Haemophagocytic lymphohistiocytosis	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Infections and infestations					
-Total	15 (50.0)	2 (6.7)	6 (20.0)	5 (16.7)	2 (6.7)
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Clostridium difficile infection	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Conjunctivitis	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Parainfluenzae virus infection	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Rhinovirus infection	3 (10.0)	0	2 (6.7)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	3 (10.0)	0	0	3 (10.0)	0
Nasopharyngitis	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Pneumonia	2 (6.7)	0	0	0	2 (6.7)
Bronchitis	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis viral	1 (3.3)	1 (3.3)	0	0	0
Localised infection	1 (3.3)	0	0	1 (3.3)	0
Oral herpes	1 (3.3)	0	0	1 (3.3)	0
Otitis media	1 (3.3)	0	1 (3.3)	0	0
Sialoadenitis	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal infection	1 (3.3)	0	1 (3.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Transfusion reaction	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Infusion related reaction	1 (3.3)	0	0	1 (3.3)	0
Investigations					
-Total	21 (70.0)	1 (3.3)	1 (3.3)	8 (26.7)	11 (36.7)

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	10 (33.3)	1 (3.3)	1 (3.3)	1 (3.3)	7 (23.3)
Aspartate aminotransferase increased	9 (30.0)	0	3 (10.0)	5 (16.7)	1 (3.3)
Platelet count decreased	8 (26.7)	3 (10.0)	1 (3.3)	1 (3.3)	3 (10.0)
Alanine aminotransferase increased	7 (23.3)	1 (3.3)	5 (16.7)	1 (3.3)	0
Lymphocyte count decreased	7 (23.3)	0	0	3 (10.0)	4 (13.3)
Serum ferritin increased	7 (23.3)	1 (3.3)	3 (10.0)	2 (6.7)	1 (3.3)
Blood bilirubin increased	6 (20.0)	0	1 (3.3)	5 (16.7)	0
Neutrophil count decreased	6 (20.0)	0	0	1 (3.3)	5 (16.7)
C-reactive protein increased	5 (16.7)	1 (3.3)	0	3 (10.0)	1 (3.3)
Blood fibrinogen decreased	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood immunoglobulin a decreased	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood immunoglobulin g decreased	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Blood immunoglobulin m decreased	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Blood lactate dehydrogenase increased	3 (10.0)	1 (3.3)	0	2 (6.7)	0
Electrocardiogram qt prolonged	3 (10.0)	0	1 (3.3)	1 (3.3)	1 (3.3)

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	3 (10.0)	1 (3.3)	0	1 (3.3)	1 (3.3)
International normalised ratio increased	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Oxygen saturation decreased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Blood creatinine increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Weight increased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Lipase increased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	19 (63.3)	1 (3.3)	6 (20.0)	8 (26.7)	4 (13.3)
Decreased appetite	10 (33.3)	2 (6.7)	1 (3.3)	7 (23.3)	0
Hypocalcaemia	7 (23.3)	1 (3.3)	4 (13.3)	2 (6.7)	0
Hypokalaemia	7 (23.3)	1 (3.3)	4 (13.3)	2 (6.7)	0
Hyperglycaemia	5 (16.7)	0	2 (6.7)	3 (10.0)	0
Hypervolaemia	5 (16.7)	0	0	5 (16.7)	0
Hypoalbuminaemia	5 (16.7)	0	4 (13.3)	1 (3.3)	0
Hypophosphataemia	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hyperuricaemia	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Hyperphosphataemia	3 (10.0)	3 (10.0)	0	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Metabolic acidosis	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Tumour lysis syndrome	3 (10.0)	0	0	3 (10.0)	0
Acidosis	1 (3.3)	0	0	0	1 (3.3)
Hyperkalaemia	1 (3.3)	0	0	1 (3.3)	0
Hyponatraemia	1 (3.3)	0	0	0	1 (3.3)
Musculoskeletal and connective tissue disorders					
-Total	12 (40.0)	7 (23.3)	4 (13.3)	1 (3.3)	0
Pain in extremity	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Arthralgia	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Back pain	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Myalgia	1 (3.3)	1 (3.3)	0	0	0
Myositis	1 (3.3)	0	1 (3.3)	0	0
Nervous system disorders					
-Total	9 (30.0)	5 (16.7)	2 (6.7)	2 (6.7)	0
Headache	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Encephalopathy	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Somnolence	1 (3.3)	0	0	1 (3.3)	0
Psychiatric disorders					
-Total	11 (36.7)	4 (13.3)	2 (6.7)	5 (16.7)	0
Delirium	4 (13.3)	1 (3.3)	0	3 (10.0)	0
Anxiety	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Agitation	2 (6.7)	0	2 (6.7)	0	0
Confusional state	2 (6.7)	2 (6.7)	0	0	0
Irritability	2 (6.7)	2 (6.7)	0	0	0
Mental status changes	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Renal and urinary disorders					
-Total	6 (20.0)	2 (6.7)	1 (3.3)	1 (3.3)	2 (6.7)
Acute kidney injury	4 (13.3)	1 (3.3)	0	1 (3.3)	2 (6.7)
Dysuria	1 (3.3)	1 (3.3)	0	0	0
Urinary retention	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (60.0)	4 (13.3)	1 (3.3)	4 (13.3)	9 (30.0)

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	8 (26.7)	0	2 (6.7)	3 (10.0)	3 (10.0)
Cough	7 (23.3)	7 (23.3)	0	0	0
Pulmonary oedema	7 (23.3)	2 (6.7)	2 (6.7)	2 (6.7)	1 (3.3)
Pleural effusion	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Respiratory failure	4 (13.3)	0	0	0	4 (13.3)
Tachypnoea	4 (13.3)	2 (6.7)	0	1 (3.3)	1 (3.3)
Epistaxis	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Respiratory distress	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Oropharyngeal pain	2 (6.7)	0	2 (6.7)	0	0
Acute respiratory distress syndrome	1 (3.3)	0	0	0	1 (3.3)
Atelectasis	1 (3.3)	0	0	1 (3.3)	0
Dyspnoea	1 (3.3)	0	0	0	1 (3.3)
Nasal congestion	1 (3.3)	1 (3.3)	0	0	0
Rhinorrhoea	1 (3.3)	1 (3.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (43.3)	6 (20.0)	6 (20.0)	1 (3.3)	0
Pruritus	4 (13.3)	2 (6.7)	2 (6.7)	0	0

Number of previous relapses: 1

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	2 (6.7)	2 (6.7)	0	0	0
Erythema	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Skin ulcer	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Hyperhidrosis	1 (3.3)	0	1 (3.3)	0	0
Ingrowing nail	1 (3.3)	0	1 (3.3)	0	0
Petechiae	1 (3.3)	1 (3.3)	0	0	0
Rash	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	14 (46.7)	0	3 (10.0)	6 (20.0)	5 (16.7)
Hypotension	12 (40.0)	0	2 (6.7)	5 (16.7)	5 (16.7)
Hypertension	8 (26.7)	1 (3.3)	5 (16.7)	2 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (100)	0	1 (5.6)	3 (16.7)	14 (77.8)
Blood and lymphatic system disorders					
-Total	15 (83.3)	0	1 (5.6)	10 (55.6)	4 (22.2)
Febrile neutropenia	12 (66.7)	0	0	12 (66.7)	0
Anaemia	9 (50.0)	1 (5.6)	4 (22.2)	3 (16.7)	1 (5.6)
Neutropenia	5 (27.8)	1 (5.6)	1 (5.6)	0	3 (16.7)
Thrombocytopenia	3 (16.7)	1 (5.6)	0	1 (5.6)	1 (5.6)
Splenomegaly	2 (11.1)	2 (11.1)	0	0	0
Disseminated intravascular coagulation	1 (5.6)	0	0	1 (5.6)	0
Cardiac disorders					

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (38.9)	3 (16.7)	2 (11.1)	0	2 (11.1)
Tachycardia	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Cardiac arrest	2 (11.1)	0	0	0	2 (11.1)
Bradycardia	1 (5.6)	0	1 (5.6)	0	0
Sinus tachycardia	1 (5.6)	1 (5.6)	0	0	0
Endocrine disorders					
-Total	2 (11.1)	0	2 (11.1)	0	0
Hypothyroidism	2 (11.1)	0	2 (11.1)	0	0
Eye disorders					
-Total	2 (11.1)	2 (11.1)	0	0	0
Dry eye	2 (11.1)	2 (11.1)	0	0	0
Gastrointestinal disorders					
-Total	14 (77.8)	4 (22.2)	8 (44.4)	2 (11.1)	0
Nausea	8 (44.4)	4 (22.2)	4 (22.2)	0	0
Diarrhoea	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Vomiting	6 (33.3)	4 (22.2)	1 (5.6)	1 (5.6)	0
Constipation	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Stomatitis	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (11.1)	0	2 (11.1)	0	0
Haematemesis	2 (11.1)	2 (11.1)	0	0	0
Oral pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Pancreatitis	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Gingival erythema	1 (5.6)	1 (5.6)	0	0	0
General disorders and administration site conditions					
-Total	16 (88.9)	7 (38.9)	6 (33.3)	3 (16.7)	0
Pyrexia	12 (66.7)	4 (22.2)	5 (27.8)	3 (16.7)	0
Fatigue	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Generalised oedema	2 (11.1)	2 (11.1)	0	0	0
Oedema peripheral	2 (11.1)	2 (11.1)	0	0	0
Catheter site pain	1 (5.6)	0	1 (5.6)	0	0
Face oedema	1 (5.6)	1 (5.6)	0	0	0
Hepatobiliary disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Hyperbilirubinaemia	2 (11.1)	0	2 (11.1)	0	0
Hypertransaminasaemia	2 (11.1)	1 (5.6)	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	12 (66.7)	0	4 (22.2)	4 (22.2)	4 (22.2)
Cytokine release syndrome	12 (66.7)	0	4 (22.2)	4 (22.2)	4 (22.2)
Hypogammaglobulinaemia	6 (33.3)	1 (5.6)	4 (22.2)	1 (5.6)	0
Seasonal allergy	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Haemophagocytic lymphohistiocytosis	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	11 (61.1)	0	4 (22.2)	7 (38.9)	0
Sinusitis	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Staphylococcal bacteraemia	3 (16.7)	0	0	3 (16.7)	0
Staphylococcal infection	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Upper respiratory tract infection	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Bronchitis	2 (11.1)	0	2 (11.1)	0	0
Bronchopulmonary aspergillosis	2 (11.1)	0	0	2 (11.1)	0
Nail infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oral herpes	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Otitis media	2 (11.1)	0	2 (11.1)	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Respiratory tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Conjunctivitis	1 (5.6)	1 (5.6)	0	0	0
Gastroenteritis viral	1 (5.6)	0	1 (5.6)	0	0
Nasopharyngitis	1 (5.6)	1 (5.6)	0	0	0
Rhinovirus infection	1 (5.6)	0	1 (5.6)	0	0
Injury, poisoning and procedural complications					
-Total	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Transfusion reaction	1 (5.6)	0	1 (5.6)	0	0
Wound	1 (5.6)	0	1 (5.6)	0	0
Investigations					
-Total	12 (66.7)	0	1 (5.6)	2 (11.1)	9 (50.0)
Alanine aminotransferase increased	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Platelet count decreased	6 (33.3)	0	1 (5.6)	2 (11.1)	3 (16.7)

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (33.3)	0	0	0	6 (33.3)
Aspartate aminotransferase increased	5 (27.8)	1 (5.6)	2 (11.1)	1 (5.6)	1 (5.6)
Activated partial thromboplastin time prolonged	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	4 (22.2)	0	0	0	4 (22.2)
Blood bilirubin increased	3 (16.7)	0	0	3 (16.7)	0
International normalised ratio increased	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Lymphocyte count decreased	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Blood creatinine increased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Blood fibrinogen decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
C-reactive protein increased	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Electrocardiogram qt prolonged	2 (11.1)	2 (11.1)	0	0	0
Fibrin d dimer increased	2 (11.1)	2 (11.1)	0	0	0
Gamma-glutamyltransferase increased	2 (11.1)	0	0	2 (11.1)	0
Serum ferritin increased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Blood immunoglobulin a decreased	1 (5.6)	1 (5.6)	0	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (5.6)	1 (5.6)	0	0	0
Blood lactate dehydrogenase increased	1 (5.6)	0	0	1 (5.6)	0
Weight increased	1 (5.6)	0	0	1 (5.6)	0
Metabolism and nutrition disorders					
-Total	11 (61.1)	1 (5.6)	2 (11.1)	5 (27.8)	3 (16.7)
Decreased appetite	7 (38.9)	2 (11.1)	3 (16.7)	2 (11.1)	0
Hypokalaemia	6 (33.3)	0	0	5 (27.8)	1 (5.6)
Hypophosphataemia	5 (27.8)	0	1 (5.6)	3 (16.7)	1 (5.6)
Hypocalcaemia	4 (22.2)	0	3 (16.7)	1 (5.6)	0
Hypoalbuminaemia	3 (16.7)	0	3 (16.7)	0	0
Hyperkalaemia	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Hyperphosphataemia	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Hyperuricaemia	1 (5.6)	1 (5.6)	0	0	0
Hypervolaemia	1 (5.6)	0	1 (5.6)	0	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Hyponatraemia	1 (5.6)	1 (5.6)	0	0	0
Metabolic acidosis	1 (5.6)	0	0	0	1 (5.6)

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	12 (66.7)	6 (33.3)	3 (16.7)	3 (16.7)	0
Arthralgia	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Pain in extremity	5 (27.8)	2 (11.1)	2 (11.1)	1 (5.6)	0
Back pain	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Myalgia	2 (11.1)	0	2 (11.1)	0	0
Osteopenia	2 (11.1)	2 (11.1)	0	0	0
Nervous system disorders					
-Total	11 (61.1)	2 (11.1)	7 (38.9)	2 (11.1)	0
Headache	8 (44.4)	2 (11.1)	5 (27.8)	1 (5.6)	0
Neuralgia	2 (11.1)	0	2 (11.1)	0	0
Cognitive disorder	1 (5.6)	0	1 (5.6)	0	0
Encephalopathy	1 (5.6)	0	0	1 (5.6)	0
Somnolence	1 (5.6)	0	0	1 (5.6)	0
Tremor	1 (5.6)	0	1 (5.6)	0	0
Psychiatric disorders					

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (55.6)	3 (16.7)	4 (22.2)	3 (16.7)	0
Anxiety	5 (27.8)	0	4 (22.2)	1 (5.6)	0
Confusional state	3 (16.7)	3 (16.7)	0	0	0
Delirium	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Agitation	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Mental status changes	2 (11.1)	0	0	2 (11.1)	0
Renal and urinary disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Acute kidney injury	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Dysuria	1 (5.6)	0	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (44.4)	3 (16.7)	1 (5.6)	2 (11.1)	2 (11.1)
Cough	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Hypoxia	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Nasal congestion	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Rhinorrhoea	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Dyspnoea	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (11.1)	2 (11.1)	0	0	0
Pleural effusion	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Tachypnoea	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Wheezing	2 (11.1)	0	2 (11.1)	0	0
Atelectasis	1 (5.6)	0	0	1 (5.6)	0
Epistaxis	1 (5.6)	0	1 (5.6)	0	0
Pulmonary oedema	1 (5.6)	0	1 (5.6)	0	0
Respiratory distress	1 (5.6)	0	1 (5.6)	0	0
Respiratory failure	1 (5.6)	0	0	0	1 (5.6)
Skin and subcutaneous tissue disorders					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Pruritus	3 (16.7)	3 (16.7)	0	0	0
Dry skin	2 (11.1)	2 (11.1)	0	0	0
Erythema	1 (5.6)	1 (5.6)	0	0	0
Ingrowing nail	1 (5.6)	0	1 (5.6)	0	0
Petechiae	1 (5.6)	0	1 (5.6)	0	0
Rash	1 (5.6)	0	1 (5.6)	0	0

Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	10 (55.6)	0	4 (22.2)	4 (22.2)	2 (11.1)
Hypotension	6 (33.3)	0	2 (11.1)	2 (11.1)	2 (11.1)
Hypertension	5 (27.8)	0	3 (16.7)	2 (11.1)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 218r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (95.2)	0	2 (4.8)	9 (21.4)	29 (69.0)
Blood and lymphatic system disorders					
-Total	31 (73.8)	0	3 (7.1)	18 (42.9)	10 (23.8)
Anaemia	21 (50.0)	2 (4.8)	4 (9.5)	15 (35.7)	0
Febrile neutropenia	19 (45.2)	0	0	18 (42.9)	1 (2.4)
Neutropenia	11 (26.2)	0	1 (2.4)	2 (4.8)	8 (19.0)
Thrombocytopenia	6 (14.3)	0	1 (2.4)	2 (4.8)	3 (7.1)
Disseminated intravascular coagulation	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Coagulopathy	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Splenomegaly	1 (2.4)	0	1 (2.4)	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	9 (21.4)	3 (7.1)	3 (7.1)	2 (4.8)	1 (2.4)
Tachycardia	6 (14.3)	3 (7.1)	2 (4.8)	1 (2.4)	0
Left ventricular dysfunction	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Cardiac arrest	1 (2.4)	0	0	0	1 (2.4)
Sinus tachycardia	1 (2.4)	0	1 (2.4)	0	0
Endocrine disorders					
-Total	6 (14.3)	0	5 (11.9)	1 (2.4)	0
Adrenal insufficiency	5 (11.9)	0	4 (9.5)	1 (2.4)	0
Hypothyroidism	1 (2.4)	0	1 (2.4)	0	0
Eye disorders					
-Total	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Eyelid oedema	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Gastrointestinal disorders					
-Total	31 (73.8)	8 (19.0)	16 (38.1)	7 (16.7)	0
Diarrhoea	15 (35.7)	6 (14.3)	7 (16.7)	2 (4.8)	0
Nausea	15 (35.7)	5 (11.9)	9 (21.4)	1 (2.4)	0
Vomiting	13 (31.0)	8 (19.0)	5 (11.9)	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	11 (26.2)	3 (7.1)	7 (16.7)	1 (2.4)	0
Constipation	8 (19.0)	5 (11.9)	3 (7.1)	0	0
Stomatitis	5 (11.9)	0	2 (4.8)	3 (7.1)	0
Mouth haemorrhage	4 (9.5)	2 (4.8)	1 (2.4)	1 (2.4)	0
Abdominal distension	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Ascites	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Pancreatitis	2 (4.8)	1 (2.4)	1 (2.4)	0	0
General disorders and administration site conditions					
-Total	23 (54.8)	9 (21.4)	8 (19.0)	5 (11.9)	1 (2.4)
Pyrexia	18 (42.9)	9 (21.4)	5 (11.9)	3 (7.1)	1 (2.4)
Fatigue	9 (21.4)	7 (16.7)	2 (4.8)	0	0
Pain	7 (16.7)	1 (2.4)	2 (4.8)	4 (9.5)	0
Chills	5 (11.9)	3 (7.1)	2 (4.8)	0	0
Catheter site pain	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Face oedema	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Generalised oedema	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Oedema peripheral	1 (2.4)	1 (2.4)	0	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	5 (11.9)	1 (2.4)	2 (4.8)	2 (4.8)	0
Hyperbilirubinaemia	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Cholelithiasis	1 (2.4)	0	1 (2.4)	0	0
Hypertransaminasaemia	1 (2.4)	0	0	1 (2.4)	0
Immune system disorders					
-Total	32 (76.2)	1 (2.4)	10 (23.8)	12 (28.6)	9 (21.4)
Cytokine release syndrome	29 (69.0)	3 (7.1)	8 (19.0)	9 (21.4)	9 (21.4)
Hypogammaglobulinaemia	21 (50.0)	0	15 (35.7)	6 (14.3)	0
Haemophagocytic lymphohistiocytosis	1 (2.4)	1 (2.4)	0	0	0
Infections and infestations					
-Total	27 (64.3)	2 (4.8)	9 (21.4)	12 (28.6)	4 (9.5)
Upper respiratory tract infection	6 (14.3)	3 (7.1)	1 (2.4)	2 (4.8)	0
Gastroenteritis	5 (11.9)	2 (4.8)	1 (2.4)	2 (4.8)	0
Nasopharyngitis	5 (11.9)	3 (7.1)	2 (4.8)	0	0
Pneumonia	5 (11.9)	1 (2.4)	1 (2.4)	2 (4.8)	1 (2.4)
Sinusitis	5 (11.9)	0	3 (7.1)	2 (4.8)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	4 (9.5)	1 (2.4)	3 (7.1)	0	0
Oral herpes	4 (9.5)	1 (2.4)	2 (4.8)	1 (2.4)	0
Parainfluenzae virus infection	4 (9.5)	0	0	3 (7.1)	1 (2.4)
Rhinovirus infection	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Nail infection	2 (4.8)	2 (4.8)	0	0	0
Otitis externa	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Otitis media	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Respiratory tract infection	2 (4.8)	0	1 (2.4)	1 (2.4)	0
Staphylococcal infection	2 (4.8)	0	0	2 (4.8)	0
Bronchopulmonary aspergillosis	1 (2.4)	0	0	0	1 (2.4)
Clostridium difficile colitis	1 (2.4)	0	1 (2.4)	0	0
Clostridium difficile infection	1 (2.4)	0	0	1 (2.4)	0
Encephalitis	1 (2.4)	0	0	0	1 (2.4)
Respiratory syncytial virus infection	1 (2.4)	0	0	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	0	0	1 (2.4)	0
Injury, poisoning and procedural complications					
-Total	7 (16.7)	3 (7.1)	2 (4.8)	2 (4.8)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Procedural pain	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Transfusion reaction	1 (2.4)	0	1 (2.4)	0	0
Wound	1 (2.4)	1 (2.4)	0	0	0
Investigations					
-Total	27 (64.3)	0	0	8 (19.0)	19 (45.2)
Neutrophil count decreased	18 (42.9)	2 (4.8)	2 (4.8)	1 (2.4)	13 (31.0)
Platelet count decreased	17 (40.5)	3 (7.1)	0	3 (7.1)	11 (26.2)
White blood cell count decreased	16 (38.1)	1 (2.4)	1 (2.4)	0	14 (33.3)
Lymphocyte count decreased	12 (28.6)	0	1 (2.4)	3 (7.1)	8 (19.0)
Alanine aminotransferase increased	9 (21.4)	2 (4.8)	3 (7.1)	4 (9.5)	0
Aspartate aminotransferase increased	7 (16.7)	1 (2.4)	1 (2.4)	4 (9.5)	1 (2.4)
C-reactive protein increased	5 (11.9)	1 (2.4)	1 (2.4)	3 (7.1)	0
Blood lactate dehydrogenase increased	4 (9.5)	2 (4.8)	2 (4.8)	0	0
Serum ferritin increased	4 (9.5)	0	3 (7.1)	1 (2.4)	0
Blood bilirubin increased	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Blood immunoglobulin a decreased	3 (7.1)	2 (4.8)	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	3 (7.1)	3 (7.1)	0	0	0
Blood fibrinogen decreased	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Blood immunoglobulin m decreased	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Weight increased	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Blood creatine phosphokinase increased	1 (2.4)	0	0	1 (2.4)	0
Blood creatinine increased	1 (2.4)	0	0	1 (2.4)	0
Metabolism and nutrition disorders					
-Total	26 (61.9)	6 (14.3)	5 (11.9)	9 (21.4)	6 (14.3)
Decreased appetite	15 (35.7)	6 (14.3)	4 (9.5)	3 (7.1)	2 (4.8)
Hypokalaemia	12 (28.6)	3 (7.1)	2 (4.8)	6 (14.3)	1 (2.4)
Hypophosphataemia	8 (19.0)	2 (4.8)	4 (9.5)	2 (4.8)	0
Hyperglycaemia	4 (9.5)	0	1 (2.4)	2 (4.8)	1 (2.4)
Hypocalcaemia	4 (9.5)	1 (2.4)	1 (2.4)	2 (4.8)	0
Hypomagnesaemia	4 (9.5)	3 (7.1)	1 (2.4)	0	0
Hyperuricaemia	3 (7.1)	2 (4.8)	1 (2.4)	0	0
Hypervolaemia	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Hypoalbuminaemia	3 (7.1)	0	3 (7.1)	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (7.1)	0	0	1 (2.4)	2 (4.8)
Hypernatraemia	2 (4.8)	1 (2.4)	0	1 (2.4)	0
Hyponatraemia	2 (4.8)	2 (4.8)	0	0	0
Hypermagnesaemia	1 (2.4)	1 (2.4)	0	0	0
Hyperphosphataemia	1 (2.4)	1 (2.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	20 (47.6)	6 (14.3)	11 (26.2)	3 (7.1)	0
Pain in extremity	10 (23.8)	2 (4.8)	7 (16.7)	1 (2.4)	0
Arthralgia	8 (19.0)	4 (9.5)	4 (9.5)	0	0
Back pain	8 (19.0)	1 (2.4)	5 (11.9)	2 (4.8)	0
Myalgia	6 (14.3)	4 (9.5)	2 (4.8)	0	0
Nervous system disorders					
-Total	23 (54.8)	9 (21.4)	7 (16.7)	7 (16.7)	0
Headache	18 (42.9)	9 (21.4)	5 (11.9)	4 (9.5)	0
Encephalopathy	4 (9.5)	0	2 (4.8)	2 (4.8)	0
Tremor	4 (9.5)	4 (9.5)	0	0	0
Neuropathy peripheral	2 (4.8)	1 (2.4)	0	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Psychiatric disorders					
-Total	14 (33.3)	4 (9.5)	8 (19.0)	2 (4.8)	0
Anxiety	9 (21.4)	4 (9.5)	4 (9.5)	1 (2.4)	0
Agitation	3 (7.1)	3 (7.1)	0	0	0
Mental status changes	3 (7.1)	1 (2.4)	1 (2.4)	1 (2.4)	0
Sleep disorder	2 (4.8)	0	2 (4.8)	0	0
Confusional state	1 (2.4)	1 (2.4)	0	0	0
Delirium	1 (2.4)	0	1 (2.4)	0	0
Irritability	1 (2.4)	1 (2.4)	0	0	0
Renal and urinary disorders					
-Total	8 (19.0)	4 (9.5)	1 (2.4)	1 (2.4)	2 (4.8)
Acute kidney injury	5 (11.9)	2 (4.8)	1 (2.4)	0	2 (4.8)
Dysuria	2 (4.8)	2 (4.8)	0	0	0
Renal tubular necrosis	1 (2.4)	0	0	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	30 (71.4)	10 (23.8)	6 (14.3)	7 (16.7)	7 (16.7)

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	13 (31.0)	10 (23.8)	3 (7.1)	0	0
Hypoxia	10 (23.8)	0	4 (9.5)	4 (9.5)	2 (4.8)
Epistaxis	8 (19.0)	7 (16.7)	0	1 (2.4)	0
Dyspnoea	5 (11.9)	2 (4.8)	1 (2.4)	2 (4.8)	0
Nasal congestion	5 (11.9)	5 (11.9)	0	0	0
Pulmonary oedema	5 (11.9)	1 (2.4)	0	4 (9.5)	0
Oropharyngeal pain	4 (9.5)	4 (9.5)	0	0	0
Pleural effusion	4 (9.5)	2 (4.8)	2 (4.8)	0	0
Respiratory failure	3 (7.1)	0	0	0	3 (7.1)
Tachypnoea	3 (7.1)	0	2 (4.8)	1 (2.4)	0
Acute respiratory distress syndrome	2 (4.8)	0	0	0	2 (4.8)
Rhinorrhoea	2 (4.8)	2 (4.8)	0	0	0
Atelectasis	1 (2.4)	0	1 (2.4)	0	0
Wheezing	1 (2.4)	1 (2.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (38.1)	6 (14.3)	9 (21.4)	1 (2.4)	0
Rash	7 (16.7)	4 (9.5)	3 (7.1)	0	0

Number of previous relapses: >=3

	All patients N=42				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	4 (9.5)	1 (2.4)	3 (7.1)	0	0
Dry skin	3 (7.1)	1 (2.4)	2 (4.8)	0	0
Erythema	2 (4.8)	2 (4.8)	0	0	0
Skin ulcer	2 (4.8)	1 (2.4)	1 (2.4)	0	0
Decubitus ulcer	1 (2.4)	0	0	1 (2.4)	0
Hyperhidrosis	1 (2.4)	0	1 (2.4)	0	0
Ingrowing nail	1 (2.4)	0	1 (2.4)	0	0
Vascular disorders					
-Total	16 (38.1)	7 (16.7)	5 (11.9)	2 (4.8)	2 (4.8)
Hypertension	10 (23.8)	5 (11.9)	5 (11.9)	0	0
Hypotension	9 (21.4)	3 (7.1)	2 (4.8)	2 (4.8)	2 (4.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (81.8)	7 (21.2)	20 (60.6)
Blood and lymphatic system disorders			
-Total	16 (48.5)	12 (36.4)	4 (12.1)
Febrile neutropenia	12 (36.4)	12 (36.4)	0
Anaemia	7 (21.2)	7 (21.2)	0
Thrombocytopenia	4 (12.1)	0	4 (12.1)
Neutropenia	2 (6.1)	1 (3.0)	1 (3.0)
Disseminated intravascular coagulation	1 (3.0)	1 (3.0)	0
Lymphopenia	1 (3.0)	1 (3.0)	0
Cardiac disorders			
-Total	4 (12.1)	3 (9.1)	1 (3.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	2 (6.1)	2 (6.1)	0
Tachycardia	2 (6.1)	1 (3.0)	1 (3.0)
Gastrointestinal disorders			
-Total	4 (12.1)	4 (12.1)	0
Abdominal pain	2 (6.1)	2 (6.1)	0
Diarrhoea	1 (3.0)	1 (3.0)	0
Mouth haemorrhage	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	3 (9.1)	1 (3.0)	2 (6.1)
Pyrexia	2 (6.1)	1 (3.0)	1 (3.0)
Multiple organ dysfunction syndrome	1 (3.0)	0	1 (3.0)
Pain	1 (3.0)	1 (3.0)	0
Hepatobiliary disorders			
-Total	1 (3.0)	1 (3.0)	0
Hepatic function abnormal	1 (3.0)	1 (3.0)	0
Immune system disorders			
-Total	14 (42.4)	6 (18.2)	8 (24.2)
Cytokine release syndrome	11 (33.3)	3 (9.1)	8 (24.2)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (6.1)	2 (6.1)	0
Immunodeficiency	2 (6.1)	2 (6.1)	0
Haemophagocytic lymphohistiocytosis	1 (3.0)	0	1 (3.0)
Infections and infestations			
-Total	3 (9.1)	3 (9.1)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0
Staphylococcal bacteraemia	1 (3.0)	1 (3.0)	0
Staphylococcal infection	1 (3.0)	1 (3.0)	0
Investigations			
-Total	22 (66.7)	7 (21.2)	15 (45.5)
White blood cell count decreased	13 (39.4)	2 (6.1)	11 (33.3)
Neutrophil count decreased	11 (33.3)	1 (3.0)	10 (30.3)
Lymphocyte count decreased	8 (24.2)	5 (15.2)	3 (9.1)
Platelet count decreased	8 (24.2)	4 (12.1)	4 (12.1)
Aspartate aminotransferase increased	4 (12.1)	2 (6.1)	2 (6.1)
Blood bilirubin increased	4 (12.1)	4 (12.1)	0
Gamma-glutamyltransferase increased	2 (6.1)	2 (6.1)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (3.0)	1 (3.0)	0
Blood creatinine increased	1 (3.0)	1 (3.0)	0
C-reactive protein increased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	10 (30.3)	5 (15.2)	5 (15.2)
Decreased appetite	5 (15.2)	4 (12.1)	1 (3.0)
Hypokalaemia	4 (12.1)	2 (6.1)	2 (6.1)
Hypophosphataemia	4 (12.1)	3 (9.1)	1 (3.0)
Hyperglycaemia	3 (9.1)	3 (9.1)	0
Hypocalcaemia	2 (6.1)	2 (6.1)	0
Malnutrition	1 (3.0)	1 (3.0)	0
Metabolic acidosis	1 (3.0)	0	1 (3.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.0)	1 (3.0)	0
Back pain	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	4 (12.1)	4 (12.1)	0
Encephalopathy	2 (6.1)	2 (6.1)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	2 (6.1)	0	2 (6.1)
Acute kidney injury	2 (6.1)	0	2 (6.1)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.2)	3 (9.1)	3 (9.1)
Hypoxia	4 (12.1)	2 (6.1)	2 (6.1)
Pulmonary oedema	3 (9.1)	3 (9.1)	0
Dyspnoea	2 (6.1)	1 (3.0)	1 (3.0)
Tachypnoea	2 (6.1)	2 (6.1)	0
Acute respiratory distress syndrome	1 (3.0)	0	1 (3.0)
Pleural effusion	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	7 (21.2)	4 (12.1)	3 (9.1)
Hypotension	6 (18.2)	3 (9.1)	3 (9.1)
Hypertension	2 (6.1)	2 (6.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (84.8)	9 (27.3)	19 (57.6)
Blood and lymphatic system disorders			
-Total	17 (51.5)	9 (27.3)	8 (24.2)
Febrile neutropenia	12 (36.4)	10 (30.3)	2 (6.1)
Neutropenia	4 (12.1)	0	4 (12.1)
Thrombocytopenia	3 (9.1)	1 (3.0)	2 (6.1)
Disseminated intravascular coagulation	1 (3.0)	1 (3.0)	0
Cardiac disorders			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Cardiac arrest	1 (3.0)	0	1 (3.0)
Left ventricular dysfunction	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	4 (12.1)	3 (9.1)	1 (3.0)
Pyrexia	4 (12.1)	3 (9.1)	1 (3.0)
Hepatobiliary disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Hepatic function abnormal	2 (6.1)	1 (3.0)	1 (3.0)
Immune system disorders			
-Total	21 (63.6)	12 (36.4)	9 (27.3)
Cytokine release syndrome	19 (57.6)	10 (30.3)	9 (27.3)
Hypogammaglobulinaemia	5 (15.2)	5 (15.2)	0
Haemophagocytic lymphohistiocytosis	1 (3.0)	1 (3.0)	0
Immunodeficiency	1 (3.0)	1 (3.0)	0
Infections and infestations			
-Total	3 (9.1)	2 (6.1)	1 (3.0)
Bacteraemia	1 (3.0)	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (3.0)	0	1 (3.0)
Staphylococcal bacteraemia	1 (3.0)	1 (3.0)	0
Investigations			
-Total	17 (51.5)	7 (21.2)	10 (30.3)
Lymphocyte count decreased	5 (15.2)	3 (9.1)	2 (6.1)
Neutrophil count decreased	5 (15.2)	1 (3.0)	4 (12.1)
Alanine aminotransferase increased	4 (12.1)	4 (12.1)	0
Aspartate aminotransferase increased	4 (12.1)	3 (9.1)	1 (3.0)
Blood bilirubin increased	4 (12.1)	4 (12.1)	0
Platelet count decreased	4 (12.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	4 (12.1)	0	4 (12.1)
Blood creatinine increased	2 (6.1)	1 (3.0)	1 (3.0)
C-reactive protein increased	2 (6.1)	2 (6.1)	0
Electrocardiogram qt prolonged	2 (6.1)	1 (3.0)	1 (3.0)
Serum ferritin increased	2 (6.1)	2 (6.1)	0
Metabolism and nutrition disorders			
-Total	13 (39.4)	12 (36.4)	1 (3.0)
Hypokalaemia	5 (15.2)	5 (15.2)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	4 (12.1)	4 (12.1)	0
Hypophosphataemia	3 (9.1)	3 (9.1)	0
Tumour lysis syndrome	3 (9.1)	3 (9.1)	0
Acidosis	1 (3.0)	1 (3.0)	0
Hyperglycaemia	1 (3.0)	1 (3.0)	0
Hypervolaemia	1 (3.0)	1 (3.0)	0
Hypocalcaemia	1 (3.0)	1 (3.0)	0
Metabolic acidosis	1 (3.0)	0	1 (3.0)
Nervous system disorders			
-Total	2 (6.1)	2 (6.1)	0
Encephalopathy	1 (3.0)	1 (3.0)	0
Headache	1 (3.0)	1 (3.0)	0
Somnolence	1 (3.0)	1 (3.0)	0
Psychiatric disorders			
-Total	3 (9.1)	3 (9.1)	0
Anxiety	2 (6.1)	2 (6.1)	0
Delirium	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	4 (12.1)	2 (6.1)	2 (6.1)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	4 (12.1)	2 (6.1)	2 (6.1)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (33.3)	4 (12.1)	7 (21.2)
Hypoxia	5 (15.2)	1 (3.0)	4 (12.1)
Pleural effusion	2 (6.1)	1 (3.0)	1 (3.0)
Respiratory failure	2 (6.1)	0	2 (6.1)
Tachypnoea	2 (6.1)	2 (6.1)	0
Acute respiratory distress syndrome	1 (3.0)	0	1 (3.0)
Pulmonary oedema	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	6 (18.2)	4 (12.1)	2 (6.1)
Hypotension	5 (15.2)	3 (9.1)	2 (6.1)
Hypertension	1 (3.0)	1 (3.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	5 (35.7)	7 (50.0)
Blood and lymphatic system disorders			
-Total	5 (35.7)	4 (28.6)	1 (7.1)
Febrile neutropenia	2 (14.3)	2 (14.3)	0
Anaemia	1 (7.1)	1 (7.1)	0
Neutropenia	1 (7.1)	0	1 (7.1)
Thrombocytopenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiac failure	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	2 (14.3)	0
Gingivitis ulcerative	1 (7.1)	1 (7.1)	0
Mouth haemorrhage	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Pyrexia	2 (14.3)	2 (14.3)	0
Catheter site pain	1 (7.1)	1 (7.1)	0
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Hepatobiliary disorders			
-Total	1 (7.1)	1 (7.1)	0
Hyperbilirubinaemia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	8 (57.1)	4 (28.6)	4 (28.6)
Cytokine release syndrome	8 (57.1)	4 (28.6)	4 (28.6)
Haemophagocytic lymphohistiocytosis	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	6 (42.9)	5 (35.7)	1 (7.1)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adenovirus infection	1 (7.1)	1 (7.1)	0
Candida infection	1 (7.1)	0	1 (7.1)
Clostridium difficile infection	1 (7.1)	1 (7.1)	0
Encephalitis viral	1 (7.1)	1 (7.1)	0
Granulicatella infection	1 (7.1)	1 (7.1)	0
Herpes simplex	1 (7.1)	1 (7.1)	0
Human herpesvirus 6 infection	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	1 (7.1)	0
Sinusitis	1 (7.1)	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	1 (7.1)	0
Staphylococcal infection	1 (7.1)	1 (7.1)	0
Systemic candida	1 (7.1)	1 (7.1)	0
Varicella zoster virus infection	1 (7.1)	1 (7.1)	0
Injury, poisoning and procedural complications			
-Total	1 (7.1)	0	1 (7.1)
Transplant failure	1 (7.1)	0	1 (7.1)
Investigations			
-Total	6 (42.9)	3 (21.4)	3 (21.4)

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (21.4)	3 (21.4)	0
Platelet count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	1 (7.1)	1 (7.1)	0
Blood glucose increased	1 (7.1)	0	1 (7.1)
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
White blood cell count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	6 (42.9)	5 (35.7)	1 (7.1)
Hypervolaemia	3 (21.4)	3 (21.4)	0
Decreased appetite	2 (14.3)	2 (14.3)	0
Hypocalcaemia	2 (14.3)	2 (14.3)	0
Hypokalaemia	2 (14.3)	2 (14.3)	0
Hypophosphataemia	2 (14.3)	2 (14.3)	0
Acidosis	1 (7.1)	0	1 (7.1)
Hypoalbuminaemia	1 (7.1)	1 (7.1)	0
Polydipsia	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	1 (7.1)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Pain in jaw	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Cognitive disorder	1 (7.1)	1 (7.1)	0
Encephalopathy	1 (7.1)	1 (7.1)	0
Neurological decompensation	1 (7.1)	0	1 (7.1)
Somnolence	1 (7.1)	1 (7.1)	0
Psychiatric disorders			
-Total	2 (14.3)	2 (14.3)	0
Delirium	2 (14.3)	2 (14.3)	0
Renal and urinary disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Acute kidney injury	1 (7.1)	1 (7.1)	0
Renal failure	1 (7.1)	0	1 (7.1)
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (35.7)	3 (21.4)	2 (14.3)
Hypoxia	3 (21.4)	3 (21.4)	0
Pulmonary oedema	3 (21.4)	2 (14.3)	1 (7.1)
Respiratory failure	2 (14.3)	0	2 (14.3)
Dyspnoea	1 (7.1)	1 (7.1)	0
Respiratory distress	1 (7.1)	0	1 (7.1)
Surgical and medical procedures			
-Total	1 (7.1)	1 (7.1)	0
Thrombolysis	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Hypotension	3 (21.4)	2 (14.3)	1 (7.1)
Hypertension	1 (7.1)	1 (7.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (46.7)	6 (20.0)	8 (26.7)
Blood and lymphatic system disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Febrile neutropenia	3 (10.0)	3 (10.0)	0
Thrombocytopenia	2 (6.7)	1 (3.3)	1 (3.3)
Anaemia	1 (3.3)	1 (3.3)	0
Lymphopenia	1 (3.3)	1 (3.3)	0
Cardiac disorders			
-Total	1 (3.3)	0	1 (3.3)
Cardiac arrest	1 (3.3)	0	1 (3.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (3.3)	1 (3.3)	0
Pain	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	8 (26.7)	5 (16.7)	3 (10.0)
Metapneumovirus infection	2 (6.7)	2 (6.7)	0
Pneumocystis jirovecii pneumonia	2 (6.7)	1 (3.3)	1 (3.3)
Gastroenteritis	1 (3.3)	1 (3.3)	0
Human herpesvirus 6 infection	1 (3.3)	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	0	1 (3.3)
Pneumonia	1 (3.3)	0	1 (3.3)
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Investigations			
-Total	7 (23.3)	4 (13.3)	3 (10.0)
Neutrophil count decreased	5 (16.7)	2 (6.7)	3 (10.0)
Lymphocyte count decreased	2 (6.7)	2 (6.7)	0
Platelet count decreased	2 (6.7)	1 (3.3)	1 (3.3)
White blood cell count decreased	2 (6.7)	1 (3.3)	1 (3.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Hypokalaemia	2 (6.7)	1 (3.3)	1 (3.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.3)	1 (3.3)	0
Back pain	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Hypoxia	2 (6.7)	2 (6.7)	0
Respiratory failure	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (35.5)	4 (12.9)	7 (22.6)
Blood and lymphatic system disorders			
-Total	4 (12.9)	2 (6.5)	2 (6.5)
Neutropenia	3 (9.7)	1 (3.2)	2 (6.5)
Disseminated intravascular coagulation	1 (3.2)	1 (3.2)	0
Cardiac disorders			
-Total	2 (6.5)	0	2 (6.5)
Cardiac failure	2 (6.5)	1 (3.2)	1 (3.2)
Cardiac arrest	1 (3.2)	0	1 (3.2)
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.5)	2 (6.5)	0
Pyrexia	2 (6.5)	2 (6.5)	0
Infections and infestations			
-Total	5 (16.1)	4 (12.9)	1 (3.2)
Adenovirus infection	1 (3.2)	1 (3.2)	0
Metapneumovirus infection	1 (3.2)	1 (3.2)	0
Respiratory syncytial virus infection	1 (3.2)	1 (3.2)	0
Septic shock	1 (3.2)	0	1 (3.2)
Sinusitis	1 (3.2)	1 (3.2)	0
Upper respiratory tract infection	1 (3.2)	1 (3.2)	0
Investigations			
-Total	3 (9.7)	2 (6.5)	1 (3.2)
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Blood bilirubin increased	1 (3.2)	1 (3.2)	0
White blood cell count decreased	1 (3.2)	1 (3.2)	0
Metabolism and nutrition disorders			
-Total	4 (12.9)	2 (6.5)	2 (6.5)
Decreased appetite	1 (3.2)	1 (3.2)	0
Hypervolaemia	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (3.2)	0	1 (3.2)
Tumour lysis syndrome	1 (3.2)	0	1 (3.2)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.2)	1 (3.2)	0
Back pain	1 (3.2)	1 (3.2)	0
Nervous system disorders			
-Total	1 (3.2)	1 (3.2)	0
Seizure	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			
-Total	1 (3.2)	0	1 (3.2)
Acute kidney injury	1 (3.2)	0	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.7)	1 (3.2)	2 (6.5)
Acute respiratory distress syndrome	1 (3.2)	0	1 (3.2)
Hypoxia	1 (3.2)	1 (3.2)	0
Respiratory distress	1 (3.2)	0	1 (3.2)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.9)	2 (6.5)	2 (6.5)
Hypotension	3 (9.7)	1 (3.2)	2 (6.5)
Venoocclusive disease	1 (3.2)	1 (3.2)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (42.9)	3 (21.4)	3 (21.4)
Blood and lymphatic system disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Neutropenia	2 (14.3)	1 (7.1)	1 (7.1)
Anaemia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	2 (14.3)	2 (14.3)	0
Allergy to immunoglobulin therapy	1 (7.1)	1 (7.1)	0
Immunodeficiency	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	4 (28.6)	3 (21.4)	1 (7.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (7.1)	0	1 (7.1)
Gastroenteritis	1 (7.1)	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Rhinovirus infection	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	1 (7.1)	1 (7.1)	0
Malnutrition	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Decubitus ulcer	1 (7.1)	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (7.1)	0	1 (7.1)
Venoocclusive disease	1 (7.1)	0	1 (7.1)

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Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (10.0)	0	2 (10.0)
Gastrointestinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Multiple organ dysfunction syndrome	1 (5.0)	0	1 (5.0)
Pyrexia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	2 (10.0)	0	2 (10.0)
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	0	1 (5.0)
Rhinovirus infection	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Hyperglycaemia	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	1 (5.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	0	1 (5.0)
Dyspnoea	1 (5.0)	0	1 (5.0)
Tachypnoea	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypertension	1 (5.0)	1 (5.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (31.8)	4 (18.2)	3 (13.6)
Blood and lymphatic system disorders			
-Total	1 (4.5)	0	1 (4.5)
Neutropenia	1 (4.5)	0	1 (4.5)
Infections and infestations			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Sepsis	2 (9.1)	1 (4.5)	1 (4.5)
Pneumonia	1 (4.5)	1 (4.5)	0
Septic shock	1 (4.5)	0	1 (4.5)
Staphylococcal bacteraemia	1 (4.5)	1 (4.5)	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (4.5)	0	1 (4.5)
Decreased appetite	1 (4.5)	0	1 (4.5)
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Seizure	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Hypoxia	1 (4.5)	1 (4.5)	0
Respiratory failure	1 (4.5)	0	1 (4.5)

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Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	1 (12.5)	2 (25.0)
Infections and infestations			
-Total	1 (12.5)	1 (12.5)	0
Staphylococcal abscess	1 (12.5)	1 (12.5)	0
Investigations			
-Total	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Reproductive system and breast disorders			
-Total	1 (12.5)	1 (12.5)	0
Endometriosis	1 (12.5)	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Laryngeal oedema	1 (12.5)	0	1 (12.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (87.9)	7 (21.2)	22 (66.7)
Blood and lymphatic system disorders			
-Total	17 (51.5)	13 (39.4)	4 (12.1)
Febrile neutropenia	13 (39.4)	13 (39.4)	0
Anaemia	7 (21.2)	7 (21.2)	0
Thrombocytopenia	5 (15.2)	1 (3.0)	4 (12.1)
Lymphopenia	2 (6.1)	2 (6.1)	0
Neutropenia	2 (6.1)	1 (3.0)	1 (3.0)
Disseminated intravascular coagulation	1 (3.0)	1 (3.0)	0
Cardiac disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (15.2)	3 (9.1)	2 (6.1)
Left ventricular dysfunction	2 (6.1)	2 (6.1)	0
Tachycardia	2 (6.1)	1 (3.0)	1 (3.0)
Cardiac arrest	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	5 (15.2)	5 (15.2)	0
Abdominal pain	2 (6.1)	2 (6.1)	0
Diarrhoea	2 (6.1)	2 (6.1)	0
Mouth haemorrhage	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Pyrexia	3 (9.1)	2 (6.1)	1 (3.0)
Multiple organ dysfunction syndrome	2 (6.1)	0	2 (6.1)
Pain	2 (6.1)	2 (6.1)	0
Hepatobiliary disorders			
-Total	1 (3.0)	1 (3.0)	0
Hepatic function abnormal	1 (3.0)	1 (3.0)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (45.5)	6 (18.2)	9 (27.3)
Cytokine release syndrome	11 (33.3)	3 (9.1)	8 (24.2)
Haemophagocytic lymphohistiocytosis	2 (6.1)	0	2 (6.1)
Hypogammaglobulinaemia	2 (6.1)	2 (6.1)	0
Immunodeficiency	2 (6.1)	2 (6.1)	0
Infections and infestations			
-Total	9 (27.3)	5 (15.2)	4 (12.1)
Metapneumovirus infection	2 (6.1)	2 (6.1)	0
Parainfluenzae virus infection	2 (6.1)	1 (3.0)	1 (3.0)
Pneumocystis jirovecii pneumonia	2 (6.1)	1 (3.0)	1 (3.0)
Pneumonia	2 (6.1)	0	2 (6.1)
Staphylococcal bacteraemia	2 (6.1)	2 (6.1)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0
Gastroenteritis	1 (3.0)	1 (3.0)	0
Human herpesvirus 6 infection	1 (3.0)	1 (3.0)	0
Rhinovirus infection	1 (3.0)	1 (3.0)	0
Sepsis	1 (3.0)	0	1 (3.0)
Staphylococcal infection	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	23 (69.7)	8 (24.2)	15 (45.5)
Neutrophil count decreased	15 (45.5)	3 (9.1)	12 (36.4)
White blood cell count decreased	13 (39.4)	2 (6.1)	11 (33.3)
Lymphocyte count decreased	10 (30.3)	7 (21.2)	3 (9.1)
Platelet count decreased	9 (27.3)	5 (15.2)	4 (12.1)
Aspartate aminotransferase increased	4 (12.1)	2 (6.1)	2 (6.1)
Blood bilirubin increased	4 (12.1)	4 (12.1)	0
Alanine aminotransferase increased	2 (6.1)	2 (6.1)	0
Gamma-glutamyltransferase increased	2 (6.1)	2 (6.1)	0
Blood creatinine increased	1 (3.0)	1 (3.0)	0
C-reactive protein increased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	11 (33.3)	6 (18.2)	5 (15.2)
Decreased appetite	5 (15.2)	4 (12.1)	1 (3.0)
Hyperglycaemia	4 (12.1)	4 (12.1)	0
Hypokalaemia	4 (12.1)	2 (6.1)	2 (6.1)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	4 (12.1)	3 (9.1)	1 (3.0)
Hypocalcaemia	2 (6.1)	2 (6.1)	0
Malnutrition	1 (3.0)	1 (3.0)	0
Metabolic acidosis	1 (3.0)	0	1 (3.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (6.1)	2 (6.1)	0
Back pain	2 (6.1)	2 (6.1)	0
Nervous system disorders			
-Total	5 (15.2)	5 (15.2)	0
Encephalopathy	2 (6.1)	2 (6.1)	0
Headache	2 (6.1)	2 (6.1)	0
Seizure	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	2 (6.1)	0	2 (6.1)
Acute kidney injury	2 (6.1)	0	2 (6.1)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (30.3)	5 (15.2)	5 (15.2)

Timing: Any time post CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=33 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	6 (18.2)	4 (12.1)	2 (6.1)
Dyspnoea	3 (9.1)	1 (3.0)	2 (6.1)
Pulmonary oedema	3 (9.1)	3 (9.1)	0
Tachypnoea	3 (9.1)	2 (6.1)	1 (3.0)
Acute respiratory distress syndrome	1 (3.0)	0	1 (3.0)
Pleural effusion	1 (3.0)	1 (3.0)	0
Respiratory failure	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	8 (24.2)	5 (15.2)	3 (9.1)
Hypotension	6 (18.2)	3 (9.1)	3 (9.1)
Hypertension	3 (9.1)	3 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (90.9)	7 (21.2)	23 (69.7)
Blood and lymphatic system disorders			
-Total	19 (57.6)	10 (30.3)	9 (27.3)
Febrile neutropenia	12 (36.4)	10 (30.3)	2 (6.1)
Neutropenia	5 (15.2)	0	5 (15.2)
Thrombocytopenia	3 (9.1)	1 (3.0)	2 (6.1)
Disseminated intravascular coagulation	2 (6.1)	2 (6.1)	0
Cardiac disorders			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Cardiac arrest	2 (6.1)	0	2 (6.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (6.1)	1 (3.0)	1 (3.0)
Left ventricular dysfunction	1 (3.0)	1 (3.0)	0
Tachycardia	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	6 (18.2)	5 (15.2)	1 (3.0)
Pyrexia	6 (18.2)	5 (15.2)	1 (3.0)
Hepatobiliary disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Hepatic function abnormal	2 (6.1)	1 (3.0)	1 (3.0)
Immune system disorders			
-Total	21 (63.6)	12 (36.4)	9 (27.3)
Cytokine release syndrome	19 (57.6)	10 (30.3)	9 (27.3)
Hypogammaglobulinaemia	5 (15.2)	5 (15.2)	0
Haemophagocytic lymphohistiocytosis	1 (3.0)	1 (3.0)	0
Immunodeficiency	1 (3.0)	1 (3.0)	0
Infections and infestations			
-Total	12 (36.4)	8 (24.2)	4 (12.1)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (6.1)	1 (3.0)	1 (3.0)
Septic shock	2 (6.1)	0	2 (6.1)
Staphylococcal bacteraemia	2 (6.1)	2 (6.1)	0
Upper respiratory tract infection	2 (6.1)	2 (6.1)	0
Adenovirus infection	1 (3.0)	1 (3.0)	0
Bacteraemia	1 (3.0)	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0
Encephalitis viral	1 (3.0)	0	1 (3.0)
Metapneumovirus infection	1 (3.0)	1 (3.0)	0
Pneumonia	1 (3.0)	1 (3.0)	0
Respiratory syncytial virus infection	1 (3.0)	1 (3.0)	0
Sinusitis	1 (3.0)	1 (3.0)	0
Investigations			
-Total	17 (51.5)	7 (21.2)	10 (30.3)
Lymphocyte count decreased	5 (15.2)	3 (9.1)	2 (6.1)
Neutrophil count decreased	5 (15.2)	1 (3.0)	4 (12.1)
Alanine aminotransferase increased	4 (12.1)	4 (12.1)	0
Aspartate aminotransferase increased	4 (12.1)	3 (9.1)	1 (3.0)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (12.1)	4 (12.1)	0
Platelet count decreased	4 (12.1)	1 (3.0)	3 (9.1)
White blood cell count decreased	4 (12.1)	0	4 (12.1)
Blood creatinine increased	2 (6.1)	1 (3.0)	1 (3.0)
C-reactive protein increased	2 (6.1)	2 (6.1)	0
Electrocardiogram qt prolonged	2 (6.1)	1 (3.0)	1 (3.0)
Serum ferritin increased	2 (6.1)	2 (6.1)	0
Metabolism and nutrition disorders			
-Total	14 (42.4)	10 (30.3)	4 (12.1)
Decreased appetite	5 (15.2)	4 (12.1)	1 (3.0)
Hypokalaemia	5 (15.2)	5 (15.2)	0
Tumour lysis syndrome	4 (12.1)	3 (9.1)	1 (3.0)
Hypophosphataemia	3 (9.1)	3 (9.1)	0
Hypervolaemia	2 (6.1)	2 (6.1)	0
Metabolic acidosis	2 (6.1)	0	2 (6.1)
Acidosis	1 (3.0)	1 (3.0)	0
Hyperglycaemia	1 (3.0)	1 (3.0)	0
Hypocalcaemia	1 (3.0)	1 (3.0)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (3.0)	1 (3.0)	0
Back pain	1 (3.0)	1 (3.0)	0
Nervous system disorders			
-Total	4 (12.1)	4 (12.1)	0
Seizure	2 (6.1)	2 (6.1)	0
Encephalopathy	1 (3.0)	1 (3.0)	0
Headache	1 (3.0)	1 (3.0)	0
Somnolence	1 (3.0)	1 (3.0)	0
Psychiatric disorders			
-Total	3 (9.1)	3 (9.1)	0
Anxiety	2 (6.1)	2 (6.1)	0
Delirium	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	5 (15.2)	2 (6.1)	3 (9.1)
Acute kidney injury	5 (15.2)	2 (6.1)	3 (9.1)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (39.4)	4 (12.1)	9 (27.3)
Hypoxia	7 (21.2)	3 (9.1)	4 (12.1)
Respiratory failure	3 (9.1)	0	3 (9.1)
Acute respiratory distress syndrome	2 (6.1)	0	2 (6.1)
Pleural effusion	2 (6.1)	1 (3.0)	1 (3.0)
Tachypnoea	2 (6.1)	2 (6.1)	0
Pulmonary oedema	1 (3.0)	1 (3.0)	0
Respiratory distress	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	8 (24.2)	4 (12.1)	4 (12.1)
Hypotension	7 (21.2)	3 (9.1)	4 (12.1)
Hypertension	1 (3.0)	1 (3.0)	0
Venoocclusive disease	1 (3.0)	1 (3.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	4 (28.6)	9 (64.3)
Blood and lymphatic system disorders			
-Total	7 (50.0)	6 (42.9)	1 (7.1)
Anaemia	2 (14.3)	2 (14.3)	0
Febrile neutropenia	2 (14.3)	2 (14.3)	0
Neutropenia	2 (14.3)	1 (7.1)	1 (7.1)
Thrombocytopenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiac failure	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	2 (14.3)	0
Gingivitis ulcerative	1 (7.1)	1 (7.1)	0
Mouth haemorrhage	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Pyrexia	2 (14.3)	2 (14.3)	0
Catheter site pain	1 (7.1)	1 (7.1)	0
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Hepatobiliary disorders			
-Total	1 (7.1)	1 (7.1)	0
Hyperbilirubinaemia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	9 (64.3)	5 (35.7)	4 (28.6)
Cytokine release syndrome	8 (57.1)	4 (28.6)	4 (28.6)
Allergy to immunoglobulin therapy	1 (7.1)	1 (7.1)	0
Haemophagocytic lymphohistiocytosis	1 (7.1)	1 (7.1)	0
Immunodeficiency	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	8 (57.1)	6 (42.9)	2 (14.3)
Adenovirus infection	1 (7.1)	1 (7.1)	0
Bacteraemia	1 (7.1)	0	1 (7.1)
Candida infection	1 (7.1)	0	1 (7.1)
Clostridium difficile infection	1 (7.1)	1 (7.1)	0
Encephalitis viral	1 (7.1)	1 (7.1)	0
Gastroenteritis	1 (7.1)	1 (7.1)	0
Granulicatella infection	1 (7.1)	1 (7.1)	0
Herpes simplex	1 (7.1)	1 (7.1)	0
Human herpesvirus 6 infection	1 (7.1)	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Rhinovirus infection	1 (7.1)	1 (7.1)	0
Sinusitis	1 (7.1)	1 (7.1)	0
Staphylococcal abscess	1 (7.1)	1 (7.1)	0
Staphylococcal bacteraemia	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (7.1)	1 (7.1)	0
Systemic candida	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Varicella zoster virus infection	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Injury, poisoning and procedural complications			
-Total	1 (7.1)	0	1 (7.1)
Transplant failure	1 (7.1)	0	1 (7.1)
Investigations			
-Total	6 (42.9)	3 (21.4)	3 (21.4)
Aspartate aminotransferase increased	3 (21.4)	3 (21.4)	0
Platelet count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	1 (7.1)	1 (7.1)	0
Blood glucose increased	1 (7.1)	0	1 (7.1)
Neutrophil count decreased	1 (7.1)	0	1 (7.1)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	6 (42.9)	5 (35.7)	1 (7.1)
Hypervolaemia	3 (21.4)	3 (21.4)	0
Decreased appetite	2 (14.3)	2 (14.3)	0
Hypocalcaemia	2 (14.3)	2 (14.3)	0
Hypokalaemia	2 (14.3)	2 (14.3)	0
Hypophosphataemia	2 (14.3)	2 (14.3)	0
Acidosis	1 (7.1)	0	1 (7.1)
Hypoalbuminaemia	1 (7.1)	1 (7.1)	0
Malnutrition	1 (7.1)	1 (7.1)	0
Polydipsia	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Pain in jaw	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cognitive disorder	1 (7.1)	1 (7.1)	0
Encephalopathy	1 (7.1)	1 (7.1)	0
Neurological decompensation	1 (7.1)	0	1 (7.1)
Somnolence	1 (7.1)	1 (7.1)	0
Psychiatric disorders			
-Total	2 (14.3)	2 (14.3)	0
Delirium	2 (14.3)	2 (14.3)	0
Renal and urinary disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Acute kidney injury	1 (7.1)	1 (7.1)	0
Renal failure	1 (7.1)	0	1 (7.1)
Reproductive system and breast disorders			
-Total	1 (7.1)	1 (7.1)	0
Endometriosis	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (42.9)	3 (21.4)	3 (21.4)
Hypoxia	3 (21.4)	3 (21.4)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	3 (21.4)	2 (14.3)	1 (7.1)
Respiratory failure	2 (14.3)	0	2 (14.3)
Dyspnoea	1 (7.1)	1 (7.1)	0
Laryngeal oedema	1 (7.1)	0	1 (7.1)
Respiratory distress	1 (7.1)	0	1 (7.1)
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Decubitus ulcer	1 (7.1)	1 (7.1)	0
Surgical and medical procedures			
-Total	1 (7.1)	1 (7.1)	0
Thrombolysis	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Hypotension	3 (21.4)	2 (14.3)	1 (7.1)
Hypertension	1 (7.1)	1 (7.1)	0
Venoocclusive disease	1 (7.1)	0	1 (7.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

		All patients N=46	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (71.7)	9 (19.6)	24 (52.2)
Blood and lymphatic system disorders			
-Total	16 (34.8)	9 (19.6)	7 (15.2)
Febrile neutropenia	11 (23.9)	11 (23.9)	0
Thrombocytopenia	5 (10.9)	0	5 (10.9)
Anaemia	3 (6.5)	3 (6.5)	0
Neutropenia	3 (6.5)	0	3 (6.5)
General disorders and administration site conditions			
-Total	3 (6.5)	1 (2.2)	2 (4.3)
Pyrexia	3 (6.5)	1 (2.2)	2 (4.3)
Immune system disorders			

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (47.8)	11 (23.9)	11 (23.9)
Cytokine release syndrome	19 (41.3)	8 (17.4)	11 (23.9)
Hypogammaglobulinaemia	3 (6.5)	3 (6.5)	0
Haemophagocytic lymphohistiocytosis	2 (4.3)	2 (4.3)	0
Immunodeficiency	2 (4.3)	2 (4.3)	0
Infections and infestations			
-Total	2 (4.3)	2 (4.3)	0
Pneumonia	1 (2.2)	1 (2.2)	0
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Investigations			
-Total	20 (43.5)	7 (15.2)	13 (28.3)
White blood cell count decreased	9 (19.6)	1 (2.2)	8 (17.4)
Neutrophil count decreased	8 (17.4)	0	8 (17.4)
Blood bilirubin increased	7 (15.2)	7 (15.2)	0
Platelet count decreased	7 (15.2)	4 (8.7)	3 (6.5)
Aspartate aminotransferase increased	6 (13.0)	4 (8.7)	2 (4.3)
Lymphocyte count decreased	5 (10.9)	2 (4.3)	3 (6.5)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	3 (6.5)	3 (6.5)	0
C-reactive protein increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	13 (28.3)	9 (19.6)	4 (8.7)
Hypokalaemia	5 (10.9)	4 (8.7)	1 (2.2)
Decreased appetite	4 (8.7)	3 (6.5)	1 (2.2)
Hyperglycaemia	3 (6.5)	3 (6.5)	0
Hypocalcaemia	3 (6.5)	3 (6.5)	0
Hypophosphataemia	3 (6.5)	2 (4.3)	1 (2.2)
Tumour lysis syndrome	3 (6.5)	3 (6.5)	0
Hypervolaemia	1 (2.2)	1 (2.2)	0
Metabolic acidosis	1 (2.2)	0	1 (2.2)
Nervous system disorders			
-Total	3 (6.5)	3 (6.5)	0
Headache	2 (4.3)	2 (4.3)	0
Encephalopathy	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	2 (4.3)	0	2 (4.3)
Acute kidney injury	2 (4.3)	0	2 (4.3)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	9 (19.6)	2 (4.3)	7 (15.2)
Hypoxia	6 (13.0)	2 (4.3)	4 (8.7)
Pleural effusion	3 (6.5)	2 (4.3)	1 (2.2)
Pulmonary oedema	3 (6.5)	2 (4.3)	1 (2.2)
Respiratory failure	2 (4.3)	0	2 (4.3)
Dyspnoea	1 (2.2)	1 (2.2)	0
Tachypnoea	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	7 (15.2)	5 (10.9)	2 (4.3)
Hypotension	5 (10.9)	3 (6.5)	2 (4.3)
Hypertension	2 (4.3)	2 (4.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (94.1)	11 (32.4)	21 (61.8)
Blood and lymphatic system disorders			
-Total	22 (64.7)	16 (47.1)	6 (17.6)
Febrile neutropenia	15 (44.1)	13 (38.2)	2 (5.9)
Anaemia	5 (14.7)	5 (14.7)	0
Neutropenia	4 (11.8)	1 (2.9)	3 (8.8)
Thrombocytopenia	3 (8.8)	2 (5.9)	1 (2.9)
Coagulopathy	2 (5.9)	2 (5.9)	0
Disseminated intravascular coagulation	2 (5.9)	2 (5.9)	0
Cardiac disorders			
-Total	2 (5.9)	0	2 (5.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.9)	0	1 (2.9)
Cardiac failure	1 (2.9)	0	1 (2.9)
General disorders and administration site conditions			
-Total	7 (20.6)	5 (14.7)	2 (5.9)
Pyrexia	5 (14.7)	5 (14.7)	0
Multiple organ dysfunction syndrome	2 (5.9)	0	2 (5.9)
Immune system disorders			
-Total	21 (61.8)	11 (32.4)	10 (29.4)
Cytokine release syndrome	19 (55.9)	9 (26.5)	10 (29.4)
Hypogammaglobulinaemia	4 (11.8)	4 (11.8)	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)
Immunodeficiency	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	6 (17.6)	5 (14.7)	1 (2.9)
Encephalitis viral	2 (5.9)	1 (2.9)	1 (2.9)
Staphylococcal bacteraemia	2 (5.9)	2 (5.9)	0
Bacteraemia	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchopulmonary aspergillosis	1 (2.9)	1 (2.9)	0
Sinusitis	1 (2.9)	1 (2.9)	0
Investigations			
-Total	21 (61.8)	9 (26.5)	12 (35.3)
Neutrophil count decreased	9 (26.5)	2 (5.9)	7 (20.6)
White blood cell count decreased	9 (26.5)	1 (2.9)	8 (23.5)
Lymphocyte count decreased	8 (23.5)	6 (17.6)	2 (5.9)
Platelet count decreased	7 (20.6)	2 (5.9)	5 (14.7)
Aspartate aminotransferase increased	5 (14.7)	4 (11.8)	1 (2.9)
Alanine aminotransferase increased	3 (8.8)	3 (8.8)	0
Blood bilirubin increased	2 (5.9)	2 (5.9)	0
C-reactive protein increased	2 (5.9)	2 (5.9)	0
Metabolism and nutrition disorders			
-Total	15 (44.1)	12 (35.3)	3 (8.8)
Decreased appetite	7 (20.6)	7 (20.6)	0
Hypokalaemia	6 (17.6)	5 (14.7)	1 (2.9)
Hypophosphataemia	6 (17.6)	6 (17.6)	0
Hypervolaemia	3 (8.8)	3 (8.8)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	2 (5.9)	1 (2.9)	1 (2.9)
Hypocalcaemia	2 (5.9)	2 (5.9)	0
Hyperglycaemia	1 (2.9)	1 (2.9)	0
Hypernatraemia	1 (2.9)	0	1 (2.9)
Metabolic acidosis	1 (2.9)	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	4 (11.8)	4 (11.8)	0
Encephalopathy	3 (8.8)	3 (8.8)	0
Seizure	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	3 (8.8)	3 (8.8)	0
Anxiety	2 (5.9)	2 (5.9)	0
Mental status changes	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	5 (14.7)	3 (8.8)	2 (5.9)
Acute kidney injury	5 (14.7)	3 (8.8)	2 (5.9)
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	13 (38.2)	8 (23.5)	5 (14.7)
Hypoxia	6 (17.6)	4 (11.8)	2 (5.9)
Pulmonary oedema	4 (11.8)	4 (11.8)	0
Tachypnoea	3 (8.8)	3 (8.8)	0
Acute respiratory distress syndrome	2 (5.9)	0	2 (5.9)
Dyspnoea	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory failure	2 (5.9)	0	2 (5.9)
Vascular disorders			
-Total	9 (26.5)	5 (14.7)	4 (11.8)
Hypotension	9 (26.5)	5 (14.7)	4 (11.8)
Hypertension	2 (5.9)	2 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

		All patients N=43	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (39.5)	11 (25.6)	6 (14.0)
Blood and lymphatic system disorders			
-Total	5 (11.6)	3 (7.0)	2 (4.7)
Febrile neutropenia	3 (7.0)	3 (7.0)	0
Thrombocytopenia	2 (4.7)	1 (2.3)	1 (2.3)
Anaemia	1 (2.3)	1 (2.3)	0
Disseminated intravascular coagulation	1 (2.3)	1 (2.3)	0
Neutropenia	1 (2.3)	0	1 (2.3)
Cardiac disorders			
-Total	1 (2.3)	0	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.3)	0	1 (2.3)
Cardiac failure	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	2 (4.7)	2 (4.7)	0
Pyrexia	2 (4.7)	2 (4.7)	0
Immune system disorders			
-Total	1 (2.3)	1 (2.3)	0
Immunodeficiency	1 (2.3)	1 (2.3)	0
Infections and infestations			
-Total	5 (11.6)	4 (9.3)	1 (2.3)
Metapneumovirus infection	3 (7.0)	3 (7.0)	0
Pneumonia	1 (2.3)	0	1 (2.3)
Staphylococcal bacteraemia	1 (2.3)	1 (2.3)	0
Investigations			
-Total	7 (16.3)	5 (11.6)	2 (4.7)
Neutrophil count decreased	4 (9.3)	2 (4.7)	2 (4.7)
Lymphocyte count decreased	2 (4.7)	2 (4.7)	0
Platelet count decreased	2 (4.7)	1 (2.3)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (2.3)	1 (2.3)	0
Blood bilirubin increased	1 (2.3)	1 (2.3)	0
White blood cell count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	3 (7.0)	2 (4.7)	1 (2.3)
Decreased appetite	1 (2.3)	1 (2.3)	0
Hypervolaemia	1 (2.3)	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	1 (2.3)
Nervous system disorders			
-Total	1 (2.3)	1 (2.3)	0
Seizure	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.0)	2 (4.7)	1 (2.3)
Hypoxia	2 (4.7)	2 (4.7)	0
Respiratory failure	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypotension	1 (2.3)	1 (2.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (37.5)	3 (9.4)	9 (28.1)
Blood and lymphatic system disorders			
-Total	5 (15.6)	3 (9.4)	2 (6.3)
Neutropenia	4 (12.5)	2 (6.3)	2 (6.3)
Anaemia	1 (3.1)	1 (3.1)	0
Cardiac disorders			
-Total	2 (6.3)	0	2 (6.3)
Cardiac arrest	1 (3.1)	0	1 (3.1)
Cardiac failure	1 (3.1)	0	1 (3.1)
Infections and infestations			
-Total	5 (15.6)	2 (6.3)	3 (9.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (6.3)	2 (6.3)	0
Bacteraemia	1 (3.1)	0	1 (3.1)
Bronchopulmonary aspergillosis	1 (3.1)	0	1 (3.1)
Septic shock	1 (3.1)	0	1 (3.1)
Sinusitis	1 (3.1)	1 (3.1)	0
Investigations			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Neutrophil count decreased	3 (9.4)	1 (3.1)	2 (6.3)
White blood cell count decreased	3 (9.4)	3 (9.4)	0
Metabolism and nutrition disorders			
-Total	3 (9.4)	1 (3.1)	2 (6.3)
Hypokalaemia	1 (3.1)	1 (3.1)	0
Metabolic acidosis	1 (3.1)	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	0	1 (3.1)
Psychiatric disorders			
-Total	1 (3.1)	1 (3.1)	0
Mental status changes	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	1 (3.1)	0	1 (3.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Acute respiratory distress syndrome	1 (3.1)	0	1 (3.1)
Hypoxia	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	2 (6.3)	0	2 (6.3)
Hypotension	2 (6.3)	0	2 (6.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (17.2)	3 (10.3)	2 (6.9)
General disorders and administration site conditions			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Multiple organ dysfunction syndrome	1 (3.4)	0	1 (3.4)
Pyrexia	1 (3.4)	1 (3.4)	0
Immune system disorders			
-Total	1 (3.4)	0	1 (3.4)
Haemophagocytic lymphohistiocytosis	1 (3.4)	0	1 (3.4)
Infections and infestations			
-Total	3 (10.3)	2 (6.9)	1 (3.4)

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (6.9)	1 (3.4)	1 (3.4)
Staphylococcal bacteraemia	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Decreased appetite	1 (3.4)	0	1 (3.4)
Hyperglycaemia	1 (3.4)	1 (3.4)	0
Nervous system disorders			
-Total	1 (3.4)	1 (3.4)	0
Headache	1 (3.4)	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	0	1 (3.4)
Dyspnoea	1 (3.4)	0	1 (3.4)
Tachypnoea	1 (3.4)	0	1 (3.4)
Vascular disorders			
-Total	1 (3.4)	1 (3.4)	0
Hypertension	1 (3.4)	1 (3.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

		All patients N=21	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (19.0)	1 (4.8)	3 (14.3)
Blood and lymphatic system disorders			
-Total	1 (4.8)	0	1 (4.8)
Neutropenia	1 (4.8)	0	1 (4.8)
Infections and infestations			
-Total	1 (4.8)	0	1 (4.8)
Septic shock	1 (4.8)	0	1 (4.8)
Investigations			
-Total	1 (4.8)	0	1 (4.8)
Neutrophil count decreased	1 (4.8)	0	1 (4.8)
Metabolism and nutrition disorders			

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.8)	1 (4.8)	0
Hypernatraemia	1 (4.8)	1 (4.8)	0
Nervous system disorders			
-Total	1 (4.8)	1 (4.8)	0
Seizure	1 (4.8)	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Hypoxia	1 (4.8)	1 (4.8)	0
Respiratory failure	1 (4.8)	0	1 (4.8)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

		All patients N=46	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (84.8)	12 (26.1)	27 (58.7)
Blood and lymphatic system disorders			
-Total	18 (39.1)	11 (23.9)	7 (15.2)
Febrile neutropenia	12 (26.1)	12 (26.1)	0
Thrombocytopenia	6 (13.0)	1 (2.2)	5 (10.9)
Anaemia	3 (6.5)	3 (6.5)	0
Neutropenia	3 (6.5)	0	3 (6.5)
Disseminated intravascular coagulation	1 (2.2)	1 (2.2)	0
Cardiac disorders			
-Total	1 (2.2)	0	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.2)	0	1 (2.2)
Cardiac failure	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	7 (15.2)	4 (8.7)	3 (6.5)
Pyrexia	6 (13.0)	4 (8.7)	2 (4.3)
Multiple organ dysfunction syndrome	1 (2.2)	0	1 (2.2)
Immune system disorders			
-Total	24 (52.2)	12 (26.1)	12 (26.1)
Cytokine release syndrome	19 (41.3)	8 (17.4)	11 (23.9)
Haemophagocytic lymphohistiocytosis	3 (6.5)	2 (4.3)	1 (2.2)
Hypogammaglobulinaemia	3 (6.5)	3 (6.5)	0
Immunodeficiency	3 (6.5)	3 (6.5)	0
Infections and infestations			
-Total	8 (17.4)	6 (13.0)	2 (4.3)
Pneumonia	4 (8.7)	2 (4.3)	2 (4.3)
Metapneumovirus infection	3 (6.5)	3 (6.5)	0
Staphylococcal bacteraemia	3 (6.5)	3 (6.5)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	21 (45.7)	8 (17.4)	13 (28.3)
Neutrophil count decreased	11 (23.9)	2 (4.3)	9 (19.6)
White blood cell count decreased	9 (19.6)	1 (2.2)	8 (17.4)
Platelet count decreased	8 (17.4)	5 (10.9)	3 (6.5)
Blood bilirubin increased	7 (15.2)	7 (15.2)	0
Lymphocyte count decreased	7 (15.2)	4 (8.7)	3 (6.5)
Aspartate aminotransferase increased	6 (13.0)	4 (8.7)	2 (4.3)
Alanine aminotransferase increased	4 (8.7)	4 (8.7)	0
C-reactive protein increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	15 (32.6)	10 (21.7)	5 (10.9)
Decreased appetite	5 (10.9)	3 (6.5)	2 (4.3)
Hypokalaemia	5 (10.9)	4 (8.7)	1 (2.2)
Hyperglycaemia	4 (8.7)	4 (8.7)	0
Hypocalcaemia	3 (6.5)	3 (6.5)	0
Hypophosphataemia	3 (6.5)	2 (4.3)	1 (2.2)
Tumour lysis syndrome	3 (6.5)	3 (6.5)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	2 (4.3)	2 (4.3)	0
Metabolic acidosis	1 (2.2)	0	1 (2.2)
Nervous system disorders			
-Total	5 (10.9)	5 (10.9)	0
Headache	3 (6.5)	3 (6.5)	0
Encephalopathy	1 (2.2)	1 (2.2)	0
Seizure	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	2 (4.3)	0	2 (4.3)
Acute kidney injury	2 (4.3)	0	2 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (26.1)	3 (6.5)	9 (19.6)
Hypoxia	8 (17.4)	4 (8.7)	4 (8.7)
Pleural effusion	3 (6.5)	2 (4.3)	1 (2.2)
Pulmonary oedema	3 (6.5)	2 (4.3)	1 (2.2)
Respiratory failure	3 (6.5)	0	3 (6.5)
Dyspnoea	2 (4.3)	1 (2.2)	1 (2.2)
Tachypnoea	2 (4.3)	1 (2.2)	1 (2.2)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	9 (19.6)	7 (15.2)	2 (4.3)
Hypotension	6 (13.0)	4 (8.7)	2 (4.3)
Hypertension	3 (6.5)	3 (6.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (94.1)	9 (26.5)	23 (67.6)
Blood and lymphatic system disorders			
-Total	25 (73.5)	18 (52.9)	7 (20.6)
Febrile neutropenia	15 (44.1)	13 (38.2)	2 (5.9)
Anaemia	6 (17.6)	6 (17.6)	0
Neutropenia	6 (17.6)	2 (5.9)	4 (11.8)
Thrombocytopenia	3 (8.8)	2 (5.9)	1 (2.9)
Coagulopathy	2 (5.9)	2 (5.9)	0
Disseminated intravascular coagulation	2 (5.9)	2 (5.9)	0
Cardiac disorders			

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (11.8)	0	4 (11.8)
Cardiac arrest	2 (5.9)	0	2 (5.9)
Cardiac failure	2 (5.9)	0	2 (5.9)
General disorders and administration site conditions			
-Total	7 (20.6)	5 (14.7)	2 (5.9)
Pyrexia	5 (14.7)	5 (14.7)	0
Multiple organ dysfunction syndrome	2 (5.9)	0	2 (5.9)
Immune system disorders			
-Total	21 (61.8)	11 (32.4)	10 (29.4)
Cytokine release syndrome	19 (55.9)	9 (26.5)	10 (29.4)
Hypogammaglobulinaemia	4 (11.8)	4 (11.8)	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)
Immunodeficiency	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	11 (32.4)	6 (17.6)	5 (14.7)
Bacteraemia	2 (5.9)	1 (2.9)	1 (2.9)
Bronchopulmonary aspergillosis	2 (5.9)	1 (2.9)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	2 (5.9)	1 (2.9)	1 (2.9)
Gastroenteritis	2 (5.9)	2 (5.9)	0
Septic shock	2 (5.9)	0	2 (5.9)
Sinusitis	2 (5.9)	2 (5.9)	0
Staphylococcal bacteraemia	2 (5.9)	2 (5.9)	0
Investigations			
-Total	21 (61.8)	9 (26.5)	12 (35.3)
Neutrophil count decreased	10 (29.4)	2 (5.9)	8 (23.5)
White blood cell count decreased	9 (26.5)	1 (2.9)	8 (23.5)
Lymphocyte count decreased	8 (23.5)	6 (17.6)	2 (5.9)
Platelet count decreased	7 (20.6)	2 (5.9)	5 (14.7)
Aspartate aminotransferase increased	5 (14.7)	4 (11.8)	1 (2.9)
Alanine aminotransferase increased	3 (8.8)	3 (8.8)	0
Blood bilirubin increased	2 (5.9)	2 (5.9)	0
C-reactive protein increased	2 (5.9)	2 (5.9)	0
Metabolism and nutrition disorders			
-Total	16 (47.1)	11 (32.4)	5 (14.7)
Decreased appetite	7 (20.6)	7 (20.6)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	6 (17.6)	5 (14.7)	1 (2.9)
Hypophosphataemia	6 (17.6)	6 (17.6)	0
Hypervolaemia	3 (8.8)	3 (8.8)	0
Acidosis	2 (5.9)	1 (2.9)	1 (2.9)
Hypernatraemia	2 (5.9)	1 (2.9)	1 (2.9)
Hypocalcaemia	2 (5.9)	2 (5.9)	0
Metabolic acidosis	2 (5.9)	0	2 (5.9)
Tumour lysis syndrome	2 (5.9)	1 (2.9)	1 (2.9)
Hyperglycaemia	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	5 (14.7)	5 (14.7)	0
Encephalopathy	3 (8.8)	3 (8.8)	0
Seizure	2 (5.9)	2 (5.9)	0
Psychiatric disorders			
-Total	4 (11.8)	4 (11.8)	0
Anxiety	2 (5.9)	2 (5.9)	0
Mental status changes	2 (5.9)	2 (5.9)	0
Renal and urinary disorders			
-Total	6 (17.6)	3 (8.8)	3 (8.8)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	6 (17.6)	3 (8.8)	3 (8.8)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (47.1)	9 (26.5)	7 (20.6)
Hypoxia	8 (23.5)	6 (17.6)	2 (5.9)
Pulmonary oedema	4 (11.8)	4 (11.8)	0
Acute respiratory distress syndrome	3 (8.8)	0	3 (8.8)
Respiratory failure	3 (8.8)	0	3 (8.8)
Tachypnoea	3 (8.8)	3 (8.8)	0
Dyspnoea	2 (5.9)	1 (2.9)	1 (2.9)
Vascular disorders			
-Total	10 (29.4)	4 (11.8)	6 (17.6)
Hypotension	10 (29.4)	4 (11.8)	6 (17.6)
Hypertension	2 (5.9)	2 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (79.7)	19 (32.2)	28 (47.5)
Blood and lymphatic system disorders			
-Total	24 (40.7)	17 (28.8)	7 (11.9)
Febrile neutropenia	18 (30.5)	17 (28.8)	1 (1.7)
Anaemia	5 (8.5)	5 (8.5)	0
Thrombocytopenia	5 (8.5)	1 (1.7)	4 (6.8)
Neutropenia	4 (6.8)	1 (1.7)	3 (5.1)
Disseminated intravascular coagulation	1 (1.7)	1 (1.7)	0
Leukopenia	1 (1.7)	1 (1.7)	0
Lymphopenia	1 (1.7)	1 (1.7)	0
Cardiac disorders			

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (10.2)	4 (6.8)	2 (3.4)
Tachycardia	3 (5.1)	2 (3.4)	1 (1.7)
Left ventricular dysfunction	2 (3.4)	2 (3.4)	0
Cardiac failure	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	3 (5.1)	3 (5.1)	0
Mouth haemorrhage	1 (1.7)	1 (1.7)	0
Nausea	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	6 (10.2)	3 (5.1)	3 (5.1)
Pyrexia	5 (8.5)	3 (5.1)	2 (3.4)
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Pain	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	31 (52.5)	19 (32.2)	12 (20.3)
Cytokine release syndrome	26 (44.1)	14 (23.7)	12 (20.3)
Hypogammaglobulinaemia	7 (11.9)	7 (11.9)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	3 (5.1)	2 (3.4)	1 (1.7)
Immunodeficiency	3 (5.1)	3 (5.1)	0
Infections and infestations			
-Total	5 (8.5)	5 (8.5)	0
Clostridium difficile infection	3 (5.1)	3 (5.1)	0
Human herpesvirus 6 infection	1 (1.7)	1 (1.7)	0
Staphylococcal bacteraemia	1 (1.7)	1 (1.7)	0
Investigations			
-Total	29 (49.2)	13 (22.0)	16 (27.1)
Lymphocyte count decreased	10 (16.9)	6 (10.2)	4 (6.8)
Neutrophil count decreased	10 (16.9)	1 (1.7)	9 (15.3)
Platelet count decreased	9 (15.3)	4 (6.8)	5 (8.5)
White blood cell count decreased	9 (15.3)	2 (3.4)	7 (11.9)
Aspartate aminotransferase increased	7 (11.9)	6 (10.2)	1 (1.7)
Blood bilirubin increased	6 (10.2)	6 (10.2)	0
Alanine aminotransferase increased	3 (5.1)	3 (5.1)	0
Blood creatinine increased	2 (3.4)	1 (1.7)	1 (1.7)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	2 (3.4)	2 (3.4)	0
Blood creatine phosphokinase increased	1 (1.7)	0	1 (1.7)
Electrocardiogram qt prolonged	1 (1.7)	1 (1.7)	0
Gamma-glutamyltransferase increased	1 (1.7)	1 (1.7)	0
Serum ferritin increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	18 (30.5)	14 (23.7)	4 (6.8)
Hypokalaemia	8 (13.6)	6 (10.2)	2 (3.4)
Decreased appetite	6 (10.2)	5 (8.5)	1 (1.7)
Hypophosphataemia	6 (10.2)	6 (10.2)	0
Hyperglycaemia	3 (5.1)	3 (5.1)	0
Hypocalcaemia	3 (5.1)	3 (5.1)	0
Hypervolaemia	2 (3.4)	2 (3.4)	0
Acidosis	1 (1.7)	1 (1.7)	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0
Hyperkalaemia	1 (1.7)	1 (1.7)	0
Malnutrition	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (1.7)	0	1 (1.7)
Tumour lysis syndrome	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Back pain	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	7 (11.9)	7 (11.9)	0
Encephalopathy	4 (6.8)	4 (6.8)	0
Headache	2 (3.4)	2 (3.4)	0
Seizure	1 (1.7)	1 (1.7)	0
Psychiatric disorders			
-Total	5 (8.5)	5 (8.5)	0
Delirium	3 (5.1)	3 (5.1)	0
Anxiety	1 (1.7)	1 (1.7)	0
Mental status changes	1 (1.7)	1 (1.7)	0
Renal and urinary disorders			
-Total	5 (8.5)	3 (5.1)	2 (3.4)
Acute kidney injury	5 (8.5)	3 (5.1)	2 (3.4)

Timing: within 8 weeks post infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	14 (23.7)	8 (13.6)	6 (10.2)
Hypoxia	7 (11.9)	5 (8.5)	2 (3.4)
Pulmonary oedema	5 (8.5)	4 (6.8)	1 (1.7)
Tachypnoea	4 (6.8)	4 (6.8)	0
Dyspnoea	3 (5.1)	2 (3.4)	1 (1.7)
Respiratory failure	3 (5.1)	0	3 (5.1)
Pleural effusion	2 (3.4)	2 (3.4)	0
Acute respiratory distress syndrome	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	12 (20.3)	8 (13.6)	4 (6.8)
Hypotension	12 (20.3)	8 (13.6)	4 (6.8)
Hypertension	1 (1.7)	1 (1.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	2 (20.0)	7 (70.0)
Blood and lymphatic system disorders			
-Total	7 (70.0)	2 (20.0)	5 (50.0)
Neutropenia	3 (30.0)	0	3 (30.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Thrombocytopenia	2 (20.0)	0	2 (20.0)
Disseminated intravascular coagulation	1 (10.0)	1 (10.0)	0
Leukopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	1 (10.0)	0	1 (10.0)
Cardiac arrest	1 (10.0)	0	1 (10.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	1 (10.0)	0
Hepatobiliary disorders			
-Total	4 (40.0)	2 (20.0)	2 (20.0)
Hepatic function abnormal	3 (30.0)	2 (20.0)	1 (10.0)
Hepatomegaly	1 (10.0)	0	1 (10.0)
Immune system disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	5 (50.0)	2 (20.0)	3 (30.0)
Infections and infestations			
-Total	4 (40.0)	3 (30.0)	1 (10.0)
Bacteraemia	1 (10.0)	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	1 (10.0)
Meningitis bacterial	1 (10.0)	1 (10.0)	0
Oral herpes	1 (10.0)	1 (10.0)	0
Pneumonia	1 (10.0)	1 (10.0)	0
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	6 (60.0)	2 (20.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	2 (20.0)
Blood bilirubin increased	1 (10.0)	1 (10.0)	0
Blood creatine phosphokinase increased	1 (10.0)	1 (10.0)	0
Blood fibrinogen decreased	1 (10.0)	1 (10.0)	0
Gamma-glutamyltransferase increased	1 (10.0)	1 (10.0)	0
Platelet count decreased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Tumour lysis syndrome	2 (20.0)	2 (20.0)	0
Hypercalcaemia	1 (10.0)	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	1 (10.0)
Metabolic acidosis	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	1 (10.0)	0
Muscular weakness	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	2 (20.0)	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	2 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (40.0)	0	4 (40.0)
Hypoxia	4 (40.0)	0	4 (40.0)
Respiratory failure	1 (10.0)	0	1 (10.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	0	10 (90.9)
Blood and lymphatic system disorders			
-Total	7 (63.6)	6 (54.5)	1 (9.1)
Febrile neutropenia	6 (54.5)	5 (45.5)	1 (9.1)
Anaemia	3 (27.3)	3 (27.3)	0
Thrombocytopenia	1 (9.1)	1 (9.1)	0
Cardiac disorders			
-Total	1 (9.1)	1 (9.1)	0
Left ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus bradycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	2 (18.2)	0
Mouth haemorrhage	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Pyrexia	2 (18.2)	2 (18.2)	0
Multiple organ dysfunction syndrome	1 (9.1)	0	1 (9.1)
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0
Hyperbilirubinaemia	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Cytokine release syndrome	7 (63.6)	1 (9.1)	6 (54.5)
Infections and infestations			
-Total	3 (27.3)	3 (27.3)	0
Adenovirus infection	1 (9.1)	1 (9.1)	0
Encephalitis viral	1 (9.1)	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (9.1)	1 (9.1)	0
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Investigations			
-Total	9 (81.8)	2 (18.2)	7 (63.6)
Neutrophil count decreased	5 (45.5)	1 (9.1)	4 (36.4)
White blood cell count decreased	5 (45.5)	0	5 (45.5)
Aspartate aminotransferase increased	4 (36.4)	2 (18.2)	2 (18.2)
Platelet count decreased	4 (36.4)	1 (9.1)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	3 (27.3)	0
Lymphocyte count decreased	3 (27.3)	2 (18.2)	1 (9.1)
Blood bilirubin increased	2 (18.2)	2 (18.2)	0
Activated partial thromboplastin time prolonged	1 (9.1)	1 (9.1)	0
Blood creatinine increased	1 (9.1)	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	1 (9.1)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	1 (9.1)	1 (9.1)	0
Serum ferritin increased	1 (9.1)	1 (9.1)	0
Troponin increased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	7 (63.6)	5 (45.5)	2 (18.2)
Decreased appetite	5 (45.5)	5 (45.5)	0
Hypokalaemia	3 (27.3)	3 (27.3)	0
Hypophosphataemia	3 (27.3)	2 (18.2)	1 (9.1)
Hypervolaemia	2 (18.2)	2 (18.2)	0
Hypocalcaemia	2 (18.2)	2 (18.2)	0
Acidosis	1 (9.1)	0	1 (9.1)
Hyperglycaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Haemarthrosis	1 (9.1)	1 (9.1)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Cognitive disorder	1 (9.1)	1 (9.1)	0
Psychiatric disorders			
-Total	1 (9.1)	1 (9.1)	0
Anxiety	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Pulmonary oedema	2 (18.2)	2 (18.2)	0
Acute respiratory distress syndrome	1 (9.1)	0	1 (9.1)
Epistaxis	1 (9.1)	1 (9.1)	0
Hypoxia	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Rash maculo-papular	1 (9.1)	1 (9.1)	0
Surgical and medical procedures			

Timing: within 8 weeks post infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (9.1)	1 (9.1)	0
Thrombolysis	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Hypertension	3 (27.3)	3 (27.3)	0
Hypotension	2 (18.2)	0	2 (18.2)
Capillary leak syndrome	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=55	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (34.5)	11 (20.0)	8 (14.5)
Blood and lymphatic system disorders			
-Total	5 (9.1)	4 (7.3)	1 (1.8)
Febrile neutropenia	2 (3.6)	2 (3.6)	0
Neutropenia	2 (3.6)	1 (1.8)	1 (1.8)
Anaemia	1 (1.8)	1 (1.8)	0
Disseminated intravascular coagulation	1 (1.8)	1 (1.8)	0
Thrombocytopenia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	1 (1.8)	0	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (1.8)	0	1 (1.8)
Cardiac failure	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	1 (1.8)	1 (1.8)	0
Pyrexia	1 (1.8)	1 (1.8)	0
Infections and infestations			
-Total	7 (12.7)	5 (9.1)	2 (3.6)
Metapneumovirus infection	3 (5.5)	3 (5.5)	0
Parainfluenzae virus infection	2 (3.6)	1 (1.8)	1 (1.8)
Adenovirus infection	1 (1.8)	1 (1.8)	0
Pneumonia	1 (1.8)	0	1 (1.8)
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Rhinovirus infection	1 (1.8)	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Investigations			
-Total	10 (18.2)	6 (10.9)	4 (7.3)
Neutrophil count decreased	6 (10.9)	3 (5.5)	3 (5.5)
White blood cell count decreased	3 (5.5)	2 (3.6)	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (3.6)	2 (3.6)	0
Platelet count decreased	2 (3.6)	1 (1.8)	1 (1.8)
Alanine aminotransferase increased	1 (1.8)	1 (1.8)	0
Blood bilirubin increased	1 (1.8)	1 (1.8)	0
Blood uric acid increased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	4 (7.3)	2 (3.6)	2 (3.6)
Decreased appetite	1 (1.8)	1 (1.8)	0
Hypervolaemia	1 (1.8)	1 (1.8)	0
Hypokalaemia	1 (1.8)	0	1 (1.8)
Tumour lysis syndrome	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.8)	1 (1.8)	0
Back pain	1 (1.8)	1 (1.8)	0
Nervous system disorders			
-Total	1 (1.8)	1 (1.8)	0
Seizure	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.8)	0	1 (1.8)
Acute kidney injury	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (7.3)	2 (3.6)	2 (3.6)
Hypoxia	2 (3.6)	2 (3.6)	0
Acute respiratory distress syndrome	1 (1.8)	0	1 (1.8)
Respiratory failure	1 (1.8)	0	1 (1.8)
Vascular disorders			
-Total	3 (5.5)	2 (3.6)	1 (1.8)
Hypotension	2 (3.6)	1 (1.8)	1 (1.8)
Venoocclusive disease	1 (1.8)	1 (1.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (55.6)	0	5 (55.6)
Blood and lymphatic system disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Neutropenia	3 (33.3)	1 (11.1)	2 (22.2)
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Lymphopenia	1 (11.1)	1 (11.1)	0
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Cardiac failure	1 (11.1)	0	1 (11.1)
Infections and infestations			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	1 (11.1)	0
Cytomegalovirus infection reactivation	1 (11.1)	1 (11.1)	0
Human herpesvirus 6 infection	1 (11.1)	1 (11.1)	0
Viral infection	1 (11.1)	1 (11.1)	0
Investigations			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
White blood cell count decreased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Metabolic acidosis	1 (11.1)	0	1 (11.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (11.1)	1 (11.1)	0
Back pain	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypotension	1 (11.1)	0	1 (11.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	4 (36.4)	3 (27.3)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Anaemia	1 (9.1)	1 (9.1)	0
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiac arrest	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (18.2)	2 (18.2)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	2 (18.2)	2 (18.2)	0
Allergy to immunoglobulin therapy	1 (9.1)	1 (9.1)	0
Immunodeficiency	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	5 (45.5)	4 (36.4)	1 (9.1)
Bacteraemia	1 (9.1)	0	1 (9.1)
Enterobacter infection	1 (9.1)	1 (9.1)	0
Herpes zoster	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Mastoiditis	1 (9.1)	1 (9.1)	0
Otitis externa	1 (9.1)	1 (9.1)	0
Otitis media	1 (9.1)	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	1 (9.1)	1 (9.1)	0
Blood uric acid increased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	2 (18.2)	2 (18.2)	0
Hypokalaemia	1 (9.1)	1 (9.1)	0
Malnutrition	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Pain in extremity	1 (9.1)	1 (9.1)	0
Psychiatric disorders			
-Total	1 (9.1)	1 (9.1)	0
Mental status changes	1 (9.1)	1 (9.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Hypoxia	1 (9.1)	1 (9.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Decubitus ulcer	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	1 (9.1)	0	1 (9.1)
Venoocclusive disease	1 (9.1)	0	1 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (20.5)	3 (7.7)	5 (12.8)
Blood and lymphatic system disorders			
-Total	1 (2.6)	0	1 (2.6)
Neutropenia	1 (2.6)	0	1 (2.6)
General disorders and administration site conditions			
-Total	1 (2.6)	1 (2.6)	0
Pyrexia	1 (2.6)	1 (2.6)	0
Infections and infestations			
-Total	5 (12.8)	3 (7.7)	2 (5.1)
Sepsis	3 (7.7)	1 (2.6)	2 (5.1)

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (2.6)	1 (2.6)	0
Pneumonia	1 (2.6)	1 (2.6)	0
Staphylococcal bacteraemia	1 (2.6)	1 (2.6)	0
Investigations			
-Total	1 (2.6)	0	1 (2.6)
Neutrophil count decreased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			
-Total	1 (2.6)	0	1 (2.6)
Decreased appetite	1 (2.6)	0	1 (2.6)
Nervous system disorders			
-Total	2 (5.1)	2 (5.1)	0
Headache	1 (2.6)	1 (2.6)	0
Seizure	1 (2.6)	1 (2.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.1)	1 (2.6)	1 (2.6)
Hypoxia	1 (2.6)	1 (2.6)	0
Respiratory failure	1 (2.6)	0	1 (2.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (33.3)	2 (33.3)	0
Infections and infestations			
-Total	1 (16.7)	1 (16.7)	0
Upper respiratory tract infection	1 (16.7)	1 (16.7)	0
Reproductive system and breast disorders			
-Total	1 (16.7)	1 (16.7)	0
Endometriosis	1 (16.7)	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
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Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	1 (20.0)	1 (20.0)
General disorders and administration site conditions			
-Total	1 (20.0)	0	1 (20.0)
Multiple organ dysfunction syndrome	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Chronic graft versus host disease	1 (20.0)	1 (20.0)	0
Haemophagocytic lymphohistiocytosis	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	0	1 (20.0)

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Covid-19 pneumonia	1 (20.0)	0	1 (20.0)
Enterovirus infection	1 (20.0)	1 (20.0)	0
Influenza	1 (20.0)	0	1 (20.0)
Parainfluenzae virus infection	1 (20.0)	1 (20.0)	0
Pneumonia	1 (20.0)	0	1 (20.0)
Rhinovirus infection	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Oxygen saturation decreased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	2 (40.0)	2 (40.0)	0
Hyperglycaemia	1 (20.0)	1 (20.0)	0
Obesity	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Dyspnoea	1 (20.0)	0	1 (20.0)
Tachypnoea	1 (20.0)	0	1 (20.0)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	1 (20.0)	0
Hypertension	1 (20.0)	1 (20.0)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (88.1)	18 (30.5)	34 (57.6)
Blood and lymphatic system disorders			
-Total	28 (47.5)	20 (33.9)	8 (13.6)
Febrile neutropenia	19 (32.2)	18 (30.5)	1 (1.7)
Neutropenia	6 (10.2)	2 (3.4)	4 (6.8)
Thrombocytopenia	6 (10.2)	2 (3.4)	4 (6.8)
Anaemia	5 (8.5)	5 (8.5)	0
Disseminated intravascular coagulation	2 (3.4)	2 (3.4)	0
Leukopenia	1 (1.7)	1 (1.7)	0
Lymphopenia	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	7 (11.9)	4 (6.8)	3 (5.1)
Tachycardia	3 (5.1)	2 (3.4)	1 (1.7)
Cardiac failure	2 (3.4)	1 (1.7)	1 (1.7)
Left ventricular dysfunction	2 (3.4)	2 (3.4)	0
Cardiac arrest	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	3 (5.1)	3 (5.1)	0
Mouth haemorrhage	1 (1.7)	1 (1.7)	0
Nausea	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	8 (13.6)	5 (8.5)	3 (5.1)
Pyrexia	7 (11.9)	5 (8.5)	2 (3.4)
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Pain	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	31 (52.5)	19 (32.2)	12 (20.3)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	26 (44.1)	14 (23.7)	12 (20.3)
Hypogammaglobulinaemia	7 (11.9)	7 (11.9)	0
Haemophagocytic lymphohistiocytosis	3 (5.1)	2 (3.4)	1 (1.7)
Immunodeficiency	3 (5.1)	3 (5.1)	0
Infections and infestations			
-Total	14 (23.7)	10 (16.9)	4 (6.8)
Clostridium difficile infection	3 (5.1)	3 (5.1)	0
Metapneumovirus infection	3 (5.1)	3 (5.1)	0
Sepsis	3 (5.1)	1 (1.7)	2 (3.4)
Parainfluenzae virus infection	2 (3.4)	1 (1.7)	1 (1.7)
Pneumonia	2 (3.4)	1 (1.7)	1 (1.7)
Staphylococcal bacteraemia	2 (3.4)	2 (3.4)	0
Adenovirus infection	1 (1.7)	1 (1.7)	0
Herpes zoster	1 (1.7)	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	31 (52.5)	14 (23.7)	17 (28.8)
Neutrophil count decreased	14 (23.7)	3 (5.1)	11 (18.6)
Lymphocyte count decreased	12 (20.3)	8 (13.6)	4 (6.8)
Platelet count decreased	10 (16.9)	5 (8.5)	5 (8.5)
White blood cell count decreased	9 (15.3)	2 (3.4)	7 (11.9)
Aspartate aminotransferase increased	7 (11.9)	6 (10.2)	1 (1.7)
Blood bilirubin increased	6 (10.2)	6 (10.2)	0
Alanine aminotransferase increased	4 (6.8)	4 (6.8)	0
Blood creatinine increased	2 (3.4)	1 (1.7)	1 (1.7)
C-reactive protein increased	2 (3.4)	2 (3.4)	0
Blood creatine phosphokinase increased	1 (1.7)	0	1 (1.7)
Blood uric acid increased	1 (1.7)	0	1 (1.7)
Electrocardiogram qt prolonged	1 (1.7)	1 (1.7)	0
Gamma-glutamyltransferase increased	1 (1.7)	1 (1.7)	0
Serum ferritin increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (32.2)	13 (22.0)	6 (10.2)
Hypokalaemia	8 (13.6)	6 (10.2)	2 (3.4)
Decreased appetite	7 (11.9)	5 (8.5)	2 (3.4)
Hypophosphataemia	6 (10.2)	6 (10.2)	0
Hyperglycaemia	3 (5.1)	3 (5.1)	0
Hypervolaemia	3 (5.1)	3 (5.1)	0
Hypocalcaemia	3 (5.1)	3 (5.1)	0
Tumour lysis syndrome	2 (3.4)	1 (1.7)	1 (1.7)
Acidosis	1 (1.7)	1 (1.7)	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0
Hyperkalaemia	1 (1.7)	1 (1.7)	0
Malnutrition	1 (1.7)	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (3.4)	2 (3.4)	0
Back pain	2 (3.4)	2 (3.4)	0
Nervous system disorders			
-Total	10 (16.9)	10 (16.9)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	4 (6.8)	4 (6.8)	0
Headache	3 (5.1)	3 (5.1)	0
Seizure	3 (5.1)	3 (5.1)	0
Psychiatric disorders			
-Total	5 (8.5)	5 (8.5)	0
Delirium	3 (5.1)	3 (5.1)	0
Anxiety	1 (1.7)	1 (1.7)	0
Mental status changes	1 (1.7)	1 (1.7)	0
Renal and urinary disorders			
-Total	6 (10.2)	3 (5.1)	3 (5.1)
Acute kidney injury	6 (10.2)	3 (5.1)	3 (5.1)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (30.5)	9 (15.3)	9 (15.3)
Hypoxia	10 (16.9)	8 (13.6)	2 (3.4)
Pulmonary oedema	5 (8.5)	4 (6.8)	1 (1.7)
Respiratory failure	5 (8.5)	0	5 (8.5)
Tachypnoea	4 (6.8)	4 (6.8)	0
Dyspnoea	3 (5.1)	2 (3.4)	1 (1.7)

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=59 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Acute respiratory distress syndrome	2 (3.4)	0	2 (3.4)
Pleural effusion	2 (3.4)	2 (3.4)	0
Vascular disorders			
-Total	13 (22.0)	8 (13.6)	5 (8.5)
Hypotension	13 (22.0)	8 (13.6)	5 (8.5)
Hypertension	1 (1.7)	1 (1.7)	0
Venoocclusive disease	1 (1.7)	1 (1.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	2 (20.0)	7 (70.0)
Blood and lymphatic system disorders			
-Total	7 (70.0)	2 (20.0)	5 (50.0)
Neutropenia	3 (30.0)	0	3 (30.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Thrombocytopenia	2 (20.0)	0	2 (20.0)
Disseminated intravascular coagulation	1 (10.0)	1 (10.0)	0
Leukopenia	1 (10.0)	0	1 (10.0)
Lymphopenia	1 (10.0)	1 (10.0)	0
Cardiac disorders			

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (20.0)	0	2 (20.0)
Cardiac arrest	1 (10.0)	0	1 (10.0)
Cardiac failure	1 (10.0)	0	1 (10.0)
General disorders and administration site conditions			
-Total	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	1 (10.0)	0
Hepatobiliary disorders			
-Total	4 (40.0)	2 (20.0)	2 (20.0)
Hepatic function abnormal	3 (30.0)	2 (20.0)	1 (10.0)
Hepatomegaly	1 (10.0)	0	1 (10.0)
Immune system disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Cytokine release syndrome	5 (50.0)	2 (20.0)	3 (30.0)
Infections and infestations			
-Total	5 (50.0)	4 (40.0)	1 (10.0)
Bacteraemia	1 (10.0)	1 (10.0)	0
Cytomegalovirus infection reactivation	1 (10.0)	1 (10.0)	0
Encephalitis viral	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (10.0)	1 (10.0)	0
Meningitis bacterial	1 (10.0)	1 (10.0)	0
Oral herpes	1 (10.0)	1 (10.0)	0
Pneumonia	1 (10.0)	1 (10.0)	0
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0
Upper respiratory tract infection	1 (10.0)	1 (10.0)	0
Viral infection	1 (10.0)	1 (10.0)	0
Investigations			
-Total	6 (60.0)	2 (20.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	2 (20.0)
Blood bilirubin increased	1 (10.0)	1 (10.0)	0
Blood creatine phosphokinase increased	1 (10.0)	1 (10.0)	0
Blood fibrinogen decreased	1 (10.0)	1 (10.0)	0
Gamma-glutamyltransferase increased	1 (10.0)	1 (10.0)	0
Platelet count decreased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Metabolic acidosis	2 (20.0)	0	2 (20.0)
Tumour lysis syndrome	2 (20.0)	2 (20.0)	0
Hypercalcaemia	1 (10.0)	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	1 (10.0)
Hyperphosphataemia	1 (10.0)	0	1 (10.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (20.0)	2 (20.0)	0
Back pain	1 (10.0)	1 (10.0)	0
Muscular weakness	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	2 (20.0)	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	2 (20.0)
Reproductive system and breast disorders			
-Total	1 (10.0)	1 (10.0)	0
Endometriosis	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	4 (40.0)	0	4 (40.0)
Hypoxia	4 (40.0)	0	4 (40.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypotension	1 (10.0)	0	1 (10.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (100)	0	11 (100)
Blood and lymphatic system disorders			
-Total	8 (72.7)	7 (63.6)	1 (9.1)
Febrile neutropenia	6 (54.5)	5 (45.5)	1 (9.1)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	1 (9.1)	1 (9.1)	0
Cardiac disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Cardiac arrest	1 (9.1)	0	1 (9.1)
Left ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus bradycardia	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Mouth haemorrhage	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Pyrexia	3 (27.3)	3 (27.3)	0
Multiple organ dysfunction syndrome	2 (18.2)	0	2 (18.2)
Pain	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0
Hyperbilirubinaemia	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	9 (81.8)	2 (18.2)	7 (63.6)
Cytokine release syndrome	7 (63.6)	1 (9.1)	6 (54.5)
Allergy to immunoglobulin therapy	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	1 (9.1)	1 (9.1)	0
Haemophagocytic lymphohistiocytosis	1 (9.1)	0	1 (9.1)
Immunodeficiency	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	5 (45.5)	3 (27.3)	2 (18.2)
Staphylococcal bacteraemia	2 (18.2)	2 (18.2)	0
Adenovirus infection	1 (9.1)	1 (9.1)	0
Bacteraemia	1 (9.1)	0	1 (9.1)
Covid-19 pneumonia	1 (9.1)	0	1 (9.1)
Encephalitis viral	1 (9.1)	1 (9.1)	0
Enterobacter infection	1 (9.1)	1 (9.1)	0
Enterovirus infection	1 (9.1)	1 (9.1)	0
Herpes zoster	1 (9.1)	1 (9.1)	0
Influenza	1 (9.1)	0	1 (9.1)
Klebsiella infection	1 (9.1)	1 (9.1)	0
Mastoiditis	1 (9.1)	1 (9.1)	0
Otitis externa	1 (9.1)	1 (9.1)	0
Otitis media	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0
Pharyngitis streptococcal	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Viral upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	9 (81.8)	2 (18.2)	7 (63.6)
Neutrophil count decreased	5 (45.5)	1 (9.1)	4 (36.4)
White blood cell count decreased	5 (45.5)	0	5 (45.5)
Aspartate aminotransferase increased	4 (36.4)	2 (18.2)	2 (18.2)
Platelet count decreased	4 (36.4)	1 (9.1)	3 (27.3)
Alanine aminotransferase increased	3 (27.3)	3 (27.3)	0
Lymphocyte count decreased	3 (27.3)	2 (18.2)	1 (9.1)
Blood bilirubin increased	2 (18.2)	2 (18.2)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (9.1)	1 (9.1)	0
Blood creatinine increased	1 (9.1)	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Blood uric acid increased	1 (9.1)	1 (9.1)	0
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	1 (9.1)
Fibrin d dimer increased	1 (9.1)	1 (9.1)	0
Oxygen saturation decreased	1 (9.1)	1 (9.1)	0
Serum ferritin increased	1 (9.1)	1 (9.1)	0
Troponin increased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	9 (81.8)	7 (63.6)	2 (18.2)
Decreased appetite	5 (45.5)	5 (45.5)	0
Hypokalaemia	3 (27.3)	3 (27.3)	0
Hypophosphataemia	3 (27.3)	2 (18.2)	1 (9.1)
Hyperglycaemia	2 (18.2)	2 (18.2)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	2 (18.2)	2 (18.2)	0
Hypocalcaemia	2 (18.2)	2 (18.2)	0
Acidosis	1 (9.1)	0	1 (9.1)
Hypoalbuminaemia	1 (9.1)	1 (9.1)	0
Malnutrition	1 (9.1)	1 (9.1)	0
Obesity	1 (9.1)	1 (9.1)	0
Tumour lysis syndrome	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Haemarthrosis	1 (9.1)	1 (9.1)	0
Pain in extremity	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Cognitive disorder	1 (9.1)	1 (9.1)	0
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Anxiety	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Pulmonary oedema	2 (18.2)	2 (18.2)	0
Acute respiratory distress syndrome	1 (9.1)	0	1 (9.1)
Dyspnoea	1 (9.1)	0	1 (9.1)
Epistaxis	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	0	1 (9.1)
Skin and subcutaneous tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Decubitus ulcer	1 (9.1)	1 (9.1)	0
Rash maculo-papular	1 (9.1)	1 (9.1)	0
Surgical and medical procedures			
-Total	1 (9.1)	1 (9.1)	0
Thrombolysis	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	7 (63.6)	4 (36.4)	3 (27.3)
Hypertension	4 (36.4)	4 (36.4)	0
Hypotension	2 (18.2)	0	2 (18.2)
Capillary leak syndrome	1 (9.1)	1 (9.1)	0
Venoocclusive disease	1 (9.1)	0	1 (9.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (80.0)	1 (6.7)	11 (73.3)
Blood and lymphatic system disorders			
-Total	9 (60.0)	7 (46.7)	2 (13.3)
Febrile neutropenia	8 (53.3)	6 (40.0)	2 (13.3)
Anaemia	3 (20.0)	3 (20.0)	0
Coagulopathy	1 (6.7)	1 (6.7)	0
Thrombocytopenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
-Total	1 (6.7)	1 (6.7)	0
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Sinus bradycardia	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)
Mouth haemorrhage	1 (6.7)	1 (6.7)	0
Vomiting	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Pyrexia	2 (13.3)	2 (13.3)	0
Multiple organ dysfunction syndrome	1 (6.7)	0	1 (6.7)
Hepatobiliary disorders			
-Total	1 (6.7)	1 (6.7)	0
Hyperbilirubinaemia	1 (6.7)	1 (6.7)	0
Immune system disorders			
-Total	9 (60.0)	1 (6.7)	8 (53.3)
Cytokine release syndrome	9 (60.0)	1 (6.7)	8 (53.3)
Haemophagocytic lymphohistiocytosis	1 (6.7)	1 (6.7)	0
Hypogammaglobulinaemia	1 (6.7)	1 (6.7)	0
Infections and infestations			

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (20.0)	3 (20.0)	0
Staphylococcal bacteraemia	2 (13.3)	2 (13.3)	0
Adenovirus infection	1 (6.7)	1 (6.7)	0
Encephalitis viral	1 (6.7)	1 (6.7)	0
Investigations			
-Total	9 (60.0)	3 (20.0)	6 (40.0)
Aspartate aminotransferase increased	6 (40.0)	4 (26.7)	2 (13.3)
Blood bilirubin increased	4 (26.7)	4 (26.7)	0
Alanine aminotransferase increased	3 (20.0)	3 (20.0)	0
Platelet count decreased	3 (20.0)	0	3 (20.0)
White blood cell count decreased	3 (20.0)	0	3 (20.0)
Blood creatinine increased	2 (13.3)	2 (13.3)	0
Neutrophil count decreased	2 (13.3)	0	2 (13.3)
Activated partial thromboplastin time prolonged	1 (6.7)	1 (6.7)	0
Blood lactate dehydrogenase increased	1 (6.7)	1 (6.7)	0
C-reactive protein increased	1 (6.7)	1 (6.7)	0
Electrocardiogram qt prolonged	1 (6.7)	0	1 (6.7)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	1 (6.7)	1 (6.7)	0
Serum ferritin increased	1 (6.7)	1 (6.7)	0
Troponin increased	1 (6.7)	1 (6.7)	0
Urine output decreased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	9 (60.0)	6 (40.0)	3 (20.0)
Decreased appetite	5 (33.3)	5 (33.3)	0
Hypervolaemia	3 (20.0)	3 (20.0)	0
Hypocalcaemia	3 (20.0)	3 (20.0)	0
Hypokalaemia	3 (20.0)	2 (13.3)	1 (6.7)
Hypophosphataemia	3 (20.0)	3 (20.0)	0
Acidosis	2 (13.3)	1 (6.7)	1 (6.7)
Hyperglycaemia	2 (13.3)	2 (13.3)	0
Tumour lysis syndrome	2 (13.3)	2 (13.3)	0
Hypercalcaemia	1 (6.7)	1 (6.7)	0
Hyperkalaemia	1 (6.7)	1 (6.7)	0
Hyperuricaemia	1 (6.7)	1 (6.7)	0
Hypoalbuminaemia	1 (6.7)	1 (6.7)	0
Malnutrition	1 (6.7)	1 (6.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (6.7)	0	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (6.7)	1 (6.7)	0
Arthralgia	1 (6.7)	1 (6.7)	0
Haemarthrosis	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Cerebral haemorrhage	1 (6.7)	0	1 (6.7)
Cognitive disorder	1 (6.7)	1 (6.7)	0
Encephalopathy	1 (6.7)	1 (6.7)	0
Neurological decompensation	1 (6.7)	0	1 (6.7)
Somnolence	1 (6.7)	1 (6.7)	0
Psychiatric disorders			
-Total	2 (13.3)	2 (13.3)	0
Anxiety	1 (6.7)	1 (6.7)	0
Delirium	1 (6.7)	1 (6.7)	0
Renal and urinary disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (13.3)	1 (6.7)	1 (6.7)
Renal failure	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (46.7)	3 (20.0)	4 (26.7)
Hypoxia	3 (20.0)	2 (13.3)	1 (6.7)
Pulmonary oedema	3 (20.0)	2 (13.3)	1 (6.7)
Pleural effusion	2 (13.3)	1 (6.7)	1 (6.7)
Acute respiratory distress syndrome	1 (6.7)	0	1 (6.7)
Acute respiratory failure	1 (6.7)	1 (6.7)	0
Respiratory distress	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Surgical and medical procedures			
-Total	1 (6.7)	1 (6.7)	0
Thrombolysis	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	7 (46.7)	5 (33.3)	2 (13.3)
Hypotension	5 (33.3)	3 (20.0)	2 (13.3)

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	2 (13.3)	2 (13.3)	0
Capillary leak syndrome	1 (6.7)	1 (6.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

		All patients N=65	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (81.5)	19 (29.2)	34 (52.3)
Blood and lymphatic system disorders			
-Total	28 (43.1)	17 (26.2)	11 (16.9)
Febrile neutropenia	18 (27.7)	18 (27.7)	0
Neutropenia	7 (10.8)	1 (1.5)	6 (9.2)
Thrombocytopenia	7 (10.8)	1 (1.5)	6 (9.2)
Anaemia	5 (7.7)	5 (7.7)	0
Coagulopathy	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	4 (6.2)	2 (3.1)	2 (3.1)
Left ventricular dysfunction	2 (3.1)	2 (3.1)	0
Cardiac arrest	1 (1.5)	0	1 (1.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	1 (1.5)	1 (1.5)	0
Mouth haemorrhage	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	7 (10.8)	4 (6.2)	3 (4.6)
Pyrexia	6 (9.2)	4 (6.2)	2 (3.1)
Multiple organ dysfunction syndrome	1 (1.5)	0	1 (1.5)
Immune system disorders			
-Total	34 (52.3)	21 (32.3)	13 (20.0)
Cytokine release syndrome	29 (44.6)	16 (24.6)	13 (20.0)
Hypogammaglobulinaemia	6 (9.2)	6 (9.2)	0
Immunodeficiency	3 (4.6)	3 (4.6)	0
Haemophagocytic lymphohistiocytosis	2 (3.1)	1 (1.5)	1 (1.5)
Infections and infestations			
-Total	3 (4.6)	2 (3.1)	1 (1.5)
Bacteraemia	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis viral	1 (1.5)	0	1 (1.5)
Pneumonia	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	1 (1.5)	1 (1.5)	0
Investigations			
-Total	33 (50.8)	12 (18.5)	21 (32.3)
Neutrophil count decreased	15 (23.1)	2 (3.1)	13 (20.0)
White blood cell count decreased	15 (23.1)	2 (3.1)	13 (20.0)
Lymphocyte count decreased	13 (20.0)	8 (12.3)	5 (7.7)
Platelet count decreased	11 (16.9)	6 (9.2)	5 (7.7)
Aspartate aminotransferase increased	5 (7.7)	4 (6.2)	1 (1.5)
Blood bilirubin increased	5 (7.7)	5 (7.7)	0
Alanine aminotransferase increased	3 (4.6)	3 (4.6)	0
C-reactive protein increased	2 (3.1)	2 (3.1)	0
Blood creatinine increased	1 (1.5)	0	1 (1.5)
Electrocardiogram qt prolonged	1 (1.5)	1 (1.5)	0
Serum ferritin increased	1 (1.5)	1 (1.5)	0
Urine output decreased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (29.2)	15 (23.1)	4 (6.2)
Hypokalaemia	8 (12.3)	7 (10.8)	1 (1.5)
Decreased appetite	6 (9.2)	5 (7.7)	1 (1.5)
Hypophosphataemia	6 (9.2)	5 (7.7)	1 (1.5)
Hyperglycaemia	2 (3.1)	2 (3.1)	0
Hypocalcaemia	2 (3.1)	2 (3.1)	0
Tumour lysis syndrome	2 (3.1)	2 (3.1)	0
Hypercalcaemia	1 (1.5)	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	1 (1.5)
Hypervolaemia	1 (1.5)	1 (1.5)	0
Metabolic acidosis	1 (1.5)	0	1 (1.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.5)	1 (1.5)	0
Back pain	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	3 (4.6)	3 (4.6)	0
Encephalopathy	3 (4.6)	3 (4.6)	0
Somnolence	1 (1.5)	1 (1.5)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	3 (4.6)	3 (4.6)	0
Delirium	2 (3.1)	2 (3.1)	0
Anxiety	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	5 (7.7)	2 (3.1)	3 (4.6)
Acute kidney injury	5 (7.7)	2 (3.1)	3 (4.6)
Respiratory, thoracic and mediastinal disorders			
-Total	15 (23.1)	7 (10.8)	8 (12.3)
Hypoxia	9 (13.8)	4 (6.2)	5 (7.7)
Pulmonary oedema	4 (6.2)	4 (6.2)	0
Dyspnoea	3 (4.6)	2 (3.1)	1 (1.5)
Respiratory failure	3 (4.6)	0	3 (4.6)
Tachypnoea	3 (4.6)	3 (4.6)	0
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Pleural effusion	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	10 (15.4)	6 (9.2)	4 (6.2)

Timing: within 8 weeks post infusion, Ethnicity: Other

Group term Preferred term	All patients N=65 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	9 (13.8)	5 (7.7)	4 (6.2)
Hypertension	2 (3.1)	2 (3.1)	0

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Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (50.0)	3 (21.4)	4 (28.6)
Blood and lymphatic system disorders			
-Total	2 (14.3)	2 (14.3)	0
Anaemia	2 (14.3)	2 (14.3)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiac arrest	1 (7.1)	0	1 (7.1)
Cardiac failure	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	1 (7.1)	0
Pyrexia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	1 (7.1)	1 (7.1)	0
Allergy to immunoglobulin therapy	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Adenovirus infection	1 (7.1)	1 (7.1)	0
Bacteraemia	1 (7.1)	0	1 (7.1)
Bk virus infection	1 (7.1)	1 (7.1)	0
Metapneumovirus infection	1 (7.1)	1 (7.1)	0
Pharyngitis streptococcal	1 (7.1)	1 (7.1)	0
Pneumocystis jirovecii pneumonia	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Septic shock	1 (7.1)	0	1 (7.1)
Sinusitis fungal	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)
White blood cell count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Blood uric acid increased	1 (7.1)	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Hypokalaemia	1 (7.1)	0	1 (7.1)
Malnutrition	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	1 (7.1)
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Back pain	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Acute kidney injury	1 (7.1)	0	1 (7.1)
Haematuria	1 (7.1)	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.1)	0	1 (7.1)
Acute respiratory distress syndrome	1 (7.1)	0	1 (7.1)
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Decubitus ulcer	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Hypotension	2 (14.3)	1 (7.1)	1 (7.1)

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Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (37.7)	10 (16.4)	13 (21.3)
Blood and lymphatic system disorders			
-Total	7 (11.5)	3 (4.9)	4 (6.6)
Neutropenia	5 (8.2)	2 (3.3)	3 (4.9)
Febrile neutropenia	2 (3.3)	2 (3.3)	0
Thrombocytopenia	2 (3.3)	1 (1.6)	1 (1.6)
Cardiac disorders			
-Total	2 (3.3)	0	2 (3.3)
Cardiac arrest	1 (1.6)	0	1 (1.6)
Cardiac failure	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (1.6)	1 (1.6)	0
Pyrexia	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	1 (1.6)	1 (1.6)	0
Immunodeficiency	1 (1.6)	1 (1.6)	0
Infections and infestations			
-Total	6 (9.8)	4 (6.6)	2 (3.3)
Metapneumovirus infection	2 (3.3)	2 (3.3)	0
Pneumocystis jirovecii pneumonia	1 (1.6)	0	1 (1.6)
Pneumonia	1 (1.6)	0	1 (1.6)
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Investigations			
-Total	10 (16.4)	7 (11.5)	3 (4.9)
Neutrophil count decreased	5 (8.2)	2 (3.3)	3 (4.9)
Lymphocyte count decreased	2 (3.3)	2 (3.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (3.3)	2 (3.3)	0
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
Blood bilirubin increased	1 (1.6)	1 (1.6)	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0
Platelet count decreased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	4 (6.6)	3 (4.9)	1 (1.6)
Decreased appetite	1 (1.6)	1 (1.6)	0
Hypervolaemia	1 (1.6)	1 (1.6)	0
Hypokalaemia	1 (1.6)	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Back pain	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	1 (1.6)	0	1 (1.6)
Cerebral haemorrhage	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	5 (8.2)	3 (4.9)	2 (3.3)
Hypoxia	3 (4.9)	3 (4.9)	0
Respiratory distress	1 (1.6)	0	1 (1.6)
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
-Total	1 (1.6)	0	1 (1.6)
Hypotension	1 (1.6)	0	1 (1.6)

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Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Obesity	1 (14.3)	1 (14.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (23.3)	5 (11.6)	5 (11.6)
Blood and lymphatic system disorders			
-Total	1 (2.3)	0	1 (2.3)
Neutropenia	1 (2.3)	0	1 (2.3)
General disorders and administration site conditions			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Multiple organ dysfunction syndrome	1 (2.3)	0	1 (2.3)
Pyrexia	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	1 (2.3)	0	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)
Infections and infestations			
-Total	5 (11.6)	3 (7.0)	2 (4.7)
Pneumonia	2 (4.7)	1 (2.3)	1 (2.3)
Septic shock	1 (2.3)	0	1 (2.3)
Staphylococcal bacteraemia	1 (2.3)	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Investigations			
-Total	1 (2.3)	0	1 (2.3)
Neutrophil count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Decreased appetite	1 (2.3)	0	1 (2.3)
Hyperglycaemia	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.0)	1 (2.3)	2 (4.7)
Dyspnoea	1 (2.3)	0	1 (2.3)

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (2.3)	1 (2.3)	0
Respiratory failure	1 (2.3)	0	1 (2.3)
Tachypnoea	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypertension	1 (2.3)	1 (2.3)	0

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Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (86.7)	0	13 (86.7)
Blood and lymphatic system disorders			
-Total	10 (66.7)	8 (53.3)	2 (13.3)
Febrile neutropenia	8 (53.3)	6 (40.0)	2 (13.3)
Anaemia	4 (26.7)	4 (26.7)	0
Coagulopathy	1 (6.7)	1 (6.7)	0
Thrombocytopenia	1 (6.7)	1 (6.7)	0
Cardiac disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Cardiac arrest	1 (6.7)	0	1 (6.7)
Cardiac failure	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Sinus bradycardia	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	3 (20.0)	2 (13.3)	1 (6.7)
Abdominal compartment syndrome	1 (6.7)	0	1 (6.7)
Mouth haemorrhage	1 (6.7)	1 (6.7)	0
Vomiting	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Pyrexia	3 (20.0)	3 (20.0)	0
Multiple organ dysfunction syndrome	1 (6.7)	0	1 (6.7)
Hepatobiliary disorders			
-Total	1 (6.7)	1 (6.7)	0
Hyperbilirubinaemia	1 (6.7)	1 (6.7)	0
Immune system disorders			
-Total	9 (60.0)	1 (6.7)	8 (53.3)
Cytokine release syndrome	9 (60.0)	1 (6.7)	8 (53.3)
Allergy to immunoglobulin therapy	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (6.7)	1 (6.7)	0
Hypogammaglobulinaemia	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	6 (40.0)	4 (26.7)	2 (13.3)
Adenovirus infection	2 (13.3)	2 (13.3)	0
Staphylococcal bacteraemia	2 (13.3)	2 (13.3)	0
Bacteraemia	1 (6.7)	0	1 (6.7)
Bk virus infection	1 (6.7)	1 (6.7)	0
Encephalitis viral	1 (6.7)	1 (6.7)	0
Metapneumovirus infection	1 (6.7)	1 (6.7)	0
Pharyngitis streptococcal	1 (6.7)	1 (6.7)	0
Pneumocystis jirovecii pneumonia	1 (6.7)	1 (6.7)	0
Respiratory syncytial virus infection	1 (6.7)	1 (6.7)	0
Septic shock	1 (6.7)	0	1 (6.7)
Sinusitis fungal	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Urinary tract infection	1 (6.7)	1 (6.7)	0
Viral upper respiratory tract infection	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	10 (66.7)	3 (20.0)	7 (46.7)
Aspartate aminotransferase increased	6 (40.0)	4 (26.7)	2 (13.3)
Blood bilirubin increased	4 (26.7)	4 (26.7)	0
Alanine aminotransferase increased	3 (20.0)	3 (20.0)	0
Neutrophil count decreased	3 (20.0)	0	3 (20.0)
Platelet count decreased	3 (20.0)	0	3 (20.0)
White blood cell count decreased	3 (20.0)	0	3 (20.0)
Blood creatinine increased	2 (13.3)	2 (13.3)	0
Activated partial thromboplastin time prolonged	1 (6.7)	1 (6.7)	0
Blood lactate dehydrogenase increased	1 (6.7)	1 (6.7)	0
Blood uric acid increased	1 (6.7)	0	1 (6.7)
C-reactive protein increased	1 (6.7)	1 (6.7)	0
Electrocardiogram qt prolonged	1 (6.7)	0	1 (6.7)
Fibrin d dimer increased	1 (6.7)	1 (6.7)	0
Serum ferritin increased	1 (6.7)	1 (6.7)	0
Troponin increased	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urine output decreased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	10 (66.7)	6 (40.0)	4 (26.7)
Decreased appetite	5 (33.3)	5 (33.3)	0
Hypervolaemia	3 (20.0)	3 (20.0)	0
Hypocalcaemia	3 (20.0)	3 (20.0)	0
Hypokalaemia	3 (20.0)	2 (13.3)	1 (6.7)
Hypophosphataemia	3 (20.0)	3 (20.0)	0
Tumour lysis syndrome	3 (20.0)	2 (13.3)	1 (6.7)
Acidosis	2 (13.3)	1 (6.7)	1 (6.7)
Hyperglycaemia	2 (13.3)	2 (13.3)	0
Malnutrition	2 (13.3)	2 (13.3)	0
Hypercalcaemia	1 (6.7)	1 (6.7)	0
Hyperkalaemia	1 (6.7)	1 (6.7)	0
Hyperuricaemia	1 (6.7)	1 (6.7)	0
Hypoalbuminaemia	1 (6.7)	1 (6.7)	0
Metabolic acidosis	1 (6.7)	0	1 (6.7)
Obesity	1 (6.7)	1 (6.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (13.3)	2 (13.3)	0
Arthralgia	1 (6.7)	1 (6.7)	0
Back pain	1 (6.7)	1 (6.7)	0
Haemarthrosis	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Cerebral haemorrhage	1 (6.7)	0	1 (6.7)
Cognitive disorder	1 (6.7)	1 (6.7)	0
Encephalopathy	1 (6.7)	1 (6.7)	0
Neurological decompensation	1 (6.7)	0	1 (6.7)
Somnolence	1 (6.7)	1 (6.7)	0
Psychiatric disorders			
-Total	2 (13.3)	2 (13.3)	0
Anxiety	1 (6.7)	1 (6.7)	0
Delirium	1 (6.7)	1 (6.7)	0
Renal and urinary disorders			
-Total	5 (33.3)	2 (13.3)	3 (20.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	3 (20.0)	1 (6.7)	2 (13.3)
Haematuria	1 (6.7)	1 (6.7)	0
Renal failure	1 (6.7)	0	1 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (53.3)	3 (20.0)	5 (33.3)
Hypoxia	3 (20.0)	2 (13.3)	1 (6.7)
Pulmonary oedema	3 (20.0)	2 (13.3)	1 (6.7)
Acute respiratory distress syndrome	2 (13.3)	0	2 (13.3)
Pleural effusion	2 (13.3)	1 (6.7)	1 (6.7)
Acute respiratory failure	1 (6.7)	1 (6.7)	0
Respiratory distress	1 (6.7)	0	1 (6.7)
Respiratory failure	1 (6.7)	0	1 (6.7)
Tachypnoea	1 (6.7)	1 (6.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (6.7)	1 (6.7)	0
Decubitus ulcer	1 (6.7)	1 (6.7)	0
Surgical and medical procedures			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	1 (6.7)	0
Thrombolysis	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	8 (53.3)	5 (33.3)	3 (20.0)
Hypotension	6 (40.0)	3 (20.0)	3 (20.0)
Hypertension	2 (13.3)	2 (13.3)	0
Capillary leak syndrome	1 (6.7)	1 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

		All patients N=65	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (89.2)	20 (30.8)	38 (58.5)
Blood and lymphatic system disorders			
-Total	31 (47.7)	19 (29.2)	12 (18.5)
Febrile neutropenia	19 (29.2)	19 (29.2)	0
Neutropenia	9 (13.8)	2 (3.1)	7 (10.8)
Thrombocytopenia	8 (12.3)	2 (3.1)	6 (9.2)
Anaemia	5 (7.7)	5 (7.7)	0
Coagulopathy	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	6 (9.2)	2 (3.1)	4 (6.2)
Cardiac arrest	2 (3.1)	0	2 (3.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	2 (3.1)	0	2 (3.1)
Left ventricular dysfunction	2 (3.1)	2 (3.1)	0
Gastrointestinal disorders			
-Total	1 (1.5)	1 (1.5)	0
Mouth haemorrhage	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	10 (15.4)	6 (9.2)	4 (6.2)
Pyrexia	8 (12.3)	6 (9.2)	2 (3.1)
Multiple organ dysfunction syndrome	2 (3.1)	0	2 (3.1)
Immune system disorders			
-Total	36 (55.4)	22 (33.8)	14 (21.5)
Cytokine release syndrome	29 (44.6)	16 (24.6)	13 (20.0)
Hypogammaglobulinaemia	6 (9.2)	6 (9.2)	0
Immunodeficiency	4 (6.2)	4 (6.2)	0
Haemophagocytic lymphohistiocytosis	3 (4.6)	1 (1.5)	2 (3.1)
Infections and infestations			
-Total	13 (20.0)	8 (12.3)	5 (7.7)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (6.2)	2 (3.1)	2 (3.1)
Staphylococcal bacteraemia	3 (4.6)	3 (4.6)	0
Metapneumovirus infection	2 (3.1)	2 (3.1)	0
Upper respiratory tract infection	2 (3.1)	2 (3.1)	0
Bacteraemia	1 (1.5)	1 (1.5)	0
Encephalitis viral	1 (1.5)	0	1 (1.5)
Pneumocystis jirovecii pneumonia	1 (1.5)	0	1 (1.5)
Respiratory syncytial virus infection	1 (1.5)	1 (1.5)	0
Septic shock	1 (1.5)	0	1 (1.5)
Investigations			
-Total	34 (52.3)	13 (20.0)	21 (32.3)
Neutrophil count decreased	18 (27.7)	4 (6.2)	14 (21.5)
Lymphocyte count decreased	15 (23.1)	10 (15.4)	5 (7.7)
White blood cell count decreased	15 (23.1)	2 (3.1)	13 (20.0)
Platelet count decreased	12 (18.5)	7 (10.8)	5 (7.7)
Aspartate aminotransferase increased	5 (7.7)	4 (6.2)	1 (1.5)
Blood bilirubin increased	5 (7.7)	5 (7.7)	0
Alanine aminotransferase increased	4 (6.2)	4 (6.2)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	2 (3.1)	2 (3.1)	0
Blood creatinine increased	1 (1.5)	0	1 (1.5)
Blood uric acid increased	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	1 (1.5)	1 (1.5)	0
Serum ferritin increased	1 (1.5)	1 (1.5)	0
Urine output decreased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	21 (32.3)	15 (23.1)	6 (9.2)
Hypokalaemia	8 (12.3)	7 (10.8)	1 (1.5)
Decreased appetite	7 (10.8)	5 (7.7)	2 (3.1)
Hypophosphataemia	6 (9.2)	5 (7.7)	1 (1.5)
Hyperglycaemia	3 (4.6)	3 (4.6)	0
Hypervolaemia	2 (3.1)	2 (3.1)	0
Hypocalcaemia	2 (3.1)	2 (3.1)	0
Metabolic acidosis	2 (3.1)	0	2 (3.1)
Tumour lysis syndrome	2 (3.1)	2 (3.1)	0
Hypercalcaemia	1 (1.5)	1 (1.5)	0
Hyperkalaemia	1 (1.5)	0	1 (1.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=65		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (3.1)	2 (3.1)	0
Back pain	2 (3.1)	2 (3.1)	0
Nervous system disorders			
-Total	4 (6.2)	3 (4.6)	1 (1.5)
Encephalopathy	3 (4.6)	3 (4.6)	0
Cerebral haemorrhage	1 (1.5)	0	1 (1.5)
Somnolence	1 (1.5)	1 (1.5)	0
Psychiatric disorders			
-Total	3 (4.6)	3 (4.6)	0
Delirium	2 (3.1)	2 (3.1)	0
Anxiety	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	5 (7.7)	2 (3.1)	3 (4.6)
Acute kidney injury	5 (7.7)	2 (3.1)	3 (4.6)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (30.8)	9 (13.8)	11 (16.9)

Timing: Any time post CTL019 infusion, Ethnicity: Other

Group term Preferred term	All patients N=65 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	13 (20.0)	8 (12.3)	5 (7.7)
Respiratory failure	5 (7.7)	0	5 (7.7)
Dyspnoea	4 (6.2)	2 (3.1)	2 (3.1)
Pulmonary oedema	4 (6.2)	4 (6.2)	0
Tachypnoea	4 (6.2)	3 (4.6)	1 (1.5)
Acute respiratory distress syndrome	1 (1.5)	0	1 (1.5)
Pleural effusion	1 (1.5)	1 (1.5)	0
Respiratory distress	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	12 (18.5)	7 (10.8)	5 (7.7)
Hypotension	10 (15.4)	5 (7.7)	5 (7.7)
Hypertension	3 (4.6)	3 (4.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	2 (33.3)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	1 (16.7)	0
Melaena	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	1 (16.7)	0
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	1 (16.7)	0
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Wound	1 (16.7)	1 (16.7)	0
Investigations			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	1 (16.7)
Lipase increased	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Hypophosphataemia	2 (33.3)	2 (33.3)	0
Acidosis	1 (16.7)	1 (16.7)	0
Hypernatraemia	1 (16.7)	0	1 (16.7)
Hyperuricaemia	1 (16.7)	1 (16.7)	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0
Hypokalaemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Renal tubular necrosis	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (16.7)	1 (16.7)	0
Vaginal ulceration	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Atelectasis	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	1 (16.7)	0
Respiratory acidosis	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (16.7)	1 (16.7)	0
Petechiae	1 (16.7)	1 (16.7)	0
Skin necrosis	1 (16.7)	1 (16.7)	0
Vascular disorders			

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (81.1)	18 (24.3)	42 (56.8)
Blood and lymphatic system disorders			
-Total	34 (45.9)	23 (31.1)	11 (14.9)
Febrile neutropenia	23 (31.1)	22 (29.7)	1 (1.4)
Anaemia	8 (10.8)	8 (10.8)	0
Neutropenia	7 (9.5)	1 (1.4)	6 (8.1)
Thrombocytopenia	7 (9.5)	2 (2.7)	5 (6.8)
Coagulopathy	1 (1.4)	1 (1.4)	0
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	2 (2.7)	2 (2.7)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (2.7)	2 (2.7)	0
General disorders and administration site conditions			
-Total	8 (10.8)	5 (6.8)	3 (4.1)
Pyrexia	7 (9.5)	5 (6.8)	2 (2.7)
Multiple organ dysfunction syndrome	1 (1.4)	0	1 (1.4)
Immune system disorders			
-Total	41 (55.4)	22 (29.7)	19 (25.7)
Cytokine release syndrome	36 (48.6)	17 (23.0)	19 (25.7)
Hypogammaglobulinaemia	6 (8.1)	6 (8.1)	0
Immunodeficiency	3 (4.1)	3 (4.1)	0
Haemophagocytic lymphohistiocytosis	2 (2.7)	2 (2.7)	0
Infections and infestations			
-Total	4 (5.4)	4 (5.4)	0
Staphylococcal bacteraemia	3 (4.1)	3 (4.1)	0
Pneumonia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	35 (47.3)	12 (16.2)	23 (31.1)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	17 (23.0)	2 (2.7)	15 (20.3)
Neutrophil count decreased	14 (18.9)	1 (1.4)	13 (17.6)
Platelet count decreased	13 (17.6)	6 (8.1)	7 (9.5)
Lymphocyte count decreased	12 (16.2)	7 (9.5)	5 (6.8)
Aspartate aminotransferase increased	10 (13.5)	7 (9.5)	3 (4.1)
Blood bilirubin increased	8 (10.8)	8 (10.8)	0
Alanine aminotransferase increased	5 (6.8)	5 (6.8)	0
Blood creatine phosphokinase increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	24 (32.4)	20 (27.0)	4 (5.4)
Decreased appetite	11 (14.9)	10 (13.5)	1 (1.4)
Hypokalaemia	10 (13.5)	9 (12.2)	1 (1.4)
Hypophosphataemia	7 (9.5)	6 (8.1)	1 (1.4)
Hyperglycaemia	4 (5.4)	4 (5.4)	0
Hypervolaemia	4 (5.4)	4 (5.4)	0
Hypocalcaemia	4 (5.4)	4 (5.4)	0
Tumour lysis syndrome	4 (5.4)	4 (5.4)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	3 (4.1)	3 (4.1)	0
Encephalopathy	3 (4.1)	3 (4.1)	0
Renal and urinary disorders			
-Total	5 (6.8)	2 (2.7)	3 (4.1)
Acute kidney injury	5 (6.8)	2 (2.7)	3 (4.1)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (25.7)	9 (12.2)	10 (13.5)
Hypoxia	11 (14.9)	5 (6.8)	6 (8.1)
Pulmonary oedema	7 (9.5)	6 (8.1)	1 (1.4)
Respiratory failure	4 (5.4)	0	4 (5.4)
Dyspnoea	2 (2.7)	2 (2.7)	0
Tachypnoea	2 (2.7)	2 (2.7)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Atelectasis	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	14 (18.9)	9 (12.2)	5 (6.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	12 (16.2)	7 (9.5)	5 (6.8)
Hypertension	3 (4.1)	3 (4.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0
White blood cell count decreased	1 (20.0)	1 (20.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=70	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (37.1)	14 (20.0)	12 (17.1)
Blood and lymphatic system disorders			
-Total	10 (14.3)	6 (8.6)	4 (5.7)
Neutropenia	5 (7.1)	2 (2.9)	3 (4.3)
Febrile neutropenia	3 (4.3)	3 (4.3)	0
Anaemia	2 (2.9)	2 (2.9)	0
Thrombocytopenia	2 (2.9)	1 (1.4)	1 (1.4)
Disseminated intravascular coagulation	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	2 (2.9)	2 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (2.9)	2 (2.9)	0
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Immunodeficiency	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	3 (4.3)	1 (1.4)	2 (2.9)
Encephalitis	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	10 (14.3)	6 (8.6)	4 (5.7)
Neutrophil count decreased	6 (8.6)	2 (2.9)	4 (5.7)
White blood cell count decreased	3 (4.3)	2 (2.9)	1 (1.4)
Lymphocyte count decreased	2 (2.9)	2 (2.9)	0
Platelet count decreased	2 (2.9)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	5 (7.1)	3 (4.3)	2 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (2.9)	1 (1.4)	1 (1.4)
Decreased appetite	1 (1.4)	1 (1.4)	0
Hypervolaemia	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (7.1)	3 (4.3)	2 (2.9)
Hypoxia	3 (4.3)	3 (4.3)	0
Acute respiratory distress syndrome	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	3 (4.3)	1 (1.4)	2 (2.9)
Hypotension	3 (4.3)	1 (1.4)	2 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	1 (33.3)	0
Pneumonia	1 (33.3)	1 (33.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=47	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (17.0)	3 (6.4)	5 (10.6)
Blood and lymphatic system disorders			
-Total	1 (2.1)	0	1 (2.1)
Neutropenia	1 (2.1)	0	1 (2.1)
General disorders and administration site conditions			
-Total	2 (4.3)	1 (2.1)	1 (2.1)
Multiple organ dysfunction syndrome	1 (2.1)	0	1 (2.1)
Pyrexia	1 (2.1)	1 (2.1)	0
Immune system disorders			
-Total	1 (2.1)	0	1 (2.1)

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	1 (2.1)
Infections and infestations			
-Total	2 (4.3)	1 (2.1)	1 (2.1)
Pneumonia	1 (2.1)	0	1 (2.1)
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Investigations			
-Total	1 (2.1)	0	1 (2.1)
Neutrophil count decreased	1 (2.1)	0	1 (2.1)
Metabolism and nutrition disorders			
-Total	3 (6.4)	2 (4.3)	1 (2.1)
Decreased appetite	1 (2.1)	0	1 (2.1)
Hyperglycaemia	1 (2.1)	1 (2.1)	0
Hypernatraemia	1 (2.1)	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.4)	1 (2.1)	2 (4.3)
Dyspnoea	1 (2.1)	0	1 (2.1)
Hypoxia	1 (2.1)	1 (2.1)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.1)	0	1 (2.1)
Tachypnoea	1 (2.1)	0	1 (2.1)
Vascular disorders			
-Total	1 (2.1)	1 (2.1)	0
Hypertension	1 (2.1)	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	2 (33.3)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Melaena	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	1 (16.7)	0
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	1 (16.7)	0
Infections and infestations			

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	1 (16.7)	0
Encephalitis	1 (16.7)	0	1 (16.7)
Gastroenteritis escherichia coli	1 (16.7)	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	1 (16.7)	0
Pneumonia	1 (16.7)	1 (16.7)	0
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Wound	1 (16.7)	1 (16.7)	0
Investigations			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Hypophosphataemia	2 (33.3)	2 (33.3)	0
Acidosis	1 (16.7)	1 (16.7)	0
Hypernatraemia	1 (16.7)	0	1 (16.7)
Hyperuricaemia	1 (16.7)	1 (16.7)	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0
Hypokalaemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Renal tubular necrosis	1 (16.7)	0	1 (16.7)
Reproductive system and breast disorders			
-Total	1 (16.7)	1 (16.7)	0
Vaginal ulceration	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Atelectasis	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	1 (16.7)	0
Respiratory acidosis	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	1 (16.7)	0
Petechiae	1 (16.7)	1 (16.7)	0
Skin necrosis	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (87.8)	19 (25.7)	46 (62.2)
Blood and lymphatic system disorders			
-Total	39 (52.7)	27 (36.5)	12 (16.2)
Febrile neutropenia	24 (32.4)	23 (31.1)	1 (1.4)
Anaemia	9 (12.2)	9 (12.2)	0
Neutropenia	9 (12.2)	2 (2.7)	7 (9.5)
Thrombocytopenia	8 (10.8)	3 (4.1)	5 (6.8)
Disseminated intravascular coagulation	2 (2.7)	2 (2.7)	0
Coagulopathy	1 (1.4)	1 (1.4)	0
Cardiac disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.7)	2 (2.7)	0
Tachycardia	2 (2.7)	2 (2.7)	0
General disorders and administration site conditions			
-Total	12 (16.2)	8 (10.8)	4 (5.4)
Pyrexia	10 (13.5)	8 (10.8)	2 (2.7)
Multiple organ dysfunction syndrome	2 (2.7)	0	2 (2.7)
Immune system disorders			
-Total	43 (58.1)	23 (31.1)	20 (27.0)
Cytokine release syndrome	36 (48.6)	17 (23.0)	19 (25.7)
Hypogammaglobulinaemia	6 (8.1)	6 (8.1)	0
Immunodeficiency	4 (5.4)	4 (5.4)	0
Haemophagocytic lymphohistiocytosis	3 (4.1)	2 (2.7)	1 (1.4)
Infections and infestations			
-Total	8 (10.8)	5 (6.8)	3 (4.1)
Staphylococcal bacteraemia	5 (6.8)	5 (6.8)	0
Pneumonia	3 (4.1)	1 (1.4)	2 (2.7)
Encephalitis	1 (1.4)	0	1 (1.4)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	36 (48.6)	13 (17.6)	23 (31.1)
Neutrophil count decreased	18 (24.3)	3 (4.1)	15 (20.3)
White blood cell count decreased	17 (23.0)	2 (2.7)	15 (20.3)
Lymphocyte count decreased	14 (18.9)	9 (12.2)	5 (6.8)
Platelet count decreased	14 (18.9)	7 (9.5)	7 (9.5)
Aspartate aminotransferase increased	10 (13.5)	7 (9.5)	3 (4.1)
Blood bilirubin increased	8 (10.8)	8 (10.8)	0
Alanine aminotransferase increased	6 (8.1)	6 (8.1)	0
Blood creatine phosphokinase increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	27 (36.5)	21 (28.4)	6 (8.1)
Decreased appetite	12 (16.2)	10 (13.5)	2 (2.7)
Hypokalaemia	10 (13.5)	9 (12.2)	1 (1.4)
Hypophosphataemia	7 (9.5)	6 (8.1)	1 (1.4)
Hyperglycaemia	5 (6.8)	5 (6.8)	0
Hypervolaemia	5 (6.8)	5 (6.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	5 (6.8)	4 (5.4)	1 (1.4)
Hypocalcaemia	4 (5.4)	4 (5.4)	0
Acidosis	1 (1.4)	0	1 (1.4)
Hypernatraemia	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	3 (4.1)	3 (4.1)	0
Encephalopathy	3 (4.1)	3 (4.1)	0
Renal and urinary disorders			
-Total	6 (8.1)	2 (2.7)	4 (5.4)
Acute kidney injury	6 (8.1)	2 (2.7)	4 (5.4)
Respiratory, thoracic and mediastinal disorders			
-Total	25 (33.8)	11 (14.9)	14 (18.9)
Hypoxia	15 (20.3)	9 (12.2)	6 (8.1)
Pulmonary oedema	7 (9.5)	6 (8.1)	1 (1.4)
Respiratory failure	6 (8.1)	0	6 (8.1)
Dyspnoea	3 (4.1)	2 (2.7)	1 (1.4)
Tachypnoea	3 (4.1)	2 (2.7)	1 (1.4)
Acute respiratory distress syndrome	2 (2.7)	0	2 (2.7)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	17 (23.0)	10 (13.5)	7 (9.5)
Hypotension	14 (18.9)	7 (9.5)	7 (9.5)
Hypertension	4 (5.4)	4 (5.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	2 (100)	2 (100)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Pancytopenia	1 (50.0)	1 (50.0)	0
Immune system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)
Investigations			
-Total	1 (50.0)	0	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	1 (50.0)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	1 (50.0)	0
Blood creatinine increased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypocalcaemia	1 (50.0)	1 (50.0)	0
Hypokalaemia	1 (50.0)	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pleural effusion	1 (50.0)	0	1 (50.0)
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	1 (50.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (79.5)	18 (23.1)	44 (56.4)
Blood and lymphatic system disorders			
-Total	37 (47.4)	24 (30.8)	13 (16.7)
Febrile neutropenia	25 (32.1)	23 (29.5)	2 (2.6)
Anaemia	8 (10.3)	8 (10.3)	0
Thrombocytopenia	8 (10.3)	2 (2.6)	6 (7.7)
Neutropenia	7 (9.0)	1 (1.3)	6 (7.7)
Disseminated intravascular coagulation	2 (2.6)	2 (2.6)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (10.3)	6 (7.7)	2 (2.6)
Pyrexia	8 (10.3)	6 (7.7)	2 (2.6)
Immune system disorders			
-Total	41 (52.6)	21 (26.9)	20 (25.6)
Cytokine release syndrome	36 (46.2)	16 (20.5)	20 (25.6)
Hypogammaglobulinaemia	7 (9.0)	7 (9.0)	0
Haemophagocytic lymphohistiocytosis	3 (3.8)	2 (2.6)	1 (1.3)
Immunodeficiency	3 (3.8)	3 (3.8)	0
Infections and infestations			
-Total	5 (6.4)	4 (5.1)	1 (1.3)
Staphylococcal bacteraemia	3 (3.8)	3 (3.8)	0
Encephalitis	1 (1.3)	0	1 (1.3)
Pneumonia	1 (1.3)	1 (1.3)	0
Investigations			
-Total	38 (48.7)	13 (16.7)	25 (32.1)
White blood cell count decreased	18 (23.1)	2 (2.6)	16 (20.5)
Neutrophil count decreased	17 (21.8)	2 (2.6)	15 (19.2)
Platelet count decreased	14 (17.9)	6 (7.7)	8 (10.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	13 (16.7)	8 (10.3)	5 (6.4)
Aspartate aminotransferase increased	10 (12.8)	8 (10.3)	2 (2.6)
Blood bilirubin increased	8 (10.3)	8 (10.3)	0
Alanine aminotransferase increased	5 (6.4)	5 (6.4)	0
Blood creatinine increased	2 (2.6)	1 (1.3)	1 (1.3)
Metabolism and nutrition disorders			
-Total	26 (33.3)	22 (28.2)	4 (5.1)
Decreased appetite	11 (14.1)	10 (12.8)	1 (1.3)
Hypokalaemia	10 (12.8)	8 (10.3)	2 (2.6)
Hypophosphataemia	9 (11.5)	8 (10.3)	1 (1.3)
Hyperglycaemia	4 (5.1)	4 (5.1)	0
Hypervolaemia	4 (5.1)	4 (5.1)	0
Hypocalcaemia	4 (5.1)	4 (5.1)	0
Tumour lysis syndrome	3 (3.8)	3 (3.8)	0
Nervous system disorders			
-Total	6 (7.7)	5 (6.4)	1 (1.3)
Encephalopathy	4 (5.1)	4 (5.1)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	7 (9.0)	3 (3.8)	4 (5.1)
Acute kidney injury	7 (9.0)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (25.6)	10 (12.8)	10 (12.8)
Hypoxia	12 (15.4)	6 (7.7)	6 (7.7)
Pulmonary oedema	7 (9.0)	6 (7.7)	1 (1.3)
Respiratory failure	4 (5.1)	0	4 (5.1)
Tachypnoea	4 (5.1)	4 (5.1)	0
Dyspnoea	3 (3.8)	2 (2.6)	1 (1.3)
Pleural effusion	2 (2.6)	2 (2.6)	0
Vascular disorders			
-Total	16 (20.5)	10 (12.8)	6 (7.7)
Hypotension	14 (17.9)	8 (10.3)	6 (7.7)
Hypertension	4 (5.1)	4 (5.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	1 (50.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	1 (50.0)	0
Weight decreased	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Decreased appetite	1 (50.0)	1 (50.0)	0
Haemochromatosis	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	1 (50.0)
Seizure	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	1 (50.0)	1 (50.0)	0
Renal tubular disorder	1 (50.0)	1 (50.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219f
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=73	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (35.6)	15 (20.5)	11 (15.1)
Blood and lymphatic system disorders			
-Total	9 (12.3)	5 (6.8)	4 (5.5)
Neutropenia	5 (6.8)	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Anaemia	2 (2.7)	2 (2.7)	0
Thrombocytopenia	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	1 (1.4)	1 (1.4)	0
Pyrexia	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Immunodeficiency	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	11 (15.1)	7 (9.6)	4 (5.5)
Neutrophil count decreased	7 (9.6)	3 (4.1)	4 (5.5)
White blood cell count decreased	4 (5.5)	3 (4.1)	1 (1.4)
Lymphocyte count decreased	2 (2.7)	2 (2.7)	0
Platelet count decreased	2 (2.7)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	4 (5.5)	2 (2.7)	2 (2.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (2.7)	1 (1.4)	1 (1.4)
Hypervolaemia	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.5)	3 (4.1)	1 (1.4)
Hypoxia	3 (4.1)	3 (4.1)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Hypotension	3 (4.1)	1 (1.4)	2 (2.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Sepsis	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	0	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=48	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (18.8)	4 (8.3)	5 (10.4)
Blood and lymphatic system disorders			
-Total	1 (2.1)	0	1 (2.1)
Neutropenia	1 (2.1)	0	1 (2.1)
General disorders and administration site conditions			
-Total	1 (2.1)	1 (2.1)	0
Pyrexia	1 (2.1)	1 (2.1)	0
Immune system disorders			
-Total	1 (2.1)	0	1 (2.1)
Haemophagocytic lymphohistiocytosis	1 (2.1)	0	1 (2.1)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	6 (12.5)	3 (6.3)	3 (6.3)
Pneumonia	2 (4.2)	1 (2.1)	1 (2.1)
Sepsis	2 (4.2)	0	2 (4.2)
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Upper respiratory tract infection	1 (2.1)	1 (2.1)	0
Investigations			
-Total	1 (2.1)	0	1 (2.1)
Neutrophil count decreased	1 (2.1)	0	1 (2.1)
Metabolism and nutrition disorders			
-Total	1 (2.1)	1 (2.1)	0
Hyperglycaemia	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	1 (2.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.3)	1 (2.1)	2 (4.2)
Dyspnoea	1 (2.1)	0	1 (2.1)

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (2.1)	1 (2.1)	0
Respiratory failure	1 (2.1)	0	1 (2.1)
Tachypnoea	1 (2.1)	0	1 (2.1)
Vascular disorders			
-Total	1 (2.1)	1 (2.1)	0
Hypertension	1 (2.1)	1 (2.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	2 (100)	0
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Pancytopenia	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	1 (50.0)	0
Pyrexia	1 (50.0)	1 (50.0)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (100)	1 (50.0)	1 (50.0)
Cytokine release syndrome	2 (100)	1 (50.0)	1 (50.0)
Infections and infestations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Encephalitis	1 (50.0)	0	1 (50.0)
Respiratory syncytial virus infection	1 (50.0)	1 (50.0)	0
Sepsis	1 (50.0)	1 (50.0)	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0
Viral haemorrhagic cystitis	1 (50.0)	1 (50.0)	0
Investigations			
-Total	2 (100)	1 (50.0)	1 (50.0)
Activated partial thromboplastin time prolonged	1 (50.0)	1 (50.0)	0
Alanine aminotransferase increased	1 (50.0)	1 (50.0)	0
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	1 (50.0)	0
Blood creatinine increased	1 (50.0)	1 (50.0)	0
Weight decreased	1 (50.0)	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	1 (50.0)
Haemochromatosis	1 (50.0)	1 (50.0)	0
Hypocalcaemia	1 (50.0)	1 (50.0)	0
Hypokalaemia	1 (50.0)	1 (50.0)	0
Tumour lysis syndrome	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Autonomic neuropathy	1 (50.0)	1 (50.0)	0
Cerebral haemorrhage	1 (50.0)	0	1 (50.0)
Seizure	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	1 (50.0)	1 (50.0)	0
Renal tubular disorder	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Pleural effusion	1 (50.0)	0	1 (50.0)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Capillary leak syndrome	1 (50.0)	1 (50.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (87.2)	20 (25.6)	48 (61.5)
Blood and lymphatic system disorders			
-Total	41 (52.6)	27 (34.6)	14 (17.9)
Febrile neutropenia	26 (33.3)	24 (30.8)	2 (2.6)
Anaemia	9 (11.5)	9 (11.5)	0
Neutropenia	9 (11.5)	2 (2.6)	7 (9.0)
Thrombocytopenia	9 (11.5)	3 (3.8)	6 (7.7)
Disseminated intravascular coagulation	2 (2.6)	2 (2.6)	0
Pancytopenia	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (12.8)	8 (10.3)	2 (2.6)
Pyrexia	10 (12.8)	8 (10.3)	2 (2.6)
Immune system disorders			
-Total	43 (55.1)	22 (28.2)	21 (26.9)
Cytokine release syndrome	36 (46.2)	16 (20.5)	20 (25.6)
Hypogammaglobulinaemia	7 (9.0)	7 (9.0)	0
Haemophagocytic lymphohistiocytosis	4 (5.1)	2 (2.6)	2 (2.6)
Immunodeficiency	4 (5.1)	4 (5.1)	0
Infections and infestations			
-Total	13 (16.7)	8 (10.3)	5 (6.4)
Staphylococcal bacteraemia	5 (6.4)	5 (6.4)	0
Pneumonia	4 (5.1)	2 (2.6)	2 (2.6)
Sepsis	2 (2.6)	0	2 (2.6)
Upper respiratory tract infection	2 (2.6)	2 (2.6)	0
Encephalitis	1 (1.3)	0	1 (1.3)
Respiratory syncytial virus infection	1 (1.3)	1 (1.3)	0
Investigations			
-Total	39 (50.0)	14 (17.9)	25 (32.1)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

		All patients N=78	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	21 (26.9)	4 (5.1)	17 (21.8)
White blood cell count decreased	18 (23.1)	2 (2.6)	16 (20.5)
Lymphocyte count decreased	15 (19.2)	10 (12.8)	5 (6.4)
Platelet count decreased	15 (19.2)	7 (9.0)	8 (10.3)
Aspartate aminotransferase increased	10 (12.8)	8 (10.3)	2 (2.6)
Blood bilirubin increased	8 (10.3)	8 (10.3)	0
Alanine aminotransferase increased	6 (7.7)	6 (7.7)	0
Blood creatinine increased	2 (2.6)	1 (1.3)	1 (1.3)
Metabolism and nutrition disorders			
-Total	27 (34.6)	22 (28.2)	5 (6.4)
Decreased appetite	11 (14.1)	10 (12.8)	1 (1.3)
Hypokalaemia	10 (12.8)	8 (10.3)	2 (2.6)
Hypophosphataemia	9 (11.5)	8 (10.3)	1 (1.3)
Hyperglycaemia	5 (6.4)	5 (6.4)	0
Hypervolaemia	5 (6.4)	5 (6.4)	0
Hypocalcaemia	4 (5.1)	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	3 (3.8)	1 (1.3)
Nervous system disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (9.0)	6 (7.7)	1 (1.3)
Encephalopathy	4 (5.1)	4 (5.1)	0
Seizure	2 (2.6)	2 (2.6)	0
Cerebral haemorrhage	1 (1.3)	0	1 (1.3)
Renal and urinary disorders			
-Total	8 (10.3)	3 (3.8)	5 (6.4)
Acute kidney injury	8 (10.3)	3 (3.8)	5 (6.4)
Respiratory, thoracic and mediastinal disorders			
-Total	25 (32.1)	12 (15.4)	13 (16.7)
Hypoxia	16 (20.5)	10 (12.8)	6 (7.7)
Pulmonary oedema	7 (9.0)	6 (7.7)	1 (1.3)
Respiratory failure	6 (7.7)	0	6 (7.7)
Tachypnoea	5 (6.4)	4 (5.1)	1 (1.3)
Dyspnoea	4 (5.1)	2 (2.6)	2 (2.6)
Pleural effusion	2 (2.6)	2 (2.6)	0
Vascular disorders			
-Total	19 (24.4)	11 (14.1)	8 (10.3)
Hypotension	16 (20.5)	8 (10.3)	8 (10.3)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=78		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	5 (6.4)	5 (6.4)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (81.0)	19 (24.1)	45 (57.0)
Blood and lymphatic system disorders			
-Total	37 (46.8)	24 (30.4)	13 (16.5)
Febrile neutropenia	26 (32.9)	24 (30.4)	2 (2.5)
Anaemia	8 (10.1)	8 (10.1)	0
Thrombocytopenia	8 (10.1)	2 (2.5)	6 (7.6)
Neutropenia	7 (8.9)	1 (1.3)	6 (7.6)
General disorders and administration site conditions			
-Total	8 (10.1)	6 (7.6)	2 (2.5)
Pyrexia	8 (10.1)	6 (7.6)	2 (2.5)
Immune system disorders			

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	43 (54.4)	22 (27.8)	21 (26.6)
Cytokine release syndrome	38 (48.1)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	7 (8.9)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	3 (3.8)	2 (2.5)	1 (1.3)
Immunodeficiency	3 (3.8)	3 (3.8)	0
Infections and infestations			
-Total	4 (5.1)	4 (5.1)	0
Staphylococcal bacteraemia	3 (3.8)	3 (3.8)	0
Pneumonia	1 (1.3)	1 (1.3)	0
Investigations			
-Total	38 (48.1)	13 (16.5)	25 (31.6)
White blood cell count decreased	18 (22.8)	2 (2.5)	16 (20.3)
Neutrophil count decreased	17 (21.5)	2 (2.5)	15 (19.0)
Platelet count decreased	14 (17.7)	6 (7.6)	8 (10.1)
Lymphocyte count decreased	13 (16.5)	8 (10.1)	5 (6.3)
Aspartate aminotransferase increased	11 (13.9)	8 (10.1)	3 (3.8)
Blood bilirubin increased	9 (11.4)	9 (11.4)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (7.6)	6 (7.6)	0
Metabolism and nutrition disorders			
-Total	27 (34.2)	23 (29.1)	4 (5.1)
Decreased appetite	11 (13.9)	10 (12.7)	1 (1.3)
Hypokalaemia	11 (13.9)	9 (11.4)	2 (2.5)
Hypophosphataemia	9 (11.4)	8 (10.1)	1 (1.3)
Hypocalcaemia	5 (6.3)	5 (6.3)	0
Hyperglycaemia	4 (5.1)	4 (5.1)	0
Hypervolaemia	4 (5.1)	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	4 (5.1)	0
Nervous system disorders			
-Total	4 (5.1)	4 (5.1)	0
Encephalopathy	4 (5.1)	4 (5.1)	0
Renal and urinary disorders			
-Total	7 (8.9)	3 (3.8)	4 (5.1)
Acute kidney injury	7 (8.9)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (25.3)	10 (12.7)	10 (12.7)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	12 (15.2)	6 (7.6)	6 (7.6)
Pulmonary oedema	7 (8.9)	6 (7.6)	1 (1.3)
Respiratory failure	4 (5.1)	0	4 (5.1)
Tachypnoea	4 (5.1)	4 (5.1)	0
Dyspnoea	3 (3.8)	2 (2.5)	1 (1.3)
Vascular disorders			
-Total	16 (20.3)	10 (12.7)	6 (7.6)
Hypotension	14 (17.7)	8 (10.1)	6 (7.6)
Hypertension	4 (5.1)	4 (5.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (36.5)	16 (21.6)	11 (14.9)
Blood and lymphatic system disorders			
-Total	9 (12.2)	5 (6.8)	4 (5.4)
Neutropenia	5 (6.8)	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Anaemia	2 (2.7)	2 (2.7)	0
Thrombocytopenia	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	2 (2.7)	2 (2.7)	0
Pyrexia	2 (2.7)	2 (2.7)	0
Immune system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Immunodeficiency	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	11 (14.9)	7 (9.5)	4 (5.4)
Neutrophil count decreased	7 (9.5)	3 (4.1)	4 (5.4)
White blood cell count decreased	4 (5.4)	3 (4.1)	1 (1.4)
Lymphocyte count decreased	2 (2.7)	2 (2.7)	0
Platelet count decreased	2 (2.7)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	5 (6.8)	3 (4.1)	2 (2.7)
Hypokalaemia	2 (2.7)	1 (1.4)	1 (1.4)
Decreased appetite	1 (1.4)	1 (1.4)	0
Hypervolaemia	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.4)	3 (4.1)	1 (1.4)
Hypoxia	3 (4.1)	3 (4.1)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Hypotension	3 (4.1)	1 (1.4)	2 (2.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (18.0)	4 (8.0)	5 (10.0)
Blood and lymphatic system disorders			
-Total	1 (2.0)	0	1 (2.0)
Neutropenia	1 (2.0)	0	1 (2.0)
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	0	1 (2.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (6.0)	2 (4.0)	1 (2.0)
Pneumonia	2 (4.0)	1 (2.0)	1 (2.0)
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Investigations			
-Total	1 (2.0)	0	1 (2.0)
Neutrophil count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	1 (2.0)
Hyperglycaemia	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.0)	1 (2.0)	2 (4.0)
Dyspnoea	1 (2.0)	0	1 (2.0)
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)
Tachypnoea	1 (2.0)	0	1 (2.0)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	1 (2.0)	0
Hypertension	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (88.6)	21 (26.6)	49 (62.0)
Blood and lymphatic system disorders			
-Total	41 (51.9)	27 (34.2)	14 (17.7)
Febrile neutropenia	27 (34.2)	25 (31.6)	2 (2.5)
Anaemia	9 (11.4)	9 (11.4)	0
Neutropenia	9 (11.4)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	3 (3.8)	6 (7.6)
General disorders and administration site conditions			
-Total	11 (13.9)	9 (11.4)	2 (2.5)
Pyrexia	11 (13.9)	9 (11.4)	2 (2.5)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	45 (57.0)	23 (29.1)	22 (27.8)
Cytokine release syndrome	38 (48.1)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	7 (8.9)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	4 (5.1)	2 (2.5)	2 (2.5)
Immunodeficiency	4 (5.1)	4 (5.1)	0
Infections and infestations			
-Total	8 (10.1)	6 (7.6)	2 (2.5)
Staphylococcal bacteraemia	5 (6.3)	5 (6.3)	0
Pneumonia	4 (5.1)	2 (2.5)	2 (2.5)
Investigations			
-Total	39 (49.4)	14 (17.7)	25 (31.6)
Neutrophil count decreased	21 (26.6)	4 (5.1)	17 (21.5)
White blood cell count decreased	18 (22.8)	2 (2.5)	16 (20.3)
Lymphocyte count decreased	15 (19.0)	10 (12.7)	5 (6.3)
Platelet count decreased	15 (19.0)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	11 (13.9)	8 (10.1)	3 (3.8)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	9 (11.4)	9 (11.4)	0
Alanine aminotransferase increased	7 (8.9)	7 (8.9)	0
Metabolism and nutrition disorders			
-Total	29 (36.7)	23 (29.1)	6 (7.6)
Decreased appetite	12 (15.2)	10 (12.7)	2 (2.5)
Hypokalaemia	11 (13.9)	9 (11.4)	2 (2.5)
Hypophosphataemia	9 (11.4)	8 (10.1)	1 (1.3)
Hyperglycaemia	5 (6.3)	5 (6.3)	0
Hypervolaemia	5 (6.3)	5 (6.3)	0
Hypocalcaemia	5 (6.3)	5 (6.3)	0
Tumour lysis syndrome	5 (6.3)	4 (5.1)	1 (1.3)
Nervous system disorders			
-Total	4 (5.1)	4 (5.1)	0
Encephalopathy	4 (5.1)	4 (5.1)	0
Renal and urinary disorders			
-Total	8 (10.1)	3 (3.8)	5 (6.3)
Acute kidney injury	8 (10.1)	3 (3.8)	5 (6.3)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	25 (31.6)	12 (15.2)	13 (16.5)
Hypoxia	16 (20.3)	10 (12.7)	6 (7.6)
Pulmonary oedema	7 (8.9)	6 (7.6)	1 (1.3)
Respiratory failure	6 (7.6)	0	6 (7.6)
Tachypnoea	5 (6.3)	4 (5.1)	1 (1.3)
Dyspnoea	4 (5.1)	2 (2.5)	2 (2.5)
Vascular disorders			
-Total	19 (24.1)	11 (13.9)	8 (10.1)
Hypotension	16 (20.3)	8 (10.1)	8 (10.1)
Hypertension	5 (6.3)	5 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Lymphocyte count decreased	1 (100)	1 (100)	0
Neutrophil count decreased	1 (100)	0	1 (100)
White blood cell count decreased	1 (100)	1 (100)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

		All patients N=79	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (79.7)	19 (24.1)	44 (55.7)
Blood and lymphatic system disorders			
-Total	37 (46.8)	24 (30.4)	13 (16.5)
Febrile neutropenia	26 (32.9)	24 (30.4)	2 (2.5)
Anaemia	8 (10.1)	8 (10.1)	0
Thrombocytopenia	8 (10.1)	2 (2.5)	6 (7.6)
Neutropenia	7 (8.9)	1 (1.3)	6 (7.6)
General disorders and administration site conditions			
-Total	8 (10.1)	6 (7.6)	2 (2.5)
Pyrexia	8 (10.1)	6 (7.6)	2 (2.5)
Immune system disorders			

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	43 (54.4)	22 (27.8)	21 (26.6)
Cytokine release syndrome	38 (48.1)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	7 (8.9)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	3 (3.8)	2 (2.5)	1 (1.3)
Immunodeficiency	3 (3.8)	3 (3.8)	0
Infections and infestations			
-Total	4 (5.1)	4 (5.1)	0
Staphylococcal bacteraemia	3 (3.8)	3 (3.8)	0
Pneumonia	1 (1.3)	1 (1.3)	0
Investigations			
-Total	37 (46.8)	13 (16.5)	24 (30.4)
White blood cell count decreased	17 (21.5)	1 (1.3)	16 (20.3)
Neutrophil count decreased	16 (20.3)	2 (2.5)	14 (17.7)
Platelet count decreased	14 (17.7)	6 (7.6)	8 (10.1)
Lymphocyte count decreased	12 (15.2)	7 (8.9)	5 (6.3)
Aspartate aminotransferase increased	11 (13.9)	8 (10.1)	3 (3.8)
Blood bilirubin increased	9 (11.4)	9 (11.4)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (7.6)	6 (7.6)	0
Metabolism and nutrition disorders			
-Total	27 (34.2)	23 (29.1)	4 (5.1)
Decreased appetite	11 (13.9)	10 (12.7)	1 (1.3)
Hypokalaemia	11 (13.9)	9 (11.4)	2 (2.5)
Hypophosphataemia	9 (11.4)	8 (10.1)	1 (1.3)
Hypocalcaemia	5 (6.3)	5 (6.3)	0
Hyperglycaemia	4 (5.1)	4 (5.1)	0
Hypervolaemia	4 (5.1)	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	4 (5.1)	0
Nervous system disorders			
-Total	4 (5.1)	4 (5.1)	0
Encephalopathy	4 (5.1)	4 (5.1)	0
Renal and urinary disorders			
-Total	7 (8.9)	3 (3.8)	4 (5.1)
Acute kidney injury	7 (8.9)	3 (3.8)	4 (5.1)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (25.3)	10 (12.7)	10 (12.7)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	12 (15.2)	6 (7.6)	6 (7.6)
Pulmonary oedema	7 (8.9)	6 (7.6)	1 (1.3)
Respiratory failure	4 (5.1)	0	4 (5.1)
Tachypnoea	4 (5.1)	4 (5.1)	0
Dyspnoea	3 (3.8)	2 (2.5)	1 (1.3)
Vascular disorders			
-Total	16 (20.3)	10 (12.7)	6 (7.6)
Hypotension	14 (17.7)	8 (10.1)	6 (7.6)
Hypertension	4 (5.1)	4 (5.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Neutrophil count decreased	1 (100)	0	1 (100)
White blood cell count decreased	1 (100)	1 (100)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (35.1)	16 (21.6)	10 (13.5)
Blood and lymphatic system disorders			
-Total	9 (12.2)	5 (6.8)	4 (5.4)
Neutropenia	5 (6.8)	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Anaemia	2 (2.7)	2 (2.7)	0
Thrombocytopenia	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	2 (2.7)	2 (2.7)	0
Pyrexia	2 (2.7)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Immunodeficiency	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	10 (13.5)	7 (9.5)	3 (4.1)
Neutrophil count decreased	6 (8.1)	3 (4.1)	3 (4.1)
White blood cell count decreased	3 (4.1)	2 (2.7)	1 (1.4)
Lymphocyte count decreased	2 (2.7)	2 (2.7)	0
Platelet count decreased	2 (2.7)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	5 (6.8)	3 (4.1)	2 (2.7)
Hypokalaemia	2 (2.7)	1 (1.4)	1 (1.4)
Decreased appetite	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.4)	3 (4.1)	1 (1.4)
Hypoxia	3 (4.1)	3 (4.1)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Hypotension	3 (4.1)	1 (1.4)	2 (2.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (18.4)	4 (8.2)	5 (10.2)
Blood and lymphatic system disorders			
-Total	1 (2.0)	0	1 (2.0)
Neutropenia	1 (2.0)	0	1 (2.0)
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	0	1 (2.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (6.1)	2 (4.1)	1 (2.0)
Pneumonia	2 (4.1)	1 (2.0)	1 (2.0)
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Investigations			
-Total	1 (2.0)	0	1 (2.0)
Neutrophil count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	2 (4.1)	1 (2.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	1 (2.0)
Hyperglycaemia	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.1)	1 (2.0)	2 (4.1)
Dyspnoea	1 (2.0)	0	1 (2.0)
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)
Tachypnoea	1 (2.0)	0	1 (2.0)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	1 (2.0)	0
Hypertension	1 (2.0)	1 (2.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Lymphocyte count decreased	1 (100)	1 (100)	0
Neutrophil count decreased	1 (100)	0	1 (100)
White blood cell count decreased	1 (100)	1 (100)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 219h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (87.3)	21 (26.6)	48 (60.8)
Blood and lymphatic system disorders			
-Total	41 (51.9)	27 (34.2)	14 (17.7)
Febrile neutropenia	27 (34.2)	25 (31.6)	2 (2.5)
Anaemia	9 (11.4)	9 (11.4)	0
Neutropenia	9 (11.4)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	3 (3.8)	6 (7.6)
General disorders and administration site conditions			
-Total	11 (13.9)	9 (11.4)	2 (2.5)
Pyrexia	11 (13.9)	9 (11.4)	2 (2.5)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	45 (57.0)	23 (29.1)	22 (27.8)
Cytokine release syndrome	38 (48.1)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	7 (8.9)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	4 (5.1)	2 (2.5)	2 (2.5)
Immunodeficiency	4 (5.1)	4 (5.1)	0
Infections and infestations			
-Total	8 (10.1)	6 (7.6)	2 (2.5)
Staphylococcal bacteraemia	5 (6.3)	5 (6.3)	0
Pneumonia	4 (5.1)	2 (2.5)	2 (2.5)
Investigations			
-Total	38 (48.1)	14 (17.7)	24 (30.4)
Neutrophil count decreased	20 (25.3)	4 (5.1)	16 (20.3)
White blood cell count decreased	17 (21.5)	1 (1.3)	16 (20.3)
Platelet count decreased	15 (19.0)	7 (8.9)	8 (10.1)
Lymphocyte count decreased	14 (17.7)	9 (11.4)	5 (6.3)
Aspartate aminotransferase increased	11 (13.9)	8 (10.1)	3 (3.8)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	9 (11.4)	9 (11.4)	0
Alanine aminotransferase increased	7 (8.9)	7 (8.9)	0
Metabolism and nutrition disorders			
-Total	29 (36.7)	23 (29.1)	6 (7.6)
Decreased appetite	12 (15.2)	10 (12.7)	2 (2.5)
Hypokalaemia	11 (13.9)	9 (11.4)	2 (2.5)
Hypophosphataemia	9 (11.4)	8 (10.1)	1 (1.3)
Hyperglycaemia	5 (6.3)	5 (6.3)	0
Hypervolaemia	5 (6.3)	5 (6.3)	0
Hypocalcaemia	5 (6.3)	5 (6.3)	0
Tumour lysis syndrome	5 (6.3)	4 (5.1)	1 (1.3)
Nervous system disorders			
-Total	4 (5.1)	4 (5.1)	0
Encephalopathy	4 (5.1)	4 (5.1)	0
Renal and urinary disorders			
-Total	8 (10.1)	3 (3.8)	5 (6.3)
Acute kidney injury	8 (10.1)	3 (3.8)	5 (6.3)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=79 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	25 (31.6)	12 (15.2)	13 (16.5)
Hypoxia	16 (20.3)	10 (12.7)	6 (7.6)
Pulmonary oedema	7 (8.9)	6 (7.6)	1 (1.3)
Respiratory failure	6 (7.6)	0	6 (7.6)
Tachypnoea	5 (6.3)	4 (5.1)	1 (1.3)
Dyspnoea	4 (5.1)	2 (2.5)	2 (2.5)
Vascular disorders			
-Total	19 (24.1)	11 (13.9)	8 (10.1)
Hypotension	16 (20.3)	8 (10.1)	8 (10.1)
Hypertension	5 (6.3)	5 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Gamma-glutamyltransferase increased	1 (100)	1 (100)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (81.0)	19 (24.1)	45 (57.0)
Blood and lymphatic system disorders			
-Total	37 (46.8)	24 (30.4)	13 (16.5)
Febrile neutropenia	26 (32.9)	24 (30.4)	2 (2.5)
Anaemia	8 (10.1)	8 (10.1)	0
Thrombocytopenia	8 (10.1)	2 (2.5)	6 (7.6)
Neutropenia	7 (8.9)	1 (1.3)	6 (7.6)
General disorders and administration site conditions			
-Total	8 (10.1)	6 (7.6)	2 (2.5)
Pyrexia	8 (10.1)	6 (7.6)	2 (2.5)
Immune system disorders			

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	43 (54.4)	22 (27.8)	21 (26.6)
Cytokine release syndrome	38 (48.1)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	7 (8.9)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	3 (3.8)	2 (2.5)	1 (1.3)
Immunodeficiency	3 (3.8)	3 (3.8)	0
Infections and infestations			
-Total	4 (5.1)	4 (5.1)	0
Staphylococcal bacteraemia	3 (3.8)	3 (3.8)	0
Pneumonia	1 (1.3)	1 (1.3)	0
Investigations			
-Total	39 (49.4)	14 (17.7)	25 (31.6)
White blood cell count decreased	18 (22.8)	2 (2.5)	16 (20.3)
Neutrophil count decreased	17 (21.5)	2 (2.5)	15 (19.0)
Platelet count decreased	14 (17.7)	6 (7.6)	8 (10.1)
Lymphocyte count decreased	13 (16.5)	8 (10.1)	5 (6.3)
Aspartate aminotransferase increased	11 (13.9)	8 (10.1)	3 (3.8)
Blood bilirubin increased	9 (11.4)	9 (11.4)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (7.6)	6 (7.6)	0
Gamma-glutamyltransferase increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			
-Total	27 (34.2)	23 (29.1)	4 (5.1)
Decreased appetite	11 (13.9)	10 (12.7)	1 (1.3)
Hypokalaemia	11 (13.9)	9 (11.4)	2 (2.5)
Hypophosphataemia	9 (11.4)	8 (10.1)	1 (1.3)
Hypocalcaemia	5 (6.3)	5 (6.3)	0
Hyperglycaemia	4 (5.1)	4 (5.1)	0
Hypervolaemia	4 (5.1)	4 (5.1)	0
Tumour lysis syndrome	4 (5.1)	4 (5.1)	0
Nervous system disorders			
-Total	4 (5.1)	4 (5.1)	0
Encephalopathy	4 (5.1)	4 (5.1)	0
Renal and urinary disorders			
-Total	7 (8.9)	3 (3.8)	4 (5.1)
Acute kidney injury	7 (8.9)	3 (3.8)	4 (5.1)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	20 (25.3)	10 (12.7)	10 (12.7)
Hypoxia	12 (15.2)	6 (7.6)	6 (7.6)
Pulmonary oedema	7 (8.9)	6 (7.6)	1 (1.3)
Respiratory failure	4 (5.1)	0	4 (5.1)
Tachypnoea	4 (5.1)	4 (5.1)	0
Dyspnoea	3 (3.8)	2 (2.5)	1 (1.3)
Vascular disorders			
-Total	16 (20.3)	10 (12.7)	6 (7.6)
Hypotension	14 (17.7)	8 (10.1)	6 (7.6)
Hypertension	4 (5.1)	4 (5.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (36.5)	16 (21.6)	11 (14.9)
Blood and lymphatic system disorders			
-Total	9 (12.2)	5 (6.8)	4 (5.4)
Neutropenia	5 (6.8)	2 (2.7)	3 (4.1)
Febrile neutropenia	3 (4.1)	3 (4.1)	0
Anaemia	2 (2.7)	2 (2.7)	0
Thrombocytopenia	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	2 (2.7)	2 (2.7)	0
Pyrexia	2 (2.7)	2 (2.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Immunodeficiency	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Pneumonia	1 (1.4)	0	1 (1.4)
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	11 (14.9)	7 (9.5)	4 (5.4)
Neutrophil count decreased	7 (9.5)	3 (4.1)	4 (5.4)
White blood cell count decreased	4 (5.4)	3 (4.1)	1 (1.4)
Lymphocyte count decreased	2 (2.7)	2 (2.7)	0
Platelet count decreased	2 (2.7)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	5 (6.8)	3 (4.1)	2 (2.7)
Hypokalaemia	2 (2.7)	1 (1.4)	1 (1.4)
Decreased appetite	1 (1.4)	1 (1.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypervolaemia	1 (1.4)	1 (1.4)	0
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.4)	3 (4.1)	1 (1.4)
Hypoxia	3 (4.1)	3 (4.1)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	3 (4.1)	1 (1.4)	2 (2.7)
Hypotension	3 (4.1)	1 (1.4)	2 (2.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (18.4)	4 (8.2)	5 (10.2)
Blood and lymphatic system disorders			
-Total	1 (2.0)	0	1 (2.0)
Neutropenia	1 (2.0)	0	1 (2.0)
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	0	1 (2.0)
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (6.1)	2 (4.1)	1 (2.0)
Pneumonia	2 (4.1)	1 (2.0)	1 (2.0)
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Investigations			
-Total	1 (2.0)	0	1 (2.0)
Neutrophil count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	2 (4.1)	1 (2.0)	1 (2.0)
Decreased appetite	1 (2.0)	0	1 (2.0)
Hyperglycaemia	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.1)	1 (2.0)	2 (4.1)
Dyspnoea	1 (2.0)	0	1 (2.0)
Hypoxia	1 (2.0)	1 (2.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)
Tachypnoea	1 (2.0)	0	1 (2.0)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=49		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	1 (2.0)	0
Hypertension	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Gamma-glutamyltransferase increased	1 (100)	1 (100)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (88.6)	21 (26.6)	49 (62.0)
Blood and lymphatic system disorders			
-Total	41 (51.9)	27 (34.2)	14 (17.7)
Febrile neutropenia	27 (34.2)	25 (31.6)	2 (2.5)
Anaemia	9 (11.4)	9 (11.4)	0
Neutropenia	9 (11.4)	2 (2.5)	7 (8.9)
Thrombocytopenia	9 (11.4)	3 (3.8)	6 (7.6)
General disorders and administration site conditions			
-Total	11 (13.9)	9 (11.4)	2 (2.5)
Pyrexia	11 (13.9)	9 (11.4)	2 (2.5)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	45 (57.0)	23 (29.1)	22 (27.8)
Cytokine release syndrome	38 (48.1)	17 (21.5)	21 (26.6)
Hypogammaglobulinaemia	7 (8.9)	7 (8.9)	0
Haemophagocytic lymphohistiocytosis	4 (5.1)	2 (2.5)	2 (2.5)
Immunodeficiency	4 (5.1)	4 (5.1)	0
Infections and infestations			
-Total	8 (10.1)	6 (7.6)	2 (2.5)
Staphylococcal bacteraemia	5 (6.3)	5 (6.3)	0
Pneumonia	4 (5.1)	2 (2.5)	2 (2.5)
Investigations			
-Total	40 (50.6)	15 (19.0)	25 (31.6)
Neutrophil count decreased	21 (26.6)	4 (5.1)	17 (21.5)
White blood cell count decreased	18 (22.8)	2 (2.5)	16 (20.3)
Lymphocyte count decreased	15 (19.0)	10 (12.7)	5 (6.3)
Platelet count decreased	15 (19.0)	7 (8.9)	8 (10.1)
Aspartate aminotransferase increased	11 (13.9)	8 (10.1)	3 (3.8)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=79		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	9 (11.4)	9 (11.4)	0
Alanine aminotransferase increased	7 (8.9)	7 (8.9)	0
Gamma-glutamyltransferase increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			
-Total	29 (36.7)	23 (29.1)	6 (7.6)
Decreased appetite	12 (15.2)	10 (12.7)	2 (2.5)
Hypokalaemia	11 (13.9)	9 (11.4)	2 (2.5)
Hypophosphataemia	9 (11.4)	8 (10.1)	1 (1.3)
Hyperglycaemia	5 (6.3)	5 (6.3)	0
Hypervolaemia	5 (6.3)	5 (6.3)	0
Hypocalcaemia	5 (6.3)	5 (6.3)	0
Tumour lysis syndrome	5 (6.3)	4 (5.1)	1 (1.3)
Nervous system disorders			
-Total	4 (5.1)	4 (5.1)	0
Encephalopathy	4 (5.1)	4 (5.1)	0
Renal and urinary disorders			
-Total	8 (10.1)	3 (3.8)	5 (6.3)
Acute kidney injury	8 (10.1)	3 (3.8)	5 (6.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All patients N=79 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	25 (31.6)	12 (15.2)	13 (16.5)
Hypoxia	16 (20.3)	10 (12.7)	6 (7.6)
Pulmonary oedema	7 (8.9)	6 (7.6)	1 (1.3)
Respiratory failure	6 (7.6)	0	6 (7.6)
Tachypnoea	5 (6.3)	4 (5.1)	1 (1.3)
Dyspnoea	4 (5.1)	2 (2.5)	2 (2.5)
Vascular disorders			
-Total	19 (24.1)	11 (13.9)	8 (10.1)
Hypotension	16 (20.3)	8 (10.1)	8 (10.1)
Hypertension	5 (6.3)	5 (6.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (74.1)	7 (25.9)	13 (48.1)
Blood and lymphatic system disorders			
-Total	7 (25.9)	3 (11.1)	4 (14.8)
Febrile neutropenia	3 (11.1)	3 (11.1)	0
Neutropenia	2 (7.4)	0	2 (7.4)
Thrombocytopenia	2 (7.4)	0	2 (7.4)
Cardiac disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Tachycardia	2 (7.4)	1 (3.7)	1 (3.7)
Gastrointestinal disorders			
-Total	2 (7.4)	2 (7.4)	0
Diarrhoea	1 (3.7)	1 (3.7)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			
-Total	1 (3.7)	0	1 (3.7)
Pyrexia	1 (3.7)	0	1 (3.7)
Hepatobiliary disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Hepatic function abnormal	3 (11.1)	2 (7.4)	1 (3.7)
Immune system disorders			
-Total	18 (66.7)	9 (33.3)	9 (33.3)
Cytokine release syndrome	17 (63.0)	8 (29.6)	9 (33.3)
Hypogammaglobulinaemia	3 (11.1)	3 (11.1)	0
Haemophagocytic lymphohistiocytosis	2 (7.4)	1 (3.7)	1 (3.7)
Immunodeficiency	1 (3.7)	1 (3.7)	0
Infections and infestations			
-Total	1 (3.7)	1 (3.7)	0
Pneumonia	1 (3.7)	1 (3.7)	0
Investigations			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (44.4)	4 (14.8)	8 (29.6)
Neutrophil count decreased	6 (22.2)	0	6 (22.2)
White blood cell count decreased	6 (22.2)	1 (3.7)	5 (18.5)
Lymphocyte count decreased	4 (14.8)	2 (7.4)	2 (7.4)
Alanine aminotransferase increased	3 (11.1)	3 (11.1)	0
Platelet count decreased	3 (11.1)	1 (3.7)	2 (7.4)
Blood bilirubin increased	2 (7.4)	2 (7.4)	0
Blood creatine phosphokinase increased	2 (7.4)	1 (3.7)	1 (3.7)
Aspartate aminotransferase increased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	11 (40.7)	9 (33.3)	2 (7.4)
Hypokalaemia	6 (22.2)	5 (18.5)	1 (3.7)
Decreased appetite	3 (11.1)	3 (11.1)	0
Hypophosphataemia	3 (11.1)	2 (7.4)	1 (3.7)
Hypocalcaemia	2 (7.4)	2 (7.4)	0
Tumour lysis syndrome	2 (7.4)	2 (7.4)	0
Nervous system disorders			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.4)	2 (7.4)	0
Encephalopathy	2 (7.4)	2 (7.4)	0
Renal and urinary disorders			
-Total	4 (14.8)	1 (3.7)	3 (11.1)
Acute kidney injury	4 (14.8)	1 (3.7)	3 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (29.6)	3 (11.1)	5 (18.5)
Hypoxia	6 (22.2)	2 (7.4)	4 (14.8)
Atelectasis	2 (7.4)	2 (7.4)	0
Tachypnoea	2 (7.4)	2 (7.4)	0
Acute respiratory distress syndrome	1 (3.7)	0	1 (3.7)
Dyspnoea	1 (3.7)	0	1 (3.7)
Pulmonary oedema	1 (3.7)	1 (3.7)	0
Vascular disorders			
-Total	6 (22.2)	3 (11.1)	3 (11.1)
Hypotension	5 (18.5)	2 (7.4)	3 (11.1)
Hypertension	2 (7.4)	2 (7.4)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (86.8)	14 (26.4)	32 (60.4)
Blood and lymphatic system disorders			
-Total	30 (56.6)	21 (39.6)	9 (17.0)
Febrile neutropenia	23 (43.4)	21 (39.6)	2 (3.8)
Anaemia	8 (15.1)	8 (15.1)	0
Thrombocytopenia	6 (11.3)	2 (3.8)	4 (7.5)
Neutropenia	5 (9.4)	1 (1.9)	4 (7.5)
Cardiac disorders			
-Total	5 (9.4)	4 (7.5)	1 (1.9)
Left ventricular dysfunction	3 (5.7)	3 (5.7)	0
Cardiac arrest	1 (1.9)	0	1 (1.9)
Tachycardia	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	7 (13.2)	6 (11.3)	1 (1.9)
Pyrexia	7 (13.2)	6 (11.3)	1 (1.9)
Immune system disorders			
-Total	25 (47.2)	13 (24.5)	12 (22.6)
Cytokine release syndrome	21 (39.6)	9 (17.0)	12 (22.6)
Hypogammaglobulinaemia	4 (7.5)	4 (7.5)	0
Immunodeficiency	2 (3.8)	2 (3.8)	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	3 (5.7)	3 (5.7)	0
Staphylococcal bacteraemia	3 (5.7)	3 (5.7)	0
Investigations			
-Total	29 (54.7)	12 (22.6)	17 (32.1)
White blood cell count decreased	12 (22.6)	1 (1.9)	11 (20.8)
Neutrophil count decreased	11 (20.8)	2 (3.8)	9 (17.0)
Platelet count decreased	11 (20.8)	5 (9.4)	6 (11.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	10 (18.9)	7 (13.2)	3 (5.7)
Lymphocyte count decreased	9 (17.0)	6 (11.3)	3 (5.7)
Blood bilirubin increased	7 (13.2)	7 (13.2)	0
Alanine aminotransferase increased	3 (5.7)	3 (5.7)	0
C-reactive protein increased	3 (5.7)	3 (5.7)	0
Metabolism and nutrition disorders			
-Total	16 (30.2)	14 (26.4)	2 (3.8)
Decreased appetite	8 (15.1)	7 (13.2)	1 (1.9)
Hypophosphataemia	6 (11.3)	6 (11.3)	0
Hypokalaemia	5 (9.4)	4 (7.5)	1 (1.9)
Hyperglycaemia	4 (7.5)	4 (7.5)	0
Hypervolaemia	4 (7.5)	4 (7.5)	0
Hypocalcaemia	3 (5.7)	3 (5.7)	0
Tumour lysis syndrome	2 (3.8)	2 (3.8)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.9)	1 (1.9)	0
Back pain	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	3 (5.7)	3 (5.7)	0
Encephalopathy	2 (3.8)	2 (3.8)	0
Seizure	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	3 (5.7)	3 (5.7)	0
Delirium	3 (5.7)	3 (5.7)	0
Renal and urinary disorders			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Acute kidney injury	3 (5.7)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (24.5)	7 (13.2)	6 (11.3)
Hypoxia	6 (11.3)	4 (7.5)	2 (3.8)
Pulmonary oedema	6 (11.3)	5 (9.4)	1 (1.9)
Respiratory failure	4 (7.5)	0	4 (7.5)
Dyspnoea	2 (3.8)	2 (3.8)	0
Tachypnoea	2 (3.8)	2 (3.8)	0
Acute respiratory distress syndrome	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	10 (18.9)	7 (13.2)	3 (5.7)
Hypotension	9 (17.0)	6 (11.3)	3 (5.7)
Hypertension	2 (3.8)	2 (3.8)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (44.0)	6 (24.0)	5 (20.0)
Blood and lymphatic system disorders			
-Total	4 (16.0)	3 (12.0)	1 (4.0)
Neutropenia	3 (12.0)	2 (8.0)	1 (4.0)
Febrile neutropenia	1 (4.0)	1 (4.0)	0
Thrombocytopenia	1 (4.0)	1 (4.0)	0
Gastrointestinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Pancreatitis	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.0)	1 (4.0)	0
Pyrexia	1 (4.0)	1 (4.0)	0
Immune system disorders			
-Total	1 (4.0)	1 (4.0)	0
Immunodeficiency	1 (4.0)	1 (4.0)	0
Investigations			
-Total	5 (20.0)	3 (12.0)	2 (8.0)
Blood uric acid increased	2 (8.0)	1 (4.0)	1 (4.0)
Blood bilirubin increased	1 (4.0)	1 (4.0)	0
Neutrophil count decreased	1 (4.0)	0	1 (4.0)
Platelet count decreased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Hypervolaemia	1 (4.0)	1 (4.0)	0
Tumour lysis syndrome	1 (4.0)	0	1 (4.0)
Renal and urinary disorders			
-Total	1 (4.0)	0	1 (4.0)
Acute kidney injury	1 (4.0)	0	1 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Acute respiratory distress syndrome	1 (4.0)	0	1 (4.0)
Hypoxia	1 (4.0)	1 (4.0)	0
Vascular disorders			
-Total	4 (16.0)	1 (4.0)	3 (12.0)
Hypotension	2 (8.0)	0	2 (8.0)
Venoocclusive disease	2 (8.0)	1 (4.0)	1 (4.0)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (38.0)	9 (18.0)	10 (20.0)
Blood and lymphatic system disorders			
-Total	5 (10.0)	2 (4.0)	3 (6.0)
Anaemia	2 (4.0)	2 (4.0)	0
Febrile neutropenia	2 (4.0)	2 (4.0)	0
Neutropenia	2 (4.0)	0	2 (4.0)
Thrombocytopenia	1 (2.0)	0	1 (2.0)
Cardiac disorders			
-Total	2 (4.0)	0	2 (4.0)
Cardiac arrest	2 (4.0)	0	2 (4.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Infections and infestations			
-Total	4 (8.0)	2 (4.0)	2 (4.0)
Parainfluenzae virus infection	2 (4.0)	1 (2.0)	1 (2.0)
Pneumonia	1 (2.0)	0	1 (2.0)
Staphylococcal bacteraemia	1 (2.0)	1 (2.0)	0
Investigations			
-Total	8 (16.0)	5 (10.0)	3 (6.0)
Neutrophil count decreased	6 (12.0)	3 (6.0)	3 (6.0)
White blood cell count decreased	4 (8.0)	3 (6.0)	1 (2.0)
Lymphocyte count decreased	2 (4.0)	2 (4.0)	0
Alanine aminotransferase increased	1 (2.0)	1 (2.0)	0
Platelet count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	3 (6.0)	2 (4.0)	1 (2.0)
Hypokalaemia	2 (4.0)	1 (2.0)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (2.0)	1 (2.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (4.0)	2 (4.0)	0
Back pain	2 (4.0)	2 (4.0)	0
Nervous system disorders			
-Total	1 (2.0)	1 (2.0)	0
Seizure	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.0)	2 (4.0)	1 (2.0)
Hypoxia	2 (4.0)	2 (4.0)	0
Respiratory failure	1 (2.0)	0	1 (2.0)
Vascular disorders			
-Total	1 (2.0)	1 (2.0)	0
Hypotension	1 (2.0)	1 (2.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (25.0)	2 (12.5)	2 (12.5)
Blood and lymphatic system disorders			
-Total	1 (6.3)	0	1 (6.3)
Neutropenia	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Diarrhoea	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (18.8)	1 (6.3)	2 (12.5)
Sepsis	2 (12.5)	0	2 (12.5)
Staphylococcal bacteraemia	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Hypoxia	1 (6.3)	1 (6.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (14.7)	1 (2.9)	4 (11.8)
Immune system disorders			
-Total	1 (2.9)	0	1 (2.9)
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)
Infections and infestations			
-Total	3 (8.8)	2 (5.9)	1 (2.9)
Pneumonia	2 (5.9)	1 (2.9)	1 (2.9)
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0
Sepsis	1 (2.9)	1 (2.9)	0
Investigations			

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	1 (2.9)
Neutrophil count decreased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Decreased appetite	1 (2.9)	0	1 (2.9)
Hyperglycaemia	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.9)	0	2 (5.9)
Dyspnoea	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)
Tachypnoea	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	1 (2.9)	1 (2.9)	0
Hypertension	1 (2.9)	1 (2.9)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (81.5)	6 (22.2)	16 (59.3)
Blood and lymphatic system disorders			
-Total	10 (37.0)	5 (18.5)	5 (18.5)
Febrile neutropenia	4 (14.8)	4 (14.8)	0
Neutropenia	4 (14.8)	1 (3.7)	3 (11.1)
Thrombocytopenia	3 (11.1)	1 (3.7)	2 (7.4)
Cardiac disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Tachycardia	2 (7.4)	1 (3.7)	1 (3.7)
Gastrointestinal disorders			
-Total	4 (14.8)	4 (14.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (7.4)	2 (7.4)	0
Pancreatitis	2 (7.4)	2 (7.4)	0
General disorders and administration site conditions			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Pyrexia	3 (11.1)	2 (7.4)	1 (3.7)
Hepatobiliary disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Hepatic function abnormal	3 (11.1)	2 (7.4)	1 (3.7)
Immune system disorders			
-Total	19 (70.4)	10 (37.0)	9 (33.3)
Cytokine release syndrome	17 (63.0)	8 (29.6)	9 (33.3)
Hypogammaglobulinaemia	3 (11.1)	3 (11.1)	0
Haemophagocytic lymphohistiocytosis	2 (7.4)	1 (3.7)	1 (3.7)
Immunodeficiency	2 (7.4)	2 (7.4)	0
Infections and infestations			
-Total	4 (14.8)	2 (7.4)	2 (7.4)
Sepsis	2 (7.4)	0	2 (7.4)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.7)	1 (3.7)	0
Staphylococcal bacteraemia	1 (3.7)	1 (3.7)	0
Investigations			
-Total	14 (51.9)	5 (18.5)	9 (33.3)
Neutrophil count decreased	6 (22.2)	0	6 (22.2)
White blood cell count decreased	6 (22.2)	1 (3.7)	5 (18.5)
Lymphocyte count decreased	4 (14.8)	2 (7.4)	2 (7.4)
Platelet count decreased	4 (14.8)	2 (7.4)	2 (7.4)
Alanine aminotransferase increased	3 (11.1)	3 (11.1)	0
Blood bilirubin increased	2 (7.4)	2 (7.4)	0
Blood creatine phosphokinase increased	2 (7.4)	1 (3.7)	1 (3.7)
Blood uric acid increased	2 (7.4)	1 (3.7)	1 (3.7)
Aspartate aminotransferase increased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	11 (40.7)	8 (29.6)	3 (11.1)
Hypokalaemia	6 (22.2)	5 (18.5)	1 (3.7)
Decreased appetite	3 (11.1)	3 (11.1)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	3 (11.1)	2 (7.4)	1 (3.7)
Tumour lysis syndrome	3 (11.1)	2 (7.4)	1 (3.7)
Hypocalcaemia	2 (7.4)	2 (7.4)	0
Hypervolaemia	1 (3.7)	1 (3.7)	0
Nervous system disorders			
-Total	2 (7.4)	2 (7.4)	0
Encephalopathy	2 (7.4)	2 (7.4)	0
Renal and urinary disorders			
-Total	5 (18.5)	1 (3.7)	4 (14.8)
Acute kidney injury	5 (18.5)	1 (3.7)	4 (14.8)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (33.3)	3 (11.1)	6 (22.2)
Hypoxia	8 (29.6)	4 (14.8)	4 (14.8)
Acute respiratory distress syndrome	2 (7.4)	0	2 (7.4)
Atelectasis	2 (7.4)	2 (7.4)	0
Tachypnoea	2 (7.4)	2 (7.4)	0
Dyspnoea	1 (3.7)	0	1 (3.7)
Pulmonary oedema	1 (3.7)	1 (3.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	8 (29.6)	2 (7.4)	6 (22.2)
Hypotension	6 (22.2)	1 (3.7)	5 (18.5)
Hypertension	2 (7.4)	2 (7.4)	0
Venoocclusive disease	2 (7.4)	1 (3.7)	1 (3.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=53	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (92.5)	13 (24.5)	36 (67.9)
Blood and lymphatic system disorders			
-Total	31 (58.5)	22 (41.5)	9 (17.0)
Febrile neutropenia	23 (43.4)	21 (39.6)	2 (3.8)
Anaemia	9 (17.0)	9 (17.0)	0
Thrombocytopenia	6 (11.3)	2 (3.8)	4 (7.5)
Neutropenia	5 (9.4)	1 (1.9)	4 (7.5)
Cardiac disorders			
-Total	7 (13.2)	4 (7.5)	3 (5.7)
Cardiac arrest	3 (5.7)	0	3 (5.7)
Left ventricular dysfunction	3 (5.7)	3 (5.7)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	8 (15.1)	7 (13.2)	1 (1.9)
Pyrexia	8 (15.1)	7 (13.2)	1 (1.9)
Immune system disorders			
-Total	26 (49.1)	13 (24.5)	13 (24.5)
Cytokine release syndrome	21 (39.6)	9 (17.0)	12 (22.6)
Hypogammaglobulinaemia	4 (7.5)	4 (7.5)	0
Haemophagocytic lymphohistiocytosis	2 (3.8)	1 (1.9)	1 (1.9)
Immunodeficiency	2 (3.8)	2 (3.8)	0
Infections and infestations			
-Total	9 (17.0)	6 (11.3)	3 (5.7)
Staphylococcal bacteraemia	4 (7.5)	4 (7.5)	0
Parainfluenzae virus infection	3 (5.7)	2 (3.8)	1 (1.9)
Pneumonia	3 (5.7)	1 (1.9)	2 (3.8)
Sepsis	1 (1.9)	1 (1.9)	0
Investigations			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (54.7)	12 (22.6)	17 (32.1)
Neutrophil count decreased	15 (28.3)	4 (7.5)	11 (20.8)
White blood cell count decreased	12 (22.6)	1 (1.9)	11 (20.8)
Lymphocyte count decreased	11 (20.8)	8 (15.1)	3 (5.7)
Platelet count decreased	11 (20.8)	5 (9.4)	6 (11.3)
Aspartate aminotransferase increased	10 (18.9)	7 (13.2)	3 (5.7)
Blood bilirubin increased	7 (13.2)	7 (13.2)	0
Alanine aminotransferase increased	4 (7.5)	4 (7.5)	0
C-reactive protein increased	3 (5.7)	3 (5.7)	0
Metabolism and nutrition disorders			
-Total	18 (34.0)	15 (28.3)	3 (5.7)
Decreased appetite	9 (17.0)	7 (13.2)	2 (3.8)
Hypophosphataemia	6 (11.3)	6 (11.3)	0
Hyperglycaemia	5 (9.4)	5 (9.4)	0
Hypokalaemia	5 (9.4)	4 (7.5)	1 (1.9)
Hypervolaemia	4 (7.5)	4 (7.5)	0
Hypocalcaemia	3 (5.7)	3 (5.7)	0
Tumour lysis syndrome	2 (3.8)	2 (3.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	3 (5.7)	3 (5.7)	0
Back pain	3 (5.7)	3 (5.7)	0
Nervous system disorders			
-Total	5 (9.4)	5 (9.4)	0
Seizure	3 (5.7)	3 (5.7)	0
Encephalopathy	2 (3.8)	2 (3.8)	0
Psychiatric disorders			
-Total	3 (5.7)	3 (5.7)	0
Delirium	3 (5.7)	3 (5.7)	0
Renal and urinary disorders			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Acute kidney injury	3 (5.7)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (34.0)	9 (17.0)	9 (17.0)
Hypoxia	8 (15.1)	6 (11.3)	2 (3.8)
Pulmonary oedema	6 (11.3)	5 (9.4)	1 (1.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	6 (11.3)	0	6 (11.3)
Dyspnoea	3 (5.7)	2 (3.8)	1 (1.9)
Tachypnoea	3 (5.7)	2 (3.8)	1 (1.9)
Acute respiratory distress syndrome	1 (1.9)	0	1 (1.9)
Vascular disorders			
-Total	12 (22.6)	9 (17.0)	3 (5.7)
Hypotension	10 (18.9)	7 (13.2)	3 (5.7)
Hypertension	3 (5.7)	3 (5.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (75.0)	7 (25.0)	14 (50.0)
Blood and lymphatic system disorders			
-Total	11 (39.3)	9 (32.1)	2 (7.1)
Febrile neutropenia	6 (21.4)	6 (21.4)	0
Anaemia	4 (14.3)	4 (14.3)	0
Neutropenia	2 (7.1)	1 (3.6)	1 (3.6)
Pancytopenia	2 (7.1)	2 (7.1)	0
Thrombocytopenia	2 (7.1)	1 (3.6)	1 (3.6)
Leukopenia	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	16 (57.1)	8 (28.6)	8 (28.6)
Cytokine release syndrome	13 (46.4)	5 (17.9)	8 (28.6)

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	4 (14.3)	4 (14.3)	0
Immunodeficiency	3 (10.7)	3 (10.7)	0
Infections and infestations			
-Total	2 (7.1)	2 (7.1)	0
Bronchopulmonary aspergillosis	1 (3.6)	1 (3.6)	0
Encephalitis viral	1 (3.6)	1 (3.6)	0
Investigations			
-Total	9 (32.1)	2 (7.1)	7 (25.0)
Lymphocyte count decreased	6 (21.4)	3 (10.7)	3 (10.7)
Neutrophil count decreased	5 (17.9)	0	5 (17.9)
White blood cell count decreased	5 (17.9)	1 (3.6)	4 (14.3)
Platelet count decreased	3 (10.7)	1 (3.6)	2 (7.1)
Alanine aminotransferase increased	2 (7.1)	2 (7.1)	0
Aspartate aminotransferase increased	1 (3.6)	1 (3.6)	0
Blood bilirubin increased	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	5 (17.9)	4 (14.3)	1 (3.6)
Hypokalaemia	3 (10.7)	3 (10.7)	0

Timing: within 8 weeks post infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	3 (10.7)	2 (7.1)	1 (3.6)
Decreased appetite	1 (3.6)	1 (3.6)	0
Hyperglycaemia	1 (3.6)	1 (3.6)	0
Hypocalcaemia	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	2 (7.1)	2 (7.1)	0
Encephalopathy	1 (3.6)	1 (3.6)	0
Seizure	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.7)	3 (10.7)	0
Pulmonary oedema	3 (10.7)	3 (10.7)	0
Vascular disorders			
-Total	2 (7.1)	2 (7.1)	0
Hypertension	1 (3.6)	1 (3.6)	0
Hypotension	1 (3.6)	1 (3.6)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (80.0)	11 (24.4)	25 (55.6)
Blood and lymphatic system disorders			
-Total	23 (51.1)	16 (35.6)	7 (15.6)
Febrile neutropenia	20 (44.4)	18 (40.0)	2 (4.4)
Thrombocytopenia	5 (11.1)	1 (2.2)	4 (8.9)
Anaemia	4 (8.9)	4 (8.9)	0
Neutropenia	2 (4.4)	0	2 (4.4)
Cardiac disorders			
-Total	8 (17.8)	5 (11.1)	3 (6.7)
Left ventricular dysfunction	3 (6.7)	3 (6.7)	0
Tachycardia	3 (6.7)	2 (4.4)	1 (2.2)
Cardiac arrest	1 (2.2)	0	1 (2.2)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (2.2)	0	1 (2.2)
General disorders and administration site conditions			
-Total	8 (17.8)	6 (13.3)	2 (4.4)
Pyrexia	8 (17.8)	6 (13.3)	2 (4.4)
Immune system disorders			
-Total	22 (48.9)	12 (26.7)	10 (22.2)
Cytokine release syndrome	20 (44.4)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	3 (6.7)	2 (4.4)	1 (2.2)
Hypogammaglobulinaemia	3 (6.7)	3 (6.7)	0
Infections and infestations			
-Total	6 (13.3)	6 (13.3)	0
Clostridium difficile infection	3 (6.7)	3 (6.7)	0
Staphylococcal bacteraemia	3 (6.7)	3 (6.7)	0
Investigations			
-Total	25 (55.6)	11 (24.4)	14 (31.1)
Aspartate aminotransferase increased	10 (22.2)	7 (15.6)	3 (6.7)
Neutrophil count decreased	9 (20.0)	2 (4.4)	7 (15.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	9 (20.0)	4 (8.9)	5 (11.1)
White blood cell count decreased	9 (20.0)	1 (2.2)	8 (17.8)
Blood bilirubin increased	8 (17.8)	8 (17.8)	0
Lymphocyte count decreased	7 (15.6)	5 (11.1)	2 (4.4)
Alanine aminotransferase increased	4 (8.9)	4 (8.9)	0
Blood creatinine increased	3 (6.7)	2 (4.4)	1 (2.2)
Blood creatine phosphokinase increased	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	21 (46.7)	16 (35.6)	5 (11.1)
Decreased appetite	10 (22.2)	9 (20.0)	1 (2.2)
Hypokalaemia	8 (17.8)	6 (13.3)	2 (4.4)
Hypophosphataemia	6 (13.3)	6 (13.3)	0
Hypervolaemia	4 (8.9)	4 (8.9)	0
Hypocalcaemia	4 (8.9)	4 (8.9)	0
Hyperglycaemia	3 (6.7)	3 (6.7)	0
Metabolic acidosis	2 (4.4)	0	2 (4.4)
Tumour lysis syndrome	2 (4.4)	2 (4.4)	0
Nervous system disorders			

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (6.7)	3 (6.7)	0
Encephalopathy	3 (6.7)	3 (6.7)	0
Psychiatric disorders			
-Total	3 (6.7)	3 (6.7)	0
Delirium	3 (6.7)	3 (6.7)	0
Renal and urinary disorders			
-Total	5 (11.1)	3 (6.7)	2 (4.4)
Acute kidney injury	5 (11.1)	3 (6.7)	2 (4.4)
Respiratory, thoracic and mediastinal disorders			
-Total	16 (35.6)	7 (15.6)	9 (20.0)
Hypoxia	9 (20.0)	6 (13.3)	3 (6.7)
Pulmonary oedema	4 (8.9)	3 (6.7)	1 (2.2)
Respiratory failure	4 (8.9)	0	4 (8.9)
Tachypnoea	4 (8.9)	4 (8.9)	0
Dyspnoea	3 (6.7)	2 (4.4)	1 (2.2)
Pleural effusion	3 (6.7)	2 (4.4)	1 (2.2)
Acute respiratory distress syndrome	2 (4.4)	0	2 (4.4)
Vascular disorders			

Timing: within 8 weeks post infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (31.1)	8 (17.8)	6 (13.3)
Hypotension	13 (28.9)	7 (15.6)	6 (13.3)
Hypertension	3 (6.7)	3 (6.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: Rest of World

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	0	4 (57.1)
Neutropenia	3 (42.9)	0	3 (42.9)
Leukopenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Hepatobiliary disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Hepatic function abnormal	3 (42.9)	2 (28.6)	1 (14.3)
Immune system disorders			
-Total	5 (71.4)	2 (28.6)	3 (42.9)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	5 (71.4)	2 (28.6)	3 (42.9)
Infections and infestations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Bacteraemia	1 (14.3)	1 (14.3)	0
Encephalitis viral	1 (14.3)	0	1 (14.3)
Meningitis bacterial	1 (14.3)	1 (14.3)	0
Pneumonia	1 (14.3)	1 (14.3)	0
Investigations			
-Total	5 (71.4)	0	5 (71.4)
White blood cell count decreased	4 (57.1)	0	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
Platelet count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Blood creatine phosphokinase increased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	2 (28.6)	0
Renal and urinary disorders			
-Total	2 (28.6)	0	2 (28.6)

Timing: within 8 weeks post infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (28.6)	0	2 (28.6)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	0	3 (42.9)
Hypoxia	3 (42.9)	0	3 (42.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (39.3)	5 (17.9)	6 (21.4)
Blood and lymphatic system disorders			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Neutropenia	2 (7.1)	1 (3.6)	1 (3.6)
Febrile neutropenia	1 (3.6)	1 (3.6)	0
Thrombocytopenia	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	1 (3.6)	1 (3.6)	0
Immunodeficiency	1 (3.6)	1 (3.6)	0
Infections and infestations			
-Total	5 (17.9)	2 (7.1)	3 (10.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (7.1)	2 (7.1)	0
Bacteraemia	1 (3.6)	0	1 (3.6)
Bronchopulmonary aspergillosis	1 (3.6)	0	1 (3.6)
Herpes zoster	1 (3.6)	1 (3.6)	0
Pneumonia	1 (3.6)	0	1 (3.6)
Staphylococcal bacteraemia	1 (3.6)	1 (3.6)	0
Investigations			
-Total	2 (7.1)	0	2 (7.1)
Neutrophil count decreased	2 (7.1)	0	2 (7.1)
White blood cell count decreased	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	1 (3.6)	1 (3.6)	0
Decreased appetite	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	1 (3.6)	1 (3.6)	0
Seizure	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.6)	0	1 (3.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (3.6)	0	1 (3.6)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (37.5)	9 (22.5)	6 (15.0)
Blood and lymphatic system disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Anaemia	2 (5.0)	2 (5.0)	0
Febrile neutropenia	2 (5.0)	2 (5.0)	0
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	2 (5.0)	0	2 (5.0)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	1 (2.5)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (5.0)	2 (5.0)	0
Pyrexia	2 (5.0)	2 (5.0)	0
Infections and infestations			
-Total	5 (12.5)	4 (10.0)	1 (2.5)
Metapneumovirus infection	3 (7.5)	3 (7.5)	0
Parainfluenzae virus infection	1 (2.5)	0	1 (2.5)
Respiratory syncytial virus infection	1 (2.5)	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	7 (17.5)	6 (15.0)	1 (2.5)
Neutrophil count decreased	4 (10.0)	3 (7.5)	1 (2.5)
Lymphocyte count decreased	2 (5.0)	2 (5.0)	0
Platelet count decreased	2 (5.0)	1 (2.5)	1 (2.5)
White blood cell count decreased	2 (5.0)	1 (2.5)	1 (2.5)
Alanine aminotransferase increased	1 (2.5)	1 (2.5)	0
Blood bilirubin increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Hypokalaemia	2 (5.0)	1 (2.5)	1 (2.5)
Hypervolaemia	1 (2.5)	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	0	1 (2.5)
Renal and urinary disorders			
-Total	1 (2.5)	0	1 (2.5)
Acute kidney injury	1 (2.5)	0	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Hypoxia	3 (7.5)	3 (7.5)	0
Acute respiratory distress syndrome	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Hypotension	2 (5.0)	1 (2.5)	1 (2.5)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	1 (14.3)	4 (57.1)
Blood and lymphatic system disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Neutropenia	3 (42.9)	1 (14.3)	2 (28.6)
Cardiac disorders			
-Total	1 (14.3)	0	1 (14.3)
Cardiac failure	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Parainfluenzae virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (14.3)	1 (14.3)	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Investigations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
White blood cell count decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)
Metabolic acidosis	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (18.2)	0	4 (18.2)
Blood and lymphatic system disorders			
-Total	1 (4.5)	0	1 (4.5)
Neutropenia	1 (4.5)	0	1 (4.5)
General disorders and administration site conditions			
-Total	1 (4.5)	1 (4.5)	0
Pyrexia	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	1 (4.5)	0	1 (4.5)
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)

Timing: >1 year post-CTL019 infusion, Region: Europe

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	4 (18.2)	1 (4.5)	3 (13.6)
Sepsis	3 (13.6)	1 (4.5)	2 (9.1)
Herpes zoster	1 (4.5)	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	0	1 (4.5)
Rhinovirus infection	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Decreased appetite	1 (4.5)	0	1 (4.5)
Hyperglycaemia	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.5)	0	1 (4.5)
Dyspnoea	1 (4.5)	0	1 (4.5)
Tachypnoea	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	1 (4.5)	1 (4.5)	0
Hypertension	1 (4.5)	1 (4.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (17.4)	3 (13.0)	1 (4.3)
Infections and infestations			
-Total	2 (8.7)	2 (8.7)	0
Pneumonia	1 (4.3)	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	1 (4.3)	1 (4.3)	0
Seizure	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (4.3)	1 (4.3)	0
Respiratory failure	1 (4.3)	0	1 (4.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: Rest of World

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	1 (20.0)	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Europe

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (85.7)	7 (25.0)	17 (60.7)
Blood and lymphatic system disorders			
-Total	14 (50.0)	11 (39.3)	3 (10.7)
Febrile neutropenia	7 (25.0)	7 (25.0)	0
Anaemia	4 (14.3)	4 (14.3)	0
Neutropenia	4 (14.3)	2 (7.1)	2 (7.1)
Thrombocytopenia	3 (10.7)	2 (7.1)	1 (3.6)
Pancytopenia	2 (7.1)	2 (7.1)	0
Leukopenia	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.6)	1 (3.6)	0
Pyrexia	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	18 (64.3)	9 (32.1)	9 (32.1)
Cytokine release syndrome	13 (46.4)	5 (17.9)	8 (28.6)
Hypogammaglobulinaemia	4 (14.3)	4 (14.3)	0
Immunodeficiency	4 (14.3)	4 (14.3)	0
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	1 (3.6)
Infections and infestations			
-Total	9 (32.1)	3 (10.7)	6 (21.4)
Sepsis	3 (10.7)	1 (3.6)	2 (7.1)
Bronchopulmonary aspergillosis	2 (7.1)	1 (3.6)	1 (3.6)
Gastroenteritis	2 (7.1)	2 (7.1)	0
Herpes zoster	2 (7.1)	2 (7.1)	0
Pneumonia	2 (7.1)	0	2 (7.1)
Bacteraemia	1 (3.6)	0	1 (3.6)
Encephalitis viral	1 (3.6)	1 (3.6)	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.6)	1 (3.6)	0
Staphylococcal bacteraemia	1 (3.6)	1 (3.6)	0
Investigations			
-Total	9 (32.1)	2 (7.1)	7 (25.0)
Lymphocyte count decreased	6 (21.4)	3 (10.7)	3 (10.7)
Neutrophil count decreased	6 (21.4)	0	6 (21.4)
White blood cell count decreased	5 (17.9)	1 (3.6)	4 (14.3)
Platelet count decreased	3 (10.7)	1 (3.6)	2 (7.1)
Alanine aminotransferase increased	2 (7.1)	2 (7.1)	0
Aspartate aminotransferase increased	1 (3.6)	1 (3.6)	0
Blood bilirubin increased	1 (3.6)	1 (3.6)	0
Metabolism and nutrition disorders			
-Total	7 (25.0)	5 (17.9)	2 (7.1)
Hypokalaemia	3 (10.7)	3 (10.7)	0
Hypophosphataemia	3 (10.7)	2 (7.1)	1 (3.6)
Decreased appetite	2 (7.1)	1 (3.6)	1 (3.6)
Hyperglycaemia	2 (7.1)	2 (7.1)	0
Hypocalcaemia	1 (3.6)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Region: Europe

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	3 (10.7)	3 (10.7)	0
Seizure	2 (7.1)	2 (7.1)	0
Encephalopathy	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (17.9)	3 (10.7)	2 (7.1)
Pulmonary oedema	3 (10.7)	3 (10.7)	0
Dyspnoea	1 (3.6)	0	1 (3.6)
Respiratory failure	1 (3.6)	0	1 (3.6)
Tachypnoea	1 (3.6)	0	1 (3.6)
Vascular disorders			
-Total	3 (10.7)	3 (10.7)	0
Hypertension	2 (7.1)	2 (7.1)	0
Hypotension	1 (3.6)	1 (3.6)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

		All patients N=45	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (86.7)	11 (24.4)	28 (62.2)
Blood and lymphatic system disorders			
-Total	24 (53.3)	17 (37.8)	7 (15.6)
Febrile neutropenia	20 (44.4)	18 (40.0)	2 (4.4)
Anaemia	5 (11.1)	5 (11.1)	0
Thrombocytopenia	5 (11.1)	1 (2.2)	4 (8.9)
Neutropenia	2 (4.4)	0	2 (4.4)
Cardiac disorders			
-Total	10 (22.2)	5 (11.1)	5 (11.1)
Cardiac arrest	3 (6.7)	0	3 (6.7)
Left ventricular dysfunction	3 (6.7)	3 (6.7)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (6.7)	2 (4.4)	1 (2.2)
Cardiac failure	2 (4.4)	1 (2.2)	1 (2.2)
General disorders and administration site conditions			
-Total	10 (22.2)	8 (17.8)	2 (4.4)
Pyrexia	10 (22.2)	8 (17.8)	2 (4.4)
Immune system disorders			
-Total	22 (48.9)	12 (26.7)	10 (22.2)
Cytokine release syndrome	20 (44.4)	10 (22.2)	10 (22.2)
Haemophagocytic lymphohistiocytosis	3 (6.7)	2 (4.4)	1 (2.2)
Hypogammaglobulinaemia	3 (6.7)	3 (6.7)	0
Infections and infestations			
-Total	10 (22.2)	9 (20.0)	1 (2.2)
Staphylococcal bacteraemia	4 (8.9)	4 (8.9)	0
Clostridium difficile infection	3 (6.7)	3 (6.7)	0
Metapneumovirus infection	3 (6.7)	3 (6.7)	0
Parainfluenzae virus infection	1 (2.2)	0	1 (2.2)
Pneumonia	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (2.2)	1 (2.2)	0
Upper respiratory tract infection	1 (2.2)	1 (2.2)	0
Investigations			
-Total	26 (57.8)	12 (26.7)	14 (31.1)
Neutrophil count decreased	12 (26.7)	4 (8.9)	8 (17.8)
Aspartate aminotransferase increased	10 (22.2)	7 (15.6)	3 (6.7)
Platelet count decreased	10 (22.2)	5 (11.1)	5 (11.1)
Lymphocyte count decreased	9 (20.0)	7 (15.6)	2 (4.4)
White blood cell count decreased	9 (20.0)	1 (2.2)	8 (17.8)
Blood bilirubin increased	8 (17.8)	8 (17.8)	0
Alanine aminotransferase increased	5 (11.1)	5 (11.1)	0
Blood creatinine increased	3 (6.7)	2 (4.4)	1 (2.2)
Blood creatine phosphokinase increased	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	21 (46.7)	15 (33.3)	6 (13.3)
Decreased appetite	10 (22.2)	9 (20.0)	1 (2.2)
Hypokalaemia	8 (17.8)	6 (13.3)	2 (4.4)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	6 (13.3)	6 (13.3)	0
Hypervolaemia	5 (11.1)	5 (11.1)	0
Hypocalcaemia	4 (8.9)	4 (8.9)	0
Hyperglycaemia	3 (6.7)	3 (6.7)	0
Tumour lysis syndrome	3 (6.7)	2 (4.4)	1 (2.2)
Metabolic acidosis	2 (4.4)	0	2 (4.4)
Nervous system disorders			
-Total	4 (8.9)	4 (8.9)	0
Encephalopathy	3 (6.7)	3 (6.7)	0
Seizure	1 (2.2)	1 (2.2)	0
Psychiatric disorders			
-Total	3 (6.7)	3 (6.7)	0
Delirium	3 (6.7)	3 (6.7)	0
Renal and urinary disorders			
-Total	6 (13.3)	3 (6.7)	3 (6.7)
Acute kidney injury	6 (13.3)	3 (6.7)	3 (6.7)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (44.4)	9 (20.0)	11 (24.4)

Timing: Any time post CTL019 infusion, Region: US

Group term Preferred term	All patients N=45 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypoxia	13 (28.9)	10 (22.2)	3 (6.7)
Respiratory failure	5 (11.1)	0	5 (11.1)
Pulmonary oedema	4 (8.9)	3 (6.7)	1 (2.2)
Tachypnoea	4 (8.9)	4 (8.9)	0
Acute respiratory distress syndrome	3 (6.7)	0	3 (6.7)
Dyspnoea	3 (6.7)	2 (4.4)	1 (2.2)
Pleural effusion	3 (6.7)	2 (4.4)	1 (2.2)
Vascular disorders			
-Total	15 (33.3)	8 (17.8)	7 (15.6)
Hypotension	14 (31.1)	7 (15.6)	7 (15.6)
Hypertension	3 (6.7)	3 (6.7)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: Rest of World

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	0	4 (57.1)
Neutropenia	3 (42.9)	0	3 (42.9)
Leukopenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	0	1 (14.3)
Cardiac failure	1 (14.3)	0	1 (14.3)
Hepatobiliary disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic function abnormal	3 (42.9)	2 (28.6)	1 (14.3)
Immune system disorders			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Cytokine release syndrome	5 (71.4)	2 (28.6)	3 (42.9)
Infections and infestations			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Upper respiratory tract infection	2 (28.6)	2 (28.6)	0
Bacteraemia	1 (14.3)	1 (14.3)	0
Encephalitis viral	1 (14.3)	0	1 (14.3)
Meningitis bacterial	1 (14.3)	1 (14.3)	0
Parainfluenzae virus infection	1 (14.3)	1 (14.3)	0
Pneumonia	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0
Investigations			
-Total	5 (71.4)	0	5 (71.4)
White blood cell count decreased	4 (57.1)	0	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
Platelet count decreased	2 (28.6)	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Region: Rest of World

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatine phosphokinase increased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Tumour lysis syndrome	2 (28.6)	2 (28.6)	0
Metabolic acidosis	1 (14.3)	0	1 (14.3)
Renal and urinary disorders			
-Total	2 (28.6)	0	2 (28.6)
Acute kidney injury	2 (28.6)	0	2 (28.6)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	0	3 (42.9)
Hypoxia	3 (42.9)	0	3 (42.9)
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
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Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (85.4)	16 (33.3)	25 (52.1)
Blood and lymphatic system disorders			
-Total	21 (43.8)	16 (33.3)	5 (10.4)
Febrile neutropenia	14 (29.2)	14 (29.2)	0
Anaemia	7 (14.6)	7 (14.6)	0
Neutropenia	4 (8.3)	1 (2.1)	3 (6.3)
Thrombocytopenia	4 (8.3)	1 (2.1)	3 (6.3)
Cardiac disorders			
-Total	1 (2.1)	1 (2.1)	0
Tachycardia	1 (2.1)	1 (2.1)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (6.3)	2 (4.2)	1 (2.1)
Pyrexia	3 (6.3)	2 (4.2)	1 (2.1)
Immune system disorders			
-Total	27 (56.3)	16 (33.3)	11 (22.9)
Cytokine release syndrome	23 (47.9)	12 (25.0)	11 (22.9)
Hypogammaglobulinaemia	5 (10.4)	5 (10.4)	0
Immunodeficiency	2 (4.2)	2 (4.2)	0
Haemophagocytic lymphohistiocytosis	1 (2.1)	1 (2.1)	0
Infections and infestations			
-Total	3 (6.3)	3 (6.3)	0
Clostridium difficile infection	1 (2.1)	1 (2.1)	0
Pneumonia	1 (2.1)	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Investigations			
-Total	20 (41.7)	5 (10.4)	15 (31.3)
Neutrophil count decreased	11 (22.9)	1 (2.1)	10 (20.8)
Platelet count decreased	10 (20.8)	5 (10.4)	5 (10.4)
White blood cell count decreased	10 (20.8)	1 (2.1)	9 (18.8)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	9 (18.8)	4 (8.3)	5 (10.4)
Alanine aminotransferase increased	4 (8.3)	4 (8.3)	0
Aspartate aminotransferase increased	4 (8.3)	2 (4.2)	2 (4.2)
Blood bilirubin increased	4 (8.3)	4 (8.3)	0
Blood creatinine increased	1 (2.1)	1 (2.1)	0
Metabolism and nutrition disorders			
-Total	15 (31.3)	12 (25.0)	3 (6.3)
Decreased appetite	7 (14.6)	6 (12.5)	1 (2.1)
Hypokalaemia	7 (14.6)	6 (12.5)	1 (2.1)
Hypophosphataemia	5 (10.4)	4 (8.3)	1 (2.1)
Hyperglycaemia	2 (4.2)	2 (4.2)	0
Hypocalcaemia	2 (4.2)	2 (4.2)	0
Tumour lysis syndrome	2 (4.2)	2 (4.2)	0
Nervous system disorders			
-Total	4 (8.3)	4 (8.3)	0
Headache	2 (4.2)	2 (4.2)	0
Encephalopathy	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	1 (2.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	1 (2.1)	0	1 (2.1)
Acute kidney injury	1 (2.1)	0	1 (2.1)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (18.8)	5 (10.4)	4 (8.3)
Hypoxia	5 (10.4)	2 (4.2)	3 (6.3)
Pulmonary oedema	4 (8.3)	4 (8.3)	0
Dyspnoea	2 (4.2)	2 (4.2)	0
Pleural effusion	1 (2.1)	0	1 (2.1)
Tachypnoea	1 (2.1)	1 (2.1)	0
Vascular disorders			
-Total	6 (12.5)	4 (8.3)	2 (4.2)
Hypotension	5 (10.4)	3 (6.3)	2 (4.2)
Hypertension	1 (2.1)	1 (2.1)	0

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Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (75.0)	4 (12.5)	20 (62.5)
Blood and lymphatic system disorders			
-Total	17 (53.1)	9 (28.1)	8 (25.0)
Febrile neutropenia	12 (37.5)	10 (31.3)	2 (6.3)
Thrombocytopenia	4 (12.5)	1 (3.1)	3 (9.4)
Neutropenia	3 (9.4)	0	3 (9.4)
Disseminated intravascular coagulation	2 (6.3)	2 (6.3)	0
Anaemia	1 (3.1)	1 (3.1)	0
Cardiac disorders			
-Total	4 (12.5)	1 (3.1)	3 (9.4)
Tachycardia	2 (6.3)	1 (3.1)	1 (3.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (3.1)	0	1 (3.1)
Cardiac failure	1 (3.1)	0	1 (3.1)
General disorders and administration site conditions			
-Total	7 (21.9)	4 (12.5)	3 (9.4)
Pyrexia	5 (15.6)	4 (12.5)	1 (3.1)
Multiple organ dysfunction syndrome	2 (6.3)	0	2 (6.3)
Immune system disorders			
-Total	16 (50.0)	6 (18.8)	10 (31.3)
Cytokine release syndrome	15 (46.9)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	2 (6.3)	1 (3.1)	1 (3.1)
Hypogammaglobulinaemia	2 (6.3)	2 (6.3)	0
Immunodeficiency	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	4 (12.5)	4 (12.5)	0
Clostridium difficile infection	2 (6.3)	2 (6.3)	0
Staphylococcal bacteraemia	2 (6.3)	2 (6.3)	0
Investigations			

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (59.4)	8 (25.0)	11 (34.4)
White blood cell count decreased	8 (25.0)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	7 (21.9)	6 (18.8)	1 (3.1)
Neutrophil count decreased	6 (18.8)	1 (3.1)	5 (15.6)
Blood bilirubin increased	5 (15.6)	5 (15.6)	0
Lymphocyte count decreased	4 (12.5)	4 (12.5)	0
Platelet count decreased	4 (12.5)	1 (3.1)	3 (9.4)
Alanine aminotransferase increased	2 (6.3)	2 (6.3)	0
Blood creatinine increased	2 (6.3)	1 (3.1)	1 (3.1)
Urine output decreased	2 (6.3)	1 (3.1)	1 (3.1)
Metabolism and nutrition disorders			
-Total	13 (40.6)	9 (28.1)	4 (12.5)
Decreased appetite	4 (12.5)	4 (12.5)	0
Hypervolaemia	4 (12.5)	4 (12.5)	0
Hypokalaemia	4 (12.5)	3 (9.4)	1 (3.1)
Hypophosphataemia	4 (12.5)	4 (12.5)	0
Hypocalcaemia	3 (9.4)	3 (9.4)	0
Acidosis	2 (6.3)	1 (3.1)	1 (3.1)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	2 (6.3)	2 (6.3)	0
Hyperglycaemia	2 (6.3)	2 (6.3)	0
Hyperkalaemia	2 (6.3)	1 (3.1)	1 (3.1)
Metabolic acidosis	2 (6.3)	0	2 (6.3)
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Nervous system disorders			
-Total	3 (9.4)	3 (9.4)	0
Encephalopathy	3 (9.4)	3 (9.4)	0
Somnolence	2 (6.3)	2 (6.3)	0
Psychiatric disorders			
-Total	3 (9.4)	3 (9.4)	0
Delirium	3 (9.4)	3 (9.4)	0
Renal and urinary disorders			
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Acute kidney injury	6 (18.8)	3 (9.4)	3 (9.4)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (40.6)	5 (15.6)	8 (25.0)
Hypoxia	7 (21.9)	4 (12.5)	3 (9.4)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	4 (12.5)	0	4 (12.5)
Pulmonary oedema	3 (9.4)	2 (6.3)	1 (3.1)
Tachypnoea	3 (9.4)	3 (9.4)	0
Acute respiratory distress syndrome	2 (6.3)	0	2 (6.3)
Pleural effusion	2 (6.3)	2 (6.3)	0
Dyspnoea	1 (3.1)	0	1 (3.1)
Vascular disorders			
-Total	10 (31.3)	6 (18.8)	4 (12.5)
Hypotension	9 (28.1)	5 (15.6)	4 (12.5)
Hypertension	3 (9.4)	3 (9.4)	0

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Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=48	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (35.4)	8 (16.7)	9 (18.8)
Blood and lymphatic system disorders			
-Total	7 (14.6)	4 (8.3)	3 (6.3)
Febrile neutropenia	3 (6.3)	3 (6.3)	0
Neutropenia	3 (6.3)	1 (2.1)	2 (4.2)
Thrombocytopenia	2 (4.2)	1 (2.1)	1 (2.1)
Anaemia	1 (2.1)	1 (2.1)	0
Disseminated intravascular coagulation	1 (2.1)	1 (2.1)	0
Cardiac disorders			
-Total	1 (2.1)	0	1 (2.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.1)	0	1 (2.1)
General disorders and administration site conditions			
-Total	2 (4.2)	2 (4.2)	0
Pyrexia	2 (4.2)	2 (4.2)	0
Infections and infestations			
-Total	5 (10.4)	5 (10.4)	0
Metapneumovirus infection	3 (6.3)	3 (6.3)	0
Upper respiratory tract infection	2 (4.2)	2 (4.2)	0
Investigations			
-Total	7 (14.6)	3 (6.3)	4 (8.3)
Neutrophil count decreased	5 (10.4)	1 (2.1)	4 (8.3)
Platelet count decreased	2 (4.2)	1 (2.1)	1 (2.1)
White blood cell count decreased	2 (4.2)	1 (2.1)	1 (2.1)
Alanine aminotransferase increased	1 (2.1)	1 (2.1)	0
Blood bilirubin increased	1 (2.1)	1 (2.1)	0
Lymphocyte count decreased	1 (2.1)	1 (2.1)	0
Metabolism and nutrition disorders			
-Total	5 (10.4)	3 (6.3)	2 (4.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (4.2)	1 (2.1)	1 (2.1)
Decreased appetite	1 (2.1)	1 (2.1)	0
Hypervolaemia	1 (2.1)	1 (2.1)	0
Tumour lysis syndrome	1 (2.1)	0	1 (2.1)
Nervous system disorders			
-Total	1 (2.1)	1 (2.1)	0
Seizure	1 (2.1)	1 (2.1)	0
Renal and urinary disorders			
-Total	1 (2.1)	0	1 (2.1)
Acute kidney injury	1 (2.1)	0	1 (2.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.3)	2 (4.2)	1 (2.1)
Hypoxia	2 (4.2)	2 (4.2)	0
Acute respiratory distress syndrome	1 (2.1)	0	1 (2.1)
Vascular disorders			
-Total	1 (2.1)	0	1 (2.1)
Hypotension	1 (2.1)	0	1 (2.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (40.7)	7 (25.9)	4 (14.8)
Blood and lymphatic system disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Neutropenia	2 (7.4)	1 (3.7)	1 (3.7)
Anaemia	1 (3.7)	1 (3.7)	0
Cardiac disorders			
-Total	2 (7.4)	0	2 (7.4)
Cardiac failure	2 (7.4)	1 (3.7)	1 (3.7)
Cardiac arrest	1 (3.7)	0	1 (3.7)
Immune system disorders			
-Total	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (3.7)	1 (3.7)	0
Infections and infestations			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Pneumonia	1 (3.7)	0	1 (3.7)
Staphylococcal bacteraemia	1 (3.7)	1 (3.7)	0
Investigations			
-Total	4 (14.8)	4 (14.8)	0
Neutrophil count decreased	2 (7.4)	2 (7.4)	0
White blood cell count decreased	2 (7.4)	2 (7.4)	0
Lymphocyte count decreased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	1 (3.7)	0	1 (3.7)
Metabolic acidosis	1 (3.7)	0	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Hypoxia	1 (3.7)	1 (3.7)	0
Respiratory failure	1 (3.7)	0	1 (3.7)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.4)	1 (3.7)	1 (3.7)
Hypotension	2 (7.4)	1 (3.7)	1 (3.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (18.2)	1 (3.0)	5 (15.2)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Neutropenia	1 (3.0)	0	1 (3.0)
General disorders and administration site conditions			
-Total	1 (3.0)	1 (3.0)	0
Pyrexia	1 (3.0)	1 (3.0)	0
Infections and infestations			
-Total	4 (12.1)	2 (6.1)	2 (6.1)
Sepsis	3 (9.1)	1 (3.0)	2 (6.1)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (3.0)	1 (3.0)	0
Investigations			
-Total	1 (3.0)	0	1 (3.0)
Neutrophil count decreased	1 (3.0)	0	1 (3.0)
Metabolism and nutrition disorders			
-Total	1 (3.0)	0	1 (3.0)
Decreased appetite	1 (3.0)	0	1 (3.0)
Nervous system disorders			
-Total	2 (6.1)	2 (6.1)	0
Headache	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.0)	0	1 (3.0)
Respiratory failure	1 (3.0)	0	1 (3.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (23.5)	3 (17.6)	1 (5.9)
General disorders and administration site conditions			
-Total	1 (5.9)	0	1 (5.9)
Multiple organ dysfunction syndrome	1 (5.9)	0	1 (5.9)
Immune system disorders			
-Total	1 (5.9)	0	1 (5.9)
Haemophagocytic lymphohistiocytosis	1 (5.9)	0	1 (5.9)
Infections and infestations			
-Total	3 (17.6)	2 (11.8)	1 (5.9)
Pneumonia	2 (11.8)	1 (5.9)	1 (5.9)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	1 (5.9)	1 (5.9)	0
Hyperglycaemia	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Dyspnoea	1 (5.9)	0	1 (5.9)
Hypoxia	1 (5.9)	1 (5.9)	0
Tachypnoea	1 (5.9)	0	1 (5.9)
Vascular disorders			
-Total	1 (5.9)	1 (5.9)	0
Hypertension	1 (5.9)	1 (5.9)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=48	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (89.6)	14 (29.2)	29 (60.4)
Blood and lymphatic system disorders			
-Total	25 (52.1)	19 (39.6)	6 (12.5)
Febrile neutropenia	15 (31.3)	15 (31.3)	0
Anaemia	7 (14.6)	7 (14.6)	0
Neutropenia	6 (12.5)	2 (4.2)	4 (8.3)
Thrombocytopenia	5 (10.4)	2 (4.2)	3 (6.3)
Disseminated intravascular coagulation	1 (2.1)	1 (2.1)	0
Cardiac disorders			
-Total	2 (4.2)	1 (2.1)	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.1)	0	1 (2.1)
Tachycardia	1 (2.1)	1 (2.1)	0
General disorders and administration site conditions			
-Total	6 (12.5)	5 (10.4)	1 (2.1)
Pyrexia	6 (12.5)	5 (10.4)	1 (2.1)
Immune system disorders			
-Total	27 (56.3)	16 (33.3)	11 (22.9)
Cytokine release syndrome	23 (47.9)	12 (25.0)	11 (22.9)
Hypogammaglobulinaemia	5 (10.4)	5 (10.4)	0
Immunodeficiency	2 (4.2)	2 (4.2)	0
Haemophagocytic lymphohistiocytosis	1 (2.1)	1 (2.1)	0
Infections and infestations			
-Total	11 (22.9)	9 (18.8)	2 (4.2)
Metapneumovirus infection	3 (6.3)	3 (6.3)	0
Sepsis	3 (6.3)	1 (2.1)	2 (4.2)
Upper respiratory tract infection	3 (6.3)	3 (6.3)	0
Clostridium difficile infection	1 (2.1)	1 (2.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.1)	1 (2.1)	0
Staphylococcal bacteraemia	1 (2.1)	1 (2.1)	0
Investigations			
-Total	21 (43.8)	6 (12.5)	15 (31.3)
Neutrophil count decreased	14 (29.2)	2 (4.2)	12 (25.0)
Platelet count decreased	11 (22.9)	6 (12.5)	5 (10.4)
Lymphocyte count decreased	10 (20.8)	5 (10.4)	5 (10.4)
White blood cell count decreased	10 (20.8)	1 (2.1)	9 (18.8)
Alanine aminotransferase increased	5 (10.4)	5 (10.4)	0
Aspartate aminotransferase increased	4 (8.3)	2 (4.2)	2 (4.2)
Blood bilirubin increased	4 (8.3)	4 (8.3)	0
Blood creatinine increased	1 (2.1)	1 (2.1)	0
Metabolism and nutrition disorders			
-Total	16 (33.3)	11 (22.9)	5 (10.4)
Decreased appetite	8 (16.7)	6 (12.5)	2 (4.2)
Hypokalaemia	7 (14.6)	6 (12.5)	1 (2.1)
Hypophosphataemia	5 (10.4)	4 (8.3)	1 (2.1)
Tumour lysis syndrome	3 (6.3)	2 (4.2)	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	2 (4.2)	2 (4.2)	0
Hypocalcaemia	2 (4.2)	2 (4.2)	0
Hypervolaemia	1 (2.1)	1 (2.1)	0
Nervous system disorders			
-Total	7 (14.6)	7 (14.6)	0
Headache	3 (6.3)	3 (6.3)	0
Seizure	3 (6.3)	3 (6.3)	0
Encephalopathy	1 (2.1)	1 (2.1)	0
Renal and urinary disorders			
-Total	2 (4.2)	0	2 (4.2)
Acute kidney injury	2 (4.2)	0	2 (4.2)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (27.1)	7 (14.6)	6 (12.5)
Hypoxia	7 (14.6)	4 (8.3)	3 (6.3)
Pulmonary oedema	4 (8.3)	4 (8.3)	0
Dyspnoea	2 (4.2)	2 (4.2)	0
Acute respiratory distress syndrome	1 (2.1)	0	1 (2.1)
Pleural effusion	1 (2.1)	0	1 (2.1)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=48		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.1)	0	1 (2.1)
Tachypnoea	1 (2.1)	1 (2.1)	0
Vascular disorders			
-Total	6 (12.5)	3 (6.3)	3 (6.3)
Hypotension	5 (10.4)	2 (4.2)	3 (6.3)
Hypertension	1 (2.1)	1 (2.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	6 (18.8)	22 (68.8)
Blood and lymphatic system disorders			
-Total	18 (56.3)	10 (31.3)	8 (25.0)
Febrile neutropenia	12 (37.5)	10 (31.3)	2 (6.3)
Thrombocytopenia	4 (12.5)	1 (3.1)	3 (9.4)
Neutropenia	3 (9.4)	0	3 (9.4)
Anaemia	2 (6.3)	2 (6.3)	0
Disseminated intravascular coagulation	2 (6.3)	2 (6.3)	0
Cardiac disorders			
-Total	6 (18.8)	1 (3.1)	5 (15.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	3 (9.4)	1 (3.1)	2 (6.3)
Cardiac arrest	2 (6.3)	0	2 (6.3)
Tachycardia	2 (6.3)	1 (3.1)	1 (3.1)
General disorders and administration site conditions			
-Total	8 (25.0)	4 (12.5)	4 (12.5)
Pyrexia	5 (15.6)	4 (12.5)	1 (3.1)
Multiple organ dysfunction syndrome	3 (9.4)	0	3 (9.4)
Immune system disorders			
-Total	18 (56.3)	7 (21.9)	11 (34.4)
Cytokine release syndrome	15 (46.9)	5 (15.6)	10 (31.3)
Haemophagocytic lymphohistiocytosis	3 (9.4)	1 (3.1)	2 (6.3)
Hypogammaglobulinaemia	2 (6.3)	2 (6.3)	0
Immunodeficiency	2 (6.3)	2 (6.3)	0
Infections and infestations			
-Total	7 (21.9)	5 (15.6)	2 (6.3)
Staphylococcal bacteraemia	4 (12.5)	4 (12.5)	0
Pneumonia	3 (9.4)	1 (3.1)	2 (6.3)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	2 (6.3)	2 (6.3)	0
Investigations			
-Total	19 (59.4)	8 (25.0)	11 (34.4)
White blood cell count decreased	8 (25.0)	1 (3.1)	7 (21.9)
Aspartate aminotransferase increased	7 (21.9)	6 (18.8)	1 (3.1)
Neutrophil count decreased	7 (21.9)	2 (6.3)	5 (15.6)
Blood bilirubin increased	5 (15.6)	5 (15.6)	0
Lymphocyte count decreased	5 (15.6)	5 (15.6)	0
Platelet count decreased	4 (12.5)	1 (3.1)	3 (9.4)
Alanine aminotransferase increased	2 (6.3)	2 (6.3)	0
Blood creatinine increased	2 (6.3)	1 (3.1)	1 (3.1)
Urine output decreased	2 (6.3)	1 (3.1)	1 (3.1)
Metabolism and nutrition disorders			
-Total	14 (43.8)	9 (28.1)	5 (15.6)
Decreased appetite	4 (12.5)	4 (12.5)	0
Hypervolaemia	4 (12.5)	4 (12.5)	0
Hypokalaemia	4 (12.5)	3 (9.4)	1 (3.1)
Hypophosphataemia	4 (12.5)	4 (12.5)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (9.4)	3 (9.4)	0
Hypocalcaemia	3 (9.4)	3 (9.4)	0
Metabolic acidosis	3 (9.4)	0	3 (9.4)
Acidosis	2 (6.3)	1 (3.1)	1 (3.1)
Hypercalcaemia	2 (6.3)	2 (6.3)	0
Hyperkalaemia	2 (6.3)	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Nervous system disorders			
-Total	3 (9.4)	3 (9.4)	0
Encephalopathy	3 (9.4)	3 (9.4)	0
Somnolence	2 (6.3)	2 (6.3)	0
Psychiatric disorders			
-Total	3 (9.4)	3 (9.4)	0
Delirium	3 (9.4)	3 (9.4)	0
Renal and urinary disorders			
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Acute kidney injury	6 (18.8)	3 (9.4)	3 (9.4)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (46.9)	5 (15.6)	10 (31.3)
Hypoxia	9 (28.1)	6 (18.8)	3 (9.4)
Respiratory failure	5 (15.6)	0	5 (15.6)
Tachypnoea	4 (12.5)	3 (9.4)	1 (3.1)
Pulmonary oedema	3 (9.4)	2 (6.3)	1 (3.1)
Acute respiratory distress syndrome	2 (6.3)	0	2 (6.3)
Dyspnoea	2 (6.3)	0	2 (6.3)
Pleural effusion	2 (6.3)	2 (6.3)	0
Vascular disorders			
-Total	13 (40.6)	8 (25.0)	5 (15.6)
Hypotension	11 (34.4)	6 (18.8)	5 (15.6)
Hypertension	4 (12.5)	4 (12.5)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (92.3)	5 (38.5)	7 (53.8)
Blood and lymphatic system disorders			
-Total	8 (61.5)	6 (46.2)	2 (15.4)
Febrile neutropenia	6 (46.2)	6 (46.2)	0
Neutropenia	2 (15.4)	0	2 (15.4)
Leukopenia	1 (7.7)	0	1 (7.7)
Cardiac disorders			
-Total	1 (7.7)	1 (7.7)	0
Left ventricular dysfunction	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	2 (15.4)	2 (15.4)	0
Abdominal pain	1 (7.7)	1 (7.7)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic colitis	1 (7.7)	1 (7.7)	0
Proctalgia	1 (7.7)	1 (7.7)	0
Hepatobiliary disorders			
-Total	1 (7.7)	0	1 (7.7)
Hepatic function abnormal	1 (7.7)	0	1 (7.7)
Immune system disorders			
-Total	6 (46.2)	5 (38.5)	1 (7.7)
Cytokine release syndrome	6 (46.2)	5 (38.5)	1 (7.7)
Infections and infestations			
-Total	3 (23.1)	3 (23.1)	0
Anal abscess	1 (7.7)	1 (7.7)	0
Pneumonia	1 (7.7)	1 (7.7)	0
Varicella zoster virus infection	1 (7.7)	1 (7.7)	0
Investigations			
-Total	9 (69.2)	3 (23.1)	6 (46.2)
Lymphocyte count decreased	6 (46.2)	4 (30.8)	2 (15.4)
Neutrophil count decreased	5 (38.5)	0	5 (38.5)
White blood cell count decreased	5 (38.5)	0	5 (38.5)
Platelet count decreased	4 (30.8)	4 (30.8)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (23.1)	3 (23.1)	0
Alanine aminotransferase increased	2 (15.4)	2 (15.4)	0
Blood bilirubin increased	2 (15.4)	2 (15.4)	0
Blood creatine phosphokinase increased	1 (7.7)	1 (7.7)	0
Haemoglobin decreased	1 (7.7)	1 (7.7)	0
Weight increased	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	5 (38.5)	5 (38.5)	0
Decreased appetite	2 (15.4)	2 (15.4)	0
Hypokalaemia	2 (15.4)	2 (15.4)	0
Hypophosphataemia	2 (15.4)	2 (15.4)	0
Hypertriglyceridaemia	1 (7.7)	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	1 (7.7)	0
Renal and urinary disorders			
-Total	1 (7.7)	0	1 (7.7)
Acute kidney injury	1 (7.7)	0	1 (7.7)
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypoxia	2 (15.4)	1 (7.7)	1 (7.7)
Vascular disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (77.6)	14 (20.9)	38 (56.7)
Blood and lymphatic system disorders			
-Total	29 (43.3)	18 (26.9)	11 (16.4)
Febrile neutropenia	20 (29.9)	18 (26.9)	2 (3.0)
Anaemia	8 (11.9)	8 (11.9)	0
Thrombocytopenia	8 (11.9)	2 (3.0)	6 (9.0)
Neutropenia	5 (7.5)	1 (1.5)	4 (6.0)
Leukopenia	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	2 (3.0)	2 (3.0)	0
Left ventricular dysfunction	2 (3.0)	2 (3.0)	0
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.5)	1 (1.5)	0
Abdominal pain	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	8 (11.9)	6 (9.0)	2 (3.0)
Pyrexia	8 (11.9)	6 (9.0)	2 (3.0)
Hepatobiliary disorders			
-Total	2 (3.0)	2 (3.0)	0
Hepatic function abnormal	2 (3.0)	2 (3.0)	0
Immune system disorders			
-Total	37 (55.2)	17 (25.4)	20 (29.9)
Cytokine release syndrome	32 (47.8)	12 (17.9)	20 (29.9)
Hypogammaglobulinaemia	7 (10.4)	7 (10.4)	0
Haemophagocytic lymphohistiocytosis	3 (4.5)	2 (3.0)	1 (1.5)
Immunodeficiency	3 (4.5)	3 (4.5)	0
Infections and infestations			
-Total	3 (4.5)	3 (4.5)	0
Staphylococcal bacteraemia	3 (4.5)	3 (4.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	29 (43.3)	10 (14.9)	19 (28.4)
White blood cell count decreased	13 (19.4)	2 (3.0)	11 (16.4)
Neutrophil count decreased	12 (17.9)	2 (3.0)	10 (14.9)
Platelet count decreased	10 (14.9)	2 (3.0)	8 (11.9)
Aspartate aminotransferase increased	8 (11.9)	5 (7.5)	3 (4.5)
Blood bilirubin increased	7 (10.4)	7 (10.4)	0
Lymphocyte count decreased	7 (10.4)	4 (6.0)	3 (4.5)
Alanine aminotransferase increased	4 (6.0)	4 (6.0)	0
Blood creatine phosphokinase increased	1 (1.5)	0	1 (1.5)
Blood immunoglobulin m decreased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	22 (32.8)	17 (25.4)	5 (7.5)
Decreased appetite	9 (13.4)	8 (11.9)	1 (1.5)
Hypokalaemia	9 (13.4)	7 (10.4)	2 (3.0)
Hypophosphataemia	7 (10.4)	6 (9.0)	1 (1.5)
Hypocalcaemia	5 (7.5)	5 (7.5)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	4 (6.0)	4 (6.0)	0
Hypervolaemia	4 (6.0)	4 (6.0)	0
Tumour lysis syndrome	3 (4.5)	3 (4.5)	0
Hypertriglyceridaemia	1 (1.5)	0	1 (1.5)
Nervous system disorders			
-Total	4 (6.0)	4 (6.0)	0
Encephalopathy	4 (6.0)	4 (6.0)	0
Renal and urinary disorders			
-Total	6 (9.0)	3 (4.5)	3 (4.5)
Acute kidney injury	6 (9.0)	3 (4.5)	3 (4.5)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (26.9)	9 (13.4)	9 (13.4)
Hypoxia	10 (14.9)	5 (7.5)	5 (7.5)
Pulmonary oedema	7 (10.4)	6 (9.0)	1 (1.5)
Respiratory failure	4 (6.0)	0	4 (6.0)
Tachypnoea	4 (6.0)	4 (6.0)	0
Dyspnoea	3 (4.5)	2 (3.0)	1 (1.5)
Vascular disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (20.9)	9 (13.4)	5 (7.5)
Hypotension	12 (17.9)	7 (10.4)	5 (7.5)
Hypertension	4 (6.0)	4 (6.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (38.5)	2 (15.4)	3 (23.1)
Blood and lymphatic system disorders			
-Total	2 (15.4)	0	2 (15.4)
Neutropenia	2 (15.4)	0	2 (15.4)
Investigations			
-Total	4 (30.8)	3 (23.1)	1 (7.7)
Neutrophil count decreased	2 (15.4)	1 (7.7)	1 (7.7)
Blood immunoglobulin a decreased	1 (7.7)	1 (7.7)	0
Blood immunoglobulin m decreased	1 (7.7)	1 (7.7)	0
White blood cell count decreased	1 (7.7)	1 (7.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (40.3)	17 (27.4)	8 (12.9)
Blood and lymphatic system disorders			
-Total	7 (11.3)	5 (8.1)	2 (3.2)
Febrile neutropenia	3 (4.8)	3 (4.8)	0
Neutropenia	3 (4.8)	2 (3.2)	1 (1.6)
Anaemia	2 (3.2)	2 (3.2)	0
Thrombocytopenia	2 (3.2)	1 (1.6)	1 (1.6)
General disorders and administration site conditions			
-Total	2 (3.2)	2 (3.2)	0
Pyrexia	2 (3.2)	2 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (1.6)	1 (1.6)	0
Immunodeficiency	1 (1.6)	1 (1.6)	0
Infections and infestations			
-Total	4 (6.5)	3 (4.8)	1 (1.6)
Upper respiratory tract infection	2 (3.2)	2 (3.2)	0
Pneumonia	1 (1.6)	0	1 (1.6)
Staphylococcal bacteraemia	1 (1.6)	1 (1.6)	0
Investigations			
-Total	9 (14.5)	6 (9.7)	3 (4.8)
Neutrophil count decreased	5 (8.1)	2 (3.2)	3 (4.8)
White blood cell count decreased	3 (4.8)	2 (3.2)	1 (1.6)
Lymphocyte count decreased	2 (3.2)	2 (3.2)	0
Platelet count decreased	2 (3.2)	1 (1.6)	1 (1.6)
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
Blood bilirubin increased	1 (1.6)	1 (1.6)	0
Weight increased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	5 (8.1)	3 (4.8)	2 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (3.2)	1 (1.6)	1 (1.6)
Decreased appetite	1 (1.6)	1 (1.6)	0
Hypervolaemia	1 (1.6)	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	1 (1.6)
Renal and urinary disorders			
-Total	1 (1.6)	0	1 (1.6)
Acute kidney injury	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (6.5)	3 (4.8)	1 (1.6)
Hypoxia	3 (4.8)	3 (4.8)	0
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
-Total	3 (4.8)	1 (1.6)	2 (3.2)
Hypotension	3 (4.8)	1 (1.6)	2 (3.2)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

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Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	2 (25.0)	1 (12.5)
Infections and infestations			
-Total	3 (37.5)	3 (37.5)	0
Ear infection	1 (12.5)	1 (12.5)	0
Staphylococcal abscess	1 (12.5)	1 (12.5)	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Laryngeal oedema	1 (12.5)	0	1 (12.5)
Skin and subcutaneous tissue disorders			

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (12.5)	1 (12.5)	0
Eczema	1 (12.5)	1 (12.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

		All patients N=42	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (21.4)	4 (9.5)	5 (11.9)
Blood and lymphatic system disorders			
-Total	1 (2.4)	0	1 (2.4)
Neutropenia	1 (2.4)	0	1 (2.4)
General disorders and administration site conditions			
-Total	1 (2.4)	1 (2.4)	0
Pyrexia	1 (2.4)	1 (2.4)	0
Immune system disorders			
-Total	1 (2.4)	0	1 (2.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (7.1)	2 (4.8)	1 (2.4)
Pneumonia	2 (4.8)	1 (2.4)	1 (2.4)
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Investigations			
-Total	1 (2.4)	0	1 (2.4)
Neutrophil count decreased	1 (2.4)	0	1 (2.4)
Metabolism and nutrition disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)
Decreased appetite	1 (2.4)	0	1 (2.4)
Hyperglycaemia	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.1)	1 (2.4)	2 (4.8)
Dyspnoea	1 (2.4)	0	1 (2.4)
Hypoxia	1 (2.4)	1 (2.4)	0
Respiratory failure	1 (2.4)	0	1 (2.4)
Tachypnoea	1 (2.4)	0	1 (2.4)
Vascular disorders			

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.4)	1 (2.4)	0
Hypertension	1 (2.4)	1 (2.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (92.3)	4 (30.8)	8 (61.5)
Blood and lymphatic system disorders			
-Total	8 (61.5)	6 (46.2)	2 (15.4)
Febrile neutropenia	6 (46.2)	6 (46.2)	0
Neutropenia	2 (15.4)	0	2 (15.4)
Leukopenia	1 (7.7)	0	1 (7.7)
Cardiac disorders			
-Total	1 (7.7)	1 (7.7)	0
Left ventricular dysfunction	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	2 (15.4)	2 (15.4)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (7.7)	1 (7.7)	0
Neutropenic colitis	1 (7.7)	1 (7.7)	0
Proctalgia	1 (7.7)	1 (7.7)	0
Hepatobiliary disorders			
-Total	1 (7.7)	0	1 (7.7)
Hepatic function abnormal	1 (7.7)	0	1 (7.7)
Immune system disorders			
-Total	6 (46.2)	5 (38.5)	1 (7.7)
Cytokine release syndrome	6 (46.2)	5 (38.5)	1 (7.7)
Infections and infestations			
-Total	4 (30.8)	4 (30.8)	0
Anal abscess	1 (7.7)	1 (7.7)	0
Ear infection	1 (7.7)	1 (7.7)	0
Pneumonia	1 (7.7)	1 (7.7)	0
Staphylococcal abscess	1 (7.7)	1 (7.7)	0
Upper respiratory tract infection	1 (7.7)	1 (7.7)	0
Varicella zoster virus infection	1 (7.7)	1 (7.7)	0
Investigations			
-Total	9 (69.2)	3 (23.1)	6 (46.2)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	6 (46.2)	4 (30.8)	2 (15.4)
Neutrophil count decreased	6 (46.2)	1 (7.7)	5 (38.5)
White blood cell count decreased	5 (38.5)	0	5 (38.5)
Platelet count decreased	4 (30.8)	4 (30.8)	0
Aspartate aminotransferase increased	3 (23.1)	3 (23.1)	0
Alanine aminotransferase increased	2 (15.4)	2 (15.4)	0
Blood bilirubin increased	2 (15.4)	2 (15.4)	0
Blood creatine phosphokinase increased	1 (7.7)	1 (7.7)	0
Blood immunoglobulin a decreased	1 (7.7)	1 (7.7)	0
Blood immunoglobulin m decreased	1 (7.7)	1 (7.7)	0
Haemoglobin decreased	1 (7.7)	1 (7.7)	0
Weight increased	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	5 (38.5)	5 (38.5)	0
Decreased appetite	2 (15.4)	2 (15.4)	0
Hypokalaemia	2 (15.4)	2 (15.4)	0
Hypophosphataemia	2 (15.4)	2 (15.4)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	1 (7.7)	1 (7.7)	0
Tumour lysis syndrome	1 (7.7)	1 (7.7)	0
Renal and urinary disorders			
-Total	1 (7.7)	0	1 (7.7)
Acute kidney injury	1 (7.7)	0	1 (7.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (23.1)	1 (7.7)	2 (15.4)
Hypoxia	2 (15.4)	1 (7.7)	1 (7.7)
Laryngeal oedema	1 (7.7)	0	1 (7.7)
Skin and subcutaneous tissue disorders			
-Total	1 (7.7)	1 (7.7)	0
Eczema	1 (7.7)	1 (7.7)	0
Vascular disorders			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Hypotension	2 (15.4)	1 (7.7)	1 (7.7)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

		All patients N=67	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (86.6)	16 (23.9)	42 (62.7)
Blood and lymphatic system disorders			
-Total	33 (49.3)	21 (31.3)	12 (17.9)
Febrile neutropenia	21 (31.3)	19 (28.4)	2 (3.0)
Anaemia	9 (13.4)	9 (13.4)	0
Thrombocytopenia	9 (13.4)	3 (4.5)	6 (9.0)
Neutropenia	7 (10.4)	2 (3.0)	5 (7.5)
Leukopenia	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	2 (3.0)	2 (3.0)	0
Left ventricular dysfunction	2 (3.0)	2 (3.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (1.5)	1 (1.5)	0
Abdominal pain	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	11 (16.4)	9 (13.4)	2 (3.0)
Pyrexia	11 (16.4)	9 (13.4)	2 (3.0)
Hepatobiliary disorders			
-Total	2 (3.0)	2 (3.0)	0
Hepatic function abnormal	2 (3.0)	2 (3.0)	0
Immune system disorders			
-Total	39 (58.2)	18 (26.9)	21 (31.3)
Cytokine release syndrome	32 (47.8)	12 (17.9)	20 (29.9)
Hypogammaglobulinaemia	7 (10.4)	7 (10.4)	0
Haemophagocytic lymphohistiocytosis	4 (6.0)	2 (3.0)	2 (3.0)
Immunodeficiency	4 (6.0)	4 (6.0)	0
Infections and infestations			
-Total	9 (13.4)	7 (10.4)	2 (3.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	5 (7.5)	5 (7.5)	0
Pneumonia	3 (4.5)	1 (1.5)	2 (3.0)
Upper respiratory tract infection	2 (3.0)	2 (3.0)	0
Investigations			
-Total	31 (46.3)	12 (17.9)	19 (28.4)
Neutrophil count decreased	15 (22.4)	3 (4.5)	12 (17.9)
White blood cell count decreased	13 (19.4)	2 (3.0)	11 (16.4)
Platelet count decreased	11 (16.4)	3 (4.5)	8 (11.9)
Lymphocyte count decreased	9 (13.4)	6 (9.0)	3 (4.5)
Aspartate aminotransferase increased	8 (11.9)	5 (7.5)	3 (4.5)
Blood bilirubin increased	7 (10.4)	7 (10.4)	0
Alanine aminotransferase increased	5 (7.5)	5 (7.5)	0
Blood creatine phosphokinase increased	1 (1.5)	0	1 (1.5)
Blood immunoglobulin m decreased	1 (1.5)	1 (1.5)	0
Weight increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	24 (35.8)	17 (25.4)	7 (10.4)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	10 (14.9)	8 (11.9)	2 (3.0)
Hypokalaemia	9 (13.4)	7 (10.4)	2 (3.0)
Hypophosphataemia	7 (10.4)	6 (9.0)	1 (1.5)
Hyperglycaemia	5 (7.5)	5 (7.5)	0
Hypervolaemia	5 (7.5)	5 (7.5)	0
Hypocalcaemia	5 (7.5)	5 (7.5)	0
Tumour lysis syndrome	4 (6.0)	3 (4.5)	1 (1.5)
Hypertriglyceridaemia	1 (1.5)	0	1 (1.5)
Nervous system disorders			
-Total	4 (6.0)	4 (6.0)	0
Encephalopathy	4 (6.0)	4 (6.0)	0
Renal and urinary disorders			
-Total	7 (10.4)	3 (4.5)	4 (6.0)
Acute kidney injury	7 (10.4)	3 (4.5)	4 (6.0)
Respiratory, thoracic and mediastinal disorders			
-Total	23 (34.3)	11 (16.4)	12 (17.9)
Hypoxia	14 (20.9)	9 (13.4)	5 (7.5)
Pulmonary oedema	7 (10.4)	6 (9.0)	1 (1.5)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	6 (9.0)	0	6 (9.0)
Tachypnoea	5 (7.5)	4 (6.0)	1 (1.5)
Dyspnoea	4 (6.0)	2 (3.0)	2 (3.0)
Vascular disorders			
-Total	17 (25.4)	10 (14.9)	7 (10.4)
Hypotension	14 (20.9)	7 (10.4)	7 (10.4)
Hypertension	5 (7.5)	5 (7.5)	0

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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=26	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (84.6)	10 (38.5)	12 (46.2)
Blood and lymphatic system disorders			
-Total	15 (57.7)	10 (38.5)	5 (19.2)
Febrile neutropenia	10 (38.5)	9 (34.6)	1 (3.8)
Thrombocytopenia	4 (15.4)	2 (7.7)	2 (7.7)
Anaemia	3 (11.5)	3 (11.5)	0
Neutropenia	3 (11.5)	1 (3.8)	2 (7.7)
Leukopenia	2 (7.7)	1 (3.8)	1 (3.8)
Pancytopenia	2 (7.7)	2 (7.7)	0
Disseminated intravascular coagulation	1 (3.8)	1 (3.8)	0
Cardiac disorders			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Tachycardia	2 (7.7)	1 (3.8)	1 (3.8)
General disorders and administration site conditions			
-Total	2 (7.7)	0	2 (7.7)
Multiple organ dysfunction syndrome	1 (3.8)	0	1 (3.8)
Pyrexia	1 (3.8)	0	1 (3.8)
Immune system disorders			
-Total	10 (38.5)	6 (23.1)	4 (15.4)
Cytokine release syndrome	7 (26.9)	3 (11.5)	4 (15.4)
Hypogammaglobulinaemia	2 (7.7)	2 (7.7)	0
Immunodeficiency	2 (7.7)	2 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (3.8)	0	1 (3.8)
Infections and infestations			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Encephalitis	1 (3.8)	0	1 (3.8)
Staphylococcal bacteraemia	1 (3.8)	1 (3.8)	0
Investigations			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (57.7)	7 (26.9)	8 (30.8)
Neutrophil count decreased	5 (19.2)	1 (3.8)	4 (15.4)
White blood cell count decreased	5 (19.2)	1 (3.8)	4 (15.4)
Lymphocyte count decreased	4 (15.4)	4 (15.4)	0
Platelet count decreased	4 (15.4)	0	4 (15.4)
C-reactive protein increased	3 (11.5)	3 (11.5)	0
Aspartate aminotransferase increased	2 (7.7)	1 (3.8)	1 (3.8)
Blood bilirubin increased	2 (7.7)	2 (7.7)	0
Serum ferritin increased	2 (7.7)	2 (7.7)	0
Alanine aminotransferase increased	1 (3.8)	1 (3.8)	0
Metabolism and nutrition disorders			
-Total	6 (23.1)	4 (15.4)	2 (7.7)
Hypokalaemia	4 (15.4)	2 (7.7)	2 (7.7)
Hypocalcaemia	2 (7.7)	2 (7.7)	0
Hypophosphataemia	2 (7.7)	2 (7.7)	0
Decreased appetite	1 (3.8)	1 (3.8)	0
Hyperglycaemia	1 (3.8)	1 (3.8)	0
Hypervolaemia	1 (3.8)	1 (3.8)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (3.8)	1 (3.8)	0
Nervous system disorders			
-Total	3 (11.5)	3 (11.5)	0
Encephalopathy	2 (7.7)	2 (7.7)	0
Seizure	1 (3.8)	1 (3.8)	0
Renal and urinary disorders			
-Total	1 (3.8)	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	1 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (19.2)	2 (7.7)	3 (11.5)
Acute respiratory distress syndrome	2 (7.7)	0	2 (7.7)
Pleural effusion	2 (7.7)	1 (3.8)	1 (3.8)
Pulmonary oedema	2 (7.7)	2 (7.7)	0
Dyspnoea	1 (3.8)	0	1 (3.8)
Hypoxia	1 (3.8)	1 (3.8)	0
Tachypnoea	1 (3.8)	1 (3.8)	0
Vascular disorders			
-Total	3 (11.5)	2 (7.7)	1 (3.8)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	3 (11.5)	2 (7.7)	1 (3.8)
Hypertension	1 (3.8)	1 (3.8)	0

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Table 219n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (79.6)	10 (18.5)	33 (61.1)
Blood and lymphatic system disorders			
-Total	24 (44.4)	16 (29.6)	8 (14.8)
Febrile neutropenia	16 (29.6)	15 (27.8)	1 (1.9)
Anaemia	5 (9.3)	5 (9.3)	0
Neutropenia	4 (7.4)	0	4 (7.4)
Thrombocytopenia	4 (7.4)	0	4 (7.4)
Disseminated intravascular coagulation	1 (1.9)	1 (1.9)	0
Cardiac disorders			
-Total	3 (5.6)	1 (1.9)	2 (3.7)
Cardiac arrest	1 (1.9)	0	1 (1.9)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (1.9)	0	1 (1.9)
Tachycardia	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	8 (14.8)	6 (11.1)	2 (3.7)
Pyrexia	7 (13.0)	6 (11.1)	1 (1.9)
Multiple organ dysfunction syndrome	1 (1.9)	0	1 (1.9)
Hepatobiliary disorders			
-Total	3 (5.6)	2 (3.7)	1 (1.9)
Hepatic function abnormal	3 (5.6)	2 (3.7)	1 (1.9)
Immune system disorders			
-Total	33 (61.1)	16 (29.6)	17 (31.5)
Cytokine release syndrome	31 (57.4)	14 (25.9)	17 (31.5)
Hypogammaglobulinaemia	5 (9.3)	5 (9.3)	0
Haemophagocytic lymphohistiocytosis	2 (3.7)	2 (3.7)	0
Immunodeficiency	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	3 (5.6)	3 (5.6)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (3.7)	2 (3.7)	0
Pneumonia	1 (1.9)	1 (1.9)	0
Investigations			
-Total	26 (48.1)	9 (16.7)	17 (31.5)
White blood cell count decreased	13 (24.1)	1 (1.9)	12 (22.2)
Neutrophil count decreased	12 (22.2)	1 (1.9)	11 (20.4)
Platelet count decreased	10 (18.5)	6 (11.1)	4 (7.4)
Aspartate aminotransferase increased	9 (16.7)	7 (13.0)	2 (3.7)
Lymphocyte count decreased	9 (16.7)	4 (7.4)	5 (9.3)
Blood bilirubin increased	7 (13.0)	7 (13.0)	0
Alanine aminotransferase increased	5 (9.3)	5 (9.3)	0
Metabolism and nutrition disorders			
-Total	22 (40.7)	18 (33.3)	4 (7.4)
Decreased appetite	10 (18.5)	9 (16.7)	1 (1.9)
Hypokalaemia	7 (13.0)	7 (13.0)	0
Hypophosphataemia	7 (13.0)	6 (11.1)	1 (1.9)
Hyperglycaemia	3 (5.6)	3 (5.6)	0
Hypervolaemia	3 (5.6)	3 (5.6)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	3 (5.6)	3 (5.6)	0
Tumour lysis syndrome	3 (5.6)	3 (5.6)	0
Metabolic acidosis	2 (3.7)	0	2 (3.7)
Nervous system disorders			
-Total	2 (3.7)	2 (3.7)	0
Encephalopathy	2 (3.7)	2 (3.7)	0
Psychiatric disorders			
-Total	3 (5.6)	3 (5.6)	0
Delirium	3 (5.6)	3 (5.6)	0
Renal and urinary disorders			
-Total	6 (11.1)	3 (5.6)	3 (5.6)
Acute kidney injury	6 (11.1)	3 (5.6)	3 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	17 (31.5)	8 (14.8)	9 (16.7)
Hypoxia	11 (20.4)	5 (9.3)	6 (11.1)
Pulmonary oedema	5 (9.3)	4 (7.4)	1 (1.9)
Respiratory failure	4 (7.4)	0	4 (7.4)
Tachypnoea	3 (5.6)	3 (5.6)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Group term Preferred term	All grades n (%)	All patients N=54 Grade 3 n (%)	Grade 4 n (%)
Dyspnoea	2 (3.7)	2 (3.7)	0
Pleural effusion	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	13 (24.1)	8 (14.8)	5 (9.3)
Hypotension	11 (20.4)	6 (11.1)	5 (9.3)
Hypertension	3 (5.6)	3 (5.6)	0

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Table 219n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (36.0)	6 (24.0)	3 (12.0)
Blood and lymphatic system disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Anaemia	1 (4.0)	1 (4.0)	0
Disseminated intravascular coagulation	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
Neutropenia	1 (4.0)	0	1 (4.0)
General disorders and administration site conditions			
-Total	1 (4.0)	1 (4.0)	0
Pyrexia	1 (4.0)	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	4 (16.0)	3 (12.0)	1 (4.0)
Respiratory syncytial virus infection	2 (8.0)	2 (8.0)	0
Upper respiratory tract infection	2 (8.0)	2 (8.0)	0
Encephalitis	1 (4.0)	0	1 (4.0)
Parainfluenzae virus infection	1 (4.0)	1 (4.0)	0
Rhinovirus infection	1 (4.0)	1 (4.0)	0
Staphylococcal bacteraemia	1 (4.0)	1 (4.0)	0
Investigations			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Neutrophil count decreased	2 (8.0)	1 (4.0)	1 (4.0)
Lymphocyte count decreased	1 (4.0)	1 (4.0)	0
Platelet count decreased	1 (4.0)	0	1 (4.0)
White blood cell count decreased	1 (4.0)	0	1 (4.0)
Metabolism and nutrition disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Decreased appetite	1 (4.0)	1 (4.0)	0
Hypokalaemia	1 (4.0)	0	1 (4.0)
Nervous system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.0)	1 (4.0)	0
Seizure	1 (4.0)	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Hypoxia	1 (4.0)	1 (4.0)	0

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Table 219n
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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (40.0)	8 (16.0)	12 (24.0)
Blood and lymphatic system disorders			
-Total	7 (14.0)	4 (8.0)	3 (6.0)
Neutropenia	4 (8.0)	2 (4.0)	2 (4.0)
Febrile neutropenia	2 (4.0)	2 (4.0)	0
Thrombocytopenia	2 (4.0)	1 (2.0)	1 (2.0)
Anaemia	1 (2.0)	1 (2.0)	0
Cardiac disorders			
-Total	3 (6.0)	0	3 (6.0)
Cardiac arrest	2 (4.0)	0	2 (4.0)
Cardiac failure	2 (4.0)	1 (2.0)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	1 (2.0)	0
Immunodeficiency	1 (2.0)	1 (2.0)	0
Infections and infestations			
-Total	2 (4.0)	0	2 (4.0)
Parainfluenzae virus infection	1 (2.0)	0	1 (2.0)
Pneumonia	1 (2.0)	0	1 (2.0)
Investigations			
-Total	8 (16.0)	5 (10.0)	3 (6.0)
Neutrophil count decreased	5 (10.0)	2 (4.0)	3 (6.0)
White blood cell count decreased	3 (6.0)	3 (6.0)	0
Alanine aminotransferase increased	1 (2.0)	1 (2.0)	0
Blood bilirubin increased	1 (2.0)	1 (2.0)	0
Lymphocyte count decreased	1 (2.0)	1 (2.0)	0
Platelet count decreased	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (8.0)	2 (4.0)	2 (4.0)
Hypervolaemia	1 (2.0)	1 (2.0)	0
Hypokalaemia	1 (2.0)	1 (2.0)	0
Metabolic acidosis	1 (2.0)	0	1 (2.0)
Tumour lysis syndrome	1 (2.0)	0	1 (2.0)
Renal and urinary disorders			
-Total	1 (2.0)	0	1 (2.0)
Acute kidney injury	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (8.0)	2 (4.0)	2 (4.0)
Hypoxia	2 (4.0)	2 (4.0)	0
Acute respiratory distress syndrome	1 (2.0)	0	1 (2.0)
Respiratory failure	1 (2.0)	0	1 (2.0)
Vascular disorders			
-Total	3 (6.0)	1 (2.0)	2 (4.0)
Hypotension	3 (6.0)	1 (2.0)	2 (4.0)

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Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (25.0)	2 (10.0)	3 (15.0)
General disorders and administration site conditions			
-Total	1 (5.0)	0	1 (5.0)
Multiple organ dysfunction syndrome	1 (5.0)	0	1 (5.0)
Immune system disorders			
-Total	1 (5.0)	0	1 (5.0)
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Pneumonia	2 (10.0)	1 (5.0)	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Investigations			
-Total	1 (5.0)	0	1 (5.0)
Neutrophil count decreased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Decreased appetite	1 (5.0)	0	1 (5.0)
Hyperglycaemia	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	0	1 (5.0)
Dyspnoea	1 (5.0)	0	1 (5.0)
Tachypnoea	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypertension	1 (5.0)	1 (5.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (16.7)	3 (10.0)	2 (6.7)
Blood and lymphatic system disorders			
-Total	1 (3.3)	0	1 (3.3)
Neutropenia	1 (3.3)	0	1 (3.3)
General disorders and administration site conditions			
-Total	1 (3.3)	1 (3.3)	0
Pyrexia	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	1 (3.3)	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	1 (3.3)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (3.3)	1 (3.3)	0
Seizure	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Hypoxia	1 (3.3)	1 (3.3)	0
Respiratory failure	1 (3.3)	0	1 (3.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=26	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (88.5)	10 (38.5)	13 (50.0)
Blood and lymphatic system disorders			
-Total	15 (57.7)	10 (38.5)	5 (19.2)
Febrile neutropenia	10 (38.5)	9 (34.6)	1 (3.8)
Thrombocytopenia	4 (15.4)	2 (7.7)	2 (7.7)
Anaemia	3 (11.5)	3 (11.5)	0
Neutropenia	3 (11.5)	1 (3.8)	2 (7.7)
Disseminated intravascular coagulation	2 (7.7)	2 (7.7)	0
Leukopenia	2 (7.7)	1 (3.8)	1 (3.8)
Pancytopenia	2 (7.7)	2 (7.7)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	2 (7.7)	1 (3.8)	1 (3.8)
Tachycardia	2 (7.7)	1 (3.8)	1 (3.8)
General disorders and administration site conditions			
-Total	4 (15.4)	1 (3.8)	3 (11.5)
Multiple organ dysfunction syndrome	2 (7.7)	0	2 (7.7)
Pyrexia	2 (7.7)	1 (3.8)	1 (3.8)
Immune system disorders			
-Total	11 (42.3)	6 (23.1)	5 (19.2)
Cytokine release syndrome	7 (26.9)	3 (11.5)	4 (15.4)
Haemophagocytic lymphohistiocytosis	2 (7.7)	0	2 (7.7)
Hypogammaglobulinaemia	2 (7.7)	2 (7.7)	0
Immunodeficiency	2 (7.7)	2 (7.7)	0
Infections and infestations			
-Total	8 (30.8)	5 (19.2)	3 (11.5)
Staphylococcal bacteraemia	3 (11.5)	3 (11.5)	0
Encephalitis	2 (7.7)	0	2 (7.7)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (7.7)	2 (7.7)	0
Pneumonia	2 (7.7)	1 (3.8)	1 (3.8)
Respiratory syncytial virus infection	2 (7.7)	2 (7.7)	0
Rhinovirus infection	2 (7.7)	2 (7.7)	0
Upper respiratory tract infection	2 (7.7)	2 (7.7)	0
Investigations			
-Total	15 (57.7)	7 (26.9)	8 (30.8)
Neutrophil count decreased	7 (26.9)	2 (7.7)	5 (19.2)
Lymphocyte count decreased	5 (19.2)	5 (19.2)	0
White blood cell count decreased	5 (19.2)	1 (3.8)	4 (15.4)
Platelet count decreased	4 (15.4)	0	4 (15.4)
C-reactive protein increased	3 (11.5)	3 (11.5)	0
Aspartate aminotransferase increased	2 (7.7)	1 (3.8)	1 (3.8)
Blood bilirubin increased	2 (7.7)	2 (7.7)	0
Serum ferritin increased	2 (7.7)	2 (7.7)	0
Alanine aminotransferase increased	1 (3.8)	1 (3.8)	0
Metabolism and nutrition disorders			
-Total	8 (30.8)	5 (19.2)	3 (11.5)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	4 (15.4)	2 (7.7)	2 (7.7)
Decreased appetite	2 (7.7)	1 (3.8)	1 (3.8)
Hyperglycaemia	2 (7.7)	2 (7.7)	0
Hypocalcaemia	2 (7.7)	2 (7.7)	0
Hypophosphataemia	2 (7.7)	2 (7.7)	0
Hypervolaemia	1 (3.8)	1 (3.8)	0
Tumour lysis syndrome	1 (3.8)	1 (3.8)	0
Nervous system disorders			
-Total	4 (15.4)	4 (15.4)	0
Encephalopathy	2 (7.7)	2 (7.7)	0
Seizure	2 (7.7)	2 (7.7)	0
Renal and urinary disorders			
-Total	1 (3.8)	0	1 (3.8)
Acute kidney injury	1 (3.8)	0	1 (3.8)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (23.1)	2 (7.7)	4 (15.4)
Acute respiratory distress syndrome	2 (7.7)	0	2 (7.7)
Dyspnoea	2 (7.7)	0	2 (7.7)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=26		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (7.7)	2 (7.7)	0
Pleural effusion	2 (7.7)	1 (3.8)	1 (3.8)
Pulmonary oedema	2 (7.7)	2 (7.7)	0
Tachypnoea	2 (7.7)	1 (3.8)	1 (3.8)
Vascular disorders			
-Total	4 (15.4)	3 (11.5)	1 (3.8)
Hypotension	3 (11.5)	2 (7.7)	1 (3.8)
Hypertension	2 (7.7)	2 (7.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (88.9)	11 (20.4)	37 (68.5)
Blood and lymphatic system disorders			
-Total	28 (51.9)	19 (35.2)	9 (16.7)
Febrile neutropenia	17 (31.5)	16 (29.6)	1 (1.9)
Anaemia	6 (11.1)	6 (11.1)	0
Neutropenia	6 (11.1)	1 (1.9)	5 (9.3)
Thrombocytopenia	5 (9.3)	1 (1.9)	4 (7.4)
Disseminated intravascular coagulation	1 (1.9)	1 (1.9)	0
Cardiac disorders			
-Total	6 (11.1)	1 (1.9)	5 (9.3)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	3 (5.6)	0	3 (5.6)
Cardiac failure	3 (5.6)	1 (1.9)	2 (3.7)
Tachycardia	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	10 (18.5)	8 (14.8)	2 (3.7)
Pyrexia	9 (16.7)	8 (14.8)	1 (1.9)
Multiple organ dysfunction syndrome	1 (1.9)	0	1 (1.9)
Hepatobiliary disorders			
-Total	3 (5.6)	2 (3.7)	1 (1.9)
Hepatic function abnormal	3 (5.6)	2 (3.7)	1 (1.9)
Immune system disorders			
-Total	34 (63.0)	17 (31.5)	17 (31.5)
Cytokine release syndrome	31 (57.4)	14 (25.9)	17 (31.5)
Hypogammaglobulinaemia	5 (9.3)	5 (9.3)	0
Haemophagocytic lymphohistiocytosis	2 (3.7)	2 (3.7)	0
Immunodeficiency	2 (3.7)	2 (3.7)	0
Infections and infestations			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (11.1)	4 (7.4)	2 (3.7)
Pneumonia	2 (3.7)	1 (1.9)	1 (1.9)
Staphylococcal bacteraemia	2 (3.7)	2 (3.7)	0
Parainfluenzae virus infection	1 (1.9)	0	1 (1.9)
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	27 (50.0)	10 (18.5)	17 (31.5)
Neutrophil count decreased	14 (25.9)	2 (3.7)	12 (22.2)
White blood cell count decreased	13 (24.1)	1 (1.9)	12 (22.2)
Platelet count decreased	11 (20.4)	7 (13.0)	4 (7.4)
Lymphocyte count decreased	10 (18.5)	5 (9.3)	5 (9.3)
Aspartate aminotransferase increased	9 (16.7)	7 (13.0)	2 (3.7)
Blood bilirubin increased	7 (13.0)	7 (13.0)	0
Alanine aminotransferase increased	6 (11.1)	6 (11.1)	0
Metabolism and nutrition disorders			
-Total	22 (40.7)	16 (29.6)	6 (11.1)
Decreased appetite	10 (18.5)	9 (16.7)	1 (1.9)
Hypokalaemia	7 (13.0)	7 (13.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	7 (13.0)	6 (11.1)	1 (1.9)
Hypervolaemia	4 (7.4)	4 (7.4)	0
Tumour lysis syndrome	4 (7.4)	3 (5.6)	1 (1.9)
Hyperglycaemia	3 (5.6)	3 (5.6)	0
Hypocalcaemia	3 (5.6)	3 (5.6)	0
Metabolic acidosis	3 (5.6)	0	3 (5.6)
Nervous system disorders			
-Total	3 (5.6)	3 (5.6)	0
Encephalopathy	2 (3.7)	2 (3.7)	0
Seizure	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	3 (5.6)	3 (5.6)	0
Delirium	3 (5.6)	3 (5.6)	0
Renal and urinary disorders			
-Total	7 (13.0)	3 (5.6)	4 (7.4)
Acute kidney injury	7 (13.0)	3 (5.6)	4 (7.4)
Respiratory, thoracic and mediastinal disorders			
-Total	22 (40.7)	10 (18.5)	12 (22.2)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	14 (25.9)	8 (14.8)	6 (11.1)
Respiratory failure	6 (11.1)	0	6 (11.1)
Pulmonary oedema	5 (9.3)	4 (7.4)	1 (1.9)
Tachypnoea	3 (5.6)	3 (5.6)	0
Dyspnoea	2 (3.7)	2 (3.7)	0
Acute respiratory distress syndrome	1 (1.9)	0	1 (1.9)
Pleural effusion	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	15 (27.8)	8 (14.8)	7 (13.0)
Hypotension	13 (24.1)	6 (11.1)	7 (13.0)
Hypertension	3 (5.6)	3 (5.6)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	5 (45.5)	3 (27.3)
Blood and lymphatic system disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Pancytopenia	1 (9.1)	1 (9.1)	0
Immune system disorders			
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Cytokine release syndrome	2 (18.2)	1 (9.1)	1 (9.1)
Hypogammaglobulinaemia	2 (18.2)	2 (18.2)	0
Investigations			
-Total	5 (45.5)	2 (18.2)	3 (27.3)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	3 (27.3)	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0
Blood bilirubin increased	1 (9.1)	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	1 (9.1)
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Gamma-glutamyltransferase increased	1 (9.1)	1 (9.1)	0
Serum ferritin increased	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	1 (9.1)	1 (9.1)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	1 (9.1)	1 (9.1)	0

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Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (84.1)	16 (23.2)	42 (60.9)
Blood and lymphatic system disorders			
-Total	36 (52.2)	24 (34.8)	12 (17.4)
Febrile neutropenia	25 (36.2)	23 (33.3)	2 (2.9)
Anaemia	8 (11.6)	8 (11.6)	0
Thrombocytopenia	8 (11.6)	2 (2.9)	6 (8.7)
Neutropenia	6 (8.7)	1 (1.4)	5 (7.2)
Disseminated intravascular coagulation	2 (2.9)	2 (2.9)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	1 (1.4)	1 (1.4)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	8 (11.6)	6 (8.7)	2 (2.9)
Pyrexia	8 (11.6)	6 (8.7)	2 (2.9)
Immune system disorders			
-Total	39 (56.5)	19 (27.5)	20 (29.0)
Cytokine release syndrome	36 (52.2)	16 (23.2)	20 (29.0)
Hypogammaglobulinaemia	5 (7.2)	5 (7.2)	0
Haemophagocytic lymphohistiocytosis	3 (4.3)	2 (2.9)	1 (1.4)
Immunodeficiency	3 (4.3)	3 (4.3)	0
Infections and infestations			
-Total	5 (7.2)	4 (5.8)	1 (1.4)
Staphylococcal bacteraemia	3 (4.3)	3 (4.3)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Pneumonia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	38 (55.1)	16 (23.2)	22 (31.9)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	17 (24.6)	2 (2.9)	15 (21.7)
Neutrophil count decreased	15 (21.7)	2 (2.9)	13 (18.8)
Aspartate aminotransferase increased	11 (15.9)	8 (11.6)	3 (4.3)
Lymphocyte count decreased	11 (15.9)	8 (11.6)	3 (4.3)
Platelet count decreased	11 (15.9)	6 (8.7)	5 (7.2)
Blood bilirubin increased	8 (11.6)	8 (11.6)	0
Alanine aminotransferase increased	5 (7.2)	5 (7.2)	0
C-reactive protein increased	2 (2.9)	2 (2.9)	0
Blood fibrinogen decreased	1 (1.4)	1 (1.4)	0
Gamma-glutamyltransferase increased	1 (1.4)	1 (1.4)	0
Serum ferritin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	26 (37.7)	23 (33.3)	3 (4.3)
Decreased appetite	11 (15.9)	10 (14.5)	1 (1.4)
Hypokalaemia	11 (15.9)	9 (13.0)	2 (2.9)
Hypophosphataemia	8 (11.6)	8 (11.6)	0
Hypocalcaemia	5 (7.2)	5 (7.2)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	4 (5.8)	4 (5.8)	0
Hypervolaemia	4 (5.8)	4 (5.8)	0
Tumour lysis syndrome	4 (5.8)	4 (5.8)	0
Nervous system disorders			
-Total	7 (10.1)	6 (8.7)	1 (1.4)
Encephalopathy	4 (5.8)	4 (5.8)	0
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Headache	1 (1.4)	1 (1.4)	0
Seizure	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (10.1)	3 (4.3)	4 (5.8)
Acute kidney injury	7 (10.1)	3 (4.3)	4 (5.8)
Respiratory, thoracic and mediastinal disorders			
-Total	20 (29.0)	10 (14.5)	10 (14.5)
Hypoxia	12 (17.4)	6 (8.7)	6 (8.7)
Pulmonary oedema	7 (10.1)	6 (8.7)	1 (1.4)
Respiratory failure	4 (5.8)	0	4 (5.8)
Tachypnoea	4 (5.8)	4 (5.8)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	3 (4.3)	2 (2.9)	1 (1.4)
Vascular disorders			
-Total	15 (21.7)	9 (13.0)	6 (8.7)
Hypotension	14 (20.3)	8 (11.6)	6 (8.7)
Hypertension	3 (4.3)	3 (4.3)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	2 (18.2)	1 (9.1)
Blood and lymphatic system disorders			
-Total	1 (9.1)	1 (9.1)	0
Disseminated intravascular coagulation	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	1 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	1 (9.1)	0
Investigations			
-Total	2 (18.2)	2 (18.2)	0
Blood uric acid increased	1 (9.1)	1 (9.1)	0
Weight decreased	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	1 (9.1)	0
Decreased appetite	1 (9.1)	1 (9.1)	0
Haemochromatosis	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Autonomic neuropathy	1 (9.1)	1 (9.1)	0
Cerebral haemorrhage	1 (9.1)	0	1 (9.1)
Seizure	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	1 (9.1)	0
Renal tubular disorder	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=64	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (42.2)	15 (23.4)	12 (18.8)
Blood and lymphatic system disorders			
-Total	9 (14.1)	5 (7.8)	4 (6.3)
Neutropenia	5 (7.8)	2 (3.1)	3 (4.7)
Febrile neutropenia	3 (4.7)	3 (4.7)	0
Anaemia	2 (3.1)	2 (3.1)	0
Thrombocytopenia	2 (3.1)	1 (1.6)	1 (1.6)
General disorders and administration site conditions			
-Total	2 (3.1)	2 (3.1)	0
Pyrexia	2 (3.1)	2 (3.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (1.6)	1 (1.6)	0
Immunodeficiency	1 (1.6)	1 (1.6)	0
Infections and infestations			
-Total	4 (6.3)	2 (3.1)	2 (3.1)
Parainfluenzae virus infection	1 (1.6)	0	1 (1.6)
Pneumonia	1 (1.6)	0	1 (1.6)
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Staphylococcal bacteraemia	1 (1.6)	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Investigations			
-Total	12 (18.8)	7 (10.9)	5 (7.8)
Neutrophil count decreased	7 (10.9)	3 (4.7)	4 (6.3)
White blood cell count decreased	4 (6.3)	3 (4.7)	1 (1.6)
Lymphocyte count decreased	2 (3.1)	2 (3.1)	0
Platelet count decreased	2 (3.1)	1 (1.6)	1 (1.6)
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
Blood bilirubin increased	1 (1.6)	1 (1.6)	0
Blood uric acid increased	1 (1.6)	0	1 (1.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (6.3)	2 (3.1)	2 (3.1)
Hypokalaemia	2 (3.1)	1 (1.6)	1 (1.6)
Hypervolaemia	1 (1.6)	1 (1.6)	0
Tumour lysis syndrome	1 (1.6)	0	1 (1.6)
Renal and urinary disorders			
-Total	1 (1.6)	0	1 (1.6)
Acute kidney injury	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (6.3)	3 (4.7)	1 (1.6)
Hypoxia	3 (4.7)	3 (4.7)	0
Respiratory failure	1 (1.6)	0	1 (1.6)
Vascular disorders			
-Total	3 (4.7)	1 (1.6)	2 (3.1)
Hypotension	3 (4.7)	1 (1.6)	2 (3.1)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (33.3)	1 (11.1)	2 (22.2)
Infections and infestations			
-Total	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	1 (11.1)	0
Investigations			
-Total	1 (11.1)	0	1 (11.1)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Decreased appetite	1 (11.1)	0	1 (11.1)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (11.1)	1 (11.1)	0
Endometriosis	1 (11.1)	1 (11.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (19.5)	4 (9.8)	4 (9.8)
Blood and lymphatic system disorders			
-Total	1 (2.4)	0	1 (2.4)
Neutropenia	1 (2.4)	0	1 (2.4)
General disorders and administration site conditions			
-Total	1 (2.4)	1 (2.4)	0
Pyrexia	1 (2.4)	1 (2.4)	0
Immune system disorders			
-Total	1 (2.4)	0	1 (2.4)
Haemophagocytic lymphohistiocytosis	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	6 (14.6)	3 (7.3)	3 (7.3)
Pneumonia	2 (4.9)	1 (2.4)	1 (2.4)
Sepsis	2 (4.9)	0	2 (4.9)
Parainfluenzae virus infection	1 (2.4)	1 (2.4)	0
Rhinovirus infection	1 (2.4)	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Upper respiratory tract infection	1 (2.4)	1 (2.4)	0
Metabolism and nutrition disorders			
-Total	1 (2.4)	1 (2.4)	0
Hyperglycaemia	1 (2.4)	1 (2.4)	0
Nervous system disorders			
-Total	2 (4.9)	2 (4.9)	0
Headache	1 (2.4)	1 (2.4)	0
Seizure	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Dyspnoea	1 (2.4)	0	1 (2.4)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (2.4)	1 (2.4)	0
Respiratory failure	1 (2.4)	0	1 (2.4)
Tachypnoea	1 (2.4)	0	1 (2.4)
Vascular disorders			
-Total	1 (2.4)	1 (2.4)	0
Hypertension	1 (2.4)	1 (2.4)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	4 (36.4)	4 (36.4)
Blood and lymphatic system disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Disseminated intravascular coagulation	1 (9.1)	1 (9.1)	0
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Pancytopenia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Pancreatitis	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	4 (36.4)	3 (27.3)	1 (9.1)
Cytokine release syndrome	2 (18.2)	1 (9.1)	1 (9.1)
Hypogammaglobulinaemia	2 (18.2)	2 (18.2)	0
Infections and infestations			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Encephalitis	1 (9.1)	0	1 (9.1)
Parainfluenzae virus infection	1 (9.1)	1 (9.1)	0
Respiratory syncytial virus infection	1 (9.1)	1 (9.1)	0
Rhinovirus infection	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0
Viral haemorrhagic cystitis	1 (9.1)	1 (9.1)	0
Investigations			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Platelet count decreased	3 (27.3)	0	3 (27.3)
Lymphocyte count decreased	2 (18.2)	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (9.1)	1 (9.1)	0
Blood fibrinogen decreased	1 (9.1)	0	1 (9.1)
Blood uric acid increased	1 (9.1)	1 (9.1)	0
C-reactive protein increased	1 (9.1)	1 (9.1)	0
Gamma-glutamyltransferase increased	1 (9.1)	1 (9.1)	0
Serum ferritin increased	1 (9.1)	1 (9.1)	0
Weight decreased	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	2 (18.2)	0	2 (18.2)
Decreased appetite	1 (9.1)	0	1 (9.1)
Haemochromatosis	1 (9.1)	1 (9.1)	0
Hypophosphataemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Autonomic neuropathy	1 (9.1)	1 (9.1)	0
Cerebral haemorrhage	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	1 (9.1)	0
Renal tubular disorder	1 (9.1)	1 (9.1)	0
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Endometriosis	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	1 (9.1)	1 (9.1)	0
Hypertension	1 (9.1)	1 (9.1)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=69	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (92.8)	18 (26.1)	46 (66.7)
Blood and lymphatic system disorders			
-Total	40 (58.0)	27 (39.1)	13 (18.8)
Febrile neutropenia	26 (37.7)	24 (34.8)	2 (2.9)
Anaemia	9 (13.0)	9 (13.0)	0
Thrombocytopenia	9 (13.0)	3 (4.3)	6 (8.7)
Neutropenia	8 (11.6)	2 (2.9)	6 (8.7)
Disseminated intravascular coagulation	2 (2.9)	2 (2.9)	0
Pancytopenia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	11 (15.9)	9 (13.0)	2 (2.9)
Pyrexia	11 (15.9)	9 (13.0)	2 (2.9)
Immune system disorders			
-Total	41 (59.4)	20 (29.0)	21 (30.4)
Cytokine release syndrome	36 (52.2)	16 (23.2)	20 (29.0)
Hypogammaglobulinaemia	5 (7.2)	5 (7.2)	0
Haemophagocytic lymphohistiocytosis	4 (5.8)	2 (2.9)	2 (2.9)
Immunodeficiency	4 (5.8)	4 (5.8)	0
Infections and infestations			
-Total	14 (20.3)	8 (11.6)	6 (8.7)
Staphylococcal bacteraemia	5 (7.2)	5 (7.2)	0
Pneumonia	4 (5.8)	2 (2.9)	2 (2.9)
Parainfluenzae virus infection	2 (2.9)	1 (1.4)	1 (1.4)
Sepsis	2 (2.9)	0	2 (2.9)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (2.9)	2 (2.9)	0
Encephalitis	1 (1.4)	0	1 (1.4)
Respiratory syncytial virus infection	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	40 (58.0)	17 (24.6)	23 (33.3)
Neutrophil count decreased	19 (27.5)	4 (5.8)	15 (21.7)
White blood cell count decreased	17 (24.6)	2 (2.9)	15 (21.7)
Lymphocyte count decreased	13 (18.8)	10 (14.5)	3 (4.3)
Platelet count decreased	12 (17.4)	7 (10.1)	5 (7.2)
Aspartate aminotransferase increased	11 (15.9)	8 (11.6)	3 (4.3)
Blood bilirubin increased	8 (11.6)	8 (11.6)	0
Alanine aminotransferase increased	6 (8.7)	6 (8.7)	0
C-reactive protein increased	2 (2.9)	2 (2.9)	0
Blood fibrinogen decreased	1 (1.4)	1 (1.4)	0
Blood uric acid increased	1 (1.4)	0	1 (1.4)
Gamma-glutamyltransferase increased	1 (1.4)	1 (1.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	27 (39.1)	23 (33.3)	4 (5.8)
Decreased appetite	11 (15.9)	10 (14.5)	1 (1.4)
Hypokalaemia	11 (15.9)	9 (13.0)	2 (2.9)
Hypophosphataemia	8 (11.6)	8 (11.6)	0
Hyperglycaemia	5 (7.2)	5 (7.2)	0
Hypervolaemia	5 (7.2)	5 (7.2)	0
Hypocalcaemia	5 (7.2)	5 (7.2)	0
Tumour lysis syndrome	5 (7.2)	4 (5.8)	1 (1.4)
Nervous system disorders			
-Total	9 (13.0)	8 (11.6)	1 (1.4)
Encephalopathy	4 (5.8)	4 (5.8)	0
Headache	2 (2.9)	2 (2.9)	0
Seizure	2 (2.9)	2 (2.9)	0
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Renal and urinary disorders			
-Total	8 (11.6)	3 (4.3)	5 (7.2)
Acute kidney injury	8 (11.6)	3 (4.3)	5 (7.2)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=69		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	25 (36.2)	12 (17.4)	13 (18.8)
Hypoxia	16 (23.2)	10 (14.5)	6 (8.7)
Pulmonary oedema	7 (10.1)	6 (8.7)	1 (1.4)
Respiratory failure	6 (8.7)	0	6 (8.7)
Tachypnoea	5 (7.2)	4 (5.8)	1 (1.4)
Dyspnoea	4 (5.8)	2 (2.9)	2 (2.9)
Vascular disorders			
-Total	18 (26.1)	10 (14.5)	8 (11.6)
Hypotension	16 (23.2)	8 (11.6)	8 (11.6)
Hypertension	4 (5.8)	4 (5.8)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders			
-Total	3 (50.0)	3 (50.0)	0
Febrile neutropenia	3 (50.0)	3 (50.0)	0
Anaemia	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	1 (16.7)	0
Tachycardia	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Abdominal compartment syndrome	1 (16.7)	0	1 (16.7)
Dysphagia	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Hepatic function abnormal	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Cytokine release syndrome	3 (50.0)	0	3 (50.0)
Hypogammaglobulinaemia	1 (16.7)	1 (16.7)	0
Investigations			
-Total	6 (100)	1 (16.7)	5 (83.3)
White blood cell count decreased	3 (50.0)	0	3 (50.0)
Blood creatinine increased	2 (33.3)	1 (16.7)	1 (16.7)
Neutrophil count decreased	2 (33.3)	0	2 (33.3)
Platelet count decreased	2 (33.3)	1 (16.7)	1 (16.7)
Urine output decreased	2 (33.3)	1 (16.7)	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood bilirubin increased	1 (16.7)	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	1 (16.7)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0
Metabolism and nutrition disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Decreased appetite	2 (33.3)	2 (33.3)	0
Hypercalcaemia	1 (16.7)	1 (16.7)	0
Hyperglycaemia	1 (16.7)	1 (16.7)	0
Hyperkalaemia	1 (16.7)	1 (16.7)	0
Hypokalaemia	1 (16.7)	1 (16.7)	0
Metabolic acidosis	1 (16.7)	0	1 (16.7)
Tumour lysis syndrome	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	1 (16.7)
Encephalopathy	1 (16.7)	1 (16.7)	0
Somnolence	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	1 (16.7)	1 (16.7)	0
Mental status changes	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Acute kidney injury	3 (50.0)	1 (16.7)	2 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Hypoxia	2 (33.3)	0	2 (33.3)
Pleural effusion	1 (16.7)	1 (16.7)	0
Tachypnoea	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Hypotension	3 (50.0)	1 (16.7)	2 (33.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=74	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (78.4)	18 (24.3)	40 (54.1)
Blood and lymphatic system disorders			
-Total	34 (45.9)	21 (28.4)	13 (17.6)
Febrile neutropenia	23 (31.1)	21 (28.4)	2 (2.7)
Thrombocytopenia	8 (10.8)	2 (2.7)	6 (8.1)
Anaemia	7 (9.5)	7 (9.5)	0
Neutropenia	7 (9.5)	1 (1.4)	6 (8.1)
Cardiac disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Tachycardia	2 (2.7)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (10.8)	6 (8.1)	2 (2.7)
Pyrexia	8 (10.8)	6 (8.1)	2 (2.7)
Hepatobiliary disorders			
-Total	2 (2.7)	2 (2.7)	0
Hepatic function abnormal	2 (2.7)	2 (2.7)	0
Immune system disorders			
-Total	39 (52.7)	21 (28.4)	18 (24.3)
Cytokine release syndrome	35 (47.3)	17 (23.0)	18 (24.3)
Hypogammaglobulinaemia	6 (8.1)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	3 (4.1)	2 (2.7)	1 (1.4)
Immunodeficiency	3 (4.1)	3 (4.1)	0
Infections and infestations			
-Total	4 (5.4)	4 (5.4)	0
Staphylococcal bacteraemia	3 (4.1)	3 (4.1)	0
Pneumonia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	33 (44.6)	12 (16.2)	21 (28.4)
Neutrophil count decreased	15 (20.3)	2 (2.7)	13 (17.6)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	15 (20.3)	2 (2.7)	13 (17.6)
Lymphocyte count decreased	13 (17.6)	8 (10.8)	5 (6.8)
Platelet count decreased	12 (16.2)	5 (6.8)	7 (9.5)
Aspartate aminotransferase increased	10 (13.5)	8 (10.8)	2 (2.7)
Blood bilirubin increased	8 (10.8)	8 (10.8)	0
Alanine aminotransferase increased	6 (8.1)	6 (8.1)	0
Blood creatine phosphokinase increased	1 (1.4)	0	1 (1.4)
Blood creatinine increased	1 (1.4)	1 (1.4)	0
Weight increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	25 (33.8)	20 (27.0)	5 (6.8)
Hypokalaemia	10 (13.5)	8 (10.8)	2 (2.7)
Decreased appetite	9 (12.2)	8 (10.8)	1 (1.4)
Hypophosphataemia	9 (12.2)	8 (10.8)	1 (1.4)
Hypocalcaemia	5 (6.8)	5 (6.8)	0
Hypervolaemia	4 (5.4)	4 (5.4)	0
Hyperglycaemia	3 (4.1)	3 (4.1)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (4.1)	3 (4.1)	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	3 (4.1)	3 (4.1)	0
Encephalopathy	3 (4.1)	3 (4.1)	0
Somnolence	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	4 (5.4)	2 (2.7)	2 (2.7)
Acute kidney injury	4 (5.4)	2 (2.7)	2 (2.7)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (24.3)	9 (12.2)	9 (12.2)
Hypoxia	10 (13.5)	6 (8.1)	4 (5.4)
Pulmonary oedema	7 (9.5)	6 (8.1)	1 (1.4)
Respiratory failure	4 (5.4)	0	4 (5.4)
Dyspnoea	3 (4.1)	2 (2.7)	1 (1.4)
Tachypnoea	3 (4.1)	3 (4.1)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)
Vascular disorders			
-Total	13 (17.6)	9 (12.2)	4 (5.4)
Hypotension	11 (14.9)	7 (9.5)	4 (5.4)
Hypertension	4 (5.4)	4 (5.4)	0

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Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	3 (60.0)	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Metapneumovirus infection	1 (20.0)	1 (20.0)	0
Investigations			
-Total	4 (80.0)	3 (60.0)	1 (20.0)
Lymphocyte count decreased	2 (40.0)	2 (40.0)	0
Neutrophil count decreased	2 (40.0)	1 (20.0)	1 (20.0)
Alanine aminotransferase increased	1 (20.0)	1 (20.0)	0
Weight increased	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Hypoxia	1 (20.0)	1 (20.0)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

		All patients N=70	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (37.1)	15 (21.4)	11 (15.7)
Blood and lymphatic system disorders			
-Total	9 (12.9)	5 (7.1)	4 (5.7)
Neutropenia	5 (7.1)	2 (2.9)	3 (4.3)
Febrile neutropenia	3 (4.3)	3 (4.3)	0
Anaemia	2 (2.9)	2 (2.9)	0
Thrombocytopenia	2 (2.9)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	2 (2.9)	2 (2.9)	0
Pyrexia	2 (2.9)	2 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (1.4)	1 (1.4)	0
Immunodeficiency	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	6 (8.6)	5 (7.1)	1 (1.4)
Metapneumovirus infection	2 (2.9)	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	2 (2.9)	0
Pneumonia	1 (1.4)	0	1 (1.4)
Staphylococcal bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	9 (12.9)	6 (8.6)	3 (4.3)
Neutrophil count decreased	5 (7.1)	2 (2.9)	3 (4.3)
White blood cell count decreased	4 (5.7)	3 (4.3)	1 (1.4)
Platelet count decreased	2 (2.9)	1 (1.4)	1 (1.4)
Blood bilirubin increased	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	6 (8.6)	3 (4.3)	3 (4.3)
Hypokalaemia	2 (2.9)	1 (1.4)	1 (1.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (1.4)	1 (1.4)	0
Hypervolaemia	1 (1.4)	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)
Tumour lysis syndrome	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	1 (1.4)	0	1 (1.4)
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	1 (1.4)	0	1 (1.4)
Acute kidney injury	1 (1.4)	0	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (4.3)	2 (2.9)	1 (1.4)
Hypoxia	2 (2.9)	2 (2.9)	0
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.3)	1 (1.4)	2 (2.9)
Hypotension	3 (4.3)	1 (1.4)	2 (2.9)

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Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	3 (75.0)	0
Infections and infestations			
-Total	2 (50.0)	2 (50.0)	0
Bronchiolitis	1 (25.0)	1 (25.0)	0
Pneumonia respiratory syncytial viral	1 (25.0)	1 (25.0)	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Obesity	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	1 (25.0)	0
Hypoxia	1 (25.0)	1 (25.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (17.4)	3 (6.5)	5 (10.9)
Blood and lymphatic system disorders			
-Total	1 (2.2)	0	1 (2.2)
Neutropenia	1 (2.2)	0	1 (2.2)
General disorders and administration site conditions			
-Total	1 (2.2)	1 (2.2)	0
Pyrexia	1 (2.2)	1 (2.2)	0
Immune system disorders			
-Total	1 (2.2)	0	1 (2.2)
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (6.5)	2 (4.3)	1 (2.2)
Pneumonia	2 (4.3)	1 (2.2)	1 (2.2)
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Investigations			
-Total	1 (2.2)	0	1 (2.2)
Neutrophil count decreased	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	2 (4.3)	1 (2.2)	1 (2.2)
Decreased appetite	1 (2.2)	0	1 (2.2)
Hyperglycaemia	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.3)	0	2 (4.3)
Dyspnoea	1 (2.2)	0	1 (2.2)
Respiratory failure	1 (2.2)	0	1 (2.2)
Tachypnoea	1 (2.2)	0	1 (2.2)
Vascular disorders			
-Total	1 (2.2)	1 (2.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=46		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	1 (2.2)	1 (2.2)	0

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Table 219p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	1 (16.7)	5 (83.3)
Blood and lymphatic system disorders			
-Total	3 (50.0)	3 (50.0)	0
Febrile neutropenia	3 (50.0)	3 (50.0)	0
Anaemia	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	1 (16.7)	0
Tachycardia	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Abdominal compartment syndrome	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Hepatic function abnormal	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Cytokine release syndrome	3 (50.0)	0	3 (50.0)
Hypogammaglobulinaemia	1 (16.7)	1 (16.7)	0
Infections and infestations			
-Total	3 (50.0)	3 (50.0)	0
Bronchiolitis	1 (16.7)	1 (16.7)	0
Metapneumovirus infection	1 (16.7)	1 (16.7)	0
Pneumonia respiratory syncytial viral	1 (16.7)	1 (16.7)	0
Upper respiratory tract infection	1 (16.7)	1 (16.7)	0
Investigations			
-Total	6 (100)	1 (16.7)	5 (83.3)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
White blood cell count decreased	3 (50.0)	0	3 (50.0)
Blood creatinine increased	2 (33.3)	1 (16.7)	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (33.3)	2 (33.3)	0
Platelet count decreased	2 (33.3)	1 (16.7)	1 (16.7)
Urine output decreased	2 (33.3)	1 (16.7)	1 (16.7)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood bilirubin increased	1 (16.7)	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	1 (16.7)	0
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0
Weight increased	1 (16.7)	1 (16.7)	0
Metabolism and nutrition disorders			
-Total	4 (66.7)	3 (50.0)	1 (16.7)
Decreased appetite	2 (33.3)	2 (33.3)	0
Hypercalcaemia	1 (16.7)	1 (16.7)	0
Hyperglycaemia	1 (16.7)	1 (16.7)	0
Hyperkalaemia	1 (16.7)	1 (16.7)	0
Hypokalaemia	1 (16.7)	1 (16.7)	0
Metabolic acidosis	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Obesity	1 (16.7)	1 (16.7)	0
Tumour lysis syndrome	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Cerebral haemorrhage	1 (16.7)	0	1 (16.7)
Encephalopathy	1 (16.7)	1 (16.7)	0
Somnolence	1 (16.7)	1 (16.7)	0
Psychiatric disorders			
-Total	1 (16.7)	1 (16.7)	0
Mental status changes	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Acute kidney injury	3 (50.0)	1 (16.7)	2 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Hypoxia	4 (66.7)	2 (33.3)	2 (33.3)
Pleural effusion	1 (16.7)	1 (16.7)	0
Tachypnoea	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Hypotension	3 (50.0)	1 (16.7)	2 (33.3)

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Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (86.5)	20 (27.0)	44 (59.5)
Blood and lymphatic system disorders			
-Total	38 (51.4)	24 (32.4)	14 (18.9)
Febrile neutropenia	24 (32.4)	22 (29.7)	2 (2.7)
Neutropenia	9 (12.2)	2 (2.7)	7 (9.5)
Thrombocytopenia	9 (12.2)	3 (4.1)	6 (8.1)
Anaemia	8 (10.8)	8 (10.8)	0
Cardiac disorders			
-Total	2 (2.7)	1 (1.4)	1 (1.4)
Tachycardia	2 (2.7)	1 (1.4)	1 (1.4)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	11 (14.9)	9 (12.2)	2 (2.7)
Pyrexia	11 (14.9)	9 (12.2)	2 (2.7)
Hepatobiliary disorders			
-Total	2 (2.7)	2 (2.7)	0
Hepatic function abnormal	2 (2.7)	2 (2.7)	0
Immune system disorders			
-Total	41 (55.4)	22 (29.7)	19 (25.7)
Cytokine release syndrome	35 (47.3)	17 (23.0)	18 (24.3)
Hypogammaglobulinaemia	6 (8.1)	6 (8.1)	0
Haemophagocytic lymphohistiocytosis	4 (5.4)	2 (2.7)	2 (2.7)
Immunodeficiency	4 (5.4)	4 (5.4)	0
Infections and infestations			
-Total	11 (14.9)	9 (12.2)	2 (2.7)
Staphylococcal bacteraemia	5 (6.8)	5 (6.8)	0
Pneumonia	4 (5.4)	2 (2.7)	2 (2.7)
Metapneumovirus infection	2 (2.7)	2 (2.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (2.7)	2 (2.7)	0
Investigations			
-Total	34 (45.9)	13 (17.6)	21 (28.4)
Neutrophil count decreased	18 (24.3)	3 (4.1)	15 (20.3)
White blood cell count decreased	15 (20.3)	2 (2.7)	13 (17.6)
Lymphocyte count decreased	13 (17.6)	8 (10.8)	5 (6.8)
Platelet count decreased	13 (17.6)	6 (8.1)	7 (9.5)
Aspartate aminotransferase increased	10 (13.5)	8 (10.8)	2 (2.7)
Blood bilirubin increased	8 (10.8)	8 (10.8)	0
Alanine aminotransferase increased	6 (8.1)	6 (8.1)	0
Blood creatine phosphokinase increased	1 (1.4)	0	1 (1.4)
Blood creatinine increased	1 (1.4)	1 (1.4)	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0
Weight increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	27 (36.5)	19 (25.7)	8 (10.8)
Decreased appetite	10 (13.5)	8 (10.8)	2 (2.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	10 (13.5)	8 (10.8)	2 (2.7)
Hypophosphataemia	9 (12.2)	8 (10.8)	1 (1.4)
Hypervolaemia	5 (6.8)	5 (6.8)	0
Hypocalcaemia	5 (6.8)	5 (6.8)	0
Hyperglycaemia	4 (5.4)	4 (5.4)	0
Tumour lysis syndrome	4 (5.4)	3 (4.1)	1 (1.4)
Metabolic acidosis	2 (2.7)	0	2 (2.7)
Hypercalcaemia	1 (1.4)	1 (1.4)	0
Hyperkalaemia	1 (1.4)	0	1 (1.4)
Nervous system disorders			
-Total	4 (5.4)	3 (4.1)	1 (1.4)
Encephalopathy	3 (4.1)	3 (4.1)	0
Cerebral haemorrhage	1 (1.4)	0	1 (1.4)
Somnolence	1 (1.4)	1 (1.4)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	5 (6.8)	2 (2.7)	3 (4.1)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	5 (6.8)	2 (2.7)	3 (4.1)
Respiratory, thoracic and mediastinal disorders			
-Total	22 (29.7)	10 (13.5)	12 (16.2)
Hypoxia	12 (16.2)	8 (10.8)	4 (5.4)
Pulmonary oedema	7 (9.5)	6 (8.1)	1 (1.4)
Respiratory failure	6 (8.1)	0	6 (8.1)
Dyspnoea	4 (5.4)	2 (2.7)	2 (2.7)
Tachypnoea	4 (5.4)	3 (4.1)	1 (1.4)
Pleural effusion	2 (2.7)	1 (1.4)	1 (1.4)
Vascular disorders			
-Total	16 (21.6)	10 (13.5)	6 (8.1)
Hypotension	13 (17.6)	7 (9.5)	6 (8.1)
Hypertension	5 (6.8)	5 (6.8)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (90.0)	12 (30.0)	24 (60.0)
Blood and lymphatic system disorders			
-Total	21 (52.5)	12 (30.0)	9 (22.5)
Febrile neutropenia	11 (27.5)	10 (25.0)	1 (2.5)
Anaemia	6 (15.0)	6 (15.0)	0
Neutropenia	6 (15.0)	1 (2.5)	5 (12.5)
Thrombocytopenia	5 (12.5)	1 (2.5)	4 (10.0)
Coagulopathy	2 (5.0)	2 (5.0)	0
Leukopenia	2 (5.0)	1 (2.5)	1 (2.5)
Pancytopenia	2 (5.0)	2 (5.0)	0
Lymphopenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.5)	1 (2.5)	0
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	2 (5.0)	2 (5.0)	0
Nausea	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Pyrexia	4 (10.0)	3 (7.5)	1 (2.5)
Pain	1 (2.5)	1 (2.5)	0
Hepatobiliary disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	3 (7.5)	2 (5.0)	1 (2.5)
Immune system disorders			
-Total	24 (60.0)	14 (35.0)	10 (25.0)
Cytokine release syndrome	20 (50.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	6 (15.0)	6 (15.0)	0
Immunodeficiency	3 (7.5)	3 (7.5)	0
Infections and infestations			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (17.5)	6 (15.0)	1 (2.5)
Encephalitis viral	2 (5.0)	1 (2.5)	1 (2.5)
Staphylococcal infection	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	1 (2.5)	0
Bronchopulmonary aspergillosis	1 (2.5)	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0
Investigations			
-Total	20 (50.0)	6 (15.0)	14 (35.0)
Neutrophil count decreased	10 (25.0)	1 (2.5)	9 (22.5)
White blood cell count decreased	10 (25.0)	1 (2.5)	9 (22.5)
Platelet count decreased	8 (20.0)	4 (10.0)	4 (10.0)
Lymphocyte count decreased	6 (15.0)	3 (7.5)	3 (7.5)
Alanine aminotransferase increased	3 (7.5)	3 (7.5)	0
Aspartate aminotransferase increased	3 (7.5)	2 (5.0)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gamma-glutamyltransferase increased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	1 (2.5)	1 (2.5)	0
C-reactive protein increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	10 (25.0)	9 (22.5)	1 (2.5)
Hypokalaemia	5 (12.5)	5 (12.5)	0
Decreased appetite	3 (7.5)	2 (5.0)	1 (2.5)
Hypophosphataemia	3 (7.5)	3 (7.5)	0
Hyperglycaemia	2 (5.0)	2 (5.0)	0
Tumour lysis syndrome	2 (5.0)	2 (5.0)	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	1 (2.5)	0
Back pain	1 (2.5)	1 (2.5)	0
Nervous system disorders			
-Total	3 (7.5)	3 (7.5)	0
Encephalopathy	1 (2.5)	1 (2.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (2.5)	1 (2.5)	0
Seizure	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Hypoxia	5 (12.5)	2 (5.0)	3 (7.5)
Pulmonary oedema	4 (10.0)	4 (10.0)	0
Dyspnoea	2 (5.0)	2 (5.0)	0
Tachypnoea	2 (5.0)	2 (5.0)	0
Vascular disorders			
-Total	3 (7.5)	3 (7.5)	0
Hypotension	3 (7.5)	3 (7.5)	0

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Table 219q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (77.5)	10 (25.0)	21 (52.5)
Blood and lymphatic system disorders			
-Total	18 (45.0)	14 (35.0)	4 (10.0)
Febrile neutropenia	15 (37.5)	14 (35.0)	1 (2.5)
Thrombocytopenia	3 (7.5)	1 (2.5)	2 (5.0)
Anaemia	2 (5.0)	2 (5.0)	0
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Neutropenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	7 (17.5)	4 (10.0)	3 (7.5)
Tachycardia	3 (7.5)	2 (5.0)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	2 (5.0)	2 (5.0)	0
Cardiac arrest	1 (2.5)	0	1 (2.5)
Cardiac failure	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	2 (5.0)	2 (5.0)	0
Diarrhoea	1 (2.5)	1 (2.5)	0
Pancreatitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	6 (15.0)	3 (7.5)	3 (7.5)
Pyrexia	4 (10.0)	3 (7.5)	1 (2.5)
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Immune system disorders			
-Total	19 (47.5)	8 (20.0)	11 (27.5)
Cytokine release syndrome	18 (45.0)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	3 (7.5)	2 (5.0)	1 (2.5)
Hypogammaglobulinaemia	1 (2.5)	1 (2.5)	0
Infections and infestations			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.5)	5 (12.5)	0
Staphylococcal bacteraemia	3 (7.5)	3 (7.5)	0
Clostridium difficile infection	2 (5.0)	2 (5.0)	0
Investigations			
-Total	24 (60.0)	11 (27.5)	13 (32.5)
Aspartate aminotransferase increased	8 (20.0)	6 (15.0)	2 (5.0)
Blood bilirubin increased	8 (20.0)	8 (20.0)	0
White blood cell count decreased	8 (20.0)	1 (2.5)	7 (17.5)
Lymphocyte count decreased	7 (17.5)	5 (12.5)	2 (5.0)
Neutrophil count decreased	7 (17.5)	1 (2.5)	6 (15.0)
Platelet count decreased	6 (15.0)	2 (5.0)	4 (10.0)
Alanine aminotransferase increased	3 (7.5)	3 (7.5)	0
Blood creatinine increased	3 (7.5)	2 (5.0)	1 (2.5)
Blood fibrinogen decreased	2 (5.0)	1 (2.5)	1 (2.5)
C-reactive protein increased	2 (5.0)	2 (5.0)	0
Electrocardiogram qt prolonged	2 (5.0)	1 (2.5)	1 (2.5)
Serum ferritin increased	2 (5.0)	2 (5.0)	0
Urine output decreased	2 (5.0)	1 (2.5)	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	18 (45.0)	12 (30.0)	6 (15.0)
Decreased appetite	8 (20.0)	8 (20.0)	0
Hypokalaemia	6 (15.0)	4 (10.0)	2 (5.0)
Hypophosphataemia	6 (15.0)	5 (12.5)	1 (2.5)
Hypervolaemia	4 (10.0)	4 (10.0)	0
Hypocalcaemia	4 (10.0)	4 (10.0)	0
Hypercalcaemia	2 (5.0)	2 (5.0)	0
Hyperglycaemia	2 (5.0)	2 (5.0)	0
Hyperkalaemia	2 (5.0)	1 (2.5)	1 (2.5)
Hypertriglyceridaemia	2 (5.0)	1 (2.5)	1 (2.5)
Metabolic acidosis	2 (5.0)	0	2 (5.0)
Tumour lysis syndrome	2 (5.0)	2 (5.0)	0
Hypernatraemia	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	4 (10.0)	4 (10.0)	0
Encephalopathy	3 (7.5)	3 (7.5)	0
Somnolence	2 (5.0)	2 (5.0)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	3 (7.5)	3 (7.5)	0
Delirium	3 (7.5)	3 (7.5)	0
Renal and urinary disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Acute kidney injury	4 (10.0)	2 (5.0)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (32.5)	4 (10.0)	9 (22.5)
Hypoxia	7 (17.5)	4 (10.0)	3 (7.5)
Respiratory failure	4 (10.0)	0	4 (10.0)
Pleural effusion	3 (7.5)	2 (5.0)	1 (2.5)
Pulmonary oedema	3 (7.5)	2 (5.0)	1 (2.5)
Acute respiratory distress syndrome	2 (5.0)	0	2 (5.0)
Atelectasis	2 (5.0)	2 (5.0)	0
Tachypnoea	2 (5.0)	2 (5.0)	0
Dyspnoea	1 (2.5)	0	1 (2.5)
Respiratory distress	1 (2.5)	0	1 (2.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	13 (32.5)	7 (17.5)	6 (15.0)
Hypotension	11 (27.5)	5 (12.5)	6 (15.0)
Hypertension	4 (10.0)	4 (10.0)	0

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (50.0)	7 (17.5)	13 (32.5)
Blood and lymphatic system disorders			
-Total	7 (17.5)	3 (7.5)	4 (10.0)
Neutropenia	5 (12.5)	2 (5.0)	3 (7.5)
Disseminated intravascular coagulation	1 (2.5)	1 (2.5)	0
Febrile neutropenia	1 (2.5)	1 (2.5)	0
Lymphopenia	1 (2.5)	1 (2.5)	0
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	2 (5.0)	0	2 (5.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (2.5)	0	1 (2.5)
Cardiac failure	1 (2.5)	0	1 (2.5)
General disorders and administration site conditions			
-Total	1 (2.5)	1 (2.5)	0
Pain	1 (2.5)	1 (2.5)	0
Immune system disorders			
-Total	1 (2.5)	1 (2.5)	0
Immunodeficiency	1 (2.5)	1 (2.5)	0
Infections and infestations			
-Total	10 (25.0)	6 (15.0)	4 (10.0)
Gastroenteritis	2 (5.0)	2 (5.0)	0
Parainfluenzae virus infection	2 (5.0)	1 (2.5)	1 (2.5)
Bacteraemia	1 (2.5)	0	1 (2.5)
Bronchopulmonary aspergillosis	1 (2.5)	0	1 (2.5)
Herpes zoster	1 (2.5)	1 (2.5)	0
Human herpesvirus 6 infection	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	0	1 (2.5)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (2.5)	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	6 (15.0)	3 (7.5)	3 (7.5)
Neutrophil count decreased	5 (12.5)	2 (5.0)	3 (7.5)
White blood cell count decreased	3 (7.5)	3 (7.5)	0
Alanine aminotransferase increased	1 (2.5)	1 (2.5)	0
Lymphocyte count decreased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Decreased appetite	1 (2.5)	1 (2.5)	0
Hypokalaemia	1 (2.5)	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	1 (2.5)	0
Back pain	1 (2.5)	1 (2.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (2.5)	1 (2.5)	0
Seizure	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Hypoxia	2 (5.0)	2 (5.0)	0
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypotension	1 (2.5)	0	1 (2.5)

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Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (37.1)	8 (22.9)	5 (14.3)
Blood and lymphatic system disorders			
-Total	3 (8.6)	3 (8.6)	0
Anaemia	2 (5.7)	2 (5.7)	0
Febrile neutropenia	2 (5.7)	2 (5.7)	0
Thrombocytopenia	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	1 (2.9)	0	1 (2.9)
Cardiac arrest	1 (2.9)	0	1 (2.9)
Cardiac failure	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	1 (2.9)	0
Pancreatitis	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	2 (5.7)	2 (5.7)	0
Pyrexia	2 (5.7)	2 (5.7)	0
Infections and infestations			
-Total	5 (14.3)	3 (8.6)	2 (5.7)
Metapneumovirus infection	2 (5.7)	2 (5.7)	0
Pneumocystis jirovecii pneumonia	2 (5.7)	1 (2.9)	1 (2.9)
Septic shock	1 (2.9)	0	1 (2.9)
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Investigations			
-Total	8 (22.9)	6 (17.1)	2 (5.7)
Blood uric acid increased	2 (5.7)	1 (2.9)	1 (2.9)
Neutrophil count decreased	2 (5.7)	1 (2.9)	1 (2.9)
Platelet count decreased	2 (5.7)	1 (2.9)	1 (2.9)
Blood bilirubin increased	1 (2.9)	1 (2.9)	0
Lymphocyte count decreased	1 (2.9)	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (2.9)	1 (2.9)	0
White blood cell count decreased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	3 (8.6)	1 (2.9)	2 (5.7)
Hypervolaemia	1 (2.9)	1 (2.9)	0
Hypokalaemia	1 (2.9)	0	1 (2.9)
Tumour lysis syndrome	1 (2.9)	0	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Back pain	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (8.6)	1 (2.9)	2 (5.7)
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Hypoxia	1 (2.9)	1 (2.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Hypotension	2 (5.7)	1 (2.9)	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (16.7)	1 (3.3)	4 (13.3)
Blood and lymphatic system disorders			
-Total	1 (3.3)	0	1 (3.3)
Neutropenia	1 (3.3)	0	1 (3.3)
General disorders and administration site conditions			
-Total	1 (3.3)	0	1 (3.3)
Multiple organ dysfunction syndrome	1 (3.3)	0	1 (3.3)
Immune system disorders			
-Total	1 (3.3)	0	1 (3.3)
Haemophagocytic lymphohistiocytosis	1 (3.3)	0	1 (3.3)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	4 (13.3)	2 (6.7)	2 (6.7)
Sepsis	2 (6.7)	1 (3.3)	1 (3.3)
Herpes zoster	1 (3.3)	1 (3.3)	0
Parainfluenzae virus infection	1 (3.3)	1 (3.3)	0
Pneumonia	1 (3.3)	0	1 (3.3)
Rhinovirus infection	1 (3.3)	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Investigations			
-Total	1 (3.3)	0	1 (3.3)
Neutrophil count decreased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Decreased appetite	1 (3.3)	0	1 (3.3)
Hyperglycaemia	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.3)	0	1 (3.3)
Dyspnoea	1 (3.3)	0	1 (3.3)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	1 (3.3)	1 (3.3)	0
Hypertension	1 (3.3)	1 (3.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (25.0)	3 (15.0)	2 (10.0)
Gastrointestinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	1 (5.0)	1 (5.0)	0
Pyrexia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Pneumonia	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (5.0)	0	1 (5.0)
Septic shock	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypernatraemia	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Headache	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypoxia	1 (5.0)	1 (5.0)	0
Respiratory failure	1 (5.0)	0	1 (5.0)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	12 (30.0)	26 (65.0)
Blood and lymphatic system disorders			
-Total	23 (57.5)	13 (32.5)	10 (25.0)
Febrile neutropenia	11 (27.5)	10 (25.0)	1 (2.5)
Neutropenia	8 (20.0)	2 (5.0)	6 (15.0)
Anaemia	6 (15.0)	6 (15.0)	0
Thrombocytopenia	5 (12.5)	1 (2.5)	4 (10.0)
Coagulopathy	2 (5.0)	2 (5.0)	0
Leukopenia	2 (5.0)	1 (2.5)	1 (2.5)
Lymphopenia	2 (5.0)	2 (5.0)	0
Pancytopenia	2 (5.0)	2 (5.0)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated intravascular coagulation	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Cardiac arrest	1 (2.5)	0	1 (2.5)
Cardiac failure	1 (2.5)	0	1 (2.5)
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	2 (5.0)	2 (5.0)	0
Nausea	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
-Total	5 (12.5)	3 (7.5)	2 (5.0)
Pyrexia	4 (10.0)	3 (7.5)	1 (2.5)
Pain	2 (5.0)	2 (5.0)	0
Multiple organ dysfunction syndrome	1 (2.5)	0	1 (2.5)
Hepatobiliary disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Hepatic function abnormal	3 (7.5)	2 (5.0)	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	26 (65.0)	15 (37.5)	11 (27.5)
Cytokine release syndrome	20 (50.0)	10 (25.0)	10 (25.0)
Hypogammaglobulinaemia	6 (15.0)	6 (15.0)	0
Immunodeficiency	4 (10.0)	4 (10.0)	0
Haemophagocytic lymphohistiocytosis	1 (2.5)	0	1 (2.5)
Infections and infestations			
-Total	17 (42.5)	10 (25.0)	7 (17.5)
Parainfluenzae virus infection	3 (7.5)	2 (5.0)	1 (2.5)
Pneumonia	3 (7.5)	1 (2.5)	2 (5.0)
Bacteraemia	2 (5.0)	1 (2.5)	1 (2.5)
Bronchopulmonary aspergillosis	2 (5.0)	1 (2.5)	1 (2.5)
Encephalitis viral	2 (5.0)	1 (2.5)	1 (2.5)
Gastroenteritis	2 (5.0)	2 (5.0)	0
Herpes zoster	2 (5.0)	2 (5.0)	0
Human herpesvirus 6 infection	2 (5.0)	2 (5.0)	0
Rhinovirus infection	2 (5.0)	2 (5.0)	0
Sepsis	2 (5.0)	1 (2.5)	1 (2.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	2 (5.0)	0
Upper respiratory tract infection	2 (5.0)	2 (5.0)	0
Clostridium difficile infection	1 (2.5)	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	1 (2.5)	0
Investigations			
-Total	20 (50.0)	6 (15.0)	14 (35.0)
Neutrophil count decreased	12 (30.0)	2 (5.0)	10 (25.0)
White blood cell count decreased	10 (25.0)	1 (2.5)	9 (22.5)
Platelet count decreased	8 (20.0)	4 (10.0)	4 (10.0)
Lymphocyte count decreased	7 (17.5)	4 (10.0)	3 (7.5)
Alanine aminotransferase increased	4 (10.0)	4 (10.0)	0
Aspartate aminotransferase increased	3 (7.5)	2 (5.0)	1 (2.5)
Gamma-glutamyltransferase increased	2 (5.0)	2 (5.0)	0
Blood bilirubin increased	1 (2.5)	1 (2.5)	0
C-reactive protein increased	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	12 (30.0)	9 (22.5)	3 (7.5)
Hypokalaemia	5 (12.5)	5 (12.5)	0
Decreased appetite	4 (10.0)	2 (5.0)	2 (5.0)
Hyperglycaemia	3 (7.5)	3 (7.5)	0
Hypophosphataemia	3 (7.5)	3 (7.5)	0
Tumour lysis syndrome	2 (5.0)	2 (5.0)	0
Hypocalcaemia	1 (2.5)	1 (2.5)	0
Metabolic acidosis	1 (2.5)	0	1 (2.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	2 (5.0)	0
Back pain	2 (5.0)	2 (5.0)	0
Nervous system disorders			
-Total	4 (10.0)	4 (10.0)	0
Seizure	2 (5.0)	2 (5.0)	0
Encephalopathy	1 (2.5)	1 (2.5)	0
Headache	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Acute kidney injury	3 (7.5)	1 (2.5)	2 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (32.5)	8 (20.0)	5 (12.5)
Hypoxia	7 (17.5)	4 (10.0)	3 (7.5)
Pulmonary oedema	4 (10.0)	4 (10.0)	0
Dyspnoea	3 (7.5)	2 (5.0)	1 (2.5)
Tachypnoea	3 (7.5)	2 (5.0)	1 (2.5)
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	5 (12.5)	4 (10.0)	1 (2.5)
Hypotension	4 (10.0)	3 (7.5)	1 (2.5)
Hypertension	1 (2.5)	1 (2.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (85.0)	9 (22.5)	25 (62.5)
Blood and lymphatic system disorders			
-Total	20 (50.0)	16 (40.0)	4 (10.0)
Febrile neutropenia	16 (40.0)	15 (37.5)	1 (2.5)
Thrombocytopenia	4 (10.0)	2 (5.0)	2 (5.0)
Anaemia	3 (7.5)	3 (7.5)	0
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Neutropenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	8 (20.0)	4 (10.0)	4 (10.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (7.5)	2 (5.0)	1 (2.5)
Cardiac arrest	2 (5.0)	0	2 (5.0)
Cardiac failure	2 (5.0)	1 (2.5)	1 (2.5)
Left ventricular dysfunction	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			
-Total	4 (10.0)	4 (10.0)	0
Diarrhoea	2 (5.0)	2 (5.0)	0
Pancreatitis	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
-Total	9 (22.5)	6 (15.0)	3 (7.5)
Pyrexia	7 (17.5)	6 (15.0)	1 (2.5)
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Immune system disorders			
-Total	19 (47.5)	8 (20.0)	11 (27.5)
Cytokine release syndrome	18 (45.0)	7 (17.5)	11 (27.5)
Haemophagocytic lymphohistiocytosis	3 (7.5)	2 (5.0)	1 (2.5)
Hypogammaglobulinaemia	1 (2.5)	1 (2.5)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	11 (27.5)	8 (20.0)	3 (7.5)
Staphylococcal bacteraemia	4 (10.0)	4 (10.0)	0
Clostridium difficile infection	2 (5.0)	2 (5.0)	0
Metapneumovirus infection	2 (5.0)	2 (5.0)	0
Pneumocystis jirovecii pneumonia	2 (5.0)	1 (2.5)	1 (2.5)
Septic shock	2 (5.0)	0	2 (5.0)
Pneumonia	1 (2.5)	1 (2.5)	0
Sepsis	1 (2.5)	0	1 (2.5)
Upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	26 (65.0)	12 (30.0)	14 (35.0)
Neutrophil count decreased	9 (22.5)	2 (5.0)	7 (17.5)
Aspartate aminotransferase increased	8 (20.0)	6 (15.0)	2 (5.0)
Blood bilirubin increased	8 (20.0)	8 (20.0)	0
Lymphocyte count decreased	8 (20.0)	6 (15.0)	2 (5.0)
White blood cell count decreased	8 (20.0)	1 (2.5)	7 (17.5)
Platelet count decreased	7 (17.5)	3 (7.5)	4 (10.0)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	3 (7.5)	3 (7.5)	0
Blood creatinine increased	3 (7.5)	2 (5.0)	1 (2.5)
Blood fibrinogen decreased	2 (5.0)	1 (2.5)	1 (2.5)
Blood uric acid increased	2 (5.0)	1 (2.5)	1 (2.5)
C-reactive protein increased	2 (5.0)	2 (5.0)	0
Electrocardiogram qt prolonged	2 (5.0)	1 (2.5)	1 (2.5)
Serum ferritin increased	2 (5.0)	2 (5.0)	0
Urine output decreased	2 (5.0)	1 (2.5)	1 (2.5)
Weight increased	2 (5.0)	2 (5.0)	0
Metabolism and nutrition disorders			
-Total	19 (47.5)	12 (30.0)	7 (17.5)
Decreased appetite	8 (20.0)	8 (20.0)	0
Hypokalaemia	6 (15.0)	4 (10.0)	2 (5.0)
Hypophosphataemia	6 (15.0)	5 (12.5)	1 (2.5)
Hypervolaemia	5 (12.5)	5 (12.5)	0
Hypocalcaemia	4 (10.0)	4 (10.0)	0
Tumour lysis syndrome	3 (7.5)	2 (5.0)	1 (2.5)
Hypercalcaemia	2 (5.0)	2 (5.0)	0
Hyperglycaemia	2 (5.0)	2 (5.0)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	2 (5.0)	1 (2.5)	1 (2.5)
Hypernatraemia	2 (5.0)	1 (2.5)	1 (2.5)
Hypertriglyceridaemia	2 (5.0)	1 (2.5)	1 (2.5)
Metabolic acidosis	2 (5.0)	0	2 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	1 (2.5)	0
Back pain	1 (2.5)	1 (2.5)	0
Nervous system disorders			
-Total	6 (15.0)	6 (15.0)	0
Encephalopathy	3 (7.5)	3 (7.5)	0
Headache	2 (5.0)	2 (5.0)	0
Somnolence	2 (5.0)	2 (5.0)	0
Seizure	1 (2.5)	1 (2.5)	0
Psychiatric disorders			
-Total	3 (7.5)	3 (7.5)	0
Delirium	3 (7.5)	3 (7.5)	0
Renal and urinary disorders			
-Total	5 (12.5)	2 (5.0)	3 (7.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	5 (12.5)	2 (5.0)	3 (7.5)
Respiratory, thoracic and mediastinal disorders			
-Total	15 (37.5)	4 (10.0)	11 (27.5)
Hypoxia	9 (22.5)	6 (15.0)	3 (7.5)
Respiratory failure	5 (12.5)	0	5 (12.5)
Acute respiratory distress syndrome	3 (7.5)	0	3 (7.5)
Pleural effusion	3 (7.5)	2 (5.0)	1 (2.5)
Pulmonary oedema	3 (7.5)	2 (5.0)	1 (2.5)
Atelectasis	2 (5.0)	2 (5.0)	0
Respiratory distress	2 (5.0)	0	2 (5.0)
Tachypnoea	2 (5.0)	2 (5.0)	0
Dyspnoea	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	14 (35.0)	7 (17.5)	7 (17.5)
Hypotension	12 (30.0)	5 (12.5)	7 (17.5)
Hypertension	4 (10.0)	4 (10.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	1 (16.7)	3 (50.0)
Blood and lymphatic system disorders			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	2 (33.3)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)
Gastrointestinal disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	1 (16.7)	0
Melaena	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	1 (16.7)	0
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	1 (16.7)	0
Infections and infestations			
-Total	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalitis	1 (16.7)	0	1 (16.7)
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Wound	1 (16.7)	1 (16.7)	0
Investigations			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	1 (16.7)
Lipase increased	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Hypophosphataemia	2 (33.3)	2 (33.3)	0
Acidosis	1 (16.7)	1 (16.7)	0
Hypernatraemia	1 (16.7)	0	1 (16.7)
Hyperuricaemia	1 (16.7)	1 (16.7)	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0
Hypokalaemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Renal tubular necrosis	1 (16.7)	0	1 (16.7)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=6	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (16.7)	1 (16.7)	0
Vaginal ulceration	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Atelectasis	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	1 (16.7)	0
Respiratory acidosis	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			
-Total	1 (16.7)	1 (16.7)	0
Petechiae	1 (16.7)	1 (16.7)	0
Skin necrosis	1 (16.7)	1 (16.7)	0
Vascular disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	1 (16.7)	0

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-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (81.8)	2 (9.1)	16 (72.7)
Blood and lymphatic system disorders			
-Total	9 (40.9)	3 (13.6)	6 (27.3)
Febrile neutropenia	6 (27.3)	5 (22.7)	1 (4.5)
Neutropenia	3 (13.6)	0	3 (13.6)
Thrombocytopenia	3 (13.6)	1 (4.5)	2 (9.1)
Anaemia	1 (4.5)	1 (4.5)	0
Cardiac disorders			
-Total	5 (22.7)	4 (18.2)	1 (4.5)
Left ventricular dysfunction	2 (9.1)	2 (9.1)	0
Tachycardia	2 (9.1)	2 (9.1)	0
Cardiac failure	1 (4.5)	0	1 (4.5)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (4.5)	1 (4.5)	0
Pancreatitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Pyrexia	2 (9.1)	1 (4.5)	1 (4.5)
Multiple organ dysfunction syndrome	1 (4.5)	0	1 (4.5)
Hepatobiliary disorders			
-Total	1 (4.5)	1 (4.5)	0
Hepatic function abnormal	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	11 (50.0)	5 (22.7)	6 (27.3)
Cytokine release syndrome	10 (45.5)	4 (18.2)	6 (27.3)
Haemophagocytic lymphohistiocytosis	2 (9.1)	2 (9.1)	0
Hypogammaglobulinaemia	1 (4.5)	1 (4.5)	0
Immunodeficiency	1 (4.5)	1 (4.5)	0
Infections and infestations			

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (13.6)	3 (13.6)	0
Clostridium difficile infection	2 (9.1)	2 (9.1)	0
Staphylococcal bacteraemia	1 (4.5)	1 (4.5)	0
Investigations			
-Total	15 (68.2)	6 (27.3)	9 (40.9)
White blood cell count decreased	7 (31.8)	2 (9.1)	5 (22.7)
Aspartate aminotransferase increased	6 (27.3)	5 (22.7)	1 (4.5)
Blood bilirubin increased	5 (22.7)	5 (22.7)	0
Lymphocyte count decreased	4 (18.2)	3 (13.6)	1 (4.5)
Neutrophil count decreased	4 (18.2)	0	4 (18.2)
Platelet count decreased	3 (13.6)	1 (4.5)	2 (9.1)
Electrocardiogram qt prolonged	2 (9.1)	1 (4.5)	1 (4.5)
Blood creatinine increased	1 (4.5)	1 (4.5)	0
C-reactive protein increased	1 (4.5)	1 (4.5)	0
Urine output decreased	1 (4.5)	1 (4.5)	0
Weight increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	9 (40.9)	6 (27.3)	3 (13.6)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	5 (22.7)	5 (22.7)	0
Hypervolaemia	4 (18.2)	4 (18.2)	0
Hyperglycaemia	2 (9.1)	2 (9.1)	0
Hypertriglyceridaemia	2 (9.1)	1 (4.5)	1 (4.5)
Hypocalcaemia	2 (9.1)	2 (9.1)	0
Tumour lysis syndrome	2 (9.1)	2 (9.1)	0
Acidosis	1 (4.5)	0	1 (4.5)
Hypercalcaemia	1 (4.5)	1 (4.5)	0
Hyperkalaemia	1 (4.5)	1 (4.5)	0
Hypokalaemia	1 (4.5)	1 (4.5)	0
Hypophosphataemia	1 (4.5)	1 (4.5)	0
Metabolic acidosis	1 (4.5)	0	1 (4.5)
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Encephalopathy	1 (4.5)	1 (4.5)	0
Somnolence	1 (4.5)	1 (4.5)	0
Psychiatric disorders			
-Total	3 (13.6)	3 (13.6)	0
Delirium	3 (13.6)	3 (13.6)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Acute kidney injury	3 (13.6)	1 (4.5)	2 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (40.9)	2 (9.1)	7 (31.8)
Hypoxia	5 (22.7)	2 (9.1)	3 (13.6)
Pulmonary oedema	3 (13.6)	2 (9.1)	1 (4.5)
Respiratory failure	3 (13.6)	0	3 (13.6)
Pleural effusion	2 (9.1)	2 (9.1)	0
Acute respiratory distress syndrome	1 (4.5)	0	1 (4.5)
Atelectasis	1 (4.5)	1 (4.5)	0
Respiratory distress	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	6 (27.3)	3 (13.6)	3 (13.6)
Hypotension	6 (27.3)	3 (13.6)	3 (13.6)
Hypertension	1 (4.5)	1 (4.5)	0

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Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (76.5)	3 (17.6)	10 (58.8)
Blood and lymphatic system disorders			
-Total	10 (58.8)	8 (47.1)	2 (11.8)
Febrile neutropenia	8 (47.1)	8 (47.1)	0
Anaemia	1 (5.9)	1 (5.9)	0
Disseminated intravascular coagulation	1 (5.9)	1 (5.9)	0
Neutropenia	1 (5.9)	0	1 (5.9)
Thrombocytopenia	1 (5.9)	0	1 (5.9)
Cardiac disorders			
-Total	1 (5.9)	0	1 (5.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac arrest	1 (5.9)	0	1 (5.9)
Gastrointestinal disorders			
-Total	1 (5.9)	1 (5.9)	0
Dysphagia	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	2 (11.8)	2 (11.8)	0
Pyrexia	2 (11.8)	2 (11.8)	0
Hepatobiliary disorders			
-Total	1 (5.9)	0	1 (5.9)
Hepatomegaly	1 (5.9)	0	1 (5.9)
Immune system disorders			
-Total	8 (47.1)	4 (23.5)	4 (23.5)
Cytokine release syndrome	8 (47.1)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	4 (23.5)	4 (23.5)	0
Staphylococcal bacteraemia	2 (11.8)	2 (11.8)	0
Bronchopulmonary aspergillosis	1 (5.9)	1 (5.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (5.9)	1 (5.9)	0
Investigations			
-Total	10 (58.8)	3 (17.6)	7 (41.2)
White blood cell count decreased	5 (29.4)	0	5 (29.4)
Platelet count decreased	4 (23.5)	2 (11.8)	2 (11.8)
Blood bilirubin increased	3 (17.6)	3 (17.6)	0
Lymphocyte count decreased	3 (17.6)	2 (11.8)	1 (5.9)
Neutrophil count decreased	3 (17.6)	0	3 (17.6)
Alanine aminotransferase increased	2 (11.8)	2 (11.8)	0
Blood creatinine increased	2 (11.8)	1 (5.9)	1 (5.9)
Blood fibrinogen decreased	2 (11.8)	1 (5.9)	1 (5.9)
Gamma-glutamyltransferase increased	2 (11.8)	2 (11.8)	0
Activated partial thromboplastin time prolonged	1 (5.9)	1 (5.9)	0
Aspartate aminotransferase increased	1 (5.9)	0	1 (5.9)
Urine output decreased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
-Total	8 (47.1)	5 (29.4)	3 (17.6)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	5 (29.4)	4 (23.5)	1 (5.9)
Hypophosphataemia	4 (23.5)	3 (17.6)	1 (5.9)
Decreased appetite	2 (11.8)	2 (11.8)	0
Hypercalcaemia	1 (5.9)	1 (5.9)	0
Hyperkalaemia	1 (5.9)	0	1 (5.9)
Hyperphosphataemia	1 (5.9)	0	1 (5.9)
Hypocalcaemia	1 (5.9)	1 (5.9)	0
Malnutrition	1 (5.9)	1 (5.9)	0
Metabolic acidosis	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.9)	1 (5.9)	0
Muscular weakness	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	1 (5.9)	1 (5.9)	0
Encephalopathy	1 (5.9)	1 (5.9)	0
Somnolence	1 (5.9)	1 (5.9)	0
Psychiatric disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	1 (5.9)	0
Mental status changes	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Acute kidney injury	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (23.5)	2 (11.8)	2 (11.8)
Hypoxia	2 (11.8)	1 (5.9)	1 (5.9)
Pleural effusion	1 (5.9)	0	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			
-Total	6 (35.3)	4 (23.5)	2 (11.8)
Hypotension	3 (17.6)	1 (5.9)	2 (11.8)
Hypertension	2 (11.8)	2 (11.8)	0
Capillary leak syndrome	1 (5.9)	1 (5.9)	0

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Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (91.4)	16 (45.7)	16 (45.7)
Blood and lymphatic system disorders			
-Total	16 (45.7)	13 (37.1)	3 (8.6)
Febrile neutropenia	9 (25.7)	9 (25.7)	0
Anaemia	6 (17.1)	6 (17.1)	0
Neutropenia	3 (8.6)	1 (2.9)	2 (5.7)
Thrombocytopenia	3 (8.6)	1 (2.9)	2 (5.7)
Pancytopenia	2 (5.7)	2 (5.7)	0
Coagulopathy	1 (2.9)	1 (2.9)	0
Lymphopenia	1 (2.9)	1 (2.9)	0
Cardiac disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	1 (2.9)	0
Left ventricular dysfunction	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			
-Total	1 (2.9)	1 (2.9)	0
Diarrhoea	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	3 (8.6)	2 (5.7)	1 (2.9)
Pyrexia	3 (8.6)	2 (5.7)	1 (2.9)
Pain	1 (2.9)	1 (2.9)	0
Hepatobiliary disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Hepatic function abnormal	2 (5.7)	1 (2.9)	1 (2.9)
Immune system disorders			
-Total	22 (62.9)	13 (37.1)	9 (25.7)
Cytokine release syndrome	18 (51.4)	9 (25.7)	9 (25.7)
Hypogammaglobulinaemia	4 (11.4)	4 (11.4)	0
Immunodeficiency	2 (5.7)	2 (5.7)	0
Infections and infestations			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (14.3)	5 (14.3)	0
Staphylococcal infection	2 (5.7)	2 (5.7)	0
Adenovirus infection	1 (2.9)	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	1 (2.9)	0
Human herpesvirus 6 infection	1 (2.9)	1 (2.9)	0
Pneumonia	1 (2.9)	1 (2.9)	0
Sinusitis	1 (2.9)	1 (2.9)	0
Investigations			
-Total	16 (45.7)	7 (20.0)	9 (25.7)
Neutrophil count decreased	7 (20.0)	1 (2.9)	6 (17.1)
Platelet count decreased	6 (17.1)	3 (8.6)	3 (8.6)
Lymphocyte count decreased	5 (14.3)	2 (5.7)	3 (8.6)
White blood cell count decreased	5 (14.3)	0	5 (14.3)
Alanine aminotransferase increased	3 (8.6)	3 (8.6)	0
Aspartate aminotransferase increased	3 (8.6)	2 (5.7)	1 (2.9)
C-reactive protein increased	2 (5.7)	2 (5.7)	0
Blood creatine phosphokinase increased	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	8 (22.9)	7 (20.0)	1 (2.9)
Decreased appetite	4 (11.4)	3 (8.6)	1 (2.9)
Hypokalaemia	4 (11.4)	4 (11.4)	0
Hyperglycaemia	2 (5.7)	2 (5.7)	0
Hypophosphataemia	2 (5.7)	2 (5.7)	0
Hypocalcaemia	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Back pain	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	4 (11.4)	4 (11.4)	0
Headache	2 (5.7)	2 (5.7)	0
Encephalopathy	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (20.0)	5 (14.3)	2 (5.7)
Hypoxia	4 (11.4)	2 (5.7)	2 (5.7)
Pulmonary oedema	4 (11.4)	4 (11.4)	0
Dyspnoea	2 (5.7)	2 (5.7)	0
Tachypnoea	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	3 (8.6)	3 (8.6)	0
Hypotension	3 (8.6)	3 (8.6)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	1 (20.0)	0
White blood cell count decreased	1 (20.0)	1 (20.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (50.0)	5 (25.0)	5 (25.0)
Blood and lymphatic system disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Neutropenia	2 (10.0)	1 (5.0)	1 (5.0)
Anaemia	1 (5.0)	1 (5.0)	0
Cardiac disorders			
-Total	1 (5.0)	0	1 (5.0)
Cardiac failure	1 (5.0)	0	1 (5.0)
General disorders and administration site conditions			
-Total	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Metapneumovirus infection	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Investigations			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Neutrophil count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	1 (5.0)	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	1 (5.0)	0
White blood cell count decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypervolaemia	1 (5.0)	1 (5.0)	0
Metabolic acidosis	1 (5.0)	0	1 (5.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	1 (5.0)	2 (10.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (5.0)	1 (5.0)	0
Respiratory distress	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypotension	1 (5.0)	0	1 (5.0)
Venoocclusive disease	1 (5.0)	1 (5.0)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=15	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (53.3)	3 (20.0)	5 (33.3)
Blood and lymphatic system disorders			
-Total	3 (20.0)	1 (6.7)	2 (13.3)
Febrile neutropenia	2 (13.3)	2 (13.3)	0
Anaemia	1 (6.7)	1 (6.7)	0
Lymphopenia	1 (6.7)	1 (6.7)	0
Neutropenia	1 (6.7)	0	1 (6.7)
Thrombocytopenia	1 (6.7)	0	1 (6.7)
Cardiac disorders			
-Total	1 (6.7)	0	1 (6.7)
Cardiac arrest	1 (6.7)	0	1 (6.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	1 (6.7)	1 (6.7)	0
Pancreatitis	1 (6.7)	1 (6.7)	0
General disorders and administration site conditions			
-Total	1 (6.7)	1 (6.7)	0
Pyrexia	1 (6.7)	1 (6.7)	0
Immune system disorders			
-Total	1 (6.7)	1 (6.7)	0
Immunodeficiency	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	4 (26.7)	4 (26.7)	0
Adenovirus infection	1 (6.7)	1 (6.7)	0
Bk virus infection	1 (6.7)	1 (6.7)	0
Cytomegalovirus infection reactivation	1 (6.7)	1 (6.7)	0
Human herpesvirus 6 infection	1 (6.7)	1 (6.7)	0
Metapneumovirus infection	1 (6.7)	1 (6.7)	0
Pneumocystis jirovecii pneumonia	1 (6.7)	1 (6.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (6.7)	1 (6.7)	0
Sinusitis fungal	1 (6.7)	1 (6.7)	0
Upper respiratory tract infection	1 (6.7)	1 (6.7)	0
Viral infection	1 (6.7)	1 (6.7)	0
Investigations			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
White blood cell count decreased	2 (13.3)	1 (6.7)	1 (6.7)
Blood uric acid increased	1 (6.7)	1 (6.7)	0
Neutrophil count decreased	1 (6.7)	0	1 (6.7)
Platelet count decreased	1 (6.7)	0	1 (6.7)
Weight increased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	1 (6.7)	0	1 (6.7)
Hypokalaemia	1 (6.7)	0	1 (6.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (13.3)	2 (13.3)	0
Back pain	2 (13.3)	2 (13.3)	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.7)	1 (6.7)	0
Haematuria	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Hypotension	1 (6.7)	1 (6.7)	0
Venoocclusive disease	1 (6.7)	0	1 (6.7)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (40.0)	5 (14.3)	9 (25.7)
Blood and lymphatic system disorders			
-Total	4 (11.4)	3 (8.6)	1 (2.9)
Neutropenia	2 (5.7)	1 (2.9)	1 (2.9)
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Febrile neutropenia	1 (2.9)	1 (2.9)	0
Thrombocytopenia	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	1 (2.9)	0	1 (2.9)
Cardiac arrest	1 (2.9)	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.9)	1 (2.9)	0
Pain	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	9 (25.7)	4 (11.4)	5 (14.3)
Gastroenteritis	2 (5.7)	2 (5.7)	0
Parainfluenzae virus infection	2 (5.7)	1 (2.9)	1 (2.9)
Bronchopulmonary aspergillosis	1 (2.9)	0	1 (2.9)
Encephalitis	1 (2.9)	0	1 (2.9)
Metapneumovirus infection	1 (2.9)	1 (2.9)	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	1 (2.9)
Respiratory syncytial virus infection	1 (2.9)	1 (2.9)	0
Septic shock	1 (2.9)	0	1 (2.9)
Sinusitis	1 (2.9)	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Investigations			
-Total	5 (14.3)	2 (5.7)	3 (8.6)
Neutrophil count decreased	3 (8.6)	1 (2.9)	2 (5.7)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (2.9)	1 (2.9)	0
Blood uric acid increased	1 (2.9)	0	1 (2.9)
Lymphocyte count decreased	1 (2.9)	1 (2.9)	0
Platelet count decreased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	4 (11.4)	3 (8.6)	1 (2.9)
Decreased appetite	1 (2.9)	1 (2.9)	0
Hypokalaemia	1 (2.9)	1 (2.9)	0
Malnutrition	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	1 (2.9)
Nervous system disorders			
-Total	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	1 (2.9)	1 (2.9)	0
Mental status changes	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	0	1 (2.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (8.6)	2 (5.7)	1 (2.9)
Hypoxia	2 (5.7)	2 (5.7)	0
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Vascular disorders			
-Total	1 (2.9)	0	1 (2.9)
Hypotension	1 (2.9)	0	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Clostridium difficile colitis	1 (33.3)	1 (33.3)	0
Gastroenteritis escherichia coli	1 (33.3)	1 (33.3)	0
Gastroenteritis salmonella	1 (33.3)	1 (33.3)	0
Pneumonia	1 (33.3)	1 (33.3)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

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Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

		All patients N=13	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (15.4)	1 (7.7)	1 (7.7)
General disorders and administration site conditions			
-Total	1 (7.7)	0	1 (7.7)
Multiple organ dysfunction syndrome	1 (7.7)	0	1 (7.7)
Immune system disorders			
-Total	1 (7.7)	0	1 (7.7)
Haemophagocytic lymphohistiocytosis	1 (7.7)	0	1 (7.7)
Infections and infestations			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Parainfluenzae virus infection	1 (7.7)	1 (7.7)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (7.7)	0	1 (7.7)
Staphylococcal bacteraemia	1 (7.7)	1 (7.7)	0
Metabolism and nutrition disorders			
-Total	1 (7.7)	1 (7.7)	0
Hyperglycaemia	1 (7.7)	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.7)	0	1 (7.7)
Dyspnoea	1 (7.7)	0	1 (7.7)
Tachypnoea	1 (7.7)	0	1 (7.7)
Vascular disorders			
-Total	1 (7.7)	1 (7.7)	0
Hypertension	1 (7.7)	1 (7.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	3 (27.3)	0
Infections and infestations			
-Total	2 (18.2)	2 (18.2)	0
Bronchiolitis	1 (9.1)	1 (9.1)	0
Device related sepsis	1 (9.1)	1 (9.1)	0
Pneumonia respiratory syncytial viral	1 (9.1)	1 (9.1)	0
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Endometriosis	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	1 (9.1)	0
Hypoxia	1 (9.1)	1 (9.1)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
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Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (26.1)	1 (4.3)	5 (21.7)
Blood and lymphatic system disorders			
-Total	1 (4.3)	0	1 (4.3)
Neutropenia	1 (4.3)	0	1 (4.3)
Gastrointestinal disorders			
-Total	1 (4.3)	1 (4.3)	0
Diarrhoea	1 (4.3)	1 (4.3)	0
General disorders and administration site conditions			
-Total	1 (4.3)	1 (4.3)	0
Pyrexia	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	5 (21.7)	2 (8.7)	3 (13.0)
Sepsis	3 (13.0)	1 (4.3)	2 (8.7)
Septic shock	1 (4.3)	0	1 (4.3)
Upper respiratory tract infection	1 (4.3)	1 (4.3)	0
Investigations			
-Total	1 (4.3)	0	1 (4.3)
Neutrophil count decreased	1 (4.3)	0	1 (4.3)
Metabolism and nutrition disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Decreased appetite	1 (4.3)	0	1 (4.3)
Hypernatraemia	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	2 (8.7)	2 (8.7)	0
Headache	1 (4.3)	1 (4.3)	0
Seizure	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.3)	0	1 (4.3)

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (4.3)	0	1 (4.3)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
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Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Febrile neutropenia	3 (50.0)	2 (33.3)	1 (16.7)
Coagulopathy	1 (16.7)	1 (16.7)	0
Disseminated intravascular coagulation	1 (16.7)	1 (16.7)	0
Thrombocytopenia	1 (16.7)	0	1 (16.7)
Cardiac disorders			
-Total	1 (16.7)	0	1 (16.7)
Tachycardia	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Melaena	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Multiple organ dysfunction syndrome	1 (16.7)	0	1 (16.7)
Pyrexia	1 (16.7)	1 (16.7)	0
Systemic inflammatory response syndrome	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Cholestasis	1 (16.7)	0	1 (16.7)
Immune system disorders			
-Total	2 (33.3)	0	2 (33.3)
Cytokine release syndrome	2 (33.3)	0	2 (33.3)
Haemophagocytic lymphohistiocytosis	1 (16.7)	0	1 (16.7)
Hypogammaglobulinaemia	1 (16.7)	1 (16.7)	0
Infections and infestations			

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Clostridium difficile colitis	1 (16.7)	1 (16.7)	0
Encephalitis	1 (16.7)	0	1 (16.7)
Gastroenteritis escherichia coli	1 (16.7)	1 (16.7)	0
Gastroenteritis salmonella	1 (16.7)	1 (16.7)	0
Pneumonia	1 (16.7)	1 (16.7)	0
Injury, poisoning and procedural complications			
-Total	1 (16.7)	0	1 (16.7)
Vasoplegia syndrome	1 (16.7)	0	1 (16.7)
Wound	1 (16.7)	1 (16.7)	0
Investigations			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	1 (16.7)	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	1 (16.7)	0
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Blood bilirubin increased	1 (16.7)	1 (16.7)	0
Blood creatine phosphokinase increased	1 (16.7)	0	1 (16.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (16.7)	0	1 (16.7)
Lymphocyte count decreased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	3 (50.0)	2 (33.3)	1 (16.7)
Hypophosphataemia	2 (33.3)	2 (33.3)	0
Acidosis	1 (16.7)	1 (16.7)	0
Hypernatraemia	1 (16.7)	0	1 (16.7)
Hyperuricaemia	1 (16.7)	1 (16.7)	0
Hypocalcaemia	1 (16.7)	1 (16.7)	0
Hypokalaemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (16.7)	0	1 (16.7)
Rhabdomyolysis	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Encephalopathy	1 (16.7)	1 (16.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Acute kidney injury	2 (33.3)	1 (16.7)	1 (16.7)
Renal tubular necrosis	1 (16.7)	0	1 (16.7)
Reproductive system and breast disorders			
-Total	1 (16.7)	1 (16.7)	0
Vaginal ulceration	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Tachypnoea	2 (33.3)	2 (33.3)	0
Acute respiratory distress syndrome	1 (16.7)	0	1 (16.7)
Acute respiratory failure	1 (16.7)	1 (16.7)	0
Atelectasis	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	0	1 (16.7)
Hypoxia	1 (16.7)	1 (16.7)	0
Respiratory acidosis	1 (16.7)	1 (16.7)	0
Skin and subcutaneous tissue disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	1 (16.7)	0
Petechiae	1 (16.7)	1 (16.7)	0
Skin necrosis	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	1 (16.7)	1 (16.7)
Hypertension	1 (16.7)	1 (16.7)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (86.4)	2 (9.1)	17 (77.3)
Blood and lymphatic system disorders			
-Total	10 (45.5)	4 (18.2)	6 (27.3)
Febrile neutropenia	6 (27.3)	5 (22.7)	1 (4.5)
Neutropenia	3 (13.6)	0	3 (13.6)
Thrombocytopenia	3 (13.6)	1 (4.5)	2 (9.1)
Anaemia	2 (9.1)	2 (9.1)	0
Cardiac disorders			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Cardiac failure	2 (9.1)	0	2 (9.1)
Left ventricular dysfunction	2 (9.1)	2 (9.1)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (9.1)	2 (9.1)	0
Gastrointestinal disorders			
-Total	1 (4.5)	1 (4.5)	0
Pancreatitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	5 (22.7)	2 (9.1)	3 (13.6)
Pyrexia	3 (13.6)	2 (9.1)	1 (4.5)
Multiple organ dysfunction syndrome	2 (9.1)	0	2 (9.1)
Hepatobiliary disorders			
-Total	1 (4.5)	1 (4.5)	0
Hepatic function abnormal	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	12 (54.5)	5 (22.7)	7 (31.8)
Cytokine release syndrome	10 (45.5)	4 (18.2)	6 (27.3)
Haemophagocytic lymphohistiocytosis	3 (13.6)	2 (9.1)	1 (4.5)
Hypogammaglobulinaemia	1 (4.5)	1 (4.5)	0
Immunodeficiency	1 (4.5)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Staphylococcal bacteraemia	3 (13.6)	3 (13.6)	0
Clostridium difficile infection	2 (9.1)	2 (9.1)	0
Pneumonia	2 (9.1)	0	2 (9.1)
Metapneumovirus infection	1 (4.5)	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	1 (4.5)	0
Investigations			
-Total	15 (68.2)	6 (27.3)	9 (40.9)
White blood cell count decreased	7 (31.8)	2 (9.1)	5 (22.7)
Aspartate aminotransferase increased	6 (27.3)	5 (22.7)	1 (4.5)
Blood bilirubin increased	5 (22.7)	5 (22.7)	0
Lymphocyte count decreased	5 (22.7)	4 (18.2)	1 (4.5)
Neutrophil count decreased	5 (22.7)	1 (4.5)	4 (18.2)
Platelet count decreased	3 (13.6)	1 (4.5)	2 (9.1)
Electrocardiogram qt prolonged	2 (9.1)	1 (4.5)	1 (4.5)
Blood creatinine increased	1 (4.5)	1 (4.5)	0
C-reactive protein increased	1 (4.5)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urine output decreased	1 (4.5)	1 (4.5)	0
Weight increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	10 (45.5)	6 (27.3)	4 (18.2)
Decreased appetite	5 (22.7)	5 (22.7)	0
Hypervolaemia	5 (22.7)	5 (22.7)	0
Hyperglycaemia	3 (13.6)	3 (13.6)	0
Hypertriglyceridaemia	2 (9.1)	1 (4.5)	1 (4.5)
Hypocalcaemia	2 (9.1)	2 (9.1)	0
Metabolic acidosis	2 (9.1)	0	2 (9.1)
Tumour lysis syndrome	2 (9.1)	2 (9.1)	0
Acidosis	1 (4.5)	0	1 (4.5)
Hypercalcaemia	1 (4.5)	1 (4.5)	0
Hyperkalaemia	1 (4.5)	1 (4.5)	0
Hypokalaemia	1 (4.5)	1 (4.5)	0
Hypophosphataemia	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Encephalopathy	1 (4.5)	1 (4.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	1 (4.5)	1 (4.5)	0
Psychiatric disorders			
-Total	3 (13.6)	3 (13.6)	0
Delirium	3 (13.6)	3 (13.6)	0
Renal and urinary disorders			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Acute kidney injury	3 (13.6)	1 (4.5)	2 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (50.0)	2 (9.1)	9 (40.9)
Hypoxia	6 (27.3)	3 (13.6)	3 (13.6)
Respiratory failure	4 (18.2)	0	4 (18.2)
Pulmonary oedema	3 (13.6)	2 (9.1)	1 (4.5)
Pleural effusion	2 (9.1)	2 (9.1)	0
Respiratory distress	2 (9.1)	0	2 (9.1)
Acute respiratory distress syndrome	1 (4.5)	0	1 (4.5)
Atelectasis	1 (4.5)	1 (4.5)	0
Dyspnoea	1 (4.5)	0	1 (4.5)
Tachypnoea	1 (4.5)	0	1 (4.5)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	8 (36.4)	4 (18.2)	4 (18.2)
Hypotension	7 (31.8)	3 (13.6)	4 (18.2)
Hypertension	2 (9.1)	2 (9.1)	0
Venoocclusive disease	1 (4.5)	1 (4.5)	0

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (88.2)	3 (17.6)	12 (70.6)
Blood and lymphatic system disorders			
-Total	10 (58.8)	8 (47.1)	2 (11.8)
Febrile neutropenia	8 (47.1)	8 (47.1)	0
Anaemia	1 (5.9)	1 (5.9)	0
Disseminated intravascular coagulation	1 (5.9)	1 (5.9)	0
Lymphopenia	1 (5.9)	1 (5.9)	0
Neutropenia	1 (5.9)	0	1 (5.9)
Thrombocytopenia	1 (5.9)	0	1 (5.9)
Cardiac disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.8)	0	2 (11.8)
Cardiac arrest	2 (11.8)	0	2 (11.8)
Cardiac failure	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	2 (11.8)	2 (11.8)	0
Dysphagia	1 (5.9)	1 (5.9)	0
Pancreatitis	1 (5.9)	1 (5.9)	0
General disorders and administration site conditions			
-Total	3 (17.6)	3 (17.6)	0
Pyrexia	3 (17.6)	3 (17.6)	0
Hepatobiliary disorders			
-Total	1 (5.9)	0	1 (5.9)
Hepatomegaly	1 (5.9)	0	1 (5.9)
Immune system disorders			
-Total	9 (52.9)	5 (29.4)	4 (23.5)
Cytokine release syndrome	8 (47.1)	4 (23.5)	4 (23.5)
Hypogammaglobulinaemia	1 (5.9)	1 (5.9)	0
Immunodeficiency	1 (5.9)	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	7 (41.2)	7 (41.2)	0
Staphylococcal bacteraemia	2 (11.8)	2 (11.8)	0
Adenovirus infection	1 (5.9)	1 (5.9)	0
Bk virus infection	1 (5.9)	1 (5.9)	0
Bronchiolitis	1 (5.9)	1 (5.9)	0
Bronchopulmonary aspergillosis	1 (5.9)	1 (5.9)	0
Cytomegalovirus infection reactivation	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Human herpesvirus 6 infection	1 (5.9)	1 (5.9)	0
Metapneumovirus infection	1 (5.9)	1 (5.9)	0
Oral herpes	1 (5.9)	1 (5.9)	0
Pneumocystis jirovecii pneumonia	1 (5.9)	1 (5.9)	0
Pneumonia respiratory syncytial viral	1 (5.9)	1 (5.9)	0
Respiratory syncytial virus infection	1 (5.9)	1 (5.9)	0
Sinusitis fungal	1 (5.9)	1 (5.9)	0
Upper respiratory tract infection	1 (5.9)	1 (5.9)	0
Viral infection	1 (5.9)	1 (5.9)	0
Investigations			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (58.8)	3 (17.6)	7 (41.2)
White blood cell count decreased	5 (29.4)	0	5 (29.4)
Neutrophil count decreased	4 (23.5)	0	4 (23.5)
Platelet count decreased	4 (23.5)	2 (11.8)	2 (11.8)
Blood bilirubin increased	3 (17.6)	3 (17.6)	0
Lymphocyte count decreased	3 (17.6)	2 (11.8)	1 (5.9)
Alanine aminotransferase increased	2 (11.8)	2 (11.8)	0
Blood creatinine increased	2 (11.8)	1 (5.9)	1 (5.9)
Blood fibrinogen decreased	2 (11.8)	1 (5.9)	1 (5.9)
Gamma-glutamyltransferase increased	2 (11.8)	2 (11.8)	0
Activated partial thromboplastin time prolonged	1 (5.9)	1 (5.9)	0
Aspartate aminotransferase increased	1 (5.9)	0	1 (5.9)
Blood uric acid increased	1 (5.9)	1 (5.9)	0
Urine output decreased	1 (5.9)	0	1 (5.9)
Weight increased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	8 (47.1)	5 (29.4)	3 (17.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	5 (29.4)	4 (23.5)	1 (5.9)
Hypophosphataemia	4 (23.5)	3 (17.6)	1 (5.9)
Decreased appetite	2 (11.8)	2 (11.8)	0
Hypercalcaemia	1 (5.9)	1 (5.9)	0
Hyperkalaemia	1 (5.9)	0	1 (5.9)
Hyperphosphataemia	1 (5.9)	0	1 (5.9)
Hypocalcaemia	1 (5.9)	1 (5.9)	0
Malnutrition	1 (5.9)	1 (5.9)	0
Metabolic acidosis	1 (5.9)	0	1 (5.9)
Tumour lysis syndrome	1 (5.9)	1 (5.9)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (17.6)	3 (17.6)	0
Back pain	2 (11.8)	2 (11.8)	0
Muscular weakness	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	1 (5.9)	1 (5.9)	0
Encephalopathy	1 (5.9)	1 (5.9)	0
Somnolence	1 (5.9)	1 (5.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	1 (5.9)	1 (5.9)	0
Mental status changes	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	2 (11.8)	2 (11.8)	0
Acute kidney injury	1 (5.9)	1 (5.9)	0
Haematuria	1 (5.9)	1 (5.9)	0
Reproductive system and breast disorders			
-Total	1 (5.9)	1 (5.9)	0
Endometriosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (23.5)	2 (11.8)	2 (11.8)
Hypoxia	3 (17.6)	2 (11.8)	1 (5.9)
Pleural effusion	1 (5.9)	0	1 (5.9)
Respiratory failure	1 (5.9)	0	1 (5.9)
Tachypnoea	1 (5.9)	1 (5.9)	0
Vascular disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (47.1)	5 (29.4)	3 (17.6)
Hypotension	4 (23.5)	2 (11.8)	2 (11.8)
Hypertension	2 (11.8)	2 (11.8)	0
Capillary leak syndrome	1 (5.9)	1 (5.9)	0
Venoocclusive disease	1 (5.9)	0	1 (5.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 219r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

		All patients N=35	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (94.3)	13 (37.1)	20 (57.1)
Blood and lymphatic system disorders			
-Total	19 (54.3)	15 (42.9)	4 (11.4)
Febrile neutropenia	10 (28.6)	10 (28.6)	0
Anaemia	6 (17.1)	6 (17.1)	0
Neutropenia	5 (14.3)	2 (5.7)	3 (8.6)
Thrombocytopenia	4 (11.4)	2 (5.7)	2 (5.7)
Pancytopenia	2 (5.7)	2 (5.7)	0
Coagulopathy	1 (2.9)	1 (2.9)	0
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Cardiac arrest	1 (2.9)	0	1 (2.9)
Left ventricular dysfunction	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			
-Total	2 (5.7)	2 (5.7)	0
Diarrhoea	2 (5.7)	2 (5.7)	0
General disorders and administration site conditions			
-Total	4 (11.4)	3 (8.6)	1 (2.9)
Pyrexia	4 (11.4)	3 (8.6)	1 (2.9)
Pain	2 (5.7)	2 (5.7)	0
Hepatobiliary disorders			
-Total	2 (5.7)	1 (2.9)	1 (2.9)
Hepatic function abnormal	2 (5.7)	1 (2.9)	1 (2.9)
Immune system disorders			
-Total	22 (62.9)	13 (37.1)	9 (25.7)
Cytokine release syndrome	18 (51.4)	9 (25.7)	9 (25.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	4 (11.4)	4 (11.4)	0
Immunodeficiency	2 (5.7)	2 (5.7)	0
Infections and infestations			
-Total	15 (42.9)	8 (22.9)	7 (20.0)
Sepsis	3 (8.6)	1 (2.9)	2 (5.7)
Gastroenteritis	2 (5.7)	2 (5.7)	0
Parainfluenzae virus infection	2 (5.7)	1 (2.9)	1 (2.9)
Septic shock	2 (5.7)	0	2 (5.7)
Sinusitis	2 (5.7)	2 (5.7)	0
Staphylococcal infection	2 (5.7)	2 (5.7)	0
Upper respiratory tract infection	2 (5.7)	2 (5.7)	0
Adenovirus infection	1 (2.9)	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	0	1 (2.9)
Clostridium difficile infection	1 (2.9)	1 (2.9)	0
Encephalitis	1 (2.9)	0	1 (2.9)
Human herpesvirus 6 infection	1 (2.9)	1 (2.9)	0
Metapneumovirus infection	1 (2.9)	1 (2.9)	0
Pneumocystis jirovecii pneumonia	1 (2.9)	0	1 (2.9)
Pneumonia	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (2.9)	1 (2.9)	0
Investigations			
-Total	18 (51.4)	8 (22.9)	10 (28.6)
Neutrophil count decreased	9 (25.7)	2 (5.7)	7 (20.0)
Platelet count decreased	7 (20.0)	4 (11.4)	3 (8.6)
Lymphocyte count decreased	6 (17.1)	3 (8.6)	3 (8.6)
White blood cell count decreased	5 (14.3)	0	5 (14.3)
Alanine aminotransferase increased	4 (11.4)	4 (11.4)	0
Aspartate aminotransferase increased	3 (8.6)	2 (5.7)	1 (2.9)
C-reactive protein increased	2 (5.7)	2 (5.7)	0
Blood creatine phosphokinase increased	1 (2.9)	1 (2.9)	0
Blood uric acid increased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	10 (28.6)	7 (20.0)	3 (8.6)
Decreased appetite	5 (14.3)	3 (8.6)	2 (5.7)
Hypokalaemia	4 (11.4)	4 (11.4)	0
Hyperglycaemia	2 (5.7)	2 (5.7)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	2 (5.7)	2 (5.7)	0
Tumour lysis syndrome	2 (5.7)	1 (2.9)	1 (2.9)
Hypernatraemia	1 (2.9)	1 (2.9)	0
Hypocalcaemia	1 (2.9)	1 (2.9)	0
Malnutrition	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Back pain	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	7 (20.0)	7 (20.0)	0
Headache	3 (8.6)	3 (8.6)	0
Seizure	3 (8.6)	3 (8.6)	0
Encephalopathy	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	1 (2.9)	1 (2.9)	0
Mental status changes	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	2 (5.7)	0	2 (5.7)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	2 (5.7)	0	2 (5.7)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (31.4)	7 (20.0)	4 (11.4)
Hypoxia	6 (17.1)	4 (11.4)	2 (5.7)
Pulmonary oedema	4 (11.4)	4 (11.4)	0
Dyspnoea	2 (5.7)	2 (5.7)	0
Acute respiratory distress syndrome	1 (2.9)	0	1 (2.9)
Respiratory failure	1 (2.9)	0	1 (2.9)
Tachypnoea	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	3 (8.6)	2 (5.7)	1 (2.9)
Hypotension	3 (8.6)	2 (5.7)	1 (2.9)

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220a
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (65.9)	14 (34.1)	13 (31.7)
Blood and lymphatic system disorders			
-Total	19 (46.3)	13 (31.7)	6 (14.6)
Febrile neutropenia	11 (26.8)	11 (26.8)	0
Anaemia	6 (14.6)	6 (14.6)	0
Neutropenia	4 (9.8)	0	4 (9.8)
Leukopenia	3 (7.3)	0	3 (7.3)
Thrombocytopenia	3 (7.3)	1 (2.4)	2 (4.9)
Gastrointestinal disorders			
-Total	4 (9.8)	4 (9.8)	0
Stomatitis	3 (7.3)	3 (7.3)	0

Age: <10 years

	All patients N=41		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenic colitis	1 (2.4)	1 (2.4)	0
Infections and infestations			
-Total	3 (7.3)	2 (4.9)	1 (2.4)
Parainfluenzae virus infection	1 (2.4)	1 (2.4)	0
Pneumonia	1 (2.4)	1 (2.4)	0
Pneumonia fungal	1 (2.4)	0	1 (2.4)
Respiratory tract infection	1 (2.4)	1 (2.4)	0
Investigations			
-Total	13 (31.7)	6 (14.6)	7 (17.1)
Neutrophil count decreased	7 (17.1)	3 (7.3)	4 (9.8)
White blood cell count decreased	3 (7.3)	0	3 (7.3)
Alanine aminotransferase increased	2 (4.9)	2 (4.9)	0
Platelet count decreased	2 (4.9)	0	2 (4.9)
Aspartate aminotransferase increased	1 (2.4)	1 (2.4)	0
C-reactive protein increased	1 (2.4)	1 (2.4)	0
Lymphocyte count decreased	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			

Age: <10 years

Group term Preferred term	All patients N=41 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (7.3)	1 (2.4)	2 (4.9)
Respiratory failure	2 (4.9)	0	2 (4.9)
Epistaxis	1 (2.4)	1 (2.4)	0

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220a
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	14 (35.0)	14 (35.0)
Blood and lymphatic system disorders			
-Total	15 (37.5)	10 (25.0)	5 (12.5)
Anaemia	8 (20.0)	7 (17.5)	1 (2.5)
Febrile neutropenia	6 (15.0)	6 (15.0)	0
Neutropenia	3 (7.5)	1 (2.5)	2 (5.0)
Thrombocytopenia	3 (7.5)	1 (2.5)	2 (5.0)
Cardiac disorders			
-Total	2 (5.0)	2 (5.0)	0
Tachycardia	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.0)	4 (10.0)	0
Neutropenic colitis	2 (5.0)	2 (5.0)	0
Stomatitis	2 (5.0)	2 (5.0)	0
Infections and infestations			
-Total	12 (30.0)	8 (20.0)	4 (10.0)
Bacteraemia	2 (5.0)	2 (5.0)	0
Herpes zoster	2 (5.0)	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Staphylococcal sepsis	2 (5.0)	0	2 (5.0)
Catheter site infection	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0
Septic shock	1 (2.5)	0	1 (2.5)
Investigations			
-Total	8 (20.0)	3 (7.5)	5 (12.5)
Neutrophil count decreased	3 (7.5)	0	3 (7.5)
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (5.0)	1 (2.5)	1 (2.5)
Platelet count decreased	2 (5.0)	0	2 (5.0)
Serum ferritin increased	2 (5.0)	2 (5.0)	0
Blood lactate dehydrogenase increased	1 (2.5)	1 (2.5)	0
Blood potassium decreased	1 (2.5)	1 (2.5)	0
White blood cell count decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	3 (7.5)	3 (7.5)	0
Metabolic acidosis	2 (5.0)	2 (5.0)	0
Decreased appetite	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	2 (5.0)	0
Pain in extremity	2 (5.0)	2 (5.0)	0
Nervous system disorders			
-Total	1 (2.5)	1 (2.5)	0
Headache	1 (2.5)	1 (2.5)	0

Age: >=10 years to <18 years

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.0)	0	2 (5.0)
Respiratory failure	2 (5.0)	0	2 (5.0)
Vascular disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Hypotension	4 (10.0)	3 (7.5)	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220a
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (82.4)	6 (35.3)	8 (47.1)
Blood and lymphatic system disorders			
-Total	11 (64.7)	6 (35.3)	5 (29.4)
Febrile neutropenia	6 (35.3)	5 (29.4)	1 (5.9)
Anaemia	3 (17.6)	3 (17.6)	0
Neutropenia	3 (17.6)	0	3 (17.6)
Pancytopenia	3 (17.6)	1 (5.9)	2 (11.8)
Thrombocytopenia	1 (5.9)	1 (5.9)	0
Cardiac disorders			
-Total	2 (11.8)	2 (11.8)	0

Age: >=18

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.9)	1 (5.9)	0
Tachycardia	1 (5.9)	1 (5.9)	0
Gastrointestinal disorders			
-Total	1 (5.9)	1 (5.9)	0
Stomatitis	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders			
-Total	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	9 (52.9)	6 (35.3)	3 (17.6)
Bacterial sepsis	1 (5.9)	0	1 (5.9)
Catheter site infection	1 (5.9)	1 (5.9)	0
Device related sepsis	1 (5.9)	1 (5.9)	0
Fungal sepsis	1 (5.9)	0	1 (5.9)
Parainfluenzae virus infection	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	1 (5.9)
Pneumonia fungal	1 (5.9)	1 (5.9)	0
Respiratory tract infection	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Septic shock	1 (5.9)	0	1 (5.9)
Staphylococcal bacteraemia	1 (5.9)	1 (5.9)	0
Staphylococcal skin infection	1 (5.9)	1 (5.9)	0
Stomatococcal infection	1 (5.9)	0	1 (5.9)
Urinary tract infection	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Transfusion reaction	1 (5.9)	1 (5.9)	0
Investigations			
-Total	7 (41.2)	2 (11.8)	5 (29.4)
Platelet count decreased	4 (23.5)	0	4 (23.5)
White blood cell count decreased	3 (17.6)	0	3 (17.6)
C-reactive protein increased	2 (11.8)	1 (5.9)	1 (5.9)
Lymphocyte count decreased	2 (11.8)	0	2 (11.8)
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0
Blood bilirubin increased	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatinine increased	1 (5.9)	1 (5.9)	0
Blood lactate dehydrogenase increased	1 (5.9)	1 (5.9)	0
Blood phosphorus decreased	1 (5.9)	1 (5.9)	0
Blood potassium decreased	1 (5.9)	0	1 (5.9)
Fibrin d dimer increased	1 (5.9)	0	1 (5.9)
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Serum ferritin increased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Decreased appetite	1 (5.9)	1 (5.9)	0
Hyperglycaemia	1 (5.9)	0	1 (5.9)
Musculoskeletal and connective tissue disorders			
-Total	2 (11.8)	2 (11.8)	0
Back pain	1 (5.9)	1 (5.9)	0
Joint effusion	1 (5.9)	1 (5.9)	0
Myopathy	1 (5.9)	1 (5.9)	0
Pain in jaw	1 (5.9)	1 (5.9)	0

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Spinal pain	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	2 (11.8)	2 (11.8)	0
Headache	1 (5.9)	1 (5.9)	0
Neuropathy peripheral	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Acute respiratory distress syndrome	1 (5.9)	0	1 (5.9)
Epistaxis	1 (5.9)	1 (5.9)	0
Hypoxia	1 (5.9)	1 (5.9)	0
Skin and subcutaneous tissue disorders			
-Total	1 (5.9)	1 (5.9)	0
Pain of skin	1 (5.9)	1 (5.9)	0
Vascular disorders			

Age: >=18

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (5.9)	0	1 (5.9)
Hypotension	1 (5.9)	0	1 (5.9)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220b
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (58.2)	12 (21.8)	20 (36.4)
Blood and lymphatic system disorders			
-Total	25 (45.5)	15 (27.3)	10 (18.2)
Anaemia	11 (20.0)	10 (18.2)	1 (1.8)
Febrile neutropenia	9 (16.4)	9 (16.4)	0
Neutropenia	8 (14.5)	1 (1.8)	7 (12.7)
Thrombocytopenia	4 (7.3)	2 (3.6)	2 (3.6)
Leukopenia	3 (5.5)	0	3 (5.5)
Gastrointestinal disorders			
-Total	3 (5.5)	3 (5.5)	0
Stomatitis	3 (5.5)	3 (5.5)	0

Gender: Male

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	13 (23.6)	5 (9.1)	8 (14.5)
Neutrophil count decreased	6 (10.9)	2 (3.6)	4 (7.3)
Alanine aminotransferase increased	3 (5.5)	3 (5.5)	0
Aspartate aminotransferase increased	3 (5.5)	2 (3.6)	1 (1.8)
Platelet count decreased	3 (5.5)	0	3 (5.5)
White blood cell count decreased	3 (5.5)	0	3 (5.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (7.3)	0	4 (7.3)
Respiratory failure	4 (7.3)	0	4 (7.3)
Vascular disorders			
-Total	4 (7.3)	3 (5.5)	1 (1.8)
Hypotension	4 (7.3)	3 (5.5)	1 (1.8)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220b
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (60.5)	14 (32.6)	12 (27.9)
Blood and lymphatic system disorders			
-Total	20 (46.5)	14 (32.6)	6 (14.0)
Febrile neutropenia	14 (32.6)	13 (30.2)	1 (2.3)
Anaemia	6 (14.0)	6 (14.0)	0
Pancytopenia	3 (7.0)	1 (2.3)	2 (4.7)
Thrombocytopenia	3 (7.0)	1 (2.3)	2 (4.7)
Neutropenia	2 (4.7)	0	2 (4.7)
Gastrointestinal disorders			
-Total	6 (14.0)	6 (14.0)	0
Neutropenic colitis	3 (7.0)	3 (7.0)	0

Gender: Female

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	3 (7.0)	3 (7.0)	0
Investigations			
-Total	12 (27.9)	3 (7.0)	9 (20.9)
Neutrophil count decreased	5 (11.6)	1 (2.3)	4 (9.3)
Platelet count decreased	5 (11.6)	0	5 (11.6)
White blood cell count decreased	4 (9.3)	0	4 (9.3)
Serum ferritin increased	3 (7.0)	2 (4.7)	1 (2.3)
Alanine aminotransferase increased	1 (2.3)	1 (2.3)	0
Aspartate aminotransferase increased	1 (2.3)	1 (2.3)	0
Vascular disorders			
-Total	1 (2.3)	0	1 (2.3)
Hypotension	1 (2.3)	0	1 (2.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220c
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (68.6)	25 (35.7)	23 (32.9)
Blood and lymphatic system disorders			
-Total	31 (44.3)	22 (31.4)	9 (12.9)
Febrile neutropenia	16 (22.9)	16 (22.9)	0
Anaemia	12 (17.1)	11 (15.7)	1 (1.4)
Neutropenia	6 (8.6)	1 (1.4)	5 (7.1)
Thrombocytopenia	4 (5.7)	2 (2.9)	2 (2.9)
Leukopenia	2 (2.9)	0	2 (2.9)
Gastrointestinal disorders			
-Total	3 (4.3)	3 (4.3)	0
Stomatitis	3 (4.3)	3 (4.3)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (1.4)	1 (1.4)	0
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	6 (8.6)	6 (8.6)	0
Pneumonia	2 (2.9)	2 (2.9)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Oral herpes	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	1 (1.4)	0
Investigations			
-Total	20 (28.6)	7 (10.0)	13 (18.6)
Neutrophil count decreased	10 (14.3)	3 (4.3)	7 (10.0)
Platelet count decreased	6 (8.6)	0	6 (8.6)
White blood cell count decreased	5 (7.1)	0	5 (7.1)
Aspartate aminotransferase increased	3 (4.3)	2 (2.9)	1 (1.4)
C-reactive protein increased	2 (2.9)	2 (2.9)	0

Race: White

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (2.9)	1 (1.4)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Blood potassium decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	4 (5.7)	3 (4.3)	1 (1.4)
Hypokalaemia	2 (2.9)	2 (2.9)	0
Tumour lysis syndrome	2 (2.9)	1 (1.4)	1 (1.4)
Musculoskeletal and connective tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Pain in extremity	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (4.3)	0	3 (4.3)
Respiratory failure	3 (4.3)	0	3 (4.3)
Vascular disorders			
-Total	4 (5.7)	2 (2.9)	2 (2.9)
Hypotension	4 (5.7)	2 (2.9)	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.
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Table 220c
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (60.0)	4 (26.7)	5 (33.3)
Blood and lymphatic system disorders			
-Total	4 (26.7)	2 (13.3)	2 (13.3)
Anaemia	3 (20.0)	3 (20.0)	0
Febrile neutropenia	2 (13.3)	2 (13.3)	0
Thrombocytopenia	2 (13.3)	0	2 (13.3)
Leukopenia	1 (6.7)	0	1 (6.7)
Lymphopenia	1 (6.7)	0	1 (6.7)
Neutropenia	1 (6.7)	0	1 (6.7)
Cardiac disorders			
-Total	1 (6.7)	1 (6.7)	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Left ventricular dysfunction	1 (6.7)	1 (6.7)	0
Gastrointestinal disorders			
-Total	3 (20.0)	3 (20.0)	0
Anal inflammation	1 (6.7)	1 (6.7)	0
Duodenal perforation	1 (6.7)	1 (6.7)	0
Oral pain	1 (6.7)	1 (6.7)	0
Stomatitis	1 (6.7)	1 (6.7)	0
Infections and infestations			
-Total	4 (26.7)	3 (20.0)	1 (6.7)
Bronchopulmonary aspergillosis	1 (6.7)	1 (6.7)	0
Escherichia bacteraemia	1 (6.7)	1 (6.7)	0
Klebsiella bacteraemia	1 (6.7)	1 (6.7)	0
Oral herpes	1 (6.7)	1 (6.7)	0
Peritonitis	1 (6.7)	1 (6.7)	0
Pneumonia fungal	1 (6.7)	0	1 (6.7)
Injury, poisoning and procedural complications			
-Total	1 (6.7)	1 (6.7)	0

Race: Asian

Group term Preferred term	All patients N=15 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Post procedural haemorrhage	1 (6.7)	1 (6.7)	0
Investigations			
-Total	4 (26.7)	4 (26.7)	0
Alanine aminotransferase increased	3 (20.0)	3 (20.0)	0
Serum ferritin increased	2 (13.3)	2 (13.3)	0
Aspartate aminotransferase increased	1 (6.7)	1 (6.7)	0
Blood calcium increased	1 (6.7)	1 (6.7)	0
Blood fibrinogen decreased	1 (6.7)	1 (6.7)	0
Blood lactate dehydrogenase increased	1 (6.7)	1 (6.7)	0
Blood potassium decreased	1 (6.7)	1 (6.7)	0
Metabolism and nutrition disorders			
-Total	2 (13.3)	1 (6.7)	1 (6.7)
Hypercalcaemia	1 (6.7)	0	1 (6.7)
Tumour lysis syndrome	1 (6.7)	1 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (6.7)	1 (6.7)	0

Race: Asian

	All patients N=15		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (6.7)	1 (6.7)	0
Nervous system disorders			
-Total	1 (6.7)	0	1 (6.7)
Haemorrhage intracranial	1 (6.7)	0	1 (6.7)
Psychiatric disorders			
-Total	1 (6.7)	1 (6.7)	0
Anxiety	1 (6.7)	1 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (6.7)	1 (6.7)	0
Dyspnoea	1 (6.7)	1 (6.7)	0
Vascular disorders			
-Total	1 (6.7)	1 (6.7)	0
Hypotension	1 (6.7)	1 (6.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220c
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=13		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (69.2)	2 (15.4)	7 (53.8)
Blood and lymphatic system disorders			
-Total	8 (61.5)	4 (30.8)	4 (30.8)
Febrile neutropenia	5 (38.5)	4 (30.8)	1 (7.7)
Neutropenia	3 (23.1)	0	3 (23.1)
Anaemia	2 (15.4)	2 (15.4)	0
Thrombocytopenia	1 (7.7)	1 (7.7)	0
Gastrointestinal disorders			
-Total	2 (15.4)	2 (15.4)	0
Stomatitis	2 (15.4)	2 (15.4)	0

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders			
-Total	1 (7.7)	1 (7.7)	0
Hyperbilirubinaemia	1 (7.7)	1 (7.7)	0
Infections and infestations			
-Total	2 (15.4)	1 (7.7)	1 (7.7)
Pneumonia	1 (7.7)	0	1 (7.7)
Respiratory tract infection	1 (7.7)	1 (7.7)	0
Injury, poisoning and procedural complications			
-Total	1 (7.7)	1 (7.7)	0
Transfusion reaction	1 (7.7)	1 (7.7)	0
Investigations			
-Total	4 (30.8)	0	4 (30.8)
Platelet count decreased	2 (15.4)	0	2 (15.4)
White blood cell count decreased	2 (15.4)	0	2 (15.4)
Blood lactate dehydrogenase increased	1 (7.7)	1 (7.7)	0
C-reactive protein increased	1 (7.7)	0	1 (7.7)
Fibrin d dimer increased	1 (7.7)	0	1 (7.7)

Race: Other

Group term Preferred term	All patients N=13 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphocyte count decreased	1 (7.7)	0	1 (7.7)
Neutrophil count decreased	1 (7.7)	0	1 (7.7)
Serum ferritin increased	1 (7.7)	0	1 (7.7)
Metabolism and nutrition disorders			
-Total	1 (7.7)	1 (7.7)	0
Hypokalaemia	1 (7.7)	1 (7.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.7)	1 (7.7)	0
Myopathy	1 (7.7)	1 (7.7)	0
Nervous system disorders			
-Total	1 (7.7)	1 (7.7)	0
Neuropathy peripheral	1 (7.7)	1 (7.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (7.7)	0	1 (7.7)
Respiratory failure	1 (7.7)	0	1 (7.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received

and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220d
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	6 (33.3)	8 (44.4)
Blood and lymphatic system disorders			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
Anaemia	2 (11.1)	1 (5.6)	1 (5.6)
Febrile neutropenia	2 (11.1)	2 (11.1)	0
Thrombocytopenia	2 (11.1)	2 (11.1)	0
Neutropenia	1 (5.6)	0	1 (5.6)
Cardiac disorders			
-Total	1 (5.6)	1 (5.6)	0
Tachycardia	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (22.2)	4 (22.2)	0
Stomatitis	2 (11.1)	2 (11.1)	0
Colitis	1 (5.6)	1 (5.6)	0
Oral disorder	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	1 (5.6)	1 (5.6)	0
Pyrexia	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	1 (5.6)	1 (5.6)	0
Hypertransaminasaemia	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	10 (55.6)	8 (44.4)	2 (11.1)
Bacteraemia	2 (11.1)	2 (11.1)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Escherichia bacteraemia	1 (5.6)	1 (5.6)	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Pneumonia fungal	1 (5.6)	1 (5.6)	0
Sinusitis	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	2 (11.1)	2 (11.1)	0
Procedural pain	1 (5.6)	1 (5.6)	0
Transfusion reaction	1 (5.6)	1 (5.6)	0
Investigations			
-Total	6 (33.3)	1 (5.6)	5 (27.8)
Platelet count decreased	3 (16.7)	0	3 (16.7)
Neutrophil count decreased	2 (11.1)	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	0	2 (11.1)
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
Blood lactate dehydrogenase increased	1 (5.6)	1 (5.6)	0
C-reactive protein increased	1 (5.6)	0	1 (5.6)
Fibrin d dimer increased	1 (5.6)	0	1 (5.6)
Lymphocyte count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	2 (11.1)	0
Decreased appetite	1 (5.6)	1 (5.6)	0
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Metabolic acidosis	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (11.1)	2 (11.1)	0
Myopathy	1 (5.6)	1 (5.6)	0
Pain in extremity	1 (5.6)	1 (5.6)	0
Nervous system disorders			

Ethnicity: Hispanic or Latino

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.1)	2 (11.1)	0
Headache	1 (5.6)	1 (5.6)	0
Neuropathy peripheral	1 (5.6)	1 (5.6)	0
Psychiatric disorders			
-Total	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Epistaxis	1 (5.6)	1 (5.6)	0
Hypoxia	1 (5.6)	1 (5.6)	0
Respiratory failure	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	1 (5.6)	1 (5.6)	0
Hypotension	1 (5.6)	1 (5.6)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220d
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (62.5)	25 (31.3)	25 (31.3)
Blood and lymphatic system disorders			
-Total	38 (47.5)	26 (32.5)	12 (15.0)
Febrile neutropenia	21 (26.3)	20 (25.0)	1 (1.3)
Anaemia	15 (18.8)	15 (18.8)	0
Neutropenia	9 (11.3)	1 (1.3)	8 (10.0)
Thrombocytopenia	5 (6.3)	1 (1.3)	4 (5.0)
Cardiac disorders			
-Total	2 (2.5)	2 (2.5)	0
Tachycardia	2 (2.5)	2 (2.5)	0
Gastrointestinal disorders			

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (5.0)	4 (5.0)	0
Stomatitis	4 (5.0)	4 (5.0)	0
General disorders and administration site conditions			
-Total	1 (1.3)	1 (1.3)	0
Pyrexia	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	2 (2.5)	1 (1.3)	1 (1.3)
Escherichia bacteraemia	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	1 (1.3)
Investigations			
-Total	22 (27.5)	10 (12.5)	12 (15.0)
Neutrophil count decreased	9 (11.3)	2 (2.5)	7 (8.8)
Platelet count decreased	5 (6.3)	0	5 (6.3)
White blood cell count decreased	5 (6.3)	0	5 (6.3)
Alanine aminotransferase increased	3 (3.8)	3 (3.8)	0
Aspartate aminotransferase increased	3 (3.8)	2 (2.5)	1 (1.3)
C-reactive protein increased	2 (2.5)	2 (2.5)	0

Ethnicity: Other

	All patients N=80		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (2.5)	1 (1.3)	1 (1.3)
Serum ferritin increased	2 (2.5)	2 (2.5)	0
Blood lactate dehydrogenase increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			
-Total	2 (2.5)	2 (2.5)	0
Decreased appetite	1 (1.3)	1 (1.3)	0
Metabolic acidosis	1 (1.3)	1 (1.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.3)	1 (1.3)	0
Pain in extremity	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	1 (1.3)	1 (1.3)	0
Headache	1 (1.3)	1 (1.3)	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Mental status changes	1 (1.3)	1 (1.3)	0

Ethnicity: Other

Group term Preferred term	All patients N=80 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.0)	1 (1.3)	3 (3.8)
Respiratory failure	3 (3.8)	0	3 (3.8)
Epistaxis	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	4 (5.0)	2 (2.5)	2 (2.5)
Hypotension	4 (5.0)	2 (2.5)	2 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220e
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	5 (62.5)	3 (37.5)
Blood and lymphatic system disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	2 (25.0)	0
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Tachycardia	2 (25.0)	2 (25.0)	0
Gastrointestinal disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (12.5)	1 (12.5)	0
Haemoperitoneum	1 (12.5)	0	1 (12.5)
Stomatitis	1 (12.5)	1 (12.5)	0
Tooth pulp haemorrhage	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	4 (50.0)	2 (25.0)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Pseudomonal bacteraemia	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Sialoadenitis	1 (12.5)	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Investigations			

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	3 (37.5)	3 (37.5)	0
Metabolic acidosis	2 (25.0)	2 (25.0)	0
Hyperkalaemia	1 (12.5)	1 (12.5)	0
Hypokalaemia	1 (12.5)	1 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	2 (25.0)	2 (25.0)	0
Hypotension	2 (25.0)	2 (25.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220e
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (55.6)	23 (25.6)	27 (30.0)
Blood and lymphatic system disorders			
-Total	39 (43.3)	26 (28.9)	13 (14.4)
Febrile neutropenia	21 (23.3)	20 (22.2)	1 (1.1)
Anaemia	15 (16.7)	14 (15.6)	1 (1.1)
Neutropenia	10 (11.1)	1 (1.1)	9 (10.0)
Thrombocytopenia	6 (6.7)	3 (3.3)	3 (3.3)
Cardiac disorders			
-Total	1 (1.1)	1 (1.1)	0
Tachycardia	1 (1.1)	1 (1.1)	0
Gastrointestinal disorders			
-Total	6 (6.7)	6 (6.7)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	5 (5.6)	5 (5.6)	0
Abdominal pain	1 (1.1)	1 (1.1)	0
General disorders and administration site conditions			
-Total	1 (1.1)	1 (1.1)	0
Pyrexia	1 (1.1)	1 (1.1)	0
Infections and infestations			
-Total	3 (3.3)	3 (3.3)	0
Staphylococcal bacteraemia	2 (2.2)	2 (2.2)	0
Sialoadenitis	1 (1.1)	1 (1.1)	0
Staphylococcal infection	1 (1.1)	1 (1.1)	0
Investigations			
-Total	20 (22.2)	6 (6.7)	14 (15.6)
Neutrophil count decreased	10 (11.1)	3 (3.3)	7 (7.8)
Platelet count decreased	8 (8.9)	0	8 (8.9)
White blood cell count decreased	7 (7.8)	0	7 (7.8)
Alanine aminotransferase increased	3 (3.3)	3 (3.3)	0
Aspartate aminotransferase increased	3 (3.3)	3 (3.3)	0

Response status at study entry: Relapsed disease

	All patients N=90		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (2.2)	2 (2.2)	0
Hypokalaemia	2 (2.2)	2 (2.2)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.1)	1 (1.1)	0
Pain in extremity	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (2.2)	0	2 (2.2)
Respiratory failure	2 (2.2)	0	2 (2.2)
Vascular disorders			
-Total	3 (3.3)	1 (1.1)	2 (2.2)
Hypotension	3 (3.3)	1 (1.1)	2 (2.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220f
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Neutropenia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Abscess limb	1 (50.0)	1 (50.0)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220f
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (54.2)	26 (27.1)	26 (27.1)
Blood and lymphatic system disorders			
-Total	42 (43.8)	29 (30.2)	13 (13.5)
Febrile neutropenia	23 (24.0)	22 (22.9)	1 (1.0)
Anaemia	17 (17.7)	16 (16.7)	1 (1.0)
Neutropenia	9 (9.4)	1 (1.0)	8 (8.3)
Thrombocytopenia	7 (7.3)	3 (3.1)	4 (4.2)
Gastrointestinal disorders			
-Total	6 (6.3)	6 (6.3)	0
Stomatitis	6 (6.3)	6 (6.3)	0
Investigations			
-Total	18 (18.8)	3 (3.1)	15 (15.6)

Philadelphia chromosome/BCR-ABL: Non-Positive

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	11 (11.5)	3 (3.1)	8 (8.3)
Platelet count decreased	8 (8.3)	0	8 (8.3)
White blood cell count decreased	7 (7.3)	0	7 (7.3)
Vascular disorders			
-Total	5 (5.2)	3 (3.1)	2 (2.1)
Hypotension	5 (5.2)	3 (3.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220g
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

		All patients N=97	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (54.6)	26 (26.8)	27 (27.8)
Blood and lymphatic system disorders			
-Total	43 (44.3)	29 (29.9)	14 (14.4)
Febrile neutropenia	23 (23.7)	22 (22.7)	1 (1.0)
Anaemia	17 (17.5)	16 (16.5)	1 (1.0)
Neutropenia	10 (10.3)	1 (1.0)	9 (9.3)
Thrombocytopenia	7 (7.2)	3 (3.1)	4 (4.1)
Gastrointestinal disorders			
-Total	6 (6.2)	6 (6.2)	0
Stomatitis	6 (6.2)	6 (6.2)	0
Investigations			
-Total	18 (18.6)	3 (3.1)	15 (15.5)

Mixed-lineage leukemia rearrangement: No			
		All patients N=97	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	11 (11.3)	3 (3.1)	8 (8.2)
Platelet count decreased	8 (8.2)	0	8 (8.2)
White blood cell count decreased	7 (7.2)	0	7 (7.2)
Vascular disorders			
-Total	5 (5.2)	3 (3.1)	2 (2.1)
Hypotension	5 (5.2)	3 (3.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220h
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	1 (33.3)	0
Anaemia	1 (33.3)	1 (33.3)	0
Cardiac disorders			
-Total	2 (66.7)	2 (66.7)	0
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Abdominal compartment syndrome	1 (33.3)	0	1 (33.3)

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoperitoneum	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Gastroenteritis adenovirus	1 (33.3)	1 (33.3)	0
Haemophilus bacteraemia	1 (33.3)	0	1 (33.3)
Klebsiella bacteraemia	1 (33.3)	1 (33.3)	0
Serratia sepsis	1 (33.3)	0	1 (33.3)
Staphylococcal infection	1 (33.3)	0	1 (33.3)
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0
Post procedural haemorrhage	1 (33.3)	1 (33.3)	0
Investigations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Aspartate aminotransferase increased	1 (33.3)	0	1 (33.3)
Neutrophil count decreased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	1 (33.3)	0

Hypodiploidy: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Cognitive disorder	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	2 (66.7)	2 (66.7)	0
Hypotension	2 (66.7)	2 (66.7)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220h
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (53.7)	22 (23.2)	29 (30.5)
Blood and lymphatic system disorders			
-Total	42 (44.2)	28 (29.5)	14 (14.7)
Febrile neutropenia	23 (24.2)	22 (23.2)	1 (1.1)
Anaemia	16 (16.8)	15 (15.8)	1 (1.1)
Neutropenia	10 (10.5)	1 (1.1)	9 (9.5)
Thrombocytopenia	7 (7.4)	3 (3.2)	4 (4.2)
Cardiac disorders			
-Total	2 (2.1)	2 (2.1)	0
Tachycardia	2 (2.1)	2 (2.1)	0
Gastrointestinal disorders			

Hypodiploidy: No

	All patients N=95		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (6.3)	6 (6.3)	0
Stomatitis	6 (6.3)	6 (6.3)	0
Infections and infestations			
-Total	1 (1.1)	1 (1.1)	0
Staphylococcal infection	1 (1.1)	1 (1.1)	0
Investigations			
-Total	19 (20.0)	4 (4.2)	15 (15.8)
Neutrophil count decreased	10 (10.5)	2 (2.1)	8 (8.4)
Platelet count decreased	8 (8.4)	0	8 (8.4)
White blood cell count decreased	7 (7.4)	0	7 (7.4)
Aspartate aminotransferase increased	3 (3.2)	3 (3.2)	0
Metabolism and nutrition disorders			
-Total	1 (1.1)	1 (1.1)	0
Metabolic acidosis	1 (1.1)	1 (1.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (3.2)	0	3 (3.2)
Respiratory failure	3 (3.2)	0	3 (3.2)

Hypodiploidy: No

Group term Preferred term	All patients N=95 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	3 (3.2)	1 (1.1)	2 (2.1)
Hypotension	3 (3.2)	1 (1.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220i
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	2 (100)	2 (100)	0
Febrile neutropenia	2 (100)	2 (100)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Acute sinusitis	1 (50.0)	1 (50.0)	0
Fungal skin infection	1 (50.0)	1 (50.0)	0
Systemic mycosis	1 (50.0)	1 (50.0)	0
Investigations			
-Total	1 (50.0)	0	1 (50.0)

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	1 (50.0)	0	1 (50.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220i
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (53.1)	25 (26.0)	26 (27.1)
Blood and lymphatic system disorders			
-Total	41 (42.7)	27 (28.1)	14 (14.6)
Febrile neutropenia	21 (21.9)	20 (20.8)	1 (1.0)
Anaemia	17 (17.7)	16 (16.7)	1 (1.0)
Neutropenia	10 (10.4)	1 (1.0)	9 (9.4)
Thrombocytopenia	7 (7.3)	3 (3.1)	4 (4.2)
Gastrointestinal disorders			
-Total	6 (6.3)	6 (6.3)	0
Stomatitis	6 (6.3)	6 (6.3)	0
Investigations			

BCR-ABL1-like: No

	All patients N=96		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (17.7)	3 (3.1)	14 (14.6)
Neutrophil count decreased	11 (11.5)	3 (3.1)	8 (8.3)
Platelet count decreased	8 (8.3)	0	8 (8.3)
White blood cell count decreased	6 (6.3)	0	6 (6.3)
Vascular disorders			
-Total	5 (5.2)	3 (3.1)	2 (2.1)
Hypotension	5 (5.2)	3 (3.1)	2 (2.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220j
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (66.7)	8 (26.7)	12 (40.0)
Blood and lymphatic system disorders			
-Total	12 (40.0)	9 (30.0)	3 (10.0)
Anaemia	6 (20.0)	6 (20.0)	0
Febrile neutropenia	6 (20.0)	6 (20.0)	0
Neutropenia	2 (6.7)	0	2 (6.7)
Thrombocytopenia	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	3 (10.0)	3 (10.0)	0
Neutropenic colitis	2 (6.7)	2 (6.7)	0
Stomatitis	1 (3.3)	1 (3.3)	0
Infections and infestations			

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (20.0)	3 (10.0)	3 (10.0)
Pneumonia	2 (6.7)	2 (6.7)	0
Staphylococcal infection	2 (6.7)	1 (3.3)	1 (3.3)
Staphylococcal sepsis	2 (6.7)	0	2 (6.7)
Investigations			
-Total	9 (30.0)	1 (3.3)	8 (26.7)
Neutrophil count decreased	5 (16.7)	0	5 (16.7)
Platelet count decreased	4 (13.3)	0	4 (13.3)
Aspartate aminotransferase increased	2 (6.7)	1 (3.3)	1 (3.3)
Lymphocyte count decreased	2 (6.7)	1 (3.3)	1 (3.3)
White blood cell count decreased	2 (6.7)	0	2 (6.7)
Metabolism and nutrition disorders			
-Total	3 (10.0)	3 (10.0)	0
Hypokalaemia	3 (10.0)	3 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.0)	0	3 (10.0)
Respiratory failure	3 (10.0)	0	3 (10.0)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (3.3)	1 (3.3)	0
Hypotension	1 (3.3)	1 (3.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220j
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (57.4)	20 (29.4)	19 (27.9)
Blood and lymphatic system disorders			
-Total	31 (45.6)	20 (29.4)	11 (16.2)
Febrile neutropenia	17 (25.0)	16 (23.5)	1 (1.5)
Anaemia	11 (16.2)	10 (14.7)	1 (1.5)
Neutropenia	8 (11.8)	1 (1.5)	7 (10.3)
Thrombocytopenia	6 (8.8)	3 (4.4)	3 (4.4)
Gastrointestinal disorders			
-Total	6 (8.8)	6 (8.8)	0
Stomatitis	5 (7.4)	5 (7.4)	0
Neutropenic colitis	1 (1.5)	1 (1.5)	0
Infections and infestations			

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.5)	0	1 (1.5)
Pneumonia	1 (1.5)	0	1 (1.5)
Investigations			
-Total	15 (22.1)	7 (10.3)	8 (11.8)
Neutrophil count decreased	6 (8.8)	3 (4.4)	3 (4.4)
White blood cell count decreased	5 (7.4)	0	5 (7.4)
Alanine aminotransferase increased	4 (5.9)	4 (5.9)	0
Platelet count decreased	4 (5.9)	0	4 (5.9)
Aspartate aminotransferase increased	2 (2.9)	2 (2.9)	0
Lymphocyte count decreased	1 (1.5)	0	1 (1.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.5)	0	1 (1.5)
Respiratory failure	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	4 (5.9)	2 (2.9)	2 (2.9)
Hypotension	4 (5.9)	2 (2.9)	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220k
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Europe

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	11 (34.4)	17 (53.1)
Blood and lymphatic system disorders			
-Total	19 (59.4)	10 (31.3)	9 (28.1)
Febrile neutropenia	8 (25.0)	7 (21.9)	1 (3.1)
Neutropenia	7 (21.9)	0	7 (21.9)
Anaemia	6 (18.8)	6 (18.8)	0
Leukopenia	2 (6.3)	0	2 (6.3)
Thrombocytopenia	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders			
-Total	4 (12.5)	4 (12.5)	0
Neutropenic colitis	2 (6.3)	2 (6.3)	0

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	2 (6.3)	2 (6.3)	0
Immunodeficiency	2 (6.3)	2 (6.3)	0
Infections and infestations			
-Total	10 (31.3)	7 (21.9)	3 (9.4)
Pneumonia	3 (9.4)	2 (6.3)	1 (3.1)
Device related infection	2 (6.3)	2 (6.3)	0
Herpes zoster	2 (6.3)	2 (6.3)	0
Respiratory tract infection	2 (6.3)	2 (6.3)	0
Staphylococcal sepsis	2 (6.3)	0	2 (6.3)
Investigations			
-Total	11 (34.4)	3 (9.4)	8 (25.0)
Neutrophil count decreased	5 (15.6)	1 (3.1)	4 (12.5)
White blood cell count decreased	5 (15.6)	0	5 (15.6)
Platelet count decreased	4 (12.5)	0	4 (12.5)
C-reactive protein increased	2 (6.3)	2 (6.3)	0
Lymphocyte count decreased	2 (6.3)	0	2 (6.3)

Region: Europe

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	1 (3.1)	1 (3.1)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220k
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (59.6)	18 (31.6)	16 (28.1)
Blood and lymphatic system disorders			
-Total	23 (40.4)	17 (29.8)	6 (10.5)
Febrile neutropenia	14 (24.6)	14 (24.6)	0
Anaemia	11 (19.3)	10 (17.5)	1 (1.8)
Thrombocytopenia	6 (10.5)	2 (3.5)	4 (7.0)
Neutropenia	3 (5.3)	1 (1.8)	2 (3.5)
Leukopenia	1 (1.8)	0	1 (1.8)
Cardiac disorders			
-Total	3 (5.3)	3 (5.3)	0
Tachycardia	3 (5.3)	3 (5.3)	0

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (8.8)	5 (8.8)	0
Stomatitis	4 (7.0)	4 (7.0)	0
Neutropenic colitis	1 (1.8)	1 (1.8)	0
Infections and infestations			
-Total	3 (5.3)	3 (5.3)	0
Staphylococcal bacteraemia	3 (5.3)	3 (5.3)	0
Investigations			
-Total	17 (29.8)	8 (14.0)	9 (15.8)
Neutrophil count decreased	6 (10.5)	2 (3.5)	4 (7.0)
Alanine aminotransferase increased	4 (7.0)	4 (7.0)	0
Aspartate aminotransferase increased	4 (7.0)	3 (5.3)	1 (1.8)
Platelet count decreased	4 (7.0)	0	4 (7.0)
Serum ferritin increased	3 (5.3)	2 (3.5)	1 (1.8)
White blood cell count decreased	2 (3.5)	0	2 (3.5)
C-reactive protein increased	1 (1.8)	0	1 (1.8)
Lymphocyte count decreased	1 (1.8)	1 (1.8)	0

Region: US

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	4 (7.0)	0	4 (7.0)
Respiratory failure	4 (7.0)	0	4 (7.0)
Vascular disorders			
-Total	5 (8.8)	3 (5.3)	2 (3.5)
Hypotension	5 (8.8)	3 (5.3)	2 (3.5)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220k
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: Rest of World

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (44.4)	3 (33.3)	1 (11.1)
Blood and lymphatic system disorders			
-Total	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	1 (11.1)	1 (11.1)	0
Duodenal perforation	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	2 (22.2)	2 (22.2)	0
Peritonitis	1 (11.1)	1 (11.1)	0

Region: Rest of World

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal skin infection	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	1 (11.1)	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	1 (11.1)	0	1 (11.1)
Haemorrhage intracranial	1 (11.1)	0	1 (11.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220l
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (58.6)	17 (29.3)	17 (29.3)
Blood and lymphatic system disorders			
-Total	26 (44.8)	18 (31.0)	8 (13.8)
Febrile neutropenia	14 (24.1)	13 (22.4)	1 (1.7)
Anaemia	8 (13.8)	8 (13.8)	0
Neutropenia	6 (10.3)	0	6 (10.3)
Pancytopenia	3 (5.2)	1 (1.7)	2 (3.4)
Thrombocytopenia	2 (3.4)	1 (1.7)	1 (1.7)
Cardiac disorders			
-Total	1 (1.7)	1 (1.7)	0
Tachycardia	1 (1.7)	1 (1.7)	0

Prior SCT therapy: Yes

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (5.2)	3 (5.2)	0
Stomatitis	3 (5.2)	3 (5.2)	0
Infections and infestations			
-Total	4 (6.9)	3 (5.2)	1 (1.7)
Pneumonia	3 (5.2)	2 (3.4)	1 (1.7)
Staphylococcal bacteraemia	1 (1.7)	1 (1.7)	0
Investigations			
-Total	15 (25.9)	5 (8.6)	10 (17.2)
Neutrophil count decreased	10 (17.2)	3 (5.2)	7 (12.1)
Platelet count decreased	6 (10.3)	0	6 (10.3)
White blood cell count decreased	5 (8.6)	0	5 (8.6)
Aspartate aminotransferase increased	3 (5.2)	3 (5.2)	0
Alanine aminotransferase increased	2 (3.4)	2 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.4)	0	2 (3.4)
Respiratory failure	2 (3.4)	0	2 (3.4)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=58 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	2 (3.4)	1 (1.7)	1 (1.7)
Hypotension	2 (3.4)	1 (1.7)	1 (1.7)

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-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220l
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	12 (30.0)	16 (40.0)
Blood and lymphatic system disorders			
-Total	19 (47.5)	12 (30.0)	7 (17.5)
Anaemia	9 (22.5)	8 (20.0)	1 (2.5)
Febrile neutropenia	9 (22.5)	9 (22.5)	0
Thrombocytopenia	5 (12.5)	2 (5.0)	3 (7.5)
Neutropenia	4 (10.0)	1 (2.5)	3 (7.5)
Cardiac disorders			
-Total	2 (5.0)	2 (5.0)	0
Tachycardia	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	3 (7.5)	0
Stomatitis	3 (7.5)	3 (7.5)	0
Infections and infestations			
-Total	7 (17.5)	5 (12.5)	2 (5.0)
Pneumonia fungal	2 (5.0)	1 (2.5)	1 (2.5)
Sialoadenitis	2 (5.0)	2 (5.0)	0
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Staphylococcal infection	2 (5.0)	1 (2.5)	1 (2.5)
Investigations			
-Total	10 (25.0)	3 (7.5)	7 (17.5)
Serum ferritin increased	3 (7.5)	2 (5.0)	1 (2.5)
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0
Platelet count decreased	2 (5.0)	0	2 (5.0)
White blood cell count decreased	2 (5.0)	0	2 (5.0)
Aspartate aminotransferase increased	1 (2.5)	0	1 (2.5)
Neutrophil count decreased	1 (2.5)	0	1 (2.5)

Prior SCT therapy: No

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (10.0)	4 (10.0)	0
Decreased appetite	2 (5.0)	2 (5.0)	0
Metabolic acidosis	2 (5.0)	2 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	2 (5.0)	0
Pain in extremity	2 (5.0)	2 (5.0)	0
Psychiatric disorders			
-Total	2 (5.0)	2 (5.0)	0
Mental status changes	2 (5.0)	2 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.0)	0	2 (5.0)
Respiratory failure	2 (5.0)	0	2 (5.0)
Vascular disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Hypotension	3 (7.5)	2 (5.0)	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220m
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (58.8)	7 (41.2)	3 (17.6)
Blood and lymphatic system disorders			
-Total	7 (41.2)	7 (41.2)	0
Febrile neutropenia	7 (41.2)	7 (41.2)	0
Gastrointestinal disorders			
-Total	4 (23.5)	4 (23.5)	0
Anal fistula	1 (5.9)	1 (5.9)	0
Duodenal perforation	1 (5.9)	1 (5.9)	0
Neutropenic colitis	1 (5.9)	1 (5.9)	0
Stomatitis	1 (5.9)	1 (5.9)	0
Hepatobiliary disorders			

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	1 (5.9)	0
Drug-induced liver injury	1 (5.9)	1 (5.9)	0
Infections and infestations			
-Total	6 (35.3)	5 (29.4)	1 (5.9)
Catheter site infection	2 (11.8)	2 (11.8)	0
Staphylococcal bacteraemia	2 (11.8)	2 (11.8)	0
Acute sinusitis	1 (5.9)	1 (5.9)	0
Aspergillus infection	1 (5.9)	0	1 (5.9)
Fungal pharyngitis	1 (5.9)	1 (5.9)	0
Fungal skin infection	1 (5.9)	1 (5.9)	0
Peritonitis	1 (5.9)	1 (5.9)	0
Staphylococcal infection	1 (5.9)	1 (5.9)	0
Systemic mycosis	1 (5.9)	1 (5.9)	0
Vascular device infection	1 (5.9)	1 (5.9)	0
Investigations			
-Total	2 (11.8)	1 (5.9)	1 (5.9)
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (5.9)	1 (5.9)	0
Blood creatinine increased	1 (5.9)	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)
Metabolism and nutrition disorders			
-Total	1 (5.9)	1 (5.9)	0
Hypokalaemia	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	1 (5.9)	0	1 (5.9)
Haemorrhage intracranial	1 (5.9)	0	1 (5.9)
Psychiatric disorders			
-Total	1 (5.9)	1 (5.9)	0
Mental status changes	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Renal tubular necrosis	1 (5.9)	1 (5.9)	0
Reproductive system and breast disorders			
-Total	1 (5.9)	1 (5.9)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=17 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Prostatitis	1 (5.9)	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.9)	1 (5.9)	0
Epistaxis	1 (5.9)	1 (5.9)	0

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220m
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (58.0)	20 (24.7)	27 (33.3)
Blood and lymphatic system disorders			
-Total	36 (44.4)	22 (27.2)	14 (17.3)
Anaemia	17 (21.0)	16 (19.8)	1 (1.2)
Febrile neutropenia	16 (19.8)	15 (18.5)	1 (1.2)
Neutropenia	10 (12.3)	1 (1.2)	9 (11.1)
Thrombocytopenia	7 (8.6)	3 (3.7)	4 (4.9)
Gastrointestinal disorders			
-Total	7 (8.6)	7 (8.6)	0
Stomatitis	5 (6.2)	5 (6.2)	0
Neutropenic colitis	2 (2.5)	2 (2.5)	0

Eligibility for SCT: No

	All patients N=81		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	2 (2.5)	1 (1.2)	1 (1.2)
Staphylococcal bacteraemia	1 (1.2)	1 (1.2)	0
Staphylococcal infection	1 (1.2)	0	1 (1.2)
Investigations			
-Total	19 (23.5)	4 (4.9)	15 (18.5)
Neutrophil count decreased	10 (12.3)	3 (3.7)	7 (8.6)
Platelet count decreased	8 (9.9)	0	8 (9.9)
White blood cell count decreased	7 (8.6)	0	7 (8.6)
Aspartate aminotransferase increased	3 (3.7)	2 (2.5)	1 (1.2)
Metabolism and nutrition disorders			
-Total	2 (2.5)	2 (2.5)	0
Hypokalaemia	2 (2.5)	2 (2.5)	0
Psychiatric disorders			
-Total	1 (1.2)	1 (1.2)	0
Mental status changes	1 (1.2)	1 (1.2)	0
Respiratory, thoracic and mediastinal disorders			

Eligibility for SCT: No

Group term Preferred term	All patients N=81 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.2)	1 (1.2)	0
Epistaxis	1 (1.2)	1 (1.2)	0
Vascular disorders			
-Total	5 (6.2)	3 (3.7)	2 (2.5)
Hypotension	5 (6.2)	3 (3.7)	2 (2.5)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220n
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (53.6)	9 (32.1)	6 (21.4)
Blood and lymphatic system disorders			
-Total	13 (46.4)	8 (28.6)	5 (17.9)
Anaemia	5 (17.9)	5 (17.9)	0
Febrile neutropenia	5 (17.9)	5 (17.9)	0
Thrombocytopenia	4 (14.3)	2 (7.1)	2 (7.1)
Neutropenia	3 (10.7)	0	3 (10.7)
Investigations			
-Total	5 (17.9)	3 (10.7)	2 (7.1)
Alanine aminotransferase increased	3 (10.7)	3 (10.7)	0
Neutrophil count decreased	2 (7.1)	1 (3.6)	1 (3.6)
White blood cell count decreased	1 (3.6)	0	1 (3.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220n
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (57.1)	16 (22.9)	24 (34.3)
Blood and lymphatic system disorders			
-Total	30 (42.9)	21 (30.0)	9 (12.9)
Febrile neutropenia	18 (25.7)	17 (24.3)	1 (1.4)
Anaemia	12 (17.1)	11 (15.7)	1 (1.4)
Neutropenia	7 (10.0)	1 (1.4)	6 (8.6)
Thrombocytopenia	3 (4.3)	1 (1.4)	2 (2.9)
Gastrointestinal disorders			
-Total	6 (8.6)	6 (8.6)	0
Stomatitis	6 (8.6)	6 (8.6)	0
Investigations			
-Total	18 (25.7)	4 (5.7)	14 (20.0)

Baseline bone marrow tumor burden: High

	All patients N=70		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	9 (12.9)	2 (2.9)	7 (10.0)
Platelet count decreased	8 (11.4)	0	8 (11.4)
White blood cell count decreased	6 (8.6)	0	6 (8.6)
Aspartate aminotransferase increased	4 (5.7)	3 (4.3)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (5.7)	0	4 (5.7)
Respiratory failure	4 (5.7)	0	4 (5.7)
Vascular disorders			
-Total	5 (7.1)	3 (4.3)	2 (2.9)
Hypotension	5 (7.1)	3 (4.3)	2 (2.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220o
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	5 (45.5)	4 (36.4)
Blood and lymphatic system disorders			
-Total	5 (45.5)	4 (36.4)	1 (9.1)
Febrile neutropenia	3 (27.3)	3 (27.3)	0
Anaemia	1 (9.1)	1 (9.1)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	1 (9.1)	0
Hepatic cytolysis	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	5 (45.5)	4 (36.4)	1 (9.1)
Abscess limb	1 (9.1)	1 (9.1)	0
Device related infection	1 (9.1)	1 (9.1)	0
Herpes zoster	1 (9.1)	1 (9.1)	0
Paronychia	1 (9.1)	1 (9.1)	0
Staphylococcal sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal skin infection	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	2 (18.2)	0	2 (18.2)
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	2 (18.2)	2 (18.2)	0
Hypokalaemia	1 (9.1)	1 (9.1)	0
Hypophagia	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Post herpetic neuralgia	1 (9.1)	1 (9.1)	0

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220o
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=87		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (55.2)	24 (27.6)	24 (27.6)
Blood and lymphatic system disorders			
-Total	38 (43.7)	25 (28.7)	13 (14.9)
Febrile neutropenia	20 (23.0)	19 (21.8)	1 (1.1)
Anaemia	16 (18.4)	15 (17.2)	1 (1.1)
Neutropenia	9 (10.3)	1 (1.1)	8 (9.2)
Thrombocytopenia	7 (8.0)	3 (3.4)	4 (4.6)
Gastrointestinal disorders			
-Total	6 (6.9)	6 (6.9)	0
Stomatitis	6 (6.9)	6 (6.9)	0
Infections and infestations			
-Total	3 (3.4)	2 (2.3)	1 (1.1)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=87 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Device related infection	1 (1.1)	1 (1.1)	0
Herpes zoster	1 (1.1)	1 (1.1)	0
Staphylococcal sepsis	1 (1.1)	0	1 (1.1)
Investigations			
-Total	16 (18.4)	3 (3.4)	13 (14.9)
Neutrophil count decreased	11 (12.6)	3 (3.4)	8 (9.2)
Platelet count decreased	7 (8.0)	0	7 (8.0)
White blood cell count decreased	6 (6.9)	0	6 (6.9)
Metabolism and nutrition disorders			
-Total	2 (2.3)	2 (2.3)	0
Hypokalaemia	2 (2.3)	2 (2.3)	0
Vascular disorders			
-Total	5 (5.7)	3 (3.4)	2 (2.3)
Hypotension	5 (5.7)	3 (3.4)	2 (2.3)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220p
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	3 (42.9)	2 (28.6)
Blood and lymphatic system disorders			
-Total	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Duodenal perforation	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	2 (28.6)	2 (28.6)	0
Escherichia bacteraemia	1 (14.3)	1 (14.3)	0
Peritonitis	1 (14.3)	1 (14.3)	0

Down syndrome: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Neutrophil count decreased	1 (14.3)	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	1 (14.3)	0	1 (14.3)
Haemorrhage intracranial	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Atelectasis	1 (14.3)	1 (14.3)	0

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220p
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (54.9)	24 (26.4)	26 (28.6)
Blood and lymphatic system disorders			
-Total	42 (46.2)	28 (30.8)	14 (15.4)
Febrile neutropenia	22 (24.2)	21 (23.1)	1 (1.1)
Anaemia	17 (18.7)	16 (17.6)	1 (1.1)
Neutropenia	10 (11.0)	1 (1.1)	9 (9.9)
Thrombocytopenia	7 (7.7)	3 (3.3)	4 (4.4)
Gastrointestinal disorders			
-Total	6 (6.6)	6 (6.6)	0
Stomatitis	6 (6.6)	6 (6.6)	0
Infections and infestations			

Down syndrome: No

	All patients N=91		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.1)	1 (1.1)	0
Escherichia bacteraemia	1 (1.1)	1 (1.1)	0
Investigations			
-Total	16 (17.6)	2 (2.2)	14 (15.4)
Neutrophil count decreased	10 (11.0)	2 (2.2)	8 (8.8)
Platelet count decreased	8 (8.8)	0	8 (8.8)
White blood cell count decreased	6 (6.6)	0	6 (6.6)
Vascular disorders			
-Total	5 (5.5)	3 (3.3)	2 (2.2)
Hypotension	5 (5.5)	3 (3.3)	2 (2.2)

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-Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
-A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220q
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (72.5)	13 (32.5)	16 (40.0)
Blood and lymphatic system disorders			
-Total	22 (55.0)	12 (30.0)	10 (25.0)
Febrile neutropenia	10 (25.0)	10 (25.0)	0
Neutropenia	9 (22.5)	0	9 (22.5)
Anaemia	8 (20.0)	8 (20.0)	0
Leukopenia	3 (7.5)	0	3 (7.5)
Thrombocytopenia	2 (5.0)	1 (2.5)	1 (2.5)
Pancytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	1 (2.5)	1 (2.5)	0
Tachycardia	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (12.5)	5 (12.5)	0
Stomatitis	3 (7.5)	3 (7.5)	0
Neutropenic colitis	2 (5.0)	2 (5.0)	0
Immune system disorders			
-Total	2 (5.0)	2 (5.0)	0
Immunodeficiency	2 (5.0)	2 (5.0)	0
Infections and infestations			
-Total	8 (20.0)	8 (20.0)	0
Catheter site infection	2 (5.0)	2 (5.0)	0
Herpes zoster	2 (5.0)	2 (5.0)	0
Respiratory tract infection	2 (5.0)	2 (5.0)	0
Device related infection	1 (2.5)	1 (2.5)	0
Oral herpes	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	1 (2.5)	0
Investigations			
-Total	13 (32.5)	4 (10.0)	9 (22.5)
Neutrophil count decreased	7 (17.5)	2 (5.0)	5 (12.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (12.5)	0	5 (12.5)
White blood cell count decreased	5 (12.5)	0	5 (12.5)
Aspartate aminotransferase increased	2 (5.0)	2 (5.0)	0
Lymphocyte count decreased	2 (5.0)	0	2 (5.0)
Alanine aminotransferase increased	1 (2.5)	1 (2.5)	0
Blood potassium decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	2 (5.0)	2 (5.0)	0
Hypokalaemia	1 (2.5)	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	1 (2.5)	0	1 (2.5)
Hypotension	1 (2.5)	0	1 (2.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
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-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220q
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (60.0)	15 (37.5)	9 (22.5)
Blood and lymphatic system disorders			
-Total	15 (37.5)	12 (30.0)	3 (7.5)
Febrile neutropenia	9 (22.5)	9 (22.5)	0
Anaemia	6 (15.0)	5 (12.5)	1 (2.5)
Thrombocytopenia	4 (10.0)	2 (5.0)	2 (5.0)
Neutropenia	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	4 (10.0)	4 (10.0)	0
Stomatitis	2 (5.0)	2 (5.0)	0
Abdominal pain	1 (2.5)	1 (2.5)	0
Neutropenic colitis	1 (2.5)	1 (2.5)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	5 (12.5)	5 (12.5)	0
Staphylococcal bacteraemia	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	1 (2.5)	0
Pneumonia fungal	1 (2.5)	1 (2.5)	0
Staphylococcal infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	10 (25.0)	4 (10.0)	6 (15.0)
Neutrophil count decreased	3 (7.5)	1 (2.5)	2 (5.0)
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0
Platelet count decreased	2 (5.0)	0	2 (5.0)
Serum ferritin increased	2 (5.0)	1 (2.5)	1 (2.5)
White blood cell count decreased	2 (5.0)	0	2 (5.0)
Aspartate aminotransferase increased	1 (2.5)	1 (2.5)	0
C-reactive protein increased	1 (2.5)	0	1 (2.5)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=40 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Lymphocyte count decreased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	4 (10.0)	4 (10.0)	0
Decreased appetite	2 (5.0)	2 (5.0)	0
Hypokalaemia	2 (5.0)	2 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Epistaxis	2 (5.0)	2 (5.0)	0
Respiratory failure	1 (2.5)	0	1 (2.5)

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-A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
-System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
-MedDRA version 25.1 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 220q
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	5 (27.8)	12 (66.7)
Blood and lymphatic system disorders			
-Total	9 (50.0)	6 (33.3)	3 (16.7)
Febrile neutropenia	4 (22.2)	3 (16.7)	1 (5.6)
Anaemia	3 (16.7)	3 (16.7)	0
Pancytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Hyperleukocytosis	1 (5.6)	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Cardiac disorders			
-Total	4 (22.2)	4 (22.2)	0
Tachycardia	2 (11.1)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac failure	1 (5.6)	1 (5.6)	0
Left ventricular dysfunction	1 (5.6)	1 (5.6)	0
Endocrine disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypercalcaemia of malignancy	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	6 (33.3)	5 (27.8)	1 (5.6)
Abdominal compartment syndrome	1 (5.6)	0	1 (5.6)
Abdominal pain	1 (5.6)	1 (5.6)	0
Colitis	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Duodenal perforation	1 (5.6)	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0
Haemoperitoneum	1 (5.6)	0	1 (5.6)
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	3 (16.7)	3 (16.7)	0
Pyrexia	2 (11.1)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (5.6)	1 (5.6)	0
Hepatobiliary disorders			
-Total	2 (11.1)	2 (11.1)	0
Hyperbilirubinaemia	2 (11.1)	2 (11.1)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	13 (72.2)	6 (33.3)	7 (38.9)
Acute sinusitis	1 (5.6)	1 (5.6)	0
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bacteraemia	1 (5.6)	1 (5.6)	0
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Device related infection	1 (5.6)	1 (5.6)	0
Device related sepsis	1 (5.6)	1 (5.6)	0
Disseminated trichosporonosis	1 (5.6)	0	1 (5.6)
Fungal sepsis	1 (5.6)	0	1 (5.6)
Fungal skin infection	1 (5.6)	1 (5.6)	0
Klebsiella bacteraemia	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (5.6)	1 (5.6)	0
Peritonitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Pneumonia fungal	1 (5.6)	0	1 (5.6)
Sepsis	1 (5.6)	0	1 (5.6)
Serratia sepsis	1 (5.6)	0	1 (5.6)
Staphylococcal infection	1 (5.6)	0	1 (5.6)
Systemic mycosis	1 (5.6)	1 (5.6)	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Post procedural haemorrhage	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
C-reactive protein increased	2 (11.1)	2 (11.1)	0
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)
Blood potassium decreased	1 (5.6)	1 (5.6)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (5.6)	0	1 (5.6)
Platelet count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Metabolic acidosis	2 (11.1)	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	1 (5.6)	1 (5.6)
Hyperammonaemia	1 (5.6)	1 (5.6)	0
Hyperglycaemia	1 (5.6)	0	1 (5.6)
Hyperkalaemia	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Cognitive disorder	1 (5.6)	1 (5.6)	0
Encephalopathy	1 (5.6)	1 (5.6)	0
Haemorrhage intracranial	1 (5.6)	0	1 (5.6)
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Mental status changes	2 (11.1)	2 (11.1)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=18 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Respiratory failure	3 (16.7)	0	3 (16.7)
Acute respiratory distress syndrome	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	0	1 (5.6)
Tachypnoea	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Hypotension	4 (22.2)	3 (16.7)	1 (5.6)

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Table 220r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	5 (62.5)	3 (37.5)
Blood and lymphatic system disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Anaemia	2 (25.0)	2 (25.0)	0
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Tachycardia	2 (25.0)	2 (25.0)	0
Gastrointestinal disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal compartment syndrome	1 (12.5)	0	1 (12.5)
Abdominal pain	1 (12.5)	1 (12.5)	0
Haemoperitoneum	1 (12.5)	0	1 (12.5)
Stomatitis	1 (12.5)	1 (12.5)	0
Tooth pulp haemorrhage	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	6 (75.0)	4 (50.0)	2 (25.0)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Disseminated trichosporonosis	1 (12.5)	0	1 (12.5)
Gastroenteritis viral	1 (12.5)	1 (12.5)	0
Pseudomonal bacteraemia	1 (12.5)	1 (12.5)	0
Serratia sepsis	1 (12.5)	0	1 (12.5)
Sialoadenitis	1 (12.5)	1 (12.5)	0
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Investigations			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Alanine aminotransferase increased	1 (12.5)	1 (12.5)	0
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	3 (37.5)	3 (37.5)	0
Metabolic acidosis	2 (25.0)	2 (25.0)	0
Hyperkalaemia	1 (12.5)	1 (12.5)	0
Hypokalaemia	1 (12.5)	1 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Cognitive disorder	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Respiratory failure	2 (25.0)	0	2 (25.0)
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	2 (25.0)	2 (25.0)	0
Hypotension	2 (25.0)	2 (25.0)	0

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Table 220r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (66.7)	11 (36.7)	9 (30.0)
Blood and lymphatic system disorders			
-Total	9 (30.0)	4 (13.3)	5 (16.7)
Anaemia	5 (16.7)	5 (16.7)	0
Thrombocytopenia	4 (13.3)	2 (6.7)	2 (6.7)
Febrile neutropenia	3 (10.0)	3 (10.0)	0
Neutropenia	3 (10.0)	1 (3.3)	2 (6.7)
Leukopenia	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	3 (10.0)	3 (10.0)	0
Stomatitis	2 (6.7)	2 (6.7)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	1 (3.3)	1 (3.3)	0
Pyrexia	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	5 (16.7)	4 (13.3)	1 (3.3)
Pneumonia fungal	2 (6.7)	1 (3.3)	1 (3.3)
Escherichia bacteraemia	1 (3.3)	1 (3.3)	0
Oral herpes	1 (3.3)	1 (3.3)	0
Sialoadenitis	1 (3.3)	1 (3.3)	0
Investigations			
-Total	7 (23.3)	4 (13.3)	3 (10.0)
C-reactive protein increased	3 (10.0)	2 (6.7)	1 (3.3)
Serum ferritin increased	2 (6.7)	1 (3.3)	1 (3.3)
Alanine aminotransferase increased	1 (3.3)	1 (3.3)	0
Blood lactate dehydrogenase increased	1 (3.3)	1 (3.3)	0
Neutrophil count decreased	1 (3.3)	1 (3.3)	0

Number of previous relapses: 1

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (3.3)	0	1 (3.3)
White blood cell count decreased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	4 (13.3)	4 (13.3)	0
Decreased appetite	2 (6.7)	2 (6.7)	0
Tumour lysis syndrome	2 (6.7)	2 (6.7)	0
Psychiatric disorders			
-Total	1 (3.3)	1 (3.3)	0
Mental status changes	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	2 (6.7)	0
Epistaxis	2 (6.7)	2 (6.7)	0
Vascular disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)
Hypotension	2 (6.7)	1 (3.3)	1 (3.3)

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Table 220r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	7 (38.9)	7 (38.9)
Blood and lymphatic system disorders			
-Total	11 (61.1)	8 (44.4)	3 (16.7)
Febrile neutropenia	7 (38.9)	7 (38.9)	0
Anaemia	3 (16.7)	2 (11.1)	1 (5.6)
Neutropenia	2 (11.1)	0	2 (11.1)
Thrombocytopenia	2 (11.1)	1 (5.6)	1 (5.6)
Leukopenia	1 (5.6)	0	1 (5.6)
Lymphopenia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (16.7)	3 (16.7)	0
Anal inflammation	1 (5.6)	1 (5.6)	0
Neutropenic colitis	1 (5.6)	1 (5.6)	0
Oral pain	1 (5.6)	1 (5.6)	0
Stomatitis	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	8 (44.4)	7 (38.9)	1 (5.6)
Aspergillus infection	1 (5.6)	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Escherichia bacteraemia	1 (5.6)	1 (5.6)	0
Oral herpes	1 (5.6)	1 (5.6)	0
Pharyngitis	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	1 (5.6)	0
Respiratory tract infection	1 (5.6)	1 (5.6)	0
Sinusitis	1 (5.6)	1 (5.6)	0
Staphylococcal bacteraemia	1 (5.6)	1 (5.6)	0
Staphylococcal infection	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Alanine aminotransferase increased	2 (11.1)	2 (11.1)	0
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0
Blood calcium increased	1 (5.6)	1 (5.6)	0
Blood fibrinogen decreased	1 (5.6)	1 (5.6)	0
Blood lactate dehydrogenase increased	1 (5.6)	1 (5.6)	0
Neutrophil count decreased	1 (5.6)	1 (5.6)	0
Platelet count decreased	1 (5.6)	0	1 (5.6)
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Weight decreased	1 (5.6)	1 (5.6)	0
White blood cell count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypercalcaemia	1 (5.6)	0	1 (5.6)
Hypokalaemia	1 (5.6)	1 (5.6)	0

Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (5.6)	1 (5.6)	0
Pain in extremity	1 (5.6)	1 (5.6)	0
Nervous system disorders			
-Total	1 (5.6)	1 (5.6)	0
Headache	1 (5.6)	1 (5.6)	0
Psychiatric disorders			
-Total	2 (11.1)	2 (11.1)	0
Anxiety	1 (5.6)	1 (5.6)	0
Mental status changes	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.1)	2 (11.1)	0
Atelectasis	1 (5.6)	1 (5.6)	0
Dyspnoea	1 (5.6)	1 (5.6)	0

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Enrolled set

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (59.5)	9 (21.4)	16 (38.1)
Blood and lymphatic system disorders			
-Total	19 (45.2)	13 (31.0)	6 (14.3)
Febrile neutropenia	11 (26.2)	10 (23.8)	1 (2.4)
Anaemia	7 (16.7)	7 (16.7)	0
Neutropenia	5 (11.9)	0	5 (11.9)
Leukopenia	1 (2.4)	0	1 (2.4)
Cardiac disorders			
-Total	1 (2.4)	1 (2.4)	0
Tachycardia	1 (2.4)	1 (2.4)	0

Number of previous relapses: >=3

	All patients N=42		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	4 (9.5)	4 (9.5)	0
Neutropenic colitis	2 (4.8)	2 (4.8)	0
Stomatitis	2 (4.8)	2 (4.8)	0
Infections and infestations			
-Total	4 (9.5)	3 (7.1)	1 (2.4)
Pneumonia	2 (4.8)	1 (2.4)	1 (2.4)
Respiratory tract infection	1 (2.4)	1 (2.4)	0
Staphylococcal bacteraemia	1 (2.4)	1 (2.4)	0
Investigations			
-Total	12 (28.6)	2 (4.8)	10 (23.8)
Neutrophil count decreased	8 (19.0)	1 (2.4)	7 (16.7)
Platelet count decreased	6 (14.3)	0	6 (14.3)
White blood cell count decreased	5 (11.9)	0	5 (11.9)
Aspartate aminotransferase increased	2 (4.8)	2 (4.8)	0
Metabolism and nutrition disorders			
-Total	2 (4.8)	1 (2.4)	1 (2.4)

Number of previous relapses: >=3

Group term Preferred term	All patients N=42 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	1 (2.4)	1 (2.4)	0
Tumour lysis syndrome	1 (2.4)	0	1 (2.4)
Nervous system disorders			
-Total	1 (2.4)	1 (2.4)	0
Headache	1 (2.4)	1 (2.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.8)	0	2 (4.8)
Respiratory failure	2 (4.8)	0	2 (4.8)
Vascular disorders			
-Total	1 (2.4)	0	1 (2.4)
Hypotension	1 (2.4)	0	1 (2.4)

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